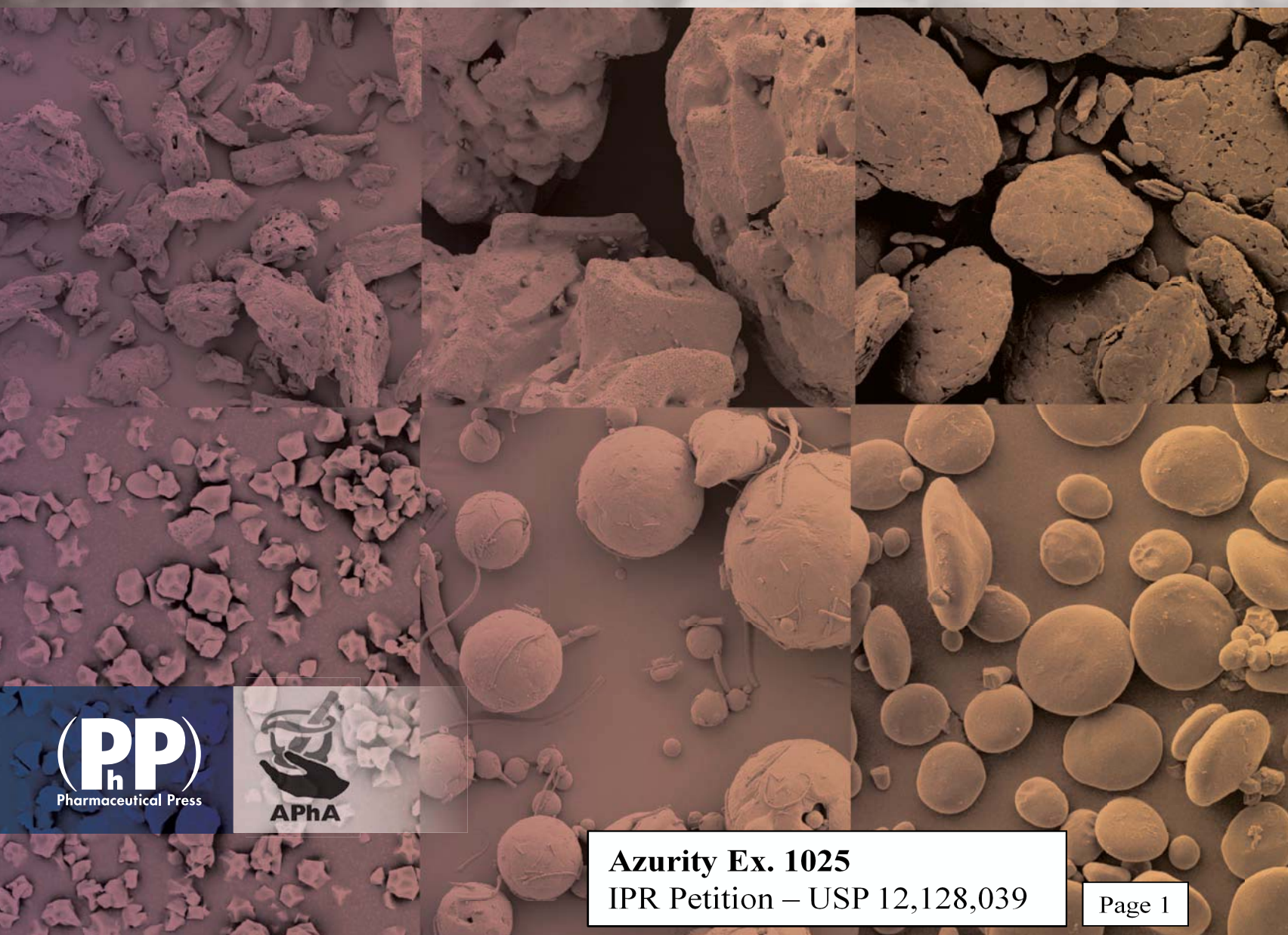


Handbook of Pharmaceutical Excipients

Sixth edition

Edited by
Raymond C Rowe, Paul J Sheskey and Marian E Quinn



(PP)
Pharmaceutical Press



Azurity Ex. 1025

IPR Petition – USP 12,128,039

Page 1

Handbook of Pharmaceutical Excipients

SIXTH EDITION

Edited by

Raymond C Rowe BPharm, PhD, DSC, FRPharmS, FRSC, CPhys, MInstP

Chief Scientist

Intelligensys Ltd, Stokesley, North Yorkshire, UK

Paul J Sheskey BSc, RPh

Application Development Leader

The Dow Chemical Company, Midland, MI, USA

Marian E Quinn BSc, MSc

Development Editor

Royal Pharmaceutical Society of Great Britain, London, UK



London • Chicago

Published by the Pharmaceutical Press

An imprint of RPS Publishing

1 Lambeth High Street, London SE1 7JN, UK
100 South Atkinson Road, Suite 200, Grayslake, IL 60030-7820, USA

and the American Pharmacists Association

2215 Constitution Avenue, NW, Washington, DC 20037-2985, USA

© Pharmaceutical Press and American Pharmacists Association 2009

(PP) is a trade mark of RPS Publishing

RPS Publishing is the publishing organisation of the Royal Pharmaceutical Society of Great Britain

First published 1986

Second edition published 1994

Third edition published 2000

Fourth edition published 2003

Fifth edition published 2006

Sixth edition published 2009

Typeset by Data Standards Ltd, Frome, Somerset

Printed in Italy by L.E.G.O. S.p.A.

ISBN 978 0 85369 792 3 (UK)

ISBN 978 1 58212 135 2 (USA)

All rights reserved. No part of this publication may be reproduced, stored in a retrieval system, or transmitted in any form or by any means, without the prior written permission of the copyright holder.

The publisher makes no representation, express or implied, with regard to the accuracy of the information contained in this book and cannot accept any legal responsibility or liability for any errors or omissions that may be made.

A catalogue record for this book is available from the British Library

Contents

<i>Preface</i>	x
<i>Arrangement</i>	xi
<i>Acknowledgments</i>	xiii
<i>Notice to Readers</i>	xiii
<i>International Steering Committee</i>	xiv
<i>Editorial Staff</i>	xv
<i>Contributors</i>	xvi
<i>About the Editors</i>	xx
<i>New Monographs</i>	xxi
<i>Related Substances</i>	xxii
<i>Bibliography</i>	xxiv
<i>Abbreviations</i>	xxv
<i>Units of Measurement</i>	xxvii

Monographs

A

Acacia	1
Acesulfame Potassium	3
Acetic Acid, Glacial	5
Acetone	7
Acetyltributyl Citrate	8
Acetyltriethyl Citrate	10
Adipic Acid	11
Agar	13
Albumin	14
Alcohol	17
Alginic Acid	20
Aliphatic Polyesters	23
Alitame	28
Almond Oil	29
Alpha Tocopherol	31
Aluminum Hydroxide Adjuvant	34
Aluminum Monostearate	35
Aluminum Oxide	37
Aluminum Phosphate Adjuvant	38
Ammonia Solution	39
Ammonium Alginate	41
Ammonium Chloride	42
Ascorbic Acid	43
Ascorbyl Palmitate	46
Aspartame	48
Attapulgate	51

B

Bentonite	53
-----------	----

Benzalkonium Chloride	56
Benzethonium Chloride	59
Benzoic Acid	61
Benzyl Alcohol	64
Benzyl Benzoate	66
Boric Acid	68
Bronopol	70
Butylated Hydroxyanisole	73
Butylated Hydroxytoluene	75
Butylene Glycol	77
Butylparaben	78

C

Calcium Acetate	82
Calcium Alginate	83
Calcium Carbonate	86
Calcium Chloride	89
Calcium Hydroxide	91
Calcium Lactate	92
Calcium Phosphate, Dibasic Anhydrous	94
Calcium Phosphate, Dibasic Dihydrate	96
Calcium Phosphate, Tribasic	99
Calcium Silicate	101
Calcium Stearate	103
Calcium Sulfate	105
Canola Oil	108
Carbomer	110
Carbon Dioxide	115
Carboxymethylcellulose Calcium	117
Carboxymethylcellulose Sodium	118
Carrageenan	122
Castor Oil	126
Castor Oil, Hydrogenated	128
Cellulose, Microcrystalline	129
Cellulose, Microcrystalline and Carboxymethylcellulose Sodium	134
Cellulose, Powdered	136
Cellulose, Silicified Microcrystalline	139
Cellulose Acetate	141
Cellulose Acetate Phthalate	143
Ceratonia	146
Ceresin	148

Cetostearyl Alcohol	150	Erythritol	251
Cetrimide	152	Ethyl Acetate	253
Cetyl Alcohol	155	Ethyl Lactate	256
Cetylpyridinium Chloride	157	Ethyl Maltol	257
Chitosan	159	Ethyl Oleate	259
Chlorhexidine	162	Ethyl Vanillin	261
Chlorobutanol	166	Ethylcellulose	262
Chlorocresol	168	Ethylene Glycol Stearates	267
Chlorodifluoroethane (HCFC)	171	Ethylene Vinyl Acetate	268
Chlorofluorocarbons (CFC)	173	Ethylparaben	270
Chloroxylenol	176	F	
Cholesterol	178	Fructose	273
Citric Acid Monohydrate	181	Fumaric Acid	276
Coconut Oil	184	G	
Colloidal Silicon Dioxide	185	Gelatin	278
Coloring Agents	189	Glucose, Liquid	282
Copovidone	196	Glycerin	283
Corn Oil	199	Glyceryl Behenate	286
Corn Starch and Pregelatinized Starch	200	Glyceryl Monooleate	288
Cottonseed Oil	202	Glyceryl Monostearate	290
Cresol	203	Glyceryl Palmitostearate	293
Croscarmellose Sodium	206	Glycine	295
Crospovidone	208	Glycofurool	297
Cyclodextrins	210	Guar Gum	298
Cyclomethicone	215	H	
D		Hectorite	301
Denatonium Benzoate	217	Heptafluoropropane (HFC)	303
Dextrates	218	Hexetidine	304
Dextrin	220	Hydrocarbons (HC)	306
Dextrose	222	Hydrochloric Acid	308
Dibutyl Phthalate	225	Hydrophobic Colloidal Silica	309
Dibutyl Sebacate	227	Hydroxyethyl Cellulose	311
Diethanolamine	228	Hydroxyethylmethyl Cellulose	314
Diethyl Phthalate	230	Hydroxypropyl Betadex	315
Difluoroethane (HFC)	232	Hydroxypropyl Cellulose	317
Dimethicone	233	Hydroxypropyl Cellulose, Low-substituted	322
Dimethyl Ether	235	Hydroxypropyl Starch	325
Dimethyl Phthalate	236	Hypromellose	326
Dimethyl Sulfoxide	238	Hypromellose Acetate Succinate	330
Dimethylacetamide	241	Hypromellose Phthalate	333
Disodium Edetate	242	I	
Docusate Sodium	244	Imidurea	337
E		Inulin	339
Edetic Acid	247		
Erythorbic Acid	250		

Iron Oxides	340	Methionine	436
Isomalt	342	Methylcellulose	438
Isopropyl Alcohol	346	Methylparaben	441
Isopropyl Myristate	348	Mineral Oil	445
Isopropyl Palmitate	350	Mineral Oil, Light	447
K		Mineral Oil and Lanolin Alcohols	449
Kaolin	352	Monoethanolamine	450
L		Monosodium Glutamate	452
Lactic Acid	355	Monothioglycerol	454
Lactitol	357	Myristic Acid	455
Lactose, Anhydrous	359	Myristyl Alcohol	456
Lactose, Inhalation	362	N	
Lactose, Monohydrate	364	Neohesperidin Dihydrochalcone	458
Lactose, Monohydrate and Corn Starch	370	Neotame	460
Lactose, Monohydrate and Microcrystalline Cellulose	371	Nitrogen	461
Lactose, Monohydrate and Povidone	373	Nitrous Oxide	463
Lactose, Monohydrate and Powdered Cellulose	374	O	
Lactose, Spray-Dried	376	Octyldodecanol	465
Lanolin	378	Oleic Acid	466
Lanolin, Hydrous	380	Oleyl Alcohol	468
Lanolin Alcohols	382	Olive Oil	470
Lauric Acid	383	P	
Lecithin	385	Palmitic Acid	473
Leucine	387	Paraffin	474
Linoleic Acid	389	Peanut Oil	476
M		Pectin	478
Macrogol 15 Hydroxystearate	391	Pentetic Acid	480
Magnesium Aluminum Silicate	393	Petrolatum	481
Magnesium Carbonate	397	Petrolatum and Lanolin Alcohols	484
Magnesium Oxide	400	Phenol	485
Magnesium Silicate	402	Phenoxyethanol	488
Magnesium Stearate	404	Phenylethyl Alcohol	490
Magnesium Trisilicate	408	Phenylmercuric Acetate	492
Maleic Acid	410	Phenylmercuric Borate	494
Malic Acid	411	Phenylmercuric Nitrate	496
Maltitol	414	Phospholipids	499
Maltitol Solution	416	Phosphoric Acid	503
Maltodextrin	418	Polacrillin Potassium	504
Maltol	421	Poloxamer	506
Maltose	422	Polycarbophil	509
Mannitol	424	Polydextrose	513
Medium-chain Triglycerides	429	Poly (DL-Lactic Acid)	515
Meglumine	431	Polyethylene Glycol	517
Menthol	433	Polyethylene Oxide	522

Polymethacrylates	525	Sodium Citrate Dihydrate	640
Poly(methyl vinyl ether/maleic anhydride)	534	Sodium Cyclamate	643
Polyoxyethylene Alkyl Ethers	536	Sodium Formaldehyde Sulfoxylate	645
Polyoxyethylene Castor Oil Derivatives	542	Sodium Hyaluronate	646
Polyoxyethylene Sorbitan Fatty Acid Esters	549	Sodium Hydroxide	648
Polyoxyethylene Stearates	554	Sodium Lactate	650
Polyoxylglycerides	557	Sodium Lauryl Sulfate	651
Polyvinyl Acetate Phthalate	562	Sodium Metabisulfite	654
Polyvinyl Alcohol	564	Sodium Phosphate, Dibasic	656
Potassium Alginate	566	Sodium Phosphate, Monobasic	659
Potassium Alum	567	Sodium Propionate	661
Potassium Benzoate	569	Sodium Starch Glycolate	663
Potassium Bicarbonate	570	Sodium Stearyl Fumarate	667
Potassium Chloride	572	Sodium Sulfite	669
Potassium Citrate	574	Sodium Thiosulfate	671
Potassium Hydroxide	576	Sorbic Acid	672
Potassium Metabisulfite	577	Sorbitan Esters (Sorbitan Fatty Acid Esters)	675
Potassium Sorbate	579	Sorbitol	679
Povidone	581	Soybean Oil	682
Propionic Acid	586	Starch	685
Propyl Gallate	587	Starch, Pregelatinized	691
Propylene Carbonate	590	Starch, Sterilizable Maize	695
Propylene Glycol	592	Stearic Acid	697
Propylene Glycol Alginate	594	Stearyl Alcohol	700
Propylparaben	596	Sucralose	701
Propylparaben Sodium	599	Sucrose	703
Pyrrolidone	600	Sucrose Octaacetate	707
R		Sugar, Compressible	709
Raffinose	603	Sugar, Confectioner's	710
S		Sugar Spheres	712
Saccharin	605	Sulfobutylether β -Cyclodextrin	714
Saccharin Sodium	608	Sulfur Dioxide	718
Safflower Oil	610	Sulfuric Acid	719
Saponite	612	Sunflower Oil	721
Sesame Oil	614	Suppository Bases, Hard Fat	722
Shellac	616	T	
Simethicone	619	Tagatose	727
Sodium Acetate	620	Talc	728
Sodium Alginate	622	Tartaric Acid	731
Sodium Ascorbate	625	Tetrafluoroethane (HFC)	733
Sodium Benzoate	627	Thaumatococcus	735
Sodium Bicarbonate	629	Thimerosal	736
Sodium Borate	633	Thymol	739
Sodium Carbonate	635	Titanium Dioxide	741
Sodium Chloride	637	Tragacanth	744

Trehalose	746	Wax, White	779
Triacetin	748	Wax, Yellow	780
Tributyl Citrate	749		
Tricaprylin	751		
Triethanolamine	754		
Triethyl Citrate	756	X	
Triolein	757	Xanthan Gum	782
		Xylitol	786
V			
Vanillin	760		
Vegetable Oil, Hydrogenated	762		
Vitamin E Polyethylene Glycol Succinate	764	Z	
		Zein	790
		Zinc Acetate	791
		Zinc Stearate	793
W			
Water	766		
Wax, Anionic Emulsifying	770	Appendix I: Suppliers Directory	795
Wax, Carnauba	772	Appendix II: List of Excipient 'E' Numbers	847
Wax, Cetyl Esters	774	Appendix III: List of Excipient 'EINECS' Numbers	849
Wax, Microcrystalline	775	Appendix IV: List of Excipient Molecular Weights	852
Wax, Nonionic Emulsifying	777	Index	855

Preface

Pharmaceutical dosage forms contain both pharmacologically active compounds and excipients added to aid the formulation and manufacture of the subsequent dosage form for administration to patients. Indeed, the properties of the final dosage form (i.e. its bioavailability and stability) are, for the most part, highly dependent on the excipients chosen, their concentration and interaction with both the active compound and each other. No longer can excipients be regarded simply as inert or inactive ingredients, and a detailed knowledge not only of the physical and chemical properties but also of the safety, handling and regulatory status of these materials is essential for formulators throughout the world. In addition, the growth of novel forms of delivery has resulted in an increase in the number of the excipients being used and suppliers of excipients have developed novel coprocessed excipient mixtures and new physical forms to improve their properties. The *Handbook of Pharmaceutical Excipients* has been conceived as a systematic, comprehensive resource of information on all of these topics.

The first edition of the *Handbook* was published in 1986 and contained 145 monographs. This was followed by the second edition in 1994 containing 203 monographs, the third edition in 2000 containing 210 monographs and the fourth edition in 2003 containing 249 monographs. Since 2000, the data has also been available on CD-ROM, updated annually, and from 2004 online. The fifth edition with its companion CD-ROM, *Pharmaceutical Excipients 5*, contained 300 monographs and was published in 2006. This new edition contains 340 excipient monographs with a new text design and enhanced online features, compiled by over 140 experts in pharmaceutical formulation or excipient manufacture from Australia, Europe, India, Japan, and the USA. All the monographs have been reviewed and revised in the light of current knowledge. There has been a greater emphasis on including published data from primary sources although some data from laboratory projects included in previous editions have been retained where relevant. Variations in test methodology can have significant effects on the data generated (especially in the case of the compactability of an excipient), and thus cause confusion. As a consequence, the editors have been more selective in including data relating to the physical properties of an excipient. However, comparative data that show differences between either source or

batch of a specific excipient have been retained as this was considered relevant to the behavior of a material in practice. Over the past few years, there has been an increased emphasis on the harmonization of excipients. For information on the current status for each excipient selected for harmonization, the reader is directed to the General Information Chapter <1196> in the USP32–NF27, the General Chapter 5.8 in PhEur 6.0, along with the ‘State of Work’ document on the PhEur EDQM website (<http://www.edqm.eu>), and also the General Information Chapter 8 in the JP XV. The Suppliers Directory (Appendix I) has also been completely updated with many more international suppliers included.

In a systematic and uniform manner, the *Handbook of Pharmaceutical Excipients* collects essential data on the physical properties of excipients such as: boiling point, bulk and tap density, compression characteristics, hygroscopicity, flowability, melting point, moisture content, moisture-absorption isotherms, particle size distribution, rheology, specific surface area, and solubility. Scanning electron microphotographs (SEMs) are also included for many of the excipients. This edition contains over 130 near-infrared (NIR) spectra specifically generated for the *Handbook*. The *Handbook* contains information from various international sources and personal observation and comments from monograph authors, steering committee members, and the editors.

All of the monographs in the *Handbook* are thoroughly cross-referenced and indexed so that excipients may be identified by either a chemical, a nonproprietary, or a trade name. Most monographs list related substances to help the formulator to develop a list of possible materials for use in a new dosage form or product. Related substances are not directly substitutable for each other but, in general, they are excipients that have been used for similar purposes in various dosage forms.

The *Handbook of Pharmaceutical Excipients* is a comprehensive, uniform guide to the uses, properties, and safety of pharmaceutical excipients, and is an essential reference source for those involved in the development, production, control, or regulation of pharmaceutical preparations. Since many pharmaceutical excipients are also used in other applications, the *Handbook of Pharmaceutical Excipients* will also be of value to persons with an interest in the formulation or production of confectionery, cosmetics, and food products.

Abbreviations

Some units, terms, and symbols are not included in this list as they are defined in the text. Common abbreviations have been omitted. The titles of journals are abbreviated according to the general style of the *Index Medicus*.

≈	approximately.	IV	intravenous.
Ad	Addendum.	J	joule(s).
ADI	acceptable daily intake.	JP	Japanese Pharmacopeia.
approx	approximately.	JPE	Japanese Pharmaceutical Excipients
atm	atmosphere.	kcal	kilocalorie(s).
BAN	British Approved Name.	kg	kilogram(s).
bp	boiling point.	kJ	kilojoule(s).
BP	British Pharmacopoeia.	kPa	kilopascal(s).
BS	British Standard (specification).	L	liter(s).
BSI	British Standards Institution.	LAL	<i>Limulus</i> amoebocyte lysate.
cal	calorie(s).	LC ₅₀	a concentration in air lethal to 50% of the specified animals on inhalation.
CAS	Chemical Abstract Service.	LD ₅₀	a dose lethal to 50% of the specified animals or microorganisms.
CFC	chlorofluorocarbon.	Ld _{Lo}	lowest lethal dose for the specified animals or microorganisms.
cfu	colony-forming unit	m	meter(s).
cm	centimeter(s).	m ²	square meter(s).
cm ²	square centimeter(s).	m ³	cubic meter(s).
cm ³	cubic centimeter(s).	M	molar.
cmc	critical micelle concentration.	max	maximum.
CNS	central nervous system.	MCA	Medicines Control Agency (UK).
cP	centipoise(s).	mg	milligram(s).
cSt	centistoke(s).	MIC	minimum inhibitory concentration.
CTFA	Cosmetic, Toiletry, and Fragrance Association.	min	minute(s) <i>or</i> minimum.
d	particle diameter (d ₁₀ at 10 percentile; d ₅₀ at 50 percentile; d ₉₀ at 90 percentile).	mL	milliliter(s).
D&C	designation applied in USA to dyes permitted for use in drugs and cosmetics.	mm	millimeter(s).
DoH	Department of Health (UK).	mM	millimolar.
DSC	differential scanning calorimetry.	mm ²	square millimeter(s).
EC	European Community.	mm ³	cubic millimeter(s).
e.g.	<i>exempli gratia</i> , 'for example'.	mmHg	millimeter(s) of mercury.
EINECS	European Inventory of Existing Commercial Chemical Substances.	mmol	millimole(s).
<i>et al</i>	<i>et alii</i> , 'and others'.	mN	millinewton(s).
EU	European Union.	mol	mole(s).
FAO	Food and Agriculture Organization of the United Nations.	mp	melting point.
FAO/WHO	Food and Agriculture Organization of the United Nations <i>and</i> the World Health Organization.	mPa	millipascal(s).
FCC	Food Chemicals Codex.	MPa	megapascal(s).
FDA	Food and Drug Administration of the USA.	μg	microgram(s).
FD&C	designation applied in USA to dyes permitted for use in foods, drugs, and cosmetics.	μm	micrometer(s).
FFBE	Flat face beveled edge.	N	newton(s) <i>or</i> normal (concentration).
g	gram(s).	NIR	near-infrared.
GMP	Good Manufacturing Practice.	nm	nanometer(s).
GRAS	generally recognized as safe by the Food and Drug Administration of the USA.	o/w	oil-in-water.
HC	hydrocarbon.	o/w/o	oil-in-water-in-oil.
HCFC	hydrochlorofluorocarbon.	Pa	pascal(s).
HFC	hydrofluorocarbon.	pH	the negative logarithm of the hydrogen ion concentration.
HIV	human immunodeficiency virus.	PhEur	European Pharmacopeia.
HLB	hydrophilic-lipophilic balance.	pK _a	the negative logarithm of the dissociation constant.
HSE	Health and Safety Executive (UK).	pph	parts per hundred.
i.e.	<i>id est</i> , 'that is'.	ppm	parts per million.
IM	intramuscular.	psia	pounds per square inch absolute.
INN	International Nonproprietary Name.	R	reflectance.
IP	intraperitoneal.	RDA	recommended dietary allowance (USA).
ISO	International Organization for Standardization.	rpm	revolutions per minute.
IU	International Units.	s	second(s).
		SC	subcutaneous.
		SEM	scanning electron microscopy <i>or</i> scanning electron microphotography.

SI	Statutory Instrument <i>or</i> Système International d'Unités (International System of Units).	USP–NF	The United States Pharmacopeia National Formulary.
TD _{Lo}	lowest toxic dose for the specified animals or microorganisms.	UV	ultraviolet.
TPN	total parental nutrition.	v/v	volume in volume.
TWA	time weighted average.	v/w	volume in weight.
UK	United Kingdom.	WHO	World Health Organization.
US <i>or</i> USA	United States of America.	w/o	water-in-oil.
USAN	United States Adopted Name.	w/o/w	water-in-oil-in-water.
USP	The United States Pharmacopeia.	w/v	weight in volume.
		w/w	weight in weight.

14 Safety

Hydrogenated castor oil is used in oral and topical pharmaceutical formulations and is generally regarded as an essentially nontoxic and nonirritant material.

Acute oral toxicity studies in animals have shown that hydrogenated castor oil is a relatively nontoxic material. Irritation tests with rabbits show that hydrogenated castor oil causes mild, transient irritation to the eye.

LD₅₀ (rat, oral): >10 g/kg

15 Handling Precautions

Observe normal precautions appropriate to the circumstances and quantity of material handled.

16 Regulatory Status

Accepted in the USA as an indirect food additive. Included in the FDA Inactive Ingredients Database (oral capsules, tablets, and sublingual tablets).

Included in nonparenteral medicines licensed in the UK. Included in the Canadian List of Acceptable Non-medicinal Ingredients.

17 Related Substances

Castor oil; vegetable oil, hydrogenated.

18 Comments

Various different grades of hydrogenated castor oil are commercially available, the composition of which may vary considerably.

Sterotex K (Karlshamns Lipid Specialities), for example, is a mixture of hydrogenated castor oil and hydrogenated cottonseed oil. See *Vegetable Oil*, hydrogenated for further information.

The EINECS number for hydrogenated castor oil is 232-292-2.

19 Specific References

- 1 Kline CH. Thixcin R-thixotrope. *Drug Cosmet Ind* 1964; 95(6): 895–897.
- 2 Yonezawa Y *et al.* Release from or through a wax matrix system. III: Basic properties of release through the wax matrix layer. *Chem Pharm Bull (Tokyo)* 2002; 50(6): 814–817.
- 3 Vergote GJ *et al.* An oral controlled release matrix pellet formulation containing microcrystalline ketoprofen. *Int J Pharm* 2002; 219: 81–87.
- 4 Danish FQ, Parrott EL. Effect of concentration and size of lubricant on flow rate of granules. *J Pharm Sci* 1971; 60: 752–754.
- 5 Hölzer AW, Sjögren J. Evaluation of some lubricants by the comparison of friction coefficients and tablet properties. *Acta Pharm Suec* 1981; 18: 139–148.

20 General References

—

21 Author

RT Guest.

22 Date of Revision

11 February 2009.

Cellulose, Microcrystalline

1 Nonproprietary Names

BP: Microcrystalline Cellulose

JP: Microcrystalline Cellulose

PhEur: Cellulose, Microcrystalline

USP-NF: Microcrystalline Cellulose

2 Synonyms

Avicel PH; *Cellets*; *Cellex*; cellulose gel; *hellulosum microcristallinum*; *Celphere*; *Ceolus KG*; crystalline cellulose; E460; *Emcocel*; *Ethispheres*; *Fibrocel*; *MCC Sanaq*; *Pharmacel*; *Tabulose*; *Vivapur*.

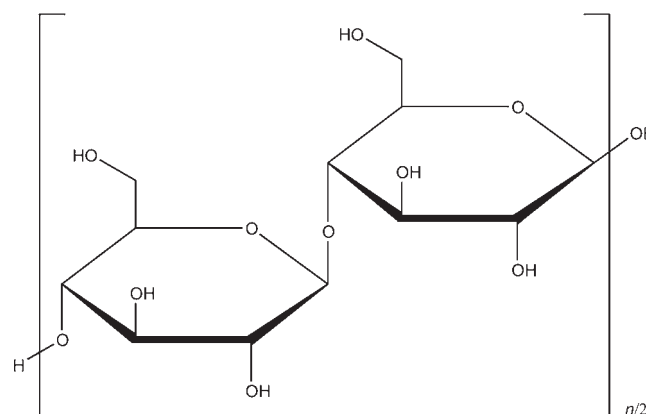
3 Chemical Name and CAS Registry Number

Cellulose [9004-34-6]

4 Empirical Formula and Molecular Weight

(C₆H₁₀O₅)_n ≈ 36 000
where *n* ≈ 220.

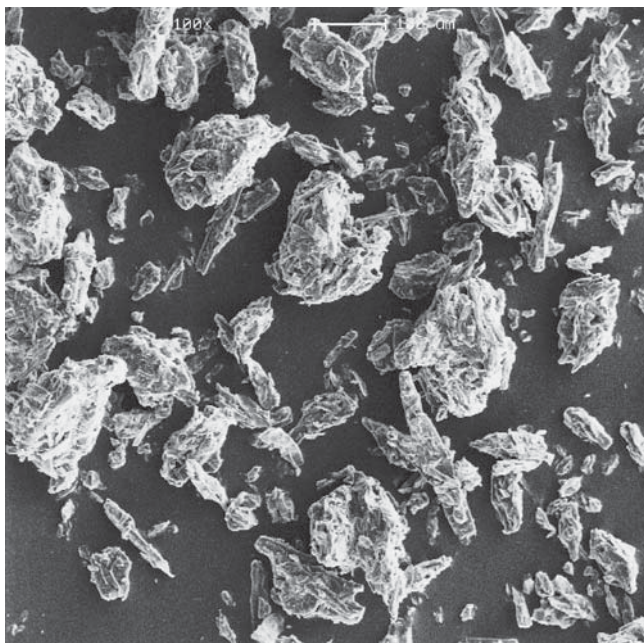
5 Structural Formula



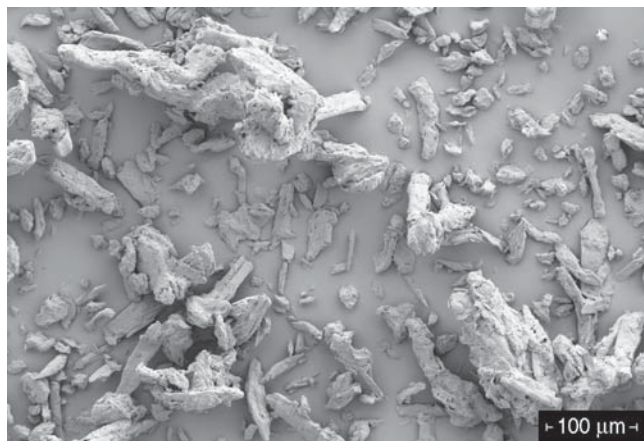
6 Functional Category

Adsorbent; suspending agent; tablet and capsule diluent; tablet disintegrant.

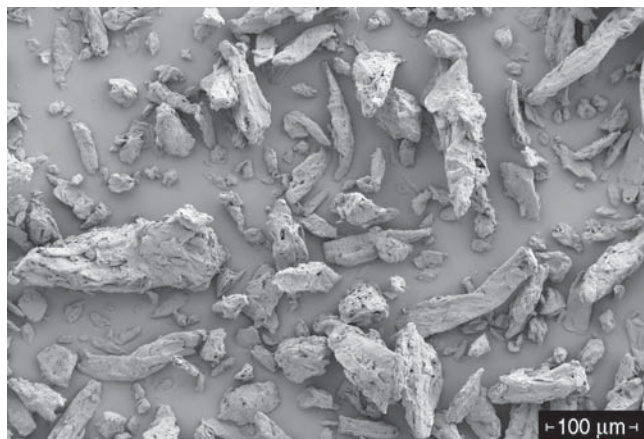
SEM 1: Excipient: microcrystalline cellulose; manufacturer: JRS Pharma LP; lot no.: 98662; magnification: 100 $\times$.



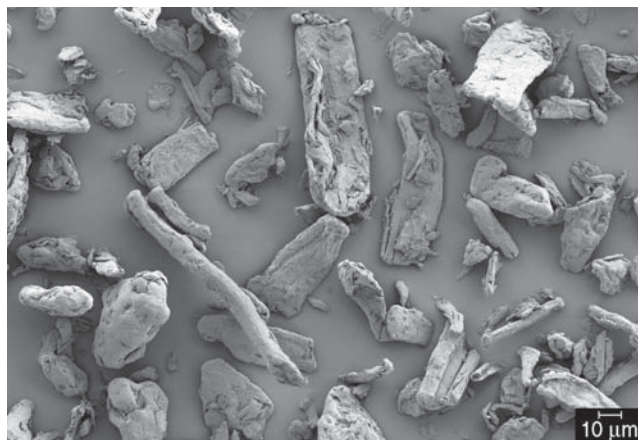
SEM 2: Excipient: microcrystalline cellulose (*Avicel PH-101*); manufacturer: FMC Biopolymer. magnification: 200 $\times$; voltage: 3 kV.



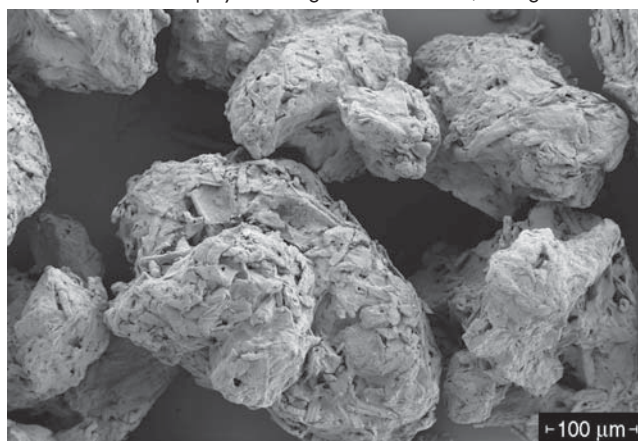
SEM 3: Excipient: microcrystalline cellulose (*Avicel PH-102*); manufacturer: FMC Biopolymer. magnification: 200 $\times$; voltage: 3 kV.



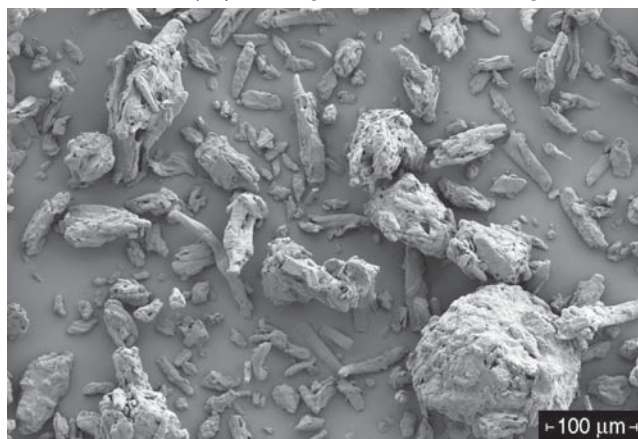
SEM 4: Excipient: microcrystalline cellulose (*Avicel PH-105*); manufacturer: FMC Biopolymer. magnification: 500 $\times$; voltage: 3 kV.



SEM 5: Excipient: microcrystalline cellulose (*Avicel PH-200*); manufacturer: FMC Biopolymer. magnification: 200 $\times$; voltage: 3 kV.



SEM 6: Excipient: microcrystalline cellulose (*Avicel PH-302*); manufacturer: FMC Biopolymer. magnification: 200 $\times$; voltage: 3 kV.



7 Applications in Pharmaceutical Formulation or Technology

Microcrystalline cellulose is widely used in pharmaceuticals, primarily as a binder/diluent in oral tablet and capsule formulations where it is used in both wet-granulation and direct-compression processes.⁽¹⁻⁷⁾ In addition to its use as a binder/diluent, microcrystalline cellulose also has some lubricant⁽⁸⁾ and disintegrant properties that make it useful in tableting.

Microcrystalline cellulose is also used in cosmetics and food products; see Table I.

8 Description

Microcrystalline cellulose is a purified, partially depolymerized cellulose that occurs as a white, odorless, tasteless, crystalline powder composed of porous particles. It is commercially available in different particle sizes and moisture grades that have different properties and applications.

Table I: Uses of microcrystalline cellulose.

Use	Concentration (%)
Adsorbent	20–90
Antiadherent	5–20
Capsule binder/diluent	20–90
Tablet disintegrant	5–15
Tablet binder/diluent	20–90

9 Pharmacopeial Specifications

See Table II. See also Section 18.

Table II: Pharmacopeial specifications for microcrystalline cellulose.

Test	JP XV	PhEur 6.3	USP32–NF27
Identification	+	+	+
Characters	+	+	—
pH	5.0–7.5	5.0–7.5	5.0–7.5
Bulk density	+	—	+
Loss on drying	≤7.0%	≤7.0%	≤7.0%
Residue on ignition	≤0.1%	—	≤0.1%
Conductivity	+	+	+
Sulfated ash	—	≤0.1%	—
Ether-soluble substances	≤0.05%	≤0.05%	≤0.05%
Water-soluble substances	+	≤0.25%	≤0.25%
Heavy metals	≤10 ppm	≤10 ppm	≤0.001%
Microbial limits	+	+	+
Aerobic	≤10 ³ cfu/g	≤10 ³ cfu/g	≤10 ³ cfu/g
Molds and yeasts	≤10 ² cfu/g	≤10 ² cfu/g	≤10 ² cfu/g
Solubility	—	+	—
Particle size distribution	—	—	+

10 Typical Properties

Angle of repose

49° for *Ceolus KG*;

34.4° for *Emcocel 90M*.⁽⁹⁾

Density (bulk)

0.337 g/cm³;

0.32 g/cm³ for *Avicel PH-101*;⁽¹⁰⁾

0.80 ± 5 g/cm³ for *Cellets 100, 200, 350, 500, 700, 1000*;

0.29 g/cm³ for *Emcocel 90M*;⁽⁹⁾

0.26–0.31 g/cm³ for *MCC Sanaq 101*;

0.28–0.33 g/cm³ for *MCC Sanaq 102*;

0.29–0.36 g/cm³ for *MCC Sanaq 200*;

0.34–0.45 g/cm³ for *MCC Sanaq 301*;

0.35–0.46 g/cm³ for *MCC Sanaq 302*;

0.13–0.23 g/cm³ for *MCC Sanaq UL-002*;

0.29 g/cm³ for *Vivapur 101*.

Density (tapped)

0.478 g/cm³;

0.45 g/cm³ for *Avicel PH-101*;

0.35 g/cm³ for *Emcocel 90M*.⁽⁹⁾

Density (true) 1.512–1.668 g/cm³;

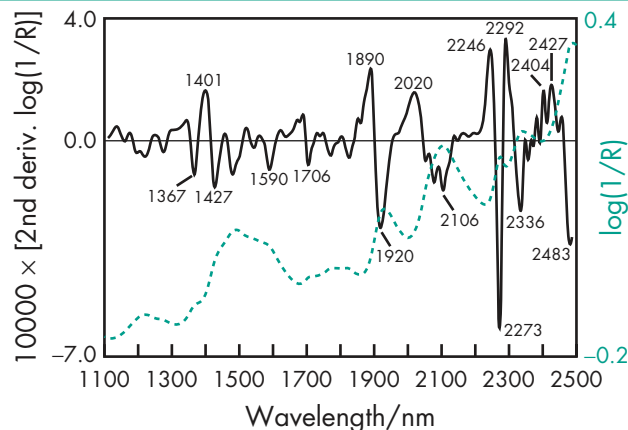


Figure 1: Near-infrared spectrum of cellulose, microcrystalline measured by reflectance.

1.420–1.460 g/cm³ for *Avicel PH-102*.⁽¹¹⁾

Flowability 1.41 g/s for *Emcocel 90M*.⁽⁹⁾

Melting point Chars at 260–270°C.

Moisture content Typically less than 5% w/w. However, different grades may contain varying amounts of water. Microcrystalline cellulose is hygroscopic.⁽¹²⁾ See Table III.

NIR spectra see Figure 1.

Particle size distribution Typical mean particle size is 20–200 μm. Different grades may have a different nominal mean particle size; see Table III.

Solubility Slightly soluble in 5% w/v sodium hydroxide solution; practically insoluble in water, dilute acids, and most organic solvents.

Specific surface area

1.06–1.12 m²/g for *Avicel PH-101*;

1.21–1.30 m²/g for *Avicel PH-102*;

0.78–1.18 m²/g for *Avicel PH-200*.

11 Stability and Storage Conditions

Microcrystalline cellulose is a stable though hygroscopic material. The bulk material should be stored in a well-closed container in a cool, dry place.

12 Incompatibilities

Microcrystalline cellulose is incompatible with strong oxidizing agents.

13 Method of Manufacture

Microcrystalline cellulose is manufactured by controlled hydrolysis with dilute mineral acid solutions of α-cellulose, obtained as a pulp from fibrous plant materials. Following hydrolysis, the hydro-cellulose is purified by filtration and the aqueous slurry is spray-dried to form dry, porous particles of a broad size distribution.

14 Safety

Microcrystalline cellulose is widely used in oral pharmaceutical formulations and food products and is generally regarded as a relatively nontoxic and nonirritant material.

Microcrystalline cellulose is not absorbed systemically following oral administration and thus has little toxic potential. Consumption of large quantities of cellulose may have a laxative effect, although this is unlikely to be a problem when cellulose is used as an excipient in pharmaceutical formulations.

Deliberate abuse of formulations containing cellulose, either by inhalation or by injection, has resulted in the formation of cellulose granulomas.⁽¹³⁾

Table III: Properties of selected commercially available grades of microcrystalline cellulose.

Grade	Nominal mean particle size (μm)	Particle size analysis		Moisture content (%)
		Mesh size	Amount retained (%)	
<i>Avicel PH-101</i> ^(a)	50	60	≤ 1.0	≤ 5.0
		200	≤ 30.0	
<i>Avicel PH-102</i> ^(a)	100	60	≤ 8.0	≤ 5.0
		200	≥ 45.0	
<i>Avicel PH-103</i> ^(a)	50	60	≤ 1.0	≤ 3.0
		200	≤ 30.0	
<i>Avicel PH-105</i> ^(a)	20	400	≤ 1.0	≤ 5.0
<i>Avicel PH-112</i> ^(a)	100	60	≤ 8.0	≤ 1.5
<i>Avicel PH-113</i> ^(a)	50	60	≤ 1.0	≤ 1.5
		200	≤ 30.0	
<i>Avicel PH-200</i> ^(a)	180	60	≥ 10.0	≤ 5.0
		100	≥ 50.0	
<i>Avicel PH-301</i> ^(a)	50	60	≤ 1.0	≤ 5.0
		200	≤ 30.0	
<i>Avicel PH-302</i> ^(a)	100	60	≤ 8.0	≤ 5.0
		200	≥ 45.0	
<i>Celex 101</i> ^(b)	75	60	≤ 1.0	≤ 5.0
		200	≥ 30.0	
<i>Ceolus KG-802</i> ^(c)	50	60	≤ 0.5	≤ 6.0
		200	≤ 30.0	
<i>Emcocel 50M</i> ^(d)	50	60	≤ 0.25	≤ 5.0
		200	≤ 30.0	
<i>Emcocel 90M</i> ^(d)	91	60	≤ 8.0	≤ 5.0
		200	≥ 45.0	
<i>MCC Sanaq 101</i> ^(e)	50	60	≤ 1.0	≤ 6.0
		200	≤ 30.0	
<i>MCC Sanaq 102</i> ^(e)	100	60	≤ 8.0	≤ 6.0
		200	≥ 45.0	
<i>MCC Sanaq 200</i> ^(e)	180	60	≥ 10.0	≤ 6.0
		100	≥ 50.0	
<i>MCC Sanaq 301</i> ^(e)	50	60	≤ 1.0	≤ 6.0
		200	≥ 30.0	
<i>MCC Sanaq 302</i> ^(e)	100	60	≤ 8.0	≤ 6.0
		200	≥ 45.0	
<i>MCC Sanaq UL-002</i> ^(e)	50	60	< 0.5	≤ 6.0
		100	< 5.0	
<i>Vivapur 101</i> ^(d)	50	200	< 5.0–30.0	
		60	≤ 1.0	≤ 5.0
<i>Vivapur 102</i> ^(d)	90	200	≤ 30.0	
		60	≤ 8.0	≤ 5.0
<i>Vivapur 12</i> ^(d)	160	200	≥ 45.0	
		38	≤ 1.0	≤ 5.0
		94	≤ 50.0	

Suppliers:

(a) FMC Biopolymer

(b) International Specialty Products

(c) Asahi Kasei Corporation

(d) JRS Pharma

(e) Pharmatrans Sanaq AG

15 Handling Precautions

Observe normal precautions appropriate to the circumstances and quantity of material handled. Microcrystalline cellulose may be irritant to the eyes. Gloves, eye protection, and a dust mask are recommended. In the UK, the workplace exposure limits for cellulose have been set at 10 mg/m³ long-term (8-hour TWA) for total inhalable dust and 4 mg/m³ for respirable dust; the short-term limit for total inhalable dust has been set at 20 mg/m³.⁽¹⁴⁾

16 Regulatory Status

GRAS listed. Accepted for use as a food additive in Europe. Included in the FDA Inactive Ingredients Database (inhalations; oral capsules, powders, suspensions, syrups, and tablets; topical and vaginal preparations). Included in nonparenteral medicines licensed in the UK. Included in the Canadian List of Acceptable Non-medicinal Ingredients.

17 Related Substances

Microcrystalline cellulose and carrageenan; microcrystalline cellulose and carboxymethylcellulose sodium; microcrystalline cellulose and guar gum; powdered cellulose; silicified microcrystalline cellulose.

Microcrystalline cellulose and carrageenan

Synonyms *Lustre Clear*.

Comments *Lustre Clear* (FMC Biopolymer) is an aqueous film coating combining microcrystalline cellulose and carrageenan.

Microcrystalline cellulose and guar gum

Synonyms *Avicel CE-15*.

Comments *Avicel CE-15* (FMC Biopolymer) is a coprocessed mixture of microcrystalline cellulose and guar gum used in chewable tablet formulations.

18 Comments

Microcrystalline cellulose is one of the materials that have been selected for harmonization by the Pharmacopeial Discussion Group. For further information see the General Information Chapter <1196> in the USP32–NF27, the General Chapter 5.8 in PhEur 6.0, along with the 'State of Work' document on the PhEur EDQM website, and also the General Information Chapter 8 in the JP XV.

Several different grades of microcrystalline cellulose are commercially available that differ in their method of manufacture,^(15,16) particle size, moisture, flow, and other physical properties.^(17–29) The larger-particle-size grades generally provide better flow properties in pharmaceutical machinery. Low-moisture grades are used with moisture-sensitive materials. Higher-density grades have improved flowability.

Several coprocessed mixtures of microcrystalline cellulose with other excipients such as carrageenan, carboxymethylcellulose sodium, and guar gum are commercially available; see Section 17.

Celphere (Asahi Kasei Corporation) is a pure spheronized microcrystalline cellulose available in several different particle size ranges. *Balocel Sanaq* (Pharmatrans Sanaq AG) is an excipient used mainly in the production of pellets and granulates in direct tableting, which contains lactose, microcrystalline cellulose, and sodium carboxymethylcellulose.

According to PhEur 6.3, microcrystalline cellulose has certain functionality related characteristics that are recognised as being relevant control parameters for one or more functions of the substance when used as an excipient. Non-mandatory testing procedures have been described for particle size distribution (2.9.31 or 2.9.38) and powder flow (2.9.36).

A specification for microcrystalline cellulose is contained in the Food Chemicals Codex (FCC).⁽³⁰⁾ The PubChem Compound ID (CID) for microcrystalline cellulose is 14055602.

19 Specific References

- Enézian GM. [Direct compression of tablets using microcrystalline cellulose.] *Pharm Acta Helv* 1972; 47: 321–363[in French].
- Lerk CF, Bolhuis GK. Comparative evaluation of excipients for direct compression I. *Pharm Weekbl* 1973; 108: 469–481.
- Lerk CF *et al.* Comparative evaluation of excipients for direct compression II. *Pharm Weekbl* 1974; 109: 945–955.
- Lamberson RF, Raynor GE. Tableting properties of microcrystalline cellulose. *Manuf Chem Aerosol News* 1976; 47(6): 55–61.

- 5 Lerk CF *et al.* Effect of microcrystalline cellulose on liquid penetration in and disintegration of directly compressed tablets. *J Pharm Sci* 1979; 68: 205–211.
- 6 Chilamkurti RN *et al.* Some studies on compression properties of tablet matrices using a computerized instrumented press. *Drug Dev Ind Pharm* 1982; 8: 63–86.
- 7 Wallace JW *et al.* Performance of pharmaceutical filler/binders as related to methods of powder characterization. *Pharm Technol* 1983; 7(9): 94–104.
- 8 Omray A, Omray P. Evaluation of microcrystalline cellulose as a glidant. *Indian J Pharm Sci* 1986; 48: 20–22.
- 9 Celik M, Okutgen E. A feasibility study for the development of a prospective compaction functionality test and the establishment of a compaction data bank. *Drug Dev Ind Pharm* 1993; 19: 2309–2334.
- 10 Parker MD *et al.* Binder–substrate interactions in wet granulation 3: the effect of excipient source variation. *Int J Pharm* 1992; 80: 179–190.
- 11 Sun CC. True density of microcrystalline cellulose. *J Pharm Sci* 2005; 94(10): 2132–2134.
- 12 Callahan JC *et al.* Equilibrium moisture content of pharmaceutical excipients. *Drug Dev Ind Pharm* 1982; 8: 355–369.
- 13 Cooper CB *et al.* Cellulose granulomas in the lungs of a cocaine sniffer. *Br Med J* 1983; 286: 2021–2022.
- 14 Health and Safety Executive. *EH40/2005: Workplace Exposure Limits*. Sudbury: HSE Books, 2005 (updated 2007). <http://www.hse.gov.uk/coshh/table1.pdf> (accessed 5 February 2009).
- 15 Jain JK *et al.* Preparation of microcrystalline cellulose from cereal straw and its evaluation as a tablet excipient. *Indian J Pharm Sci* 1983; 45: 83–85.
- 16 Singla AK *et al.* Evaluation of microcrystalline cellulose prepared from absorbent cotton as a direct compression carrier. *Drug Dev Ind Pharm* 1988; 14: 1131–1136.
- 17 Doelker E *et al.* Comparative tableting properties of sixteen microcrystalline celluloses. *Drug Dev Ind Pharm* 1987; 13: 1847–1875.
- 18 Bassam F *et al.* Effect of particle size and source on variability of Young's modulus of microcrystalline cellulose powders. *J Pharm Pharmacol* 1988; 40: 68P.
- 19 Dittgen M *et al.* Microcrystalline cellulose in direct tableting. *Manuf Chem* 1993; 64(7): 17, 19, 21.
- 20 Landin M *et al.* Effect of country of origin on the properties of microcrystalline cellulose. *Int J Pharm* 1993; 91: 123–131.
- 21 Landin M *et al.* Effect of batch variation and source of pulp on the properties of microcrystalline cellulose. *Int J Pharm* 1993; 91: 133–141.
- 22 Landin M *et al.* Influence of microcrystalline cellulose source and batch variation on tableting behavior and stability of prednisone formulations. *Int J Pharm* 1993; 91: 143–149.
- 23 Podczek F, Révész P. Evaluation of the properties of microcrystalline and microfine cellulose powders. *Int J Pharm* 1993; 91: 183–193.
- 24 Rowe RC *et al.* The effect of batch and source variation on the crystallinity of microcrystalline cellulose. *Int J Pharm* 1994; 101: 169–172.
- 25 Hasegawa M. Direct compression: microcrystalline cellulose grade 12 versus classic grade 102. *Pharm Technol* 2002; 26(5): 50, 52, 54, 56, 58, 60.
- 26 Kothari SH *et al.* Comparative evaluations of powder and mechanical properties of low crystallinity celluloses, microcrystalline celluloses, and powdered celluloses. *Int J Pharm* 2002; 232: 69–80.
- 27 Levis SR, Deasy PB. Production and evaluation of size-reduced grades of microcrystalline cellulose. *Int J Pharm* 2001; 213: 13–24.
- 28 Wu JS *et al.* A statistical design to evaluate the influence of manufacturing factors on the material properties and functionalities of microcrystalline cellulose. *Eur J Pharm Sci* 2001; 12: 417–425.
- 29 Suzuki T, Nakagami H. Effect of crystallinity of microcrystalline cellulose on the compactability and dissolution of tablets. *Eur J Pharm Biopharm* 1999; 47: 225–230.
- 30 *Food Chemicals Codex*, 6th edn. Bethesda, MD: United States Pharmacopeia, 2008; 187.

20 General References

- Asahi Kasei Corporation. *Ceolus KG, Celphere*. <http://www.ceolus.com> (accessed 6 November 2008).
- Doelker E. Comparative compaction properties of various microcrystalline cellulose types and generic products. *Drug Dev Ind Pharm* 1993; 19: 2399–2471.
- European Directorate for the Quality of Medicines and Healthcare (EDQM). European Pharmacopoeia – State Of Work Of International Harmonisation. *Pharmeuropa* 2009; 21(1): 142–143. <http://www.edqm.eu/site/-614.html> (accessed 5 February 2009).
- FMC Biopolymer. Problem Solver: *Avicel PH*, 2000.
- International Specialty Products. Material Safety data sheet: *Celex 101*, 2003.
- JRS Pharma LP. Technical literature: *Emcocel*, 2003.
- Pharmatrans Sanaq AG. Product literature: *Cellets*. <http://www.cellets.com> (accessed 6 November 2008).
- Pharmatrans Sanaq AG. Product literature: *MCC Sanaq*. <http://www.pharmatrans-sanaq.com/prod.html> (accessed 6 November 2008).
- Smolinske SC. *Handbook of Food, Drug, and Cosmetic Excipients*. Boca Raton, FL: CRC Press, 1992; 71–74.
- Staniforth JN *et al.* Effect of addition of water on the rheological and mechanical properties of microcrystalline celluloses. *Int J Pharm* 1988; 41: 231–236.

21 Author

A Guy.

22 Date of Revision

5 February 2009.



Cellulose, Silicified Microcrystalline

1 Nonproprietary Names

None adopted.

2 Synonyms

ProSolv.

3 Chemical Name and CAS Registry Number

See Section 8.

4 Empirical Formula and Molecular Weight

See Section 8.

5 Structural Formula

See Section 8.

6 Functional Category

Tablet and capsule diluent.

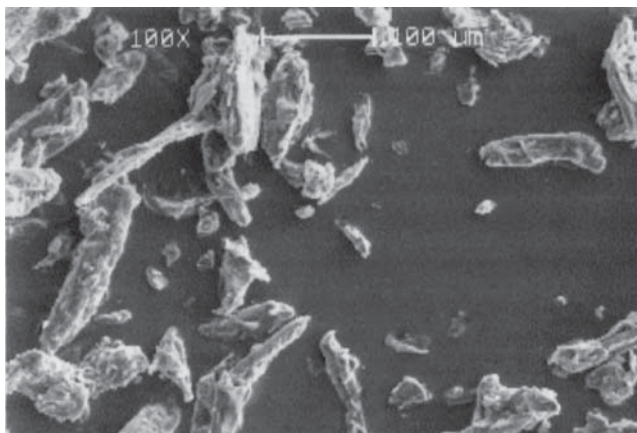
7 Applications in Pharmaceutical Formulation or Technology

Silicified microcrystalline cellulose is used as a filler in the formulation of capsules and tablets. It has improved compaction properties in both wet granulation and direct compression compared to conventional microcrystalline cellulose.^(1–5) Silicified microcrystalline cellulose was specifically developed to address the loss of compaction that occurs with microcrystalline cellulose after wet granulation. Silicified microcrystalline cellulose also appears to have beneficial properties for use in the formulation of powder-filled capsules.^(6,7)

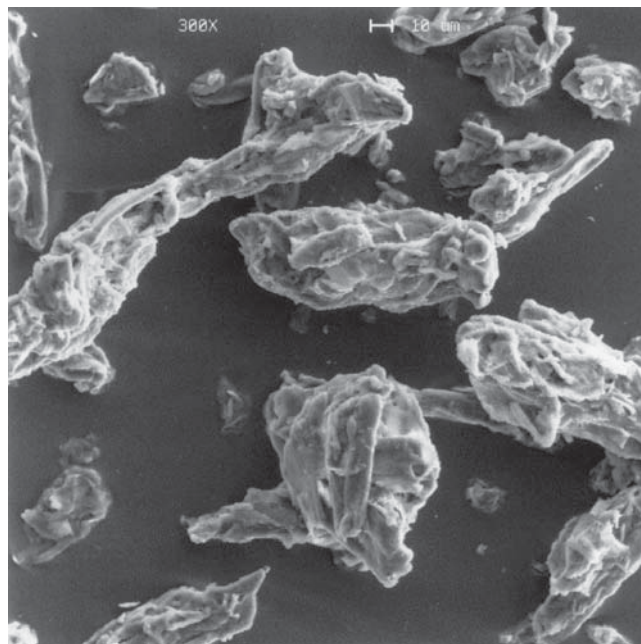
8 Description

Silicified microcrystalline cellulose is a synergistic, intimate physical mixture of two components: microcrystalline cellulose and colloidal silicon dioxide (for further information see Cellulose, Microcrystalline and Colloidal Silicon Dioxide). Silicified microcrystalline cellulose contains 2% w/w colloidal silicon dioxide.

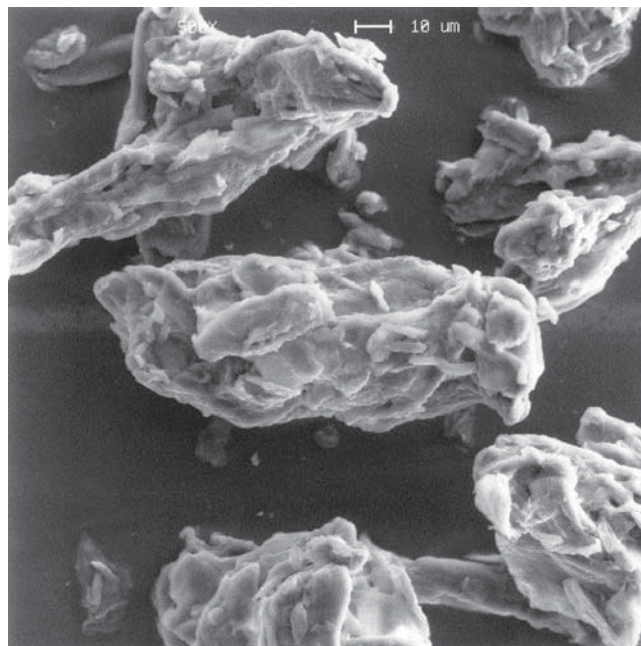
SEM 1: Excipient: silicified microcrystalline cellulose; manufacturer: JRS Pharma LP; lot no.: CSD5866; magnification: 100×.



SEM 2: Excipient: silicified microcrystalline cellulose; manufacturer: JRS Pharma LP; lot no.: CSD5866; magnification: 300×.



SEM 3: Excipient: silicified microcrystalline cellulose; manufacturer: JRS Pharma LP; lot no.: CSD5866; magnification: 500×.



9 Pharmacopeial Specifications

Both colloidal silicon dioxide and microcrystalline cellulose are listed as separate monographs in the JP, PhEur, and USP–NF, but the combination is not listed. See Cellulose, Microcrystalline and Colloidal Silicon Dioxide. See also Section 18.

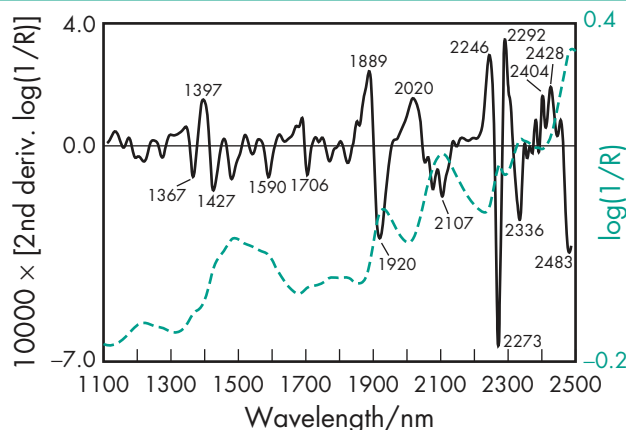


Figure 1: Near-infrared spectrum of silicified microcrystalline cellulose measured by reflectance.

10 Typical properties

Acidity/alkalinity pH = 5.0–7.5 (10% w/v suspension)

Density 1.58 g/cm³⁽⁵⁾

Density (bulk) 0.31 g/cm³

Density (tapped) 0.39 g/cm³⁽⁵⁾

Melting point The microcrystalline cellulose component chars at 260–270°C.

Moisture content Typically less than 6% w/w.

NIR spectra see Figure 1.

Particle size distribution Typical particle size is 20–200 µm. Different grades may have a different normal mean particle size.

Solubility Practically insoluble in water, dilute acids, and most organic solvents. The microcrystalline cellulose component is slightly soluble in 5% w/w sodium hydroxide solution.

11 Stability and Storage Conditions

Silicified microcrystalline cellulose is stable when stored in a well-closed container in a cool, dry place.

12 Incompatibilities

See Cellulose, Microcrystalline and Colloidal Silicon Dioxide.

13 Method of Manufacture

Silicified microcrystalline cellulose is manufactured by co-drying a suspension of microcrystalline cellulose particles and colloidal silicon dioxide such that the dried finished product contains 2% w/w colloidal silicon dioxide.

The colloidal silicon dioxide appears physically bound onto the surface and inside the silicified microcrystalline cellulose particles. Extensive studies using different spectroscopic methods have failed to show any form of chemical interaction.^(4,8,9)

14 Safety

See Cellulose, Microcrystalline and Colloidal Silicon Dioxide.

15 Handling Precautions

Observe normal precautions appropriate to the circumstances and quantity of material handled. Handling of silicified microcrystalline cellulose can generate nuisance dusts and the use of a respirator or dust mask may be necessary.

Microcrystalline cellulose may be irritant to the eyes. Gloves, eye protection, and a dust mask are recommended. In the UK the long-term workplace exposure limits (8-hour TWA) have been set at 10 mg/m³ for total inhalable dust and 4 mg/m³ for respirable dust; short-term limit for total inhalable dust has been set at 20 mg/m³.⁽¹⁰⁾

Since the colloidal silicon dioxide is physically bound to the microcrystalline cellulose the general recommendations of gloves, eye protection, and a dust mask should be followed when handling silicified microcrystalline cellulose.

16 Regulatory Status

Silicified microcrystalline cellulose is a physical mixture of two materials both of which are generally regarded as nontoxic:

Microcrystalline cellulose GRAS listed. Included in the FDA Inactive Ingredients Database (inhalations, oral capsules, powders, suspensions, syrups, and tablets). Included in nonparenteral medicines licensed in Europe and the USA. Included in the Canadian List of Acceptable Non-medicinal Ingredients.

Colloidal silicon dioxide GRAS listed. Included in the FDA Inactive Ingredients Database (oral capsules and tablets). Included in nonparenteral medicines licensed in Europe and the USA. Included in the Canadian List of Acceptable Non-medicinal Ingredients.

17 Related Substances

Cellulose, microcrystalline; colloidal silicon dioxide.

18 Comments

Colloidal silicon dioxide and microcrystalline cellulose are two of the materials that have been selected for harmonization by the Pharmacopeial Discussion Group. For further information see the General Information Chapter <1196> in the USP32–NF27, the General Chapter 5.8 in PhEur 6.0, along with the ‘State of Work’ document on the PhEur EDQM website, and also the General Information Chapter 8 in the JP XV.

Silicified microcrystalline cellulose has greater tensile strength and requires lower compression pressures than regular grades of microcrystalline cellulose. Furthermore, silicified microcrystalline cellulose maintains its compactability after wet granulation; the compacts exhibit greater stiffness and they require considerably more energy for tensile failure to occur.^(4,11,12)

19 Specific References

- 1 Sherwood BE *et al.* Silicified microcrystalline cellulose (SMCC): a new class of high functionality binders for direct compression. *Pharm Res* 1996; 13(9): S197.
- 2 Staniforth JN *et al.* Towards a new class of high functionality tablet binders. II: silicified microcrystalline cellulose (SMCC). *Pharm Res* 1996; 13(9): S197.
- 3 Toby MJ *et al.* Compaction studies on a new class of high functionality binders: silicified microcrystalline cellulose (SMCC). *Pharm Res* 1996; 13(9): S198.
- 4 Habib SY *et al.* Is silicified wet-granulated microcrystalline cellulose better than original wet-granulated microcrystalline cellulose? *Pharm Dev Technol* 1999; 4(3): 431–437.
- 5 Toby MJ *et al.* Physicochemical comparison between microcrystalline cellulose and silicified microcrystalline cellulose. *Int J Pharm* 1998; 169: 183–194.
- 6 Guo M *et al.* Evaluation of the plug information process of silicified microcrystalline cellulose. *Int J Pharm* 2002; 233: 99–109.
- 7 Guo M, Augsburger LL. Potential application of silicified microcrystalline cellulose in direct-fill formulations for capsule-filling machines. *Pharm Dev Technol* 2003; 8: 47–59.
- 8 Edge S *et al.* The mechanical properties of compacts of microcrystalline cellulose and silicified microcrystalline cellulose. *Int J Pharm* 2000; 200: 67–72.
- 9 Buckton G, Yonemochi E. Near IR spectroscopy to quantify the silica content and differences between silicified microcrystalline cellulose and physical mixtures of microcrystalline cellulose and silica. *Eur J Pharm Sci* 2000; 10(1): 77–80.
- 10 Health and Safety Executive. *EH40/2005: Workplace Exposure Limits*. Sudbury: HSE Books, 2005 (updated 2007). <http://www.hse.gov.uk/coshh/table1.pdf> (accessed 5 February 2009).

- 11 Buckton G *et al.* Water sorption and near IR spectroscopy to study the differences between microcrystalline cellulose and silicified microcrystalline cellulose after wet granulation. *Int J Pharm* 1999; 181: 41–47.
- 12 Mužíková J, Nováková P. A study of the properties of compacts from silicified microcrystalline cellulose. *Drug Dev Ind Pharm* 2007; 33: 775–781.

20 General References

European Directorate for the Quality of Medicines and Healthcare (EDQM). European Pharmacopoeia – State Of Work Of International Harmonisation. *Pharmeuropa* 2009; 21(1): 142–143. <http://www.edqm.eu/site/-614.html> (accessed 3 February 2009).

Li JX *et al.* Characterization of wet masses of pharmaceutical powders by triaxial compression test. *J Pharm Sci* 2000; 89(2): 178–190.

Staniforth JN *et al.* Pharmaceutical excipient having improved compressibility. US Patent 5,585,115, 1996.

21 Author

RC Moreton.

22 Date of Revision

5 February 2009.

Cellulose Acetate

1 Nonproprietary Names

BP: Cellulose Acetate

PhEur: Cellulose Acetate

USP-NF: Cellulose Acetate

2 Synonyms

Acetic acid, cellulose ester; acetyl cellulose; cellulose diacetate; cellulose triacetate; cellulosi acetas.

3 Chemical Name and CAS Registry Number

Cellulose acetate [9004-35-7]

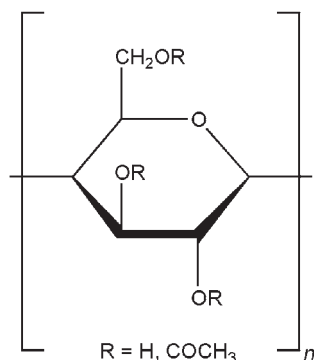
Cellulose diacetate [9035-69-2]

Cellulose triacetate [9012-09-3]

4 Empirical Formula and Molecular Weight

Cellulose acetate is cellulose in which a portion or all of the hydroxyl groups are acetylated. Cellulose acetate is available in a wide range of acetyl levels and chain lengths and thus molecular weights; see Table I.

5 Structural Formula



6 Functional Category

Coating agent; extended-release agent; tablet and capsule diluent.

7 Applications in Pharmaceutical Formulation or Technology

Cellulose acetate is widely used in pharmaceutical formulations both in sustained-release applications and for taste masking.

Cellulose acetate is used as a semipermeable coating on tablets, especially on osmotic pump-type tablets and implants. This allows for controlled, extended release of actives.^(1–5) Cellulose acetate films, in conjunction with other materials, also offer sustained release without the necessity of drilling a hole in the coating as is typical with osmotic pump systems. Cellulose acetate and other cellulose esters have also been used to form drug-loaded micro-particles with controlled-release characteristics.^(6–8)

Cellulose acetate films are used in transdermal drug delivery systems^(9,10) and also as film coatings on tablets⁽¹¹⁾ or granules for taste masking. For example, acetaminophen granules have been coated with a cellulose acetate-based coating before being processed to provide chewable tablets. Extended-release tablets can also be formulated with cellulose acetate as a directly compressible matrix former.⁽²⁾ The release profile can be modified by changing the ratio of active to cellulose acetate and by incorporation of plasticizer, but was shown to be insensitive to cellulose acetate molecular weight and particle size distribution.

Therapeutically, cellulose acetate has been used to treat cerebral aneurysms, and also for spinal perimedullary arteriovenous fistulas.⁽¹²⁾

8 Description

Cellulose acetate occurs as a hygroscopic white to off-white, free-flowing powder, pellet, or flake. It is tasteless and odorless, or may have a slight odor of acetic acid.

9 Pharmacopeial Specifications

See Table II. See also Section 18.

10 Typical Properties

Density (bulk) Typically 0.4 g/cm³ for powders.

Glass transition temperature 170–190°C

Melting point Melting range 230–300°C

NIR spectra see Figure 1.

Solubility The solubility of cellulose acetate is greatly influenced by the level of acetyl groups present. In general, cellulose acetates are soluble in acetone–water blends of varying ratios, dichloromethane–ethanol blends, dimethyl formamide, and dioxane.

It has been shown that the increased force required to expel coconut oil from plastic syringes was due to uptake of the oil into the rubber plunger; this resulted in swelling of the rubber plunger and an increased resistance to movement down the syringe barrel.⁽¹²⁾

13 Method of Manufacture

Coconut oil is the fixed oil obtained from the seeds of *Cocos nucifera* Linn. (Palmae). This oil is then refined to produce refined coconut oil, which is referred to in the coconut industry as RBD (refined, bleached, and deodorized) coconut oil.

14 Safety

When administered orally, coconut oil is essentially nontoxic, although ingestion of large amounts may cause digestive or gastrointestinal irritation or upset. Coconut oil can act as an irritant when applied to the skin and when in contact with the eyes; it may be absorbed through the skin. Inhalation of mist or vapor may cause respiratory tract irritation.

15 Handling Precautions

Observe normal precautions appropriate to the circumstances and quantity of the material handled. Coconut oil should be kept away from heat and sources of ignition, and contact with oxidizing agents, acids, and alkalis should be avoided.

If in the solid form, large spillages of coconut oil should be dealt with by shoveling the material into a waste disposal container. For liquid spillages, the oil should be absorbed with an inert material before removal for disposal.

16 Regulatory Status

Included in the FDA Inactive Ingredients Database (oral capsules and tablets; topical creams, solutions, and ointments). Included in scalp ointments and therapeutic shampoos licensed in the UK.

17 Related Substances

Almond oil; canola oil; castor oil; castor oil, hydrogenated; corn oil; cottonseed oil; medium-chain triglycerides; olive oil; peanut oil; sesame oil; soybean oil; sunflower oil.

18 Comments

A specification for coconut oil (unhydrogenated) is contained in the Food Chemicals Codex (FCC).⁽¹³⁾

19 Specific References

- Hung CF *et al.* The effect of oil components on the physicochemical properties and drug delivery of emulsions: tocol emulsion versus lipid emulsion. *Int J Pharm* 2007; 335(1–2): 193–202.
- Garti N, Arkad O. Preparation of cloudy coconut oil emulsions containing dispersed TiO₂ using atomizer. *J Dispersion Sci Technol* 1986; 7(5): 513–523.
- Fang JY *et al.* Lipid nano/submicron emulsions as delivery vehicles for topical flurbiprofen delivery. *Drug Deliv* 2004; 11(2): 97–105.
- Nielsen HW *et al.* Intranasal administration of different liquid formulations of bumetanide to rabbits. *Int J Pharm* 2000; 204(1–2): 35–41.
- Tanabe K *et al.* Effect of different suppository bases on release of indomethacin. *J Pharm Sci Technol Jpn* 1984; 44: 115–120.
- Broda H *et al.* Preparation and testing of suppositories with cephradine – evaluation of pharmaceutical availability and biological availability. *Farm Pol* 1993; 49(11–12): 1–8.
- Ogbolu DO *et al.* *In vitro* antimicrobial properties of coconut oil on *Candida* species in Ibadan, Nigeria. *J Med Food* 2007; 10(2): 384–387.
- Anonymous. Nitlotion. *Pharm J* 2000; 265: 345.
- Pajoumand A *et al.* Survival following severe aluminium phosphide poisoning. *J Pharm Pract Res* 2002; 32(4): 297–299.
- Patel HR. Sales of coconut oil. *Pharm J* 1992; 249: 252.
- Todd RG, Wade A, eds. *The Pharmaceutical Codex*, 11th edn. London: Pharmaceutical Press, 1979; 214.
- Dexter MB, Shott MJ. The evaluation of the force to expel oily injection vehicles from syringes. *J Pharm Pharmacol* 1979; 31: 497–500.
- Food Chemicals Codex*, 6th edn. Bethesda, MD: United States Pharmacopoeia, 2008; 222.

20 General References

—

21 Author

CG Cable.

22 Date of Revision

27 February 2009.

Colloidal Silicon Dioxide

1 Nonproprietary Names

BP: Colloidal Anhydrous Silica
JP: Light Anhydrous Silicic Acid
PhEur: Silica, Colloidal Anhydrous
USP-NF: Colloidal Silicon Dioxide

2 Synonyms

Aerosil; *Cab-O-Sil*; *Cab-O-Sil M-5P*; colloidal silica; fumed silica; fumed silicon dioxide; hochdisperses silicium dioxid; SAS; silica colloidalis anhydrica; silica sol; silicic anhydride; silicon dioxide colloidal; silicon dioxide fumed; synthetic amorphous silica; *Wacker HDK*.

3 Chemical Name and CAS Registry Number

Silica [7631-86-9]

4 Empirical Formula and Molecular Weight

SiO₂ 60.08

5 Structural Formula

See Section 4.

6 Functional Category

Adsorbent; anticaking agent; emulsion stabilizer; glidant; suspending agent; tablet disintegrant; thermal stabilizer; viscosity-increasing agent.

7 Applications in Pharmaceutical Formulation or Technology

Colloidal silicon dioxide is widely used in pharmaceuticals, cosmetics, and food products; see Table I. Its small particle size and large specific surface area give it desirable flow characteristics that are exploited to improve the flow properties of dry powders⁽¹⁾ in a number of processes such as tableting^(2–4) and capsule filling.

Colloidal silicon dioxide is also used to stabilize emulsions and as a thixotropic thickening and suspending agent in gels and semisolid preparations.⁽⁵⁾ With other ingredients of similar refractive index, transparent gels may be formed. The degree of viscosity increase depends on the polarity of the liquid (polar liquids generally require a greater concentration of colloidal silicon dioxide than nonpolar liquids). Viscosity is largely independent of temperature. However, changes to the pH of a system may affect the viscosity; see Section 11.

In aerosols, other than those for inhalation, colloidal silicon dioxide is used to promote particulate suspension, eliminate hard settling, and minimize the clogging of spray nozzles. Colloidal silicon dioxide is also used as a tablet disintegrant and as an adsorbent dispersing agent for liquids in powders.⁽⁶⁾ Colloidal silicon dioxide is frequently added to suppository formulations containing lipophilic excipients to increase viscosity, prevent sedimentation during molding, and decrease the release rate.^(7,8) Colloidal silicon dioxide is also used as an adsorbent during the preparation of wax microspheres;⁽⁹⁾ as a thickening agent for topical preparations;⁽¹⁰⁾ and has been used to aid the freeze-drying of nanocapsules and nanosphere suspensions.⁽¹¹⁾

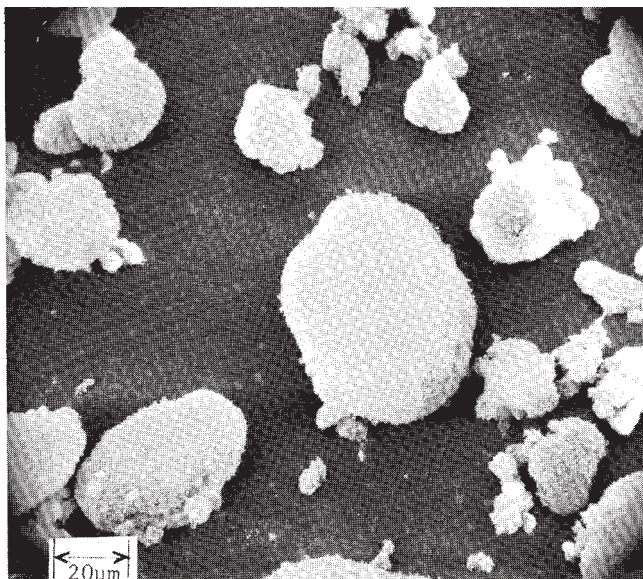
Table I: Uses of colloidal silicon dioxide.

Use	Concentration (%)
Aerosols	0.5–2.0
Emulsion stabilizer	1.0–5.0
Glidant	0.1–1.0
Suspending and thickening agent	2.0–10.0

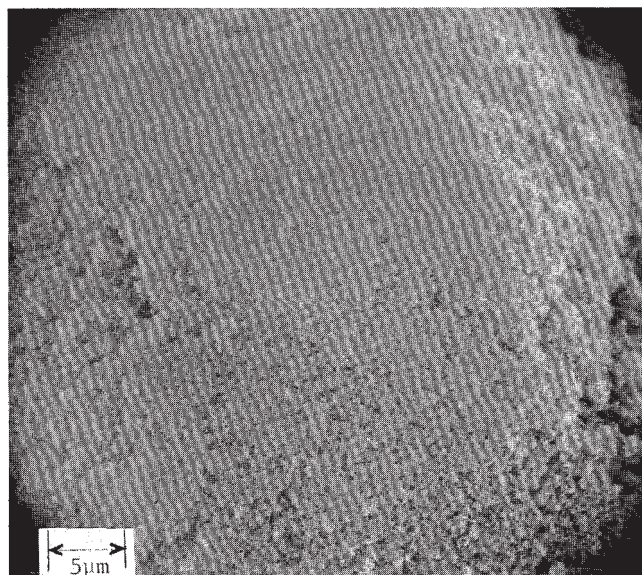
8 Description

Colloidal silicon dioxide is a submicroscopic fumed silica with a particle size of about 15 nm. It is a light, loose, bluish-white-colored, odorless, tasteless, amorphous powder.

SEM 1: Excipient: colloidal silicon dioxide (Aerosil A-200); manufacturer: Evonik Degussa Corp. lot no.: 87A-1 (04169C); magnification: 600×; voltage: 20 kV.



SEM 2: Excipient: colloidal silicon dioxide (Aerosil A-200); manufacturer: Evonik Degussa Corp. lot no.: 87A-1 (04169C); magnification: 2400×; voltage: 20 kV.



9 Pharmacopeial Specifications

See Table II. See also Section 18.

Table II: Pharmacopeial specifications for colloidal silicon dioxide.

Test	JP XV	PhEur 6.0	USP32-NF27
Identification	+	+	+
Characters	—	+	—
pH (4% w/v dispersion)	—	3.5–5.5	3.5–5.5
Arsenic	≤5 ppm	—	≤8 μg/g
Chloride	≤0.011%	≤250 ppm	—
Heavy metals	≤40 ppm	≤25 ppm	—
Aluminum	+	—	—
Calcium	+	—	—
Iron	≤500 ppm	—	—
Loss on drying	≤7.0%	—	≤2.5%
Loss on ignition	≤12.0%	≤5.0%	≤2.0%
Volume test (5 g sample)	≥70 mL	—	—
Assay (on ignited sample)	≥98.0%	99.0–100.5%	99.0–100.5%

10 Typical Properties

Acidity/alkalinity pH = 3.8–4.2 (4% w/v aqueous dispersion) and 3.5–4.0 (10% w/v aqueous dispersion) for Cab-O-Sil M-5P

Density (bulk) 0.029–0.042 g/cm³

Density (tapped) see Tables III, IV, and V.

Melting point 1600°C

Moisture content see Figure 1.^(12,13)

Particle size distribution Primary particle size is 7–16 nm. Aerosil forms loose agglomerates of 10–200 μm. See also Figure 2.

Refractive index 1.46

Solubility Practically insoluble in organic solvents, water, and acids, except hydrofluoric acid; soluble in hot solutions of alkali hydroxide. Forms a colloidal dispersion with water. For Aerosil, solubility in water is 150 mg/L at 25°C (pH 7).

Specific gravity 2.2

Specific surface area

100–400 m²/g depending on grade. See also Tables III, IV, and V.

Several grades of colloidal silicon dioxide are commercially available, which are produced by modifying the manufacturing process. The modifications do not affect the silica content,

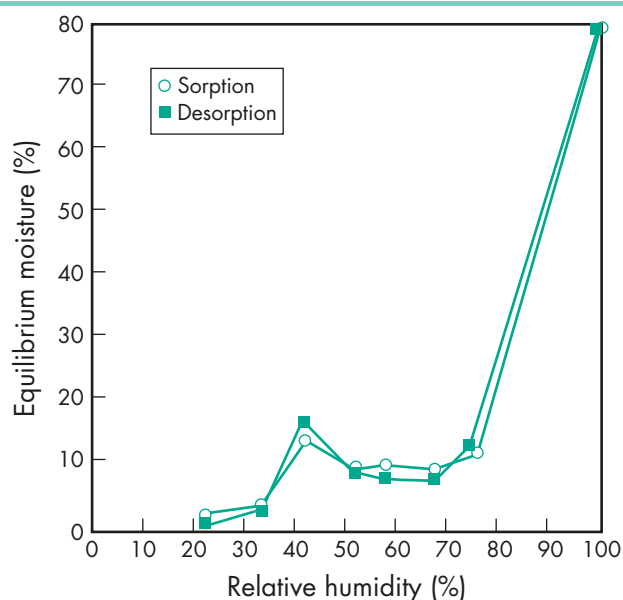


Figure 1: Sorption-desorption isotherm for colloidal silicon dioxide.

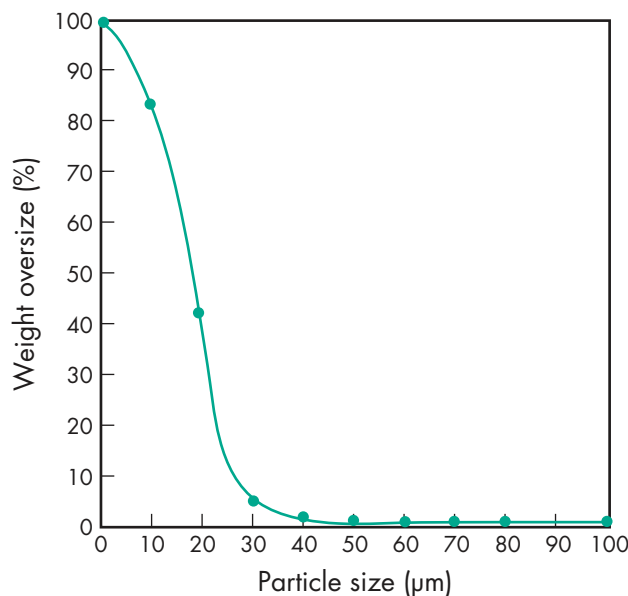


Figure 2: Particle size distribution of colloidal silicon dioxide (Aerosil A-200, Evonik Degussa Corp.).

specific gravity, refractive index, color, or amorphous form. However, particle size, surface areas, and densities are affected. The physical properties of three commercially available colloidal silicon dioxides, *Aerosil* (Evonik Degussa Corp.), *Cab-O-Sil* (Cabot Corporation), and *Wacker HDK* (Wacker-Chemie GmbH) are shown in Tables III, IV and V, respectively.

11 Stability and Storage Conditions

Colloidal silicon dioxide is hygroscopic but adsorbs large quantities of water without liquefying. When used in aqueous systems at a pH 0–7.5, colloidal silicon dioxide is effective in increasing the viscosity of a system. However, at a pH greater than 7.5 the viscosity-increasing properties of colloidal silicon dioxide are reduced; and at a pH greater than 10.7 this ability is lost entirely since the silicon dioxide dissolves to form silicates.⁽¹⁴⁾ Colloidal silicon dioxide powder should be stored in a well-closed container.

Table III: Physical properties of *Aerosil*.

Grade	Specific surface area ^(a) (m ² /g)	Density (tapped) (g/cm ³)
130	130 ± 25	0.05
130v	130 ± 25	0.12
200	200 ± 25	0.05
200v	200 ± 25	0.12
300	300 ± 30	0.05
300v	300 ± 30	0.12
380	380 ± 30	0.05
380v	380 ± 30	0.12

(a) BET method.

Table IV: Physical properties of *Cab-O-Sil*.

Grade	Specific surface area ^(a) (m ² /g)	Density (tapped) (g/cm ³)
LM-5	130 ± 25	0.04
LM-50	150 ± 25	0.04
M-5	200 ± 25	0.04
H-5	325 ± 25	0.04
EH-5	390 ± 40	0.04
M-7D	200 ± 25	0.10

(a) BET method.

Table V: Physical properties of *Wacker HDK*.

Grade	Specific surface area ^(a) (m ² /g)	Density (tapped) (g/cm ³)
S13	125 ± 15	0.05
V15	150 ± 20	0.05
N20	200 ± 30	0.04
T30	300 ± 30	0.04
T40	400 ± 40	0.04
H15	120 ± 20	0.04
H20	170 ± 30	0.04
H30	250 ± 30	0.04
H2000	140 ± 30	0.22
H3004	210 ± 30	0.08
H2015	110 ± 30	0.20
H2050	110 ± 30	0.20

(a) BET method.

12 Incompatibilities

Incompatible with diethylstilbestrol preparations.⁽¹⁵⁾

13 Method of Manufacture

Colloidal silicon dioxide is prepared by the flame hydrolysis of chlorosilanes, such as silicon tetrachloride, at 1800°C using a hydrogen-oxygen flame. Rapid cooling from the molten state during manufacture causes the product to remain amorphous.

14 Safety

Colloidal silicon dioxide is widely used in oral and topical pharmaceutical products and is generally regarded as an essentially nontoxic and nonirritant excipient. However, intraperitoneal and subcutaneous injection may produce local tissue reactions and/or granulomas. Colloidal silicon dioxide should therefore not be administered parenterally.

LD₅₀ (rat, IV): 0.015 g/kg⁽¹⁶⁾

LD₅₀ (rat, oral): 3.16 g/kg

15 Handling Precautions

Observe normal precautions appropriate to the circumstances and quantity of material handled. Eye protection and gloves are recommended. Considered a nuisance dust, precautions should be taken to avoid inhalation of colloidal silicon dioxide. In the absence of suitable containment facilities, a dust mask should be worn when handling small quantities of material. For larger quantities, a dust respirator is recommended.

Inhalation of colloidal silicon dioxide dust may cause irritation to the respiratory tract but it is not associated with fibrosis of the lungs (silicosis), which can occur upon exposure to crystalline silica.

16 Regulatory Acceptance

GRAS listed. Included in the FDA Inactive Ingredients Database (oral capsules, suspensions, and tablets; transdermal, rectal, and vaginal preparations). Also approved by the FDA as a food additive and for food contact. Included in nonparenteral medicines licensed in the UK. Included in the Canadian List of Acceptable Non-medicinal Ingredients.

17 Related Substances

Hydrophobic colloidal silica.

18 Comments

Colloidal silicon dioxide is one of the materials that have been selected for harmonization by the Pharmacopeial Discussion Group. For further information see the General Information Chapter <1196> in the USP32–NF27, the General Chapter 5.8 in PhEur 6.0, along with the ‘State of Work’ document on the PhEur EDQM website, and also the General Information Chapter 8 in the JP XV.

The PhEur 6.0 also contains a specification for hydrated colloidal silicon dioxide. The incidence of microbial contamination of colloidal silicon dioxide is low⁽¹⁷⁾ due to the high production temperatures and inorganic precursor materials.

Note that porous silica gel particles may also be used as a glidant, thickener, dispersant and to adsorb moisture, which may be an advantage for some formulations. *Syloid 244FP* meets the USP–NF requirements for silicon dioxide, and *Syloid 244 FP-BU* meets the PhEur and JP requirements for silicon dioxide.⁽¹⁸⁾

Another CAS number that is used for colloidal silicon dioxide is 112945-52-5.

The EINECS number for colloidal silicon dioxide is 231-545-4. The PubChem Compound ID (CID) for colloidal silicon dioxide is 24261.

19 Specific References

- 1 York P. Application of powder failure testing equipment in assessing effect of glidants on flowability of cohesive pharmaceutical powders. *J Pharm Sci* 1975; 64: 1216–1221.
- 2 Lerk CF *et al.* Interaction of lubricants and colloidal silica during mixing with excipients I: its effect on tableting. *Pharm Acta Helv* 1977; 52: 33–39.
- 3 Lerk CF, Bolhuis GK. Interaction of lubricants and colloidal silica during mixing with excipients II: its effect on wettability and dissolution velocity. *Pharm Acta Helv* 1977; 52: 39–44.
- 4 Jonat S *et al.* Influence of compacted hydrophobic and hydrophilic colloidal silicon dioxide on tableting properties of pharmaceutical excipients. *Drug Dev Ind Pharm* 2005; 31: 687–696.

- 5 Daniels R *et al.* The stability of drug absorbates on silica. *Drug Dev Ind Pharm* 1986; 12: 2127–2156.
- 6 Sherriff M, Enever RP. Rheological and drug release properties of oil gels containing colloidal silicon dioxide. *J Pharm Sci* 1979; 68: 842–845.
- 7 Tukker JJ, De Blaey CJ. The addition of colloidal silicon dioxide to suspension suppositories II. The impact on *in vitro* release and bioavailability. *Acta Pharm Technol* 1984; 30: 155–160.
- 8 Realdon N *et al.* Effects of silicium dioxide on drug release from suppositories. *Drug Dev Ind Pharm* 1997; 23: 1025–1041.
- 9 Mani N *et al.* Microencapsulation of a hydrophilic drug into a hydrophobic matrix using a salting-out procedure. II. Effects of adsorbents on microsphere properties. *Drug Dev Ind Pharm* 2004; 30(1): 83–93.
- 10 Gallagher SJ *et al.* Effects of membrane type and liquid/liquid phase boundary on *in vitro* release of ketoprofen from gel formulations. *J Drug Target* 2003; 11(6): 373–379.
- 11 Schaffazick SR *et al.* Freeze-drying polymeric colloidal suspensions: nanocapsules, nanospheres and nanodispersion. A comparative study. *Eur J Pharm Biopharm* 2003; 56(3): 501–505.
- 12 Ettlinger M *et al.* [Adsorption at the surface of fumed silica.] *Arch Pharm* 1987; 320: 1–15[in German].
- 13 Callahan JC *et al.* Equilibrium moisture content of pharmaceutical excipients. *Drug Dev Ind Pharm* 1982; 8: 355–369.
- 14 Cabot Corporation. Technical literature: *Cab-O-Sil* fumed silicas, the performance additives, 1995.
- 15 Johansen H, Müller N. Solvent deposition of drugs on excipients II: interpretation of dissolution, adsorption and absorption characteristics of drugs. *Arch Pharm Chem Sci Ed* 1977; 5: 33–42.
- 16 Lewis RJ, ed. *Sax's Dangerous Properties of Industrial Materials*, 11th edn. New York: Wiley, 2004; 3205.
- 17 Kienholz M. [The behaviour of bacteria in highly pure silicic acid.] *Pharm Ind* 1970; 32: 677–679[in German].
- 18 WR Grace & Co. Technical literature: *Syloid 244FP*, 2002.

20 General References

- Cabot Corporation. Technical literature PDS171: *Cab-O-Sil M-5P*, 2006.
- Evonik Degussa Corp. Technical Bulletin Fine Particles No. 11 TB0011-1: Basic characteristics of *Aerosil* fumed silica, 2006.
- Evonik Degussa Corp. Technical literature TI 1281-1: *Aerosil* colloidal silicon dioxide for pharmaceuticals, 2006.
- European Directorate for the Quality of Medicines and Healthcare (EDQM). European Pharmacopoeia – State Of Work Of International Harmonisation. *Pharmeuropa* 2009; 21(1): 142–143. <http://www.edqm.eu/site/-614.html> (accessed 3 February 2009).
- Meyer K, Zimmermann I. Effect of glidants in binary powder mixtures. *Powder Technol* 2004; 139: 40–54.
- Wacker-Chemie GmbH. Technical literature: *Wacker HDK* fumed silica, 1998.
- Waddell WW. Silica amorphous. *Kirk-Othmer Encyclopedia of Chemical Technology*, 5th edn, vol. 22: New York: John Wiley & Sons, 2001; 380–406.
- Wagner E, Brunner H. *Aerosil*: its preparation, properties and behaviour in organic liquids. *Angew Chem* 1960; 72: 744–750.
- Yang KY *et al.* Effects of amorphous silicon dioxides on drug dissolution. *J Pharm Sci* 1979; 68: 560–565.
- Zimmermann I *et al.* Nanomaterials as flow regulators in dry powders. *Z Phys Chem* 2004; 218: 51–102.

21 Author

KP Hapgood.

22 Date of Revision

3 February 2009.



Croscarmellose Sodium

1 Nonproprietary Names

BP: Croscarmellose Sodium
JP: Croscarmellose Sodium
PhEur: Croscarmellose Sodium
USP-NF: Croscarmellose Sodium

2 Synonyms

Ac-Di-Sol; carmellosum natricum conexum; crosslinked carboxymethylcellulose sodium; *Explocel*; modified cellulose gum; *Nymcel ZSX*; *Pharmacel XL*; *Primellose*; *Solutab*; *Vivasol*.

3 Chemical Name and CAS Registry Number

Cellulose, carboxymethyl ether, sodium salt, crosslinked [74811-65-7]

4 Empirical Formula and Molecular Weight

Croscarmellose sodium is a crosslinked polymer of carboxymethylcellulose sodium.

See Carboxymethylcellulose sodium.

5 Structural Formula

See Carboxymethylcellulose sodium.

6 Functional Category

Tablet and capsule disintegrant.

7 Applications in Pharmaceutical Formulation or Technology

Croscarmellose sodium is used in oral pharmaceutical formulations as a disintegrant for capsules,^(1,2) tablets,⁽³⁻¹³⁾ and granules.

In tablet formulations, croscarmellose sodium may be used in both direct-compression and wet-granulation processes. When used in wet granulations, the croscarmellose sodium should be added in both the wet and dry stages of the process (intra- and extra-granularly) so that the wicking and swelling ability of the disintegrant is best utilized.^(11,12) Croscarmellose sodium at concentrations up to 5% w/w may be used as a tablet disintegrant, although normally 2% w/w is used in tablets prepared by direct compression and 3% w/w in tablets prepared by a wet-granulation process. See Table I.

Table I: Uses of croscarmellose sodium.

Use	Concentration (%)
Disintegrant in capsules	10–25
Disintegrant in tablets	0.5–5.0

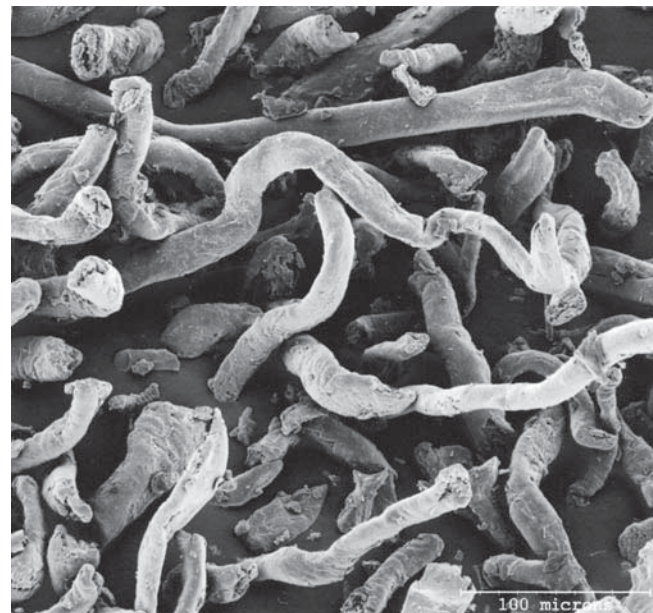
8 Description

Croscarmellose sodium occurs as an odorless, white or grayish-white powder.

SEM 1: Excipient: croscarmellose sodium (*Ac-Di-Sol*); manufacturer: FMC Biopolymer; magnification: 100×.



SEM 2: Excipient: croscarmellose sodium (*Ac-Di-Sol*); manufacturer: FMC Biopolymer; magnification: 1000×.



9 Pharmacopeial Specifications

See Table II. See also Section 18.

10 Typical Properties

Acidity/alkalinity pH = 5.0–7.0 in aqueous dispersions.

Bonding index 0.0456

Brittle fracture index 0.1000

Density (bulk) 0.529 g/cm³ for *Ac-Di-Sol*

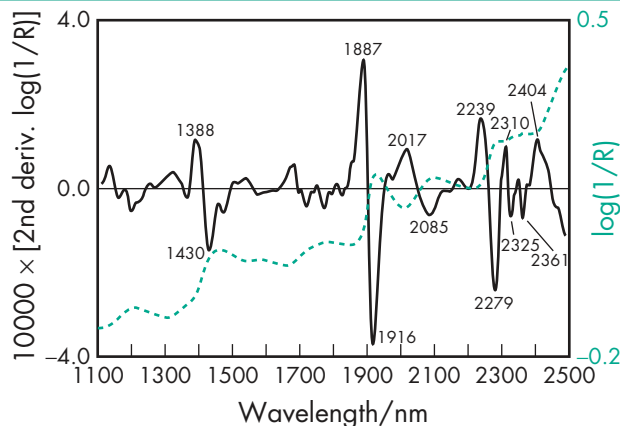


Figure 1: Near-infrared spectrum of croscarmellose sodium measured by reflectance.

Table II: Pharmacopeial specifications for croscarmellose sodium.

Test	JP XV	PhEur 6.5	USP32-NF27
Identification	+	+	+
Characters	+	+	—
pH (1% w/v dispersion)	5.0–7.0	5.0–7.0	5.0–7.0
Loss on drying	≤ 10.0%	≤ 10.0%	≤ 10.0%
Heavy metals	≤ 10 ppm	≤ 20 ppm	≤ 0.001%
Sodium chloride and sodium glycolate	≤ 0.5%	≤ 0.5%	≤ 0.5%
Sulfated ash	—	14.0–28.0%	—
Residue on ignition	14.0–28.0%	—	14.0–28.0%
Degree of substitution	0.60–0.85	0.60–0.85	0.60–0.85
Content of water-soluble material	1.0–10%	≤ 10.0%	≤ 10.0%
Settling volume	10.0–30.0 mL	10.0–30.0 mL	10.0–30.0 mL
Microbial contamination	—	+	+
Aerobic	—	10 ³ cfu/g	10 ³ cfu/g
Fungi	—	10 ² cfu/g	10 ² cfu/g

Density (tapped) 0.819 g/cm³ for *Ac-Di-Sol*

Density (true) 1.543 g/cm³ for *Ac-Di-Sol*

NIR spectra see Figure 1.

Particle size distribution

Ac-Di-Sol: not more than 2% retained on a #200 (73.7 μm) mesh and not more than 10% retained on a #325 (44.5 μm) mesh.

Solubility Insoluble in water, although croscarmellose sodium rapidly swells to 4–8 times its original volume on contact with water. Practically insoluble in acetone, ethanol and toluene.

Specific surface area 0.81–0.83 m²/g

11 Stability and Storage Conditions

Croscarmellose sodium is a stable though hygroscopic material.

A model tablet formulation prepared by direct compression, with croscarmellose sodium as a disintegrant, showed no significant difference in drug dissolution after storage at 30°C for 14 months.⁽⁹⁾

Croscarmellose sodium should be stored in a well-closed container in a cool, dry place.

12 Incompatibilities

The efficacy of disintegrants, such as croscarmellose sodium, may be slightly reduced in tablet formulations prepared by either the wet-granulation or direct-compression process that contain hygroscopic excipients such as sorbitol.⁽¹⁰⁾

Croscarmellose sodium is not compatible with strong acids or with soluble salts of iron and some other metals such as aluminum, mercury, and zinc.

13 Method of Manufacture

Alkali cellulose is prepared by steeping cellulose, obtained from wood pulp or cotton fibers, in sodium hydroxide solution. The alkali cellulose is then reacted with sodium monochloroacetate to obtain carboxymethylcellulose sodium. After the substitution reaction is completed and all of the sodium hydroxide has been used, the excess sodium monochloroacetate slowly hydrolyzes to glycolic acid. The glycolic acid changes a few of the sodium carboxymethyl groups to the free acid and catalyzes the formation of crosslinks to produce croscarmellose sodium. The croscarmellose sodium is then extracted with aqueous alcohol and any remaining sodium chloride or sodium glycolate is removed. After purification, croscarmellose sodium of purity greater than 99.5% is obtained.⁽⁴⁾ The croscarmellose sodium may be milled to break the polymer fibers into shorter lengths and hence improve its flow properties.

14 Safety

Croscarmellose sodium is mainly used as a disintegrant in oral pharmaceutical formulations and is generally regarded as an essentially nontoxic and nonirritant material. However, oral consumption of large amounts of croscarmellose sodium may have a laxative effect, although the quantities used in solid dosage formulations are unlikely to cause such problems.

In the UK, croscarmellose sodium is accepted for use in dietary supplements.

The WHO has not specified an acceptable daily intake for the related substance carboxymethylcellulose sodium, used as a food additive, since the levels necessary to achieve a desired effect were not considered sufficient to be a hazard to health.⁽¹⁴⁾

See also Carboxymethylcellulose Sodium.

15 Handling Precautions

Observe normal precautions appropriate to the circumstances and quantity of material handled. Croscarmellose sodium may be irritant to the eyes; eye protection is recommended.

16 Regulatory Status

Included in the FDA Inactive Ingredients Database (oral capsules, granules, sublingual tablets, and tablets). Included in nonparenteral medicines licensed in the UK. Included in the Canadian List of Acceptable Non-medicinal Ingredients.

17 Related Substances

Carboxymethylcellulose calcium; carboxymethylcellulose sodium.

18 Comments

Croscarmellose sodium is one of the materials that have been selected for harmonization by the Pharmacopeial Discussion Group. For further information see the General Information Chapter <1196> in the USP32–NF27, the General Chapter 5.8 in PhEur 6.0, along with the ‘State of Work’ document on the PhEur EDQM website, and also the General Information Chapter 8 in the JP XV.

Typically, the degree of substitution (DS) for croscarmellose sodium is 0.7.

The EINECS number for croscarmellose sodium is 232-674-9.

19 Specific References

- 1 Botzolakakis JE, Augsburger LL. Disintegrating agents in hard gelatin capsules. Part I: mechanism of action. *Drug Dev Ind Pharm* 1988; 14(1): 29–41.
- 2 Dahl TC *et al.* The influence of disintegrant level and capsule size on dissolution of hard gelatin capsules stored in high humidity conditions. *Drug Dev Ind Pharm* 1991; 17(7): 1001–1016.
- 3 Gissinger D, Stamm A. A comparative evaluation of the properties of some tablet disintegrants. *Drug Dev Ind Pharm* 1980; 6(5): 511–536.

- 4 Shangraw R *et al.* A new era of tablet disintegrants. *Pharm Technol* 1980; 4(10): 49–57.
- 5 Zhao N, Augsburger LI. The influence of product brand-to-brand variability on superdisintegrant performance. A case study with croscarmellose sodium. *Pharm Dev Technol* 2006; 11(2): 179–185.
- 6 Zhao N, Augsburger LI. The influence of swelling capacity of superdisintegrants in different pH media on the dissolution of hydrochlorothiazide from directly compressed tablets. *AAPS Pharm Sci Tech* 2005; 6(1): E120–E126.
- 7 Battu SK *et al.* Formulation and evaluation of rapidly disintegrating fenoverine tablets: effects of superdisintegrants. *Drug Dev Ind Pharm* 2007; 33(11): 1225–1232.
- 8 Gordon MS, Chowhan ZT. Effect of tablet solubility and hygroscopicity on disintegrant efficiency in direct compression tablets in terms of dissolution. *J Pharm Sci* 1987; 76: 907–909.
- 9 Gordon MS, Chowhan ZT. The effect of aging on disintegrant efficiency in direct compression tablets with varied solubility and hygroscopicity, in terms of dissolution. *Drug Dev Ind Pharm* 1990; 16: 437–447.
- 10 Johnson JR *et al.* Effect of formulation solubility and hygroscopicity on disintegrant efficiency in tablets prepared by wet granulation, in terms of dissolution. *J Pharm Sci* 1991; 80: 469–471.
- 11 Gordon MS *et al.* Effect of the mode of super disintegrant incorporation on dissolution in wet granulated tablets. *J Pharm Sci* 1993; 82(2): 220–226.
- 12 Khattab I *et al.* Effect of mode of incorporation of disintegrants on the characteristics of fluid-bed wet-granulated tablets. *J Pharm Pharmacol* 1993; 45(8): 687–691.
- 13 Ferrero C *et al.* Disintegrating efficiency of croscarmellose sodium in a direct compression formulation. *Int J Pharm* 1997; 147: 11–21.
- 14 FAO/WHO. Evaluation of certain food additives and contaminants. Thirty-fifth report of the joint FAO/WHO expert committee on food additives. *World Health Organ Tech Rep Ser* 1990; No. 789.

20 General References

- DMV-Frontera Excipients. Product literature: *Primellose and Primojel*, August 2008.
- European Directorate for the Quality of Medicines and Healthcare (EDQM). European Pharmacopoeia – State Of Work Of International Harmonisation. *Pharmeuropa* 2009; 21(1): 142–143. <http://www.edqm.eu/site/-614.html> (accessed 6 February 2009).
- FMC Biopolymer. Material Safety Datasheet: *Ac-Di-Sol*, May 2008.
- JRS Pharma. Product literature: *Vivasol*. http://www.jrspharma.de/Pharma/wEnglisch/produktinfo/productinfo_vivasol.shtml (accessed 6 February 2009).

21 Author

RT Guest.

22 Date of Revision

6 February 2009.

Crospovidone

1 Nonproprietary Names

BP: Crospovidone

PhEur: Crospovidone

USP-NF: Crospovidone

2 Synonyms

Crospovidonum; *Crospopharm*; crosslinked povidone; E1202; *Kollidon CL*; *Kollidon CL-M*; *Polyplasdone XL*; *Polyplasdone XL-10*; polyvinylpyrrolidone; PVPP; 1-vinyl-2-pyrrolidinone homopolymer.

3 Chemical Name and CAS Registry Number

1-Ethenyl-2-pyrrolidinone homopolymer [9003-39-8]

4 Empirical Formula and Molecular Weight

(C₆H₉NO)_n >1 000 000

The USP32–NF27 describes crospovidone as a water-insoluble synthetic crosslinked homopolymer of *N*-vinyl-2-pyrrolidinone. An exact determination of the molecular weight has not been established because of the insolubility of the material.

5 Structural Formula

See Povidone.

6 Functional Category

Tablet disintegrant.

7 Applications in Pharmaceutical Formulation or Technology

Crospovidone is a water-insoluble tablet disintegrant and dissolution agent used at 2–5% concentration in tablets prepared by direct-compression or wet- and dry-granulation methods.^(1–6) It rapidly exhibits high capillary activity and pronounced hydration capacity, with little tendency to form gels. Studies suggest that the particle size of crospovidone strongly influences disintegration of analgesic tablets.⁽⁷⁾ Larger particles provide a faster disintegration than smaller particles. Crospovidone can also be used as a solubility enhancer. With the technique of co-evaporation, crospovidone can be used to enhance the solubility of poorly soluble drugs. The drug is adsorbed on to crospovidone in the presence of a suitable solvent and the solvent is then evaporated. This technique results in faster dissolution rate.

8 Description

Crospovidone is a white to creamy-white, finely divided, free-flowing, practically tasteless, odorless or nearly odorless, hygroscopic powder.

9 Pharmacopeial Specifications

See Table I. See also Section 18.

10 Typical Properties

Acidity/alkalinity pH = 5.0–8.0 (1% w/v aqueous slurry)

Density 1.22 g/cm³

Density (bulk) see Table II.

Density (tapped) see Table II.



Magnesium Stearate

1 Nonproprietary Names

BP: Magnesium Stearate
JP: Magnesium Stearate
PhEur: Magnesium Stearate
USP-NF: Magnesium Stearate

2 Synonyms

Dibasic magnesium stearate; magnesium distearate; magnesii stearas; magnesium octadecanoate; octadecanoic acid, magnesium salt; stearic acid, magnesium salt; *Synpro 90*.

3 Chemical Name and CAS Registry Number

Octadecanoic acid magnesium salt [557-04-0]

4 Empirical Formula and Molecular Weight

$C_{36}H_{70}MgO_4$ 591.24

The USP32–NF27 describes magnesium stearate as a compound of magnesium with a mixture of solid organic acids that consists chiefly of variable proportions of magnesium stearate and magnesium palmitate ($C_{32}H_{62}MgO_4$). The PhEur 6.5 describes magnesium stearate as a mixture of solid organic acids consisting mainly of variable proportions of magnesium stearate and magnesium palmitate obtained from sources of vegetable or animal origin.

5 Structural Formula

$[CH_3(CH_2)_{16}COO]_2Mg$

6 Functional Category

Tablet and capsule lubricant.

7 Applications in Pharmaceutical Formulation or Technology

Magnesium stearate is widely used in cosmetics, foods, and pharmaceutical formulations. It is primarily used as a lubricant in capsule and tablet manufacture at concentrations between 0.25% and 5.0% w/w. It is also used in barrier creams. *See also* Section 18.

8 Description

Magnesium stearate is a very fine, light white, precipitated or milled, impalpable powder of low bulk density, having a faint odor of stearic acid and a characteristic taste. The powder is greasy to the touch and readily adheres to the skin.

9 Pharmacopeial Specifications

See Table I. *See also* Section 18.

10 Typical Properties

Crystalline forms High-purity magnesium stearate has been isolated as a trihydrate, a dihydrate, and an anhydrate.

Density (bulk) 0.159 g/cm³

Density (tapped) 0.286 g/cm³

Density (true) 1.092 g/cm³

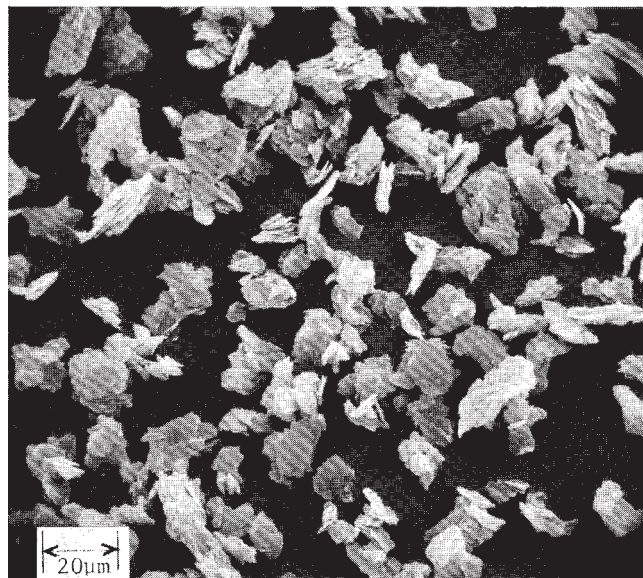
Flash point 250°C

Flowability Poorly flowing, cohesive powder.

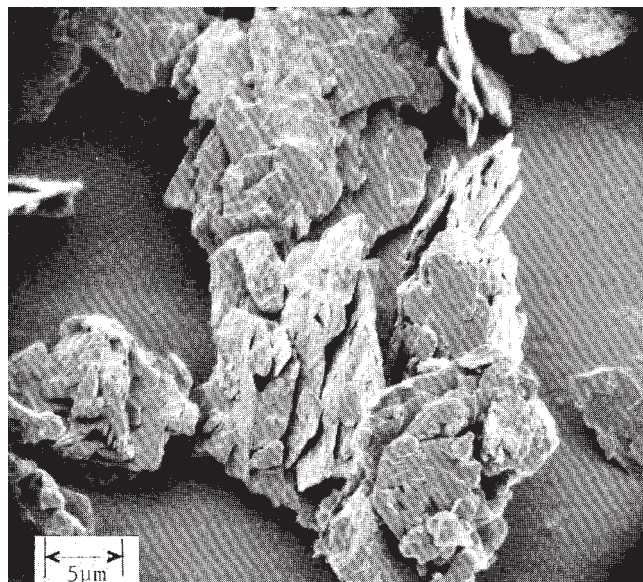
Melting range

117–150°C (commercial samples);

SEM 1: Excipient: magnesium stearate; magnification: 600×.



SEM 2: Excipient: magnesium stearate; magnification: 2400×.



126–130°C (high purity magnesium stearate).

NIR spectra *see* Figure 1.

Solubility Practically insoluble in ethanol, ethanol (95%), ether and water; slightly soluble in warm benzene and warm ethanol (95%).

Specific surface area 1.6–14.8 m²/g

11 Stability and Storage Conditions

Magnesium stearate is stable and should be stored in a well-closed container in a cool, dry place.

Table I: Pharmacopeial specifications for magnesium stearate.

Test	JP XV	PhEur 6.5	USP32–NF27
Identification	+	+	+
Characters	—	+	—
Microbial limits	+	+	+
Aerobic microbes	≤ 1000 cfu/g	≤ 10 ³ cfu/g	≤ 1000 cfu/g
Fungi and yeasts	≤ 500 cfu/g	≤ 10 ² cfu/g	≤ 500 cfu/g
Acidity or alkalinity	+	+	+
Acid value of the fatty acid	—	195–210	—
Freezing point	—	≥ 53°C	—
Nickel	—	≤ 5 ppm	—
Cadmium	—	≤ 3 ppm	—
Specific surface area	—	—	+
Loss on drying	≤ 6.0%	≤ 6.0%	≤ 6.0%
Chloride	≤ 0.1%	≤ 0.1%	≤ 0.1%
Sulfate	≤ 1.0%	≤ 1.0%	≤ 1.0%
Lead	—	≤ 10 ppm	≤ 0.001%
Heavy metals	≤ 20 ppm	—	—
Relative stearic/palmitic content	+	+	+
Assay (dried, as Mg)	4.0–5.0%	4.0–5.0%	4.0–5.0%

12 Incompatibilities

Incompatible with strong acids, alkalis, and iron salts. Avoid mixing with strong oxidizing materials. Magnesium stearate cannot be used in products containing aspirin, some vitamins, and most alkaloidal salts.

13 Method of Manufacture

Magnesium stearate is prepared either by the interaction of aqueous solutions of magnesium chloride with sodium stearate or by the interaction of magnesium oxide, hydroxide, or carbonate with stearic acid at elevated temperatures.

14 Safety

Magnesium stearate is widely used as a pharmaceutical excipient and is generally regarded as being nontoxic following oral administration. However, oral consumption of large quantities may produce a laxative effect or mucosal irritation.

No toxicity information is available relating to normal routes of occupational exposure. Limits for heavy metals in magnesium stearate have been evaluated in terms of magnesium stearate worst-case daily intake and heavy metal composition.⁽¹⁾

Toxicity assessments of magnesium stearate in rats have indicated that it is not irritating to the skin, and is nontoxic when administered orally or inhaled.^(2,3)

Magnesium stearate has not been shown to be carcinogenic when implanted into the bladder of mice.⁽⁴⁾

LD₅₀ (rat, inhalation): >2 mg/L⁽²⁾

LD₅₀ (rat, oral): >10 g/kg

15 Handling Precautions

Observe normal precautions appropriate to the circumstances and quantity of material handled. Eye protection and gloves are recommended. Excessive inhalation of magnesium stearate dust may cause upper respiratory tract discomfort, coughing, and choking. Magnesium stearate should be handled in a well-ventilated environment; a respirator is recommended. In the USA, the OSHA limit is 10 mg/m³ TWA for magnesium stearate.

16 Regulatory Acceptance

GRAS listed. Accepted as a food additive in the USA and UK. Included in the FDA Inactive Ingredients Database (oral capsules, powders, and tablets; buccal and vaginal tablets; topical prepara-

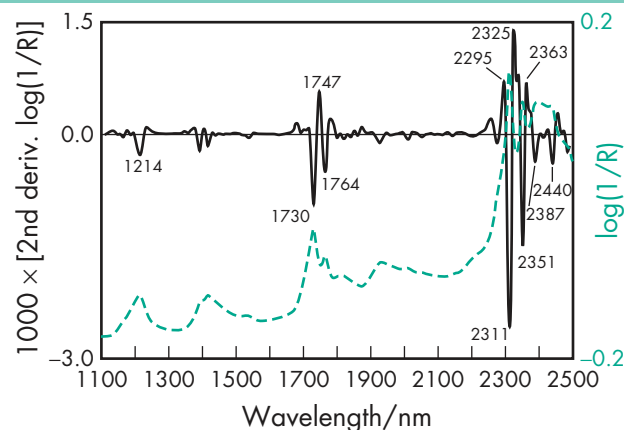


Figure 1: Near-infrared spectrum of magnesium stearate measured by reflectance.

tions; intravitreal implants and injections). Included in nonparenteral medicines licensed in the UK. Included in the Canadian List of Acceptable Non-medicinal Ingredients. Listed on the US TSCA inventory.

17 Related Substances

Calcium stearate; magnesium aluminum silicate; stearic acid; zinc stearate.

18 Comments

Magnesium stearate is one of the materials that have been selected for harmonization by the Pharmacopeial Discussion Group. For further information see the General Information Chapter <1196> in the USP32–NF27, the General Chapter 5.8 in PhEur 6.0, along with the ‘State of Work’ document on the PhEur EDQM website, and also the General Information Chapter 8 in the JP XV.

Magnesium stearate is hydrophobic and may retard the dissolution of a drug from a solid dosage form; the lowest possible concentration is therefore used in such formulations.^(5–10) Capsule dissolution is also sensitive to both the amount of magnesium stearate in the formulation and the mixing time; higher levels of magnesium stearate and long mixing times can result in the formation of hydrophobic powder beds that do not disperse after the capsule shell dissolves.^(11,12)

An increase in the coefficient of variation of mixing and a decrease in the dissolution rate have been observed following blending of magnesium stearate with a tablet granulation. Tablet dissolution rate and crushing strength decreased as the time of blending increased; and magnesium stearate may also increase tablet friability. Blending times with magnesium stearate should therefore be carefully controlled.^(13–29) A variety of online analytical techniques have been investigated to monitor magnesium stearate in powder blends and tablets.^(30–32) Inverse gas chromatography has been used to examine the surface coverage of magnesium stearate on powder blends.⁽³³⁾ Magnesium stearate also affects the flow properties of blends.⁽³⁴⁾

The existence of various crystalline forms of magnesium stearate has been established.^(35–39) A trihydrate, a dihydrate, and an anhydrate have been isolated,^(5,37,38,40) and an amorphous form has been observed.⁽⁴¹⁾ While the hydrated forms are stable in the presence of moisture, the anhydrous form adsorbs moisture at relative humidity up to 50%, and at higher humidities rehydrates to form the trihydrate. The anhydrate can be formed by drying either of the hydrates at 105°C.⁽³⁸⁾

It has not been conclusively established which form of pure magnesium stearate possesses the best lubricating properties.^(36,37,41–43) Commercial lots of magnesium stearate generally

consist of mixtures of crystalline forms.^(37,39,41,42,44–46) Because of the possibility of conversion of crystalline forms during heating, consideration should be given to the pretreatment conditions employed when determining physical properties of magnesium stearate powders such as surface area.^(47,48)

Physical properties of magnesium stearate can vary among batches from different manufacturers⁽⁴⁶⁾ because the solid-state characteristics of the powder are influenced by manufacturing variables.⁽³⁶⁾ Variations in the physical properties of different lots of magnesium stearate from the same vendor have also been observed.⁽⁴⁶⁾ Presumably because of these variations, it has not been possible to conclusively correlate the dissolution rate retardation with observed lubricity.⁽⁴⁹⁾

However, various physical properties of different batches of magnesium stearate, such as specific surface area, particle size, crystalline structure, moisture content, and fatty acid composition, have been correlated with lubricant efficacy.^(37,41,45,46,50–55) Due to variations in the specific surface area, the labeling states that specific surface area and the method specified for its determination should be listed on the label. Reduction in dissolution caused by the effects of magnesium stearate in some cases can be overcome by including a highly swelling disintegrant in the formulation.⁽⁵⁶⁾

The impact of magnesium stearate levels on tablet compaction properties and performance of roller compacted granulations has been examined.^(57–59) In other compaction studies performed with granules, magnesium stearate has been shown to exert an influence on granule relaxation and may help to prevent capping.⁽⁶⁰⁾

There is evidence to suggest that the hydrophobic nature of magnesium stearate can vary from batch to batch owing to the presence of water-soluble, surface-active impurities such as sodium stearate. Batches containing very low concentrations of these impurities have been shown to retard the dissolution of a drug to a greater extent than when using batches that contain higher levels of impurities.⁽⁴⁹⁾ One study related lubricity to the fatty acid composition (stearate:palmitate) of lubricant lots for tablet formulations based on compaction data and tablet material properties.⁽⁵⁴⁾ However, other studies have indicated that fatty acid composition has no influence on lubricant activity⁽³⁷⁾ and high-purity magnesium stearate was as effective a lubricant as the commercial material.⁽¹⁰⁾ Moisture sorption at different relative humidities can result in morphological changes in the magnesium stearate.^(61,62)

Magnesium stearate has been investigated for use in inhalation powders to control their performance.⁽⁶³⁾

A specification for magnesium stearate is included in the Food Chemicals Codex (FCC).⁽⁶⁴⁾ The EINECS number for magnesium stearate is 209-150-3.

19 Specific References

- Chowhan ZT. Harmonization of excipient standards. Weiner ML, Kotkoskie LA, eds. *Excipient Toxicity and Safety*. New York: Marcel Dekker, 2000; 321–354.
- Anonymous. Final report of the safety assessment of lithium stearate, aluminum distearate, aluminum stearate, aluminum tristearate, ammonium stearate, calcium stearate, magnesium stearate, potassium stearate, sodium stearate, and zinc stearate. *J Am Coll Toxicol* 1982; 1: 143–177.
- Sondergaard D *et al.* Magnesium stearate given perorally to rats: a short term study. *Toxicology* 1980; 17: 51–55.
- Boyland E *et al.* Further experiments on implantation of materials into the urinary bladder of mice. *Br J Cancer* 1964; 18: 575–581.
- Levy G, Gumtow RH. Effect of certain formulation factors on dissolution rate of the active ingredient III: tablet lubricants. *J Pharm Sci* 1963; 52: 1139–1144.
- Ganderton D. The effect of distribution of magnesium stearate on the penetration of a tablet by water. *J Pharm Pharmacol* 1969; 21(Suppl.): 95–185.
- Caldwell HC. Dissolution of lithium and magnesium from lithium carbonate capsules containing magnesium stearate. *J Pharm Sci* 1974; 63: 770–773.
- Chowhan ZT *et al.* Tablet-to-tablet dissolution variability and its relationship to the homogeneity of a water-soluble drug. *Drug Dev Ind Pharm* 1982; 8: 145–168.
- Lerk CF *et al.* Interaction of tablet disintegrants and magnesium stearate during mixing II: effect on dissolution rate. *Pharm Acta Helv* 1982; 57: 282–286.
- Hussain MSH *et al.* Effect of commercial and high purity magnesium stearates on in-vitro dissolution of paracetamol DC tablets. *Int J Pharm* 1992; 78: 203–207.
- Samyn JC, Jung WY. *In vitro* dissolution from several experimental capsule formulations. *J Pharm Sci* 1970; 59: 169–175.
- Murthy KS, Samyn JC. Effect of shear mixing on *in vitro* drug release of capsule formulations containing lubricants. *J Pharm Sci* 1977; 66: 1215–1219.
- Ragnarsson G *et al.* The influence of mixing time and colloidal silica on the lubricating properties of magnesium stearate. *Int J Pharm* 1979; 3: 127–131.
- Bolhuis GK *et al.* Mixing action and evaluation of tablet lubricants in direct compression. *Drug Dev Ind Pharm* 1980; 6: 573–589.
- Bossert J, Stamm A. Effect of mixing on the lubrication of crystalline lactose by magnesium stearate. *Drug Dev Ind Pharm* 1980; 6: 573–589.
- Bolhuis GK *et al.* Interaction of tablet disintegrants and magnesium stearate during mixing I: effect on tablet disintegration. *J Pharm Sci* 1981; 70: 1328–1330.
- Sheikh-Salem M, Fell JT. The influence of magnesium stearate on time dependent strength changes in tablets. *Drug Dev Ind Pharm* 1981; 7: 669–674.
- Stewart PJ. Influence of magnesium stearate on the homogeneity of a prednisone granule ordered mix. *Drug Dev Ind Pharm* 1981; 7: 485–495.
- Jaros PJ, Parrott EL. Effect of tablet lubricants on axial and radial work of failure. *Drug Dev Ind Pharm* 1982; 8: 445–453.
- Mitrevej KT, Augsburg LL. Adhesion of tablets in a rotary tablet press II: effects of blending time, running time, and lubricant concentration. *Drug Dev Ind Pharm* 1982; 8: 237–282.
- Khan KA *et al.* The effect of mixing time of magnesium stearate on the tableting properties of dried microcrystalline cellulose. *Pharm Acta Helv* 1983; 58: 109–111.
- Johansson ME. Investigations of the mixing time dependence of the lubricating properties of granular and powdered magnesium stearate. *Acta Pharm Suec* 1985; 22: 343–350.
- Johansson ME. Influence of the granulation technique and starting material properties on the lubricating effect of granular magnesium stearate. *J Pharm Pharmacol* 1985; 37: 681–685.
- Chowhan ZT, Chi LH. Drug–excipient interactions resulting from powder mixing III: solid state properties and their effect on drug dissolution. *J Pharm Sci* 1986; 75: 534–541.
- Chowhan ZT, Chi LH. Drug–excipient interactions resulting from powder mixing IV: role of lubricants and their effect on *in vitro* dissolution. *J Pharm Sci* 1986; 75: 542–545.
- Johansson ME, Nicklasson M. Influence of mixing time, particle size and colloidal silica on the surface coverage and lubrication of magnesium stearate. Rubinstein MH, ed. *Pharmaceutical Technology: Tableting Technology*. Chichester: Ellis Horwood, 1987; 43–50.
- Wang LH, Chowhan ZT. Drug–excipient interactions resulting from powder mixing V: role of sodium lauryl sulfate. *Int J Pharm* 1990; 60: 61–78.
- Muzikova J, Horacek J. The dry binders, Vivapur 102, Vivapur 12 and the effect of magnesium stearate on the strength of tablets containing these substances. *Ceske Slov Farm* 2003; 52(4): 176–180.
- Muzikova J. Effect of magnesium stearate on the tensile strength of tablets made with the binder Prosolv SMCC 90. *Ceska Slov Farm* 2002; 51(1): 41–43.
- Aguirre-Mendez C, Romanach RJ. A Raman spectroscopic method to monitor magnesium stearate in blends and tablets. *Pharmaceut Tech Eur* 2007; 19(9): 53–61.
- St-Onge L *et al.* Rapid quantitative analysis of magnesium stearate in tablets using laser-induced breakdown spectroscopy. *J Pharm Pharmacol* 2005; 8(2): 272–288.
- Duong N-H *et al.* A homogeneity study using NIR spectroscopy: tracking magnesium stearate in Bohle bin-blender. *Drug Dev Ind Pharm* 2003; 29(6): 679–687.
- Swaminathan V *et al.* Measurement of the surface energy of lubricated pharmaceutical powders by inverse gas chromatography. *Int. J. Pharm* 2006; 312(1–2): 158–165.

- 34 Faqih AM *et al.* Effect of moisture and magnesium stearate concentration on flow properties of cohesive granular materials. *Int J Pharm* 2007; 336(2): 338–345.
- 35 Muller BW. The pseudo-polymorphism of magnesium stearate. *Zbl Pharm* 1977; 116(12): 1261–1266.
- 36 Miller TA, York P. Physical and chemical characteristics of some high purity magnesium stearate and palmitate powders. *Int J Pharm* 1985; 23: 55–67.
- 37 Ertel KD, Carstensen JT. Chemical, physical, and lubricant properties of magnesium stearate. *J Pharm Sci* 1988; 77: 625–629.
- 38 Ertel KD, Carstensen JT. An examination of the physical properties of pure magnesium stearate. *Int J Pharm* 1988; 42: 171–180.
- 39 Wada Y, Matsubara T. Pseudo-polymorphism and crystalline transition of magnesium stearate. *Thermochim Acta* 1992; 196: 63–84.
- 40 Sharpe SA *et al.* Physical characterization of the polymorphic variations of magnesium stearate and magnesium palmitate hydrate species. *Struct Chem* 1997; 8(1): 73–84.
- 41 Leinonen UI *et al.* Physical and lubrication properties of magnesium stearate. *J Pharm Sci* 1992; 81(12): 1194–1198.
- 42 Muller BW. Polymorphism of magnesium stearate and the influence of the crystal structure on the lubricating behavior of excipients. *Acta Pharm Suec* 1981; 18: 74–75.
- 43 Okoye P, Wu S.H. Lubrication of direct-compressible blends with magnesium stearate monohydrate and dihydrate. *Pharm Technol* 2007; 31(9): 116–129.
- 44 Brittain HG. Raw materials. *Drug Dev Ind Pharm* 1989; 15(13): 2083–2103.
- 45 Dansereau R, Peck GE. The effect of the variability in the physical and chemical properties of magnesium stearate on the properties of compressed tablets. *Drug Dev Ind Pharm* 1987; 13: 975–999.
- 46 Barra J, Somma R. Influence of the physicochemical variability of magnesium stearate on its lubricant properties: possible solutions. *Drug Dev Ind Pharm* 1996; 22(11): 1105–1120.
- 47 Phadke DS, Collier JL. Effect of degassing temperature on the specific surface area and other physical properties of magnesium stearate. *Drug Dev Ind Pharm* 1994; 20(5): 853–858.
- 48 Koivisto M *et al.* Effect of temperature and humidity on vegetable grade magnesium stearate. *Powder Technol* 2004; 147(1–3): 79–85.
- 49 Billany MR, Richards JH. Batch variation of magnesium stearate and its effect on the dissolution rate of salicylic acid from solid dosage forms. *Drug Dev Ind Pharm* 1982; 8: 497–511.
- 50 Frattini C, Simioni L. Should magnesium stearate be assessed in the formulation of solid dosage forms by weight or by surface area? *Drug Dev Ind Pharm* 1984; 10: 1117–1130.
- 51 Bos CE *et al.* Lubricant sensitivity in relation to bulk density for granulations based on starch or cellulose. *Int J Pharm* 1991; 67: 39–49.
- 52 Phadke DS, Eichorst JL. Evaluation of particle size distribution and specific surface area of magnesium stearate. *Drug Dev Ind Pharm* 1991; 17: 901–906.
- 53 Steffens KJ, Koglin J. The magnesium stearate problem. *Manuf Chem* 1993; 64(12): 16–19.
- 54 Marwaha SB, Rubinstein MH. Structure-lubricity evaluation of magnesium stearate. *Int J Pharm* 1988; 43(3): 249–255.
- 55 Rao KP *et al.* Impact of solid-state properties on lubrication efficacy of magnesium stearate. *Pharm Dev Technol* 2005; 10(3): 423–437.
- 56 Desai DS *et al.* Physical interactions of magnesium stearate with starch-derived disintegrants and their effects on capsule and tablet dissolution. *Int J Pharm* 1993; 91(2–3): 217–226.
- 57 Wurster DE *et al.* The influence of magnesium stearate on the hiestand tableting indices and other related mechanical properties of maltodextrins. *Pharm Dev Technol* 2005; 10(4): 461–466.
- 58 Likitlersuang S *et al.* The effect of binary mixture composition and magnesium stearate concentration on the hiestand tableting indices and other related mechanical properties. *Pharm Dev Technol* 2007; 12(5): 533–541.
- 59 He X *et al.* Mechanistic study of the effect of roller compaction and lubricant on tablet mechanical strength. *J Pharm Sci* 2007; 96(5): 1342–1355.
- 60 Ebba F *et al.* Stress relaxation studies of granules as a function of different lubricants. *Eur J Pharm Biopharm* 2001; 52(2): 211–220.
- 61 Swaminathan V, Kildisig DO. An examination of the moisture sorption characteristics of commercial magnesium stearate. *AAPS Pharm Sci Tech* 2001; 2(4): 28.
- 62 Bracconi P *et al.* Structural properties of magnesium stearate pseudopolymorphs: effect of temperature. *Int J Pharm* 2003; 262(1–2): 109–124.
- 63 Guchardi R *et al.* Influence of fine lactose and magnesium stearate on low dose dry powder inhaler formulations. *Int J Pharm* 2008; 348(1–2): 10–17.
- 64 *Food Chemicals Codex*, 6th edn. Bethesda, MD: United States Pharmacopeia, 2008; 568.

20 General References

- Bohidar NR *et al.* Selecting key pharmaceutical formulation factors by regression analysis. *Drug Dev Ind Pharm* 1979; 5: 175–216.
- Butcher AE, Jones TM. Some physical characteristics of magnesium stearate. *J Pharm Pharmacol* 1972; 24: 1P–9P.
- European Directorate for the Quality of Medicines and Healthcare (EDQM). European Pharmacopoeia – State Of Work Of International Harmonisation. *Pharmeuropa* 2009; 21(1): 142–143. <http://www.edqm.eu/site/-614.html> (accessed 3 February 2009).
- Ford JL, Rubinstein MH. An investigation into some pharmaceutical interactions by differential scanning calorimetry. *Drug Dev Ind Pharm* 1981; 7: 675–682.
- Johansson ME. Granular magnesium stearate as a lubricant in tablet formulations. *Int J Pharm* 1984; 21: 307–315.
- Jones TM. The effect of glidant addition on the flowability of bulk particulate solids. *J Soc Cosmet Chem* 1970; 21: 483–500.
- Pilpel N. Metal stearates in pharmaceuticals and cosmetics. *Manuf Chem Aerosol News* 1971; 42(10): 37–40.
- York P. Tablet lubricants. Florence AT, ed. *Materials Used in Pharmaceutical Formulation*. London: Society of Chemical Industry, 1984; 37–70.
- Zanowiak P. Lubrication in solid dosage form design and manufacture. Swarbrick J, Boylan JC, eds. *Encyclopedia of Pharmaceutical Technology*, vol. 9: New York: Marcel Dekker, 1990; 87–112.

21 Authors

LV Allen Jr, PE Luner.

22 Date of Revision

3 February 2009.

The therapeutic use of sodium propionate in topical antifungal preparations has largely been superseded by a new generation of antifungal drugs.

A specification for sodium propionate is contained in the Food Chemicals Codex (FCC).⁽⁶⁾

The EINECS number for sodium propionate is 205-290-4. The PubChem Compound ID (CID) for sodium propionate is 23663426.

19 Specific References

- 1 Bishop Y, ed. *The Veterinary Formulary*, 6th edn. London: Pharmaceutical Press, 2005; 419–420.
- 2 Heseltine WW. A note on sodium propionate. *J Pharm Pharmacol* 1952; 4: 120–122.
- 3 Graham WD *et al.* Chronic toxicity of bread additives to rats. *J Pharm Pharmacol* 1954; 6: 534–545.
- 4 Lewis RJ, ed. *Sax's Dangerous Properties of Industrial Materials*, 11th edn. New York: Wiley, 2004; 3276.
- 5 Health and Safety Executive. *EH40/2005: Workplace Exposure Limits*. Sudbury: HSE Books, 2005 (updated 2007). <http://www.hse.gov.uk/coshh/table1.pdf> (accessed 5 February 2009).
- 6 *Food Chemicals Codex*, 6th edn. Bethesda, MD: United States Pharmacopeia, 2008; 906.

20 General References

- Doores S. Organic acids. Branen AL, Davidson PM, eds. *Antimicrobials in Foods*. New York: Marcel Dekker, 1983; 85–87.
- Furia TE, ed. *CRC Handbook of Food Additives*. Cleveland, OH: CRC Press, 1972; 137–141.

21 Author

T Sakurai.

22 Date of Revision

5 February 2009.

Sodium Starch Glycolate

1 Nonproprietary Names

BP: Sodium Starch Glycolate

PhEur: Sodium Starch Glycolate

USP-NF: Sodium Starch Glycolate

2 Synonyms

Carboxymethyl starch, sodium salt; carboxymethylamylum natrium; *Explosol*; *Explotab*; *Glycolys*; *Primojel*; starch carboxymethyl ether, sodium salt; *Tablo*; *Vivastar P*.

3 Chemical Name and CAS Registry Number

Sodium carboxymethyl starch [9063-38-1]

4 Empirical Formula and Molecular Weight

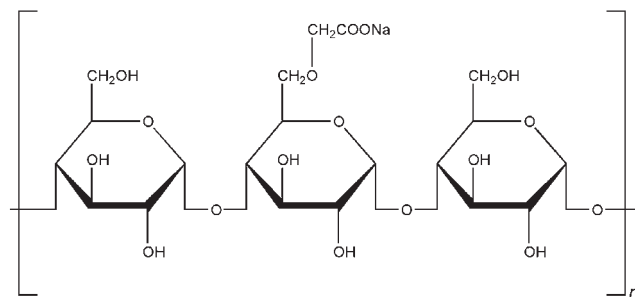
The USP32–NF27 describes two types of sodium starch glycolate, Type A and Type B, and states that sodium starch glycolate is the sodium salt of a carboxymethyl ether of starch or of a crosslinked carboxymethyl ether of starch.

The PhEur 6.0 describes three types of material: Type A and Type B are described as the sodium salt of a crosslinked partly O-carboxymethylated potato starch. Type C is described as the sodium salt of a partly O-carboxymethylated starch, crosslinked by physical dehydration. Types A, B, and C are differentiated by their pH, sodium, and sodium chloride content.

The PhEur and USP–NF monographs have been harmonized for Type A and Type B variants.

Sodium starch glycolate may be characterized by the degree of substitution and crosslinking. The molecular weight is typically 5×10^5 – 1×10^6 .

5 Structural Formula



6 Functional Category

Tablet and capsule disintegrant.

7 Applications in Pharmaceutical Formulation or Technology

Sodium starch glycolate is widely used in oral pharmaceuticals as a disintegrant in capsule^(1–6) and tablet formulations.^(7–10) It is commonly used in tablets prepared by either direct-compression^(11–13) or wet-granulation processes.^(14–16) The usual concentration employed in a formulation is between 2% and 8%, with the optimum concentration about 4%, although in many cases 2% is sufficient. Disintegration occurs by rapid uptake of water followed by rapid and enormous swelling.^(17–20)

Although the effectiveness of many disintegrants is affected by the presence of hydrophobic excipients such as lubricants, the disintegrant efficiency of sodium starch glycolate is unimpaired. Increasing the tablet compression pressure also appears to have no effect on disintegration time.^(10–12)

Sodium starch glycolate has also been investigated for use as a suspending vehicle.⁽²¹⁾

8 Description

Sodium starch glycolate is a white or almost white free-flowing very hygroscopic powder. The PhEur 6.0 states that when examined under a microscope it is seen to consist of: granules, irregularly shaped, ovoid or pear-shaped, 30–100 μm in size, or rounded, 10–35 μm in size; compound granules consisting of 2–4 components occur occasionally; the granules have an eccentric hilum and clearly visible concentric striations. Between crossed nicol prisms, the granules show a distinct black cross intersecting at the hilum; small crystals are visible at the surface of the granules. The granules show considerable swelling in contact with water.

9 Pharmacopeial Specifications

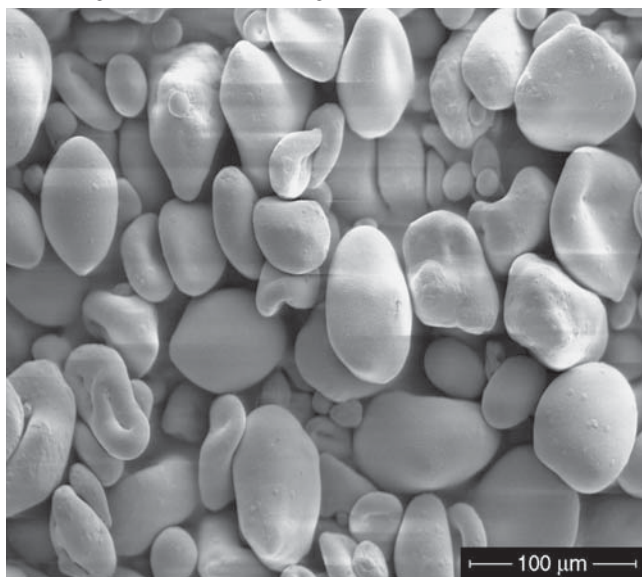
See Table I. See also Section 18.

10 Typical Properties

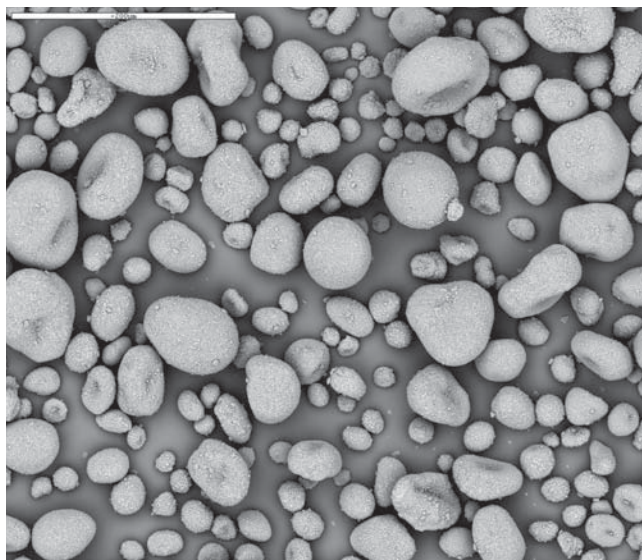
Acidity/alkalinity See Section 9.

Density (bulk)

SEM 1: Excipient: sodium starch glycolate (*Explotab*); manufacturer: JRS Pharma; magnification: 300 $\times$; voltage: 5 kV.



SEM 2: Excipient: sodium starch glycolate (*Glycolys*); manufacturer: Roquettes Frères.



0.756 g/cm³ for *Glycolys*;

0.81 g/cm³ for *Primojel*;

0.67 g/cm³ for *Tablo*.

Density (tapped)

0.945 g/cm³ for *Glycolys*;

0.98 g/cm³ for *Primojel*;

0.83 g/cm³ for *Tablo*.

Density (true)

1.56 g/cm³ for *Primojel*;

1.49 g/cm³ for *Tablo*.

Melting point Does not melt, but chars at approximately 200°C.

NIR spectra see Figure 1.

Particle size distribution 100% of particles less than 106 μm in size. Average particle size (d_{50}) is 38 μm and 42 μm for *Primojel* by microscopy and sieving, respectively.

Solubility Practically insoluble in methylene chloride. It gives a translucent suspension in water.

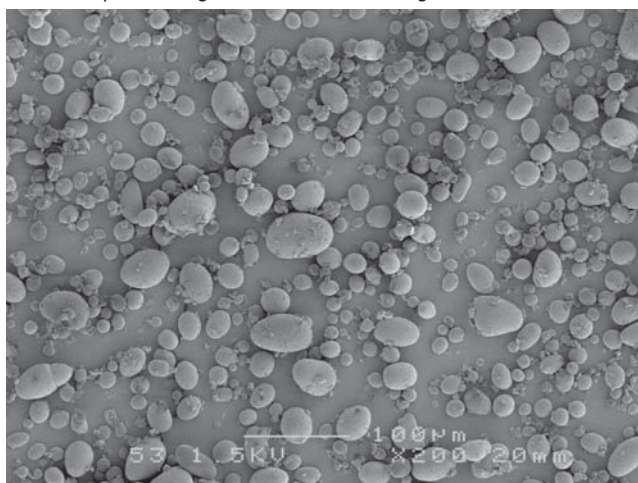
Specific surface area

0.24 m²/g for *Glycolys*;

0.185 m²/g for *Primojel*;

0.335 m²/g for *Tablo*.

SEM 3: Excipient: sodium starch glycolate (*Primojel*); manufacturer: DMV-Fonterra Excipients; magnification: 200 $\times$; voltage: 1.5 kV.



SEM 4: Excipient: sodium starch glycolate (*Vivastar P*); manufacturer: JRS Pharma; magnification: 300 $\times$; voltage: 5 kV.

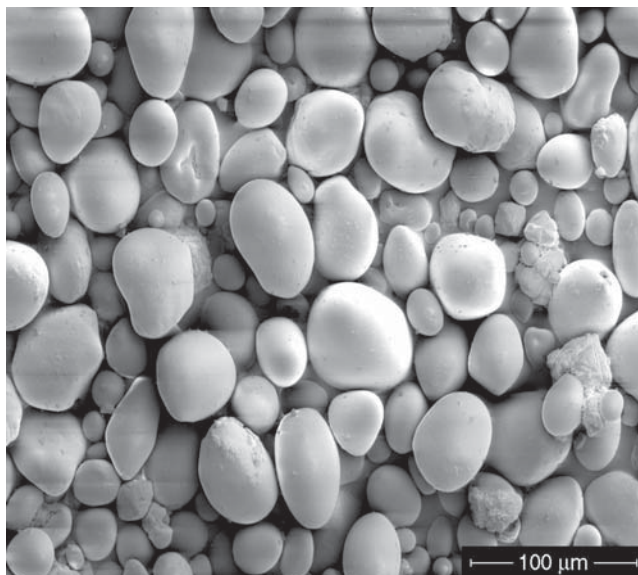


Table I: Pharmacopeial specifications for sodium starch glycolate.

Test	PhEur 6.0	USP32-NF27
Identification	+	+
Characters	+	—
Appearance of solution	+	—
pH	+	+
Type A	5.5–7.5	5.5–7.5
Type B	3.0–5.0	3.0–5.0
Type C	5.5–7.5	—
Heavy metals	≤20 ppm	≤0.002%
Iron	≤20 ppm	≤0.002%
Loss on drying	+	≤10%
Type A	≤10.0%	—
Type B	≤10.0%	—
Type C	≤7.0%	—
Microbial limits	+(a)	+(a)
Sodium chloride	+	≤7.0%
Type A	≤7.0%	—
Type B	≤7.0%	—
Type C	≤1.0%	—
Sodium glycolate	+	≤2.0%
Type A	≤2.0%	—
Type B	≤2.0%	—
Type C	≤2.0%	—
Assay (of Na)	+	+
Type A	2.8–4.2%	2.8–4.2%
Type B	2.0–3.4%	2.0–3.4%
Type C	2.8–5.0%	—

(a) Complies with tests for *Salmonella* and *Escherichia coli*.

Swelling capacity In water, sodium starch glycolate swells to up to 300 times its volume.

Viscosity (dynamic) ≤200 mPa s (200 cP) for a 4% w/v aqueous dispersion; viscosity is 4.26 mPa s for a 2% w/v aqueous dispersion (depending on source and grade).

11 Stability and Storage Conditions

Tablets prepared with sodium starch glycolate have good storage properties.^(22–24) Sodium starch glycolate is stable although very hygroscopic, and should be stored in a well-closed container in order to protect it from wide variations of humidity and temperature, which may cause caking.

The physical properties of sodium starch glycolate remain unchanged for up to 3 years if it is stored at moderate temperatures and humidity.

12 Incompatibilities

Sodium starch glycolate is incompatible with ascorbic acid.⁽²⁵⁾

13 Method of Manufacture

Sodium starch glycolate is a substituted derivative of potato starch. Typically, commercial products are also crosslinked using either sodium trimetaphosphate (Types A and B) or dehydration (Type C).⁽²⁶⁾

Starch is carboxymethylated by reacting it with sodium chloroacetate in an alkaline, nonaqueous medium, typically denatured ethanol or methanol, followed by neutralization with citric acid, acetic acid, or some other acid. *Vivastar P* is manufactured in methanolic medium, and *Explotab* in ethanolic medium.

14 Safety

Sodium starch glycolate is widely used in oral pharmaceutical formulations and is generally regarded as a nontoxic and nonirritant material. However, oral ingestion of large quantities may be harmful.

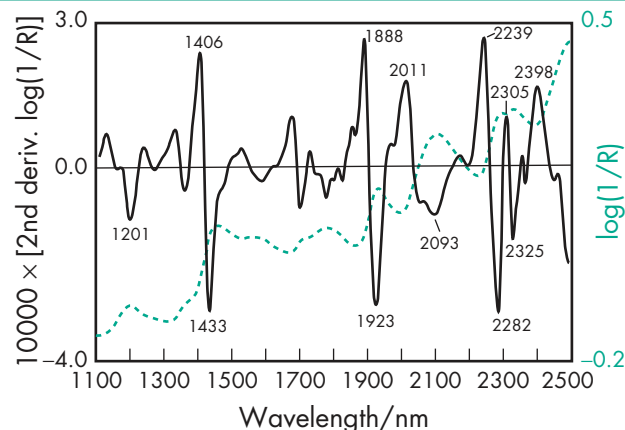


Figure 1: Near-infrared spectrum of sodium starch glycolate measured by reflectance.

15 Handling Precautions

Observe normal precautions appropriate to the circumstances and quantity of material handled. Sodium starch glycolate may be irritant to the eyes; eye protection and gloves are recommended. A dust mask or respirator is recommended for processes that generate a large quantity of dust.

16 Regulatory Acceptance

Included in the FDA Inactive Ingredients Database (oral capsules and tablets). Included in nonparenteral medicines licensed in the UK. Included in the Canadian List of Acceptable Non-medicinal Ingredients.

17 Related Substances

Pregelatinized starch; starch.

18 Comments

Sodium starch glycolate is one of the materials that have been selected for harmonization by the Pharmacopeial Discussion Group. For further information see the General Information Chapter <1196> in the USP32-NF27, the General Chapter 5.8 in PhEur 6.0, along with the 'State of Work' document on the PhEur EDQM website, and also the General Information Chapter 8 in the JP XV.

The physical properties of sodium starch glycolate, and hence its effectiveness as a disintegrant, are affected by the degree of crosslinkage, extent of carboxymethylation, and purity.^(27,28)

Sodium starch glycolate has been reported to interact with glycopeptide antibiotics,^(29,30) basic drugs, and increase the photostability of norfloxacin.⁽³¹⁾ The solubility of the formulation matrix and mode of incorporation in wet granulation can affect the disintegration time; disintegration times can be slower in tablets containing high levels of soluble excipients.⁽³²⁾

Commercially, sodium starch glycolate is available in a number of speciality grades, e.g. low pH (*Explotab Low pH*, *Glycolys Low pH*); low viscosity (*Explotab CLV*, *Glycolys LV*); low solvent (*Vivastar PSF*); and low moisture *Glycolys LM*.

A specification for sodium starch glycolate is included in the *Japanese Pharmaceutical Excipients* (JPE).⁽³³⁾

19 Specific References

- 1 Newton JM, Razzo FN. Interaction of formulation factors and dissolution fluid and the *in vitro* release of drug from hard gelatin capsules. *J Pharm Pharmacol* 1975; 27: 78P.

- 2 Stewart AG *et al.* The release of a model low-dose drug (riboflavine) from hard gelatin capsule formulations. *J Pharm Pharmacol* 1979; 31: 1–6.
- 3 Chowhan ZT, Chi L-H. Drug–excipient interactions resulting from powder mixing III: solid state properties and their effect on drug dissolution. *J Pharm Sci* 1986; 75: 534–541.
- 4 Botzolakos JE, Augsburger LL. Disintegrating agents in hard gelatin capsules part 1: mechanism of action. *Drug Dev Ind Pharm* 1988; 14(1): 29–41.
- 5 Hannula A-M *et al.* Release of ibuprofen from hard gelatin capsule formulations: effect of modern disintegrants. *Acta Pharm Fenn* 1989; 98: 189–196.
- 6 Marvola M *et al.* Effect of sodium bicarbonate and sodium starch glycolate on the *in vivo* disintegration of hard gelatin capsules – a radiological study in the dog. *Acta Pharm Nord* 1989; 1: 355–362.
- 7 Khan KA, Rooke DJ. Effect of disintegrant type upon the relationship between compressional pressure and dissolution efficiency. *J Pharm Pharmacol* 1976; 28: 633–636.
- 8 Rubinstein MH, Price EJ. *In vivo* evaluation of the effect of five disintegrants on the bioavailability of frusemide from 40 mg tablets. *J Pharm Pharmacol* 1977; 29: 5P.
- 9 Caramella C *et al.* The influence of disintegrants on the characteristics of coated acetylsalicylic acid tablets. *Farmaco (Prat)* 1978; 33: 498–507.
- 10 Gebre Mariam T *et al.* Evaluation of the disintegration efficiency of a sodium starch glycolate prepared from onset starch in compressed tablets. *Eur J Pharm Biopharm* 1996; 42(2): 124–132.
- 11 Cid E, Jaminet F. [Influence of adjuvants on the dissolution rate and stability of acetylsalicylic acid in compressed tablets.] *J Pharm Belg* 1971; 26: 38–48 [in French].
- 12 Gordon MS, Chowhan ZT. Effect of tablet solubility and hygroscopicity on disintegrant efficiency in direct compression tablets in terms of dissolution. *J Pharm Sci* 1987; 76: 907–909.
- 13 Cordoba-Diaz M *et al.* Influence of pharmacotechnical design on the interaction and availability of norfloxacin in directly compressed tablets with certain antacids. *Drug Dev Ind Pharm* 2000; 26: 159–166.
- 14 Sekulović D *et al.* The investigation of the influence of Explotab on the disintegration of tablets. *Pharmazie* 1986; 41: 153–154.
- 15 Bolhuis GK *et al.* Improvement of dissolution of poorly soluble drugs by solid deposition on a super disintegrant. Part 2. Choice of super disintegrants and effect of granulation. *Eur J Pharm Sci* 1997; 5(2): 63–69.
- 16 Gordon MS *et al.* Effect of the mode of super disintegrant incorporation on dissolution in wet granulated tablets. *J Pharm Sci* 1993; 82: 220–226.
- 17 Khan KA, Rhodes CT. Disintegration properties of calcium phosphate dibasic dihydrate tablets. *J Pharm Sci* 1975; 64: 166–168.
- 18 Khan KA, Rhodes CT. Water-sorption properties of tablet disintegrants. *J Pharm Sci* 1975; 64: 447–451.
- 19 Wan LSC, Prasad KPP. Uptake of water by excipients in tablets. *Int J Pharm* 1989; 50: 147–153.
- 20 Thibert R, Hancock BC. Direct visualization of superdisintegrant hydration using environmental scanning electron microscopy. *J Pharm Sci* 1996; 85: 1255–1258.
- 21 Danckwerts MP *et al.* Pharmaceutical formulation of a fixed-dose anti-tuberculosis combination. *Int J Tuberc Lung D* 2003; 7: 289–297.
- 22 Horhota ST *et al.* Effect of storage at specified temperature and humidity on properties of three directly compressible tablet formulations. *J Pharm Sci* 1976; 65: 1746–1749.
- 23 Sheen P-C, Kim S-I. Comparative study of disintegrating agents in tiaramide hydrochloride tablets. *Drug Dev Ind Pharm* 1989; 15(3): 401–414.
- 24 Gordon MS, Chowhan ZT. The effect of aging on disintegrant efficiency in direct compression tablets with varied solubility and hygroscopicity, in terms of dissolution. *Drug Dev Ind Pharm* 1990; 16(3): 437–447.
- 25 Botha SA *et al.* DSC screening for drug–excipient and excipient–excipient interactions in polypharmaceuticals intended for the alleviation of the symptoms of colds and flu. III. *Drug Dev Ind Pharm* 1987; 13(7): 1197–1215.
- 26 Bolhuis GK *et al.* On the similarity of sodium starch glycolate from different sources. *Drug Dev Ind Pharm* 1986; 12(4): 621–630.
- 27 Rudnic EM *et al.* Effect of molecular structure variation on the disintegrant action of sodium starch glycolate. *J Pharm Sci* 1985; 74: 647–650.
- 28 Bolhuis GK *et al.* Effect of variation of degree of substitution, crosslinking and purity on the disintegrant efficiency of sodium starch glycolate. *Acta Pharm Technol* 1984; 30: 24–32.
- 29 Claudius JS, Neau SH. Kinetic and equilibrium characterization of interactions between glycopeptide antibiotics and sodium carboxymethyl starch. *Int J Pharm* 1996; 144: 71–79.
- 30 Claudius JS, Neau SH. The solution stability of vancomycin in the presence and absence of sodium carboxymethyl starch. *Int J Pharm* 1998; 168: 41–48.
- 31 Cordoba-Borrego M *et al.* Validation of a high performance liquid chromatographic method for the determination of norfloxacin and its application to stability studies (photostability study of norfloxacin). *J Pharm Biomed Anal* 1999; 18: 919–926.
- 32 Gordon MS *et al.* Effect of the mode of super disintegrant incorporation on dissolution in wet granulated tablets. *J Pharm Sci* 1993; 82: 220–226.
- 33 Japanese Pharmaceutical Excipients Council. *Japanese Pharmaceutical Excipients* 2004. Tokyo: Yakuji Nippo, 2004; 774.

20 General References

- Augsburger LL *et al.* Superdisintegrants: characterisation and function. Swarbrick J, ed. *Encyclopedia of Pharmaceutical Technology*, 3rd edn. London: Informa Healthcare, 2007; 2553–2567.
- Blanner. Technical literature: *Tablo, Explosol*, 2008.
- DMV-Fonterra Excipients. Technical literature: *Primojel*, 2008.
- European Directorate for the Quality of Medicines and Healthcare (EDQM). European Pharmacopoeia – State Of Work Of International Harmonisation. *Pharmeuropa* 2009; 21(1): 142–143. <http://www.edqm.eu/site/-614.html> (accessed 3 February 2009).
- Edge S *et al.* Chemical characterisation of sodium starch glycolate particles. *Int J Pharm* 2002; 240: 67–78.
- Edge S *et al.* Powder compaction properties of sodium starch glycolate disintegrants. *Drug Dev Ind Pharm* 2002; 28(8): 989–999.
- JRS Pharma. Technical literature: *Explotab, Vivastar P*, 2004.
- Khan KA, Rhodes CT. Further studies of the effect of compaction pressure on the dissolution efficiency of direct compression systems. *Pharm Acta Helv* 1974; 49: 258–261.
- Mantovani F *et al.* A combination of vapor sorption and dynamic laser light scattering methods for the determination of the Flory parameter χ and the crosslink density of a powdered polymeric gel. *Fluid Phase Equilib* 2000; 167(1): 63–81.
- Mendell E. An evaluation of carboxymethyl starch as a tablet disintegrant. *Pharm Acta Helv* 1974; 49: 248–250.
- Roquette Frères. Technical literature: *Glycolys*, 2008.
- Shah U, Augsburger L. Multiple sources of sodium starch glycolate NF: evaluation of functional equivalence and development of standard performance tests. *Pharm Dev Tech* 2002; 7(3): 345–359.
- Young PM *et al.* Interaction of moisture with sodium starch glycolate. *Pharm Dev Tech* 2007; 12: 211–216.
- Young PM *et al.* The effect of moisture on the compressibility and compactability of sodium starch glycolates. *Pharm Dev Tech* 2007; 12: 217–222.

21 Author

PM Young.

22 Date of Revision

3 February 2009.



Stearic Acid

1 Nonproprietary Names

BP: Stearic Acid

JP: Stearic Acid

PhEur: Stearic Acid

USP-NF: Stearic Acid

2 Synonyms

Acidum stearicum; cetylacetic acid; *Crodacid*; *Cristal G*; *Cristal S*; *Dervacid*; E570; *Edenor*; *Emersol*; *Extra AS*; *Extra P*; *Extra S*; *Extra ST*; 1-heptadecanecarboxylic acid; *Hystrene*; *Industrene*; *Kortacid 1895*; *Pearl Steric*; *Pristerene*; stereophanic acid; *Tego-stearic*.

3 Chemical Name and CAS Registry Number

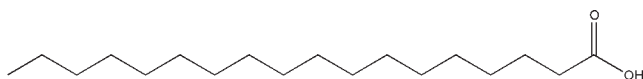
Octadecanoic acid [57-11-4]

4 Empirical Formula and Molecular Weight

$C_{18}H_{36}O_2$ 284.47 (for pure material)

The USP32–NF27 describes stearic acid as a mixture of stearic acid ($C_{18}H_{36}O_2$) and palmitic acid ($C_{16}H_{32}O_2$). In the USP32–NF27, the content of stearic acid is not less than 40.0% and the sum of the two acids is not less than 90.0%. The USP32–NF27 also contains a monograph for purified stearic acid; see Section 17. The PhEur 6.5 contains a single monograph for stearic acid but defines stearic acid 50, stearic acid 70, and stearic acid 95 as containing specific amounts of stearic acid ($C_{18}H_{36}O_2$); see Section 9.

5 Structural Formula



6 Functional Category

Emulsifying agent; solubilizing agent; tablet and capsule lubricant.

7 Applications in Pharmaceutical Formulation or Technology

Stearic acid is widely used in oral and topical pharmaceutical formulations. It is mainly used in oral formulations as a tablet and capsule lubricant;^(1–3) see Table I, although it may also be used as a binder⁽⁴⁾ or in combination with shellac as a tablet coating. It has also been suggested that stearic acid may be used in enteric tablet coatings and as a sustained-release drug carrier.⁽⁵⁾

In topical formulations, stearic acid is used as an emulsifying and solubilizing agent. When partially neutralized with alkalis or triethanolamine, stearic acid is used in the preparation of creams.^(6,7) The partially neutralized stearic acid forms a creamy base when mixed with 5–15 times its own weight of aqueous liquid, the appearance and plasticity of the cream being determined by the proportion of alkali used.

Stearic acid is used as the hardening agent in glycerin suppositories.

Stearic acid is also widely used in cosmetics and food products.

Table I: Uses of stearic acid.

Use	Concentration (%)
Ointments and creams	1–20
Tablet lubricant	1–3

8 Description

Stearic acid is a hard, white or faintly yellow-colored, somewhat glossy, crystalline solid or a white or yellowish white powder. It has a slight odor (with an odor threshold of 20 ppm) and taste suggesting tallow.

See also Section 13.

9 Pharmacopeial Specifications

See Table II. See also Section 18.

10 Typical Properties

Acid value 195–212

Boiling point 383°C

Density (bulk) $\approx 0.537 \text{ g/cm}^3$

Density (tapped) 0.571 g/cm^3

Density (true) 0.980 g/cm^3

Flash point 113°C (closed cup)

Melting point 69–70°C

Moisture content Contains practically no water.

NIR spectra see Figure 1.

Partition coefficient Log (oil : water) = 8.2

Refractive index 1.43 at 80°C

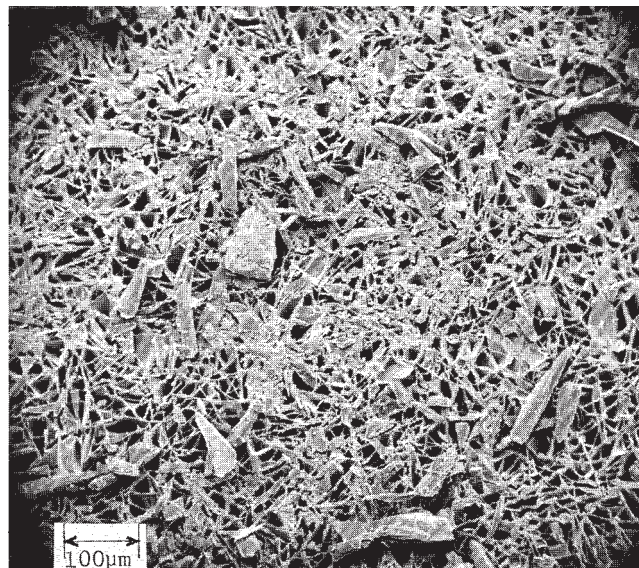
Saponification value 200–220

Solubility Freely soluble in benzene, carbon tetrachloride, chloroform, and ether; soluble in ethanol (95%), hexane, and propylene glycol; practically insoluble in water.⁽⁸⁾

Specific surface area

0.51–0.53 m²/g

SEM 1: Excipient: stearic acid, 95% (*Emersol 153*); manufacturer: Emery Industries; lot no.: 18895; magnification: 120 $\times$; voltage: 10 kV.



SEM 2: Excipient: stearic acid, food grade (Emersol 6332); manufacturer: Emery Industries; lot no.: 18895; magnification: 120×; voltage: 10 kV.

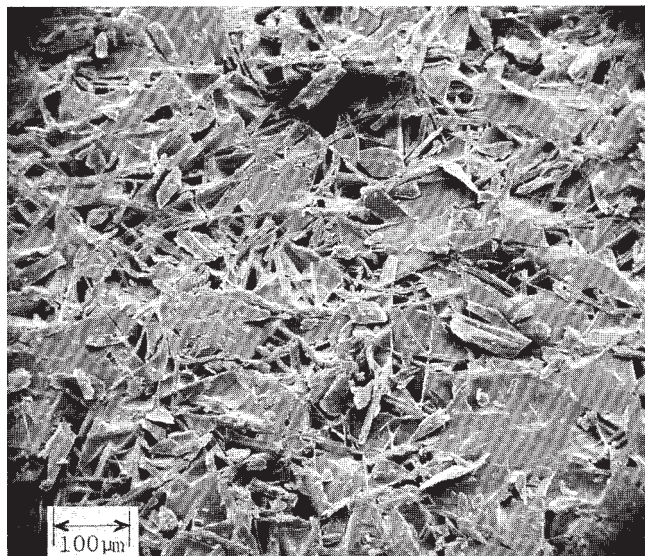


Table II: Pharmacopeial specifications for stearic acid.

Test	JP XV	PhEur 6.5	USP32-NF27
Identification	—	+	—
Characters	—	+	—
Acidity	—	+	—
Acid value	194–210	194–212	—
Appearance	—	+	—
Content of stearic acid	—	+	≥40.0%
Stearic acid 50	—	40–60%	—
Stearic acid 70	—	60–80%	—
Stearic acid 95	—	≥90.0%	—
Content of stearic and palmitic acids	—	+	≥90.0%
Stearic acid 50	—	≥90.0%	—
Stearic acid 70	—	≥90.0%	—
Stearic acid 95	—	≥96.0%	—
Congeeing temperature	56.0–72.0°C	—	≥54°C
Freezing point	—	+	—
Stearic acid 50	—	53–59°C	—
Stearic acid 70	—	57–64°C	—
Stearic acid 95	—	64–69°C	—
Iodine value	≤4.0	+	≤4.0
Stearic acid 50	—	≤4.0%	—
Stearic acid 70	—	≤4.0%	—
Stearic acid 95	—	≤1.5%	—
Nickel	—	≤1 ppm	—
Residue on ignition	≤0.1%	—	≤0.1%
Heavy metals	≤20 ppm	—	≤0.001%
Neutral fat or paraffin	+	—	+
Mineral acid	+	—	+

See also Section 17 and Table III.

11 Stability and Storage Conditions

Stearic acid is a stable material; an antioxidant may also be added to it; see Section 13. The bulk material should be stored in a well-closed container in a cool, dry place.

12 Incompatibilities

Stearic acid is incompatible with most metal hydroxides and may be incompatible with bases, reducing agents, and oxidizing agents.

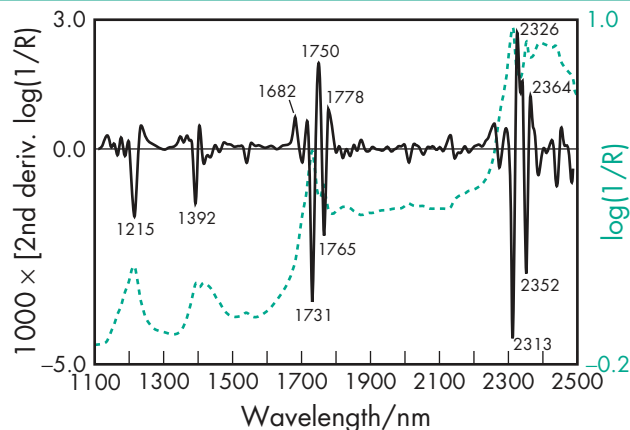


Figure 1: Near-infrared spectrum of stearic acid measured by reflectance.

Ointment bases made with stearic acid may show evidence of drying out or lumpiness due to such a reaction when compounded with zinc or calcium salts.

A number of differential scanning calorimetry studies have investigated the compatibility of stearic acid with drugs. Although such laboratory studies have suggested incompatibilities, e.g. with naproxen,⁽⁹⁾ they may not necessarily be applicable to formulated products.

Stearic acid has been reported to cause pitting in the film coating of tablets applied using an aqueous film-coating technique; the pitting was found to be a function of the melting point of the stearic acid.⁽¹⁰⁾

13 Method of Manufacture

Stearic acid is manufactured by hydrolysis of fat by continuous exposure to a countercurrent stream of high-temperature water and fat in a high-pressure chamber. The resultant mixture is purified by vacuum steam distillation and the distillates are then separated using selective solvents.

Stearic acid may also be manufactured by the hydrogenation of cottonseed and other vegetable oils; by the hydrogenation and subsequent saponification of olein followed by recrystallization from alcohol; and from edible fats and oils by boiling with sodium hydroxide, separating any glycerin, and decomposing the resulting soap with sulfuric or hydrochloric acid. The stearic acid is then subsequently separated from any oleic acid by cold expression.

Stearic acid is derived from edible fat sources unless it is intended for external use, in which case nonedible fat sources may be used. The USP32–NF27 states that stearic acid labeled solely for external use is exempt from the requirement that it be prepared from edible sources. Stearic acid may contain a suitable antioxidant such as 0.005% w/w butylated hydroxytoluene.

14 Safety

Stearic acid is widely used in oral and topical pharmaceutical formulations; it is also used in cosmetics and food products. Stearic acid is generally regarded as a nontoxic and nonirritant material. However, consumption of excessive amounts may be harmful.

LD₅₀ (mouse, IV): 23 mg/kg⁽¹¹⁾

LD₅₀ (rat, IV): 21.5 mg/kg

15 Handling Precautions

Observe normal precautions appropriate to the circumstances and quantity of material handled. Stearic acid dust may be irritant to the skin, eyes, and mucous membranes. Eye protection, gloves, and a dust respirator are recommended. Stearic acid is combustible.

Table III: Specifications of different stearic acid grades.

Product	Stearic acid content (%)	Melting range (°C)	Acid value	Iodine value	Saponification value	Unsaponifiable matter (%)
Hystrene 5016	44	54.5–56.5	206–210	≤0.5	206–211	≤0.2
Hystrene 7018	68.5	61.0–62.5	200–205	≤0.5	200–206	≤0.2
Hystrene 9718	90	66.5–68.0	196–201	≤0.8	196–202	≤0.3
Industrene 7018	65	58.0–62.0	200–207	≤1.5	200–208	≤0.5
Industrene 8718	87	64.5–67.5	196–201	≤2.0	196–202	≤1.5

16 Regulatory Status

GRAS listed. Accepted as a food additive in Europe (fatty acids). Included in the FDA Inactive Ingredients Database (sublingual tablets; oral capsules, solutions, suspensions, and tablets; topical and vaginal preparations). Included in nonparenteral medicines licensed in the UK. Included in the Canadian List of Acceptable Non-medicinal Ingredients.

17 Related Substances

Calcium stearate; magnesium stearate; polyoxyethylene stearates; purified stearic acid; zinc stearate.

Purified stearic acid

Empirical formula $C_{18}H_{36}O_2$

Molecular weight 284.47

CAS number [57-11-4]

Synonyms Octadecanoic acid

Acid value 195–200

Boiling point 361°C

Density 0.847 g/cm³ at 70°C

Flash point 196°C

Iodine number ≤1.5

Melting point 66–69°C

Refractive index $n_D^{20} = 1.4299$

Solubility Soluble 1 in 5 parts benzene, 1 in 6 parts carbon tetrachloride, 1 in 2 parts chloroform, 1 in 15 parts ethanol, 1 in 3 parts ether; practically insoluble in water.

Vapor density (relative) 9.80 (air = 1)

Comments The USP32–NF27 describes purified stearic acid as a mixture of stearic acid ($C_{18}H_{36}O_2$) and palmitic acid ($C_{16}H_{32}O_2$), which together constitute not less than 96.0% of the total content. The content of $C_{18}H_{36}O_2$ is no less than 90.0% of the total.

18 Comments

Stearic acid is one of the materials that have been selected for harmonization by the Pharmacopeial Discussion Group. For further information see the General Information Chapter <1196> in the USP32–NF27, the General Chapter 5.8 in PhEur 6.0, along with the ‘State of Work’ document on the PhEur EDQM website, and also the General Information Chapter 8 in the JP XV.

A wide range of different grades of stearic acid are commercially available that have varying chemical compositions and hence different physical and chemical properties; see Table III.⁽¹²⁾ Stearic acid is highly soluble in structurally diverse solvents. Stearic acid/solvent packing within a 24.8?³ cubic volume explains the stoichiometry of stearic acid solubility at multiple temperatures in multiple solvents.⁽¹³⁾

In one study the release of an active drug in a formulation containing stearic acid was independent of compression pressure in the range 1–7 tons; the particle size of the stearic acid did have a significant influence on the drug release.⁽¹⁴⁾

A potential application of stearic acid is in the preparation of ‘cushioning pellets’, composed of stearic acid: microcrystalline cellulose (4:1 w/w). The use of these pellets may avoid rupture of the coating of pellets during the compression step of manufacturing.⁽¹⁵⁾

A specification for stearic acid is contained in the Food Chemicals Codex (FCC).⁽¹⁶⁾

The EINECS number for stearic acid is 200-313-4.

19 Specific References

- Iranloye TA, Parrott EL. Effects of compression force, particle size, and lubricants on dissolution rate. *J Pharm Sci* 1978; 67: 535–539.
- Jaros PJ, Parrott EL. Effect of tablet lubricants on axial and radial work of failure. *Drug Dev Ind Pharm* 1982; 8: 445–453.
- Mitrevej KT, Augsburger LL. Adhesion of tablets in a rotary tablet press II: effects of blending time, running time, and lubricant concentration. *Drug Dev Ind Pharm* 1982; 8: 237–282.
- Musikabhumma P *et al.* Evaluation of stearic acid and polyethylene glycol as binders for tableting potassium phenethicillin. *Drug Dev Ind Pharm* 1982; 8: 169–188.
- Zhang Q *et al.* Studies on the cyclosporin A loaded stearic acid nanoparticles. *Int J Pharm* 2000; 200: 153–159.
- Suzuki K. Rheological study of vanishing cream. *Cosmet Toilet* 1976; 91(6): 23–31.
- Mores LR. Application of stearates in cosmetic creams and lotions. *Cosmet Toilet* 1980; 95(3): 79, 81–84.
- Yalkowsky SH, He Y, eds. *Handbook of Solubility Data*. Boca Raton, FL: CRC Press, 2003; 1119–1120.
- Botha SA, Lötter AP. Compatibility study between naproxen and tablet excipients using differential scanning calorimetry. *Drug Dev Ind Pharm* 1990; 16: 673–683.
- Rowe RC, Forse SF. Pitting: a defect on film-coated tablets. *Int J Pharm* 1983; 17: 347–349.
- Lewis RJ, ed. *Sax’s Dangerous Properties of Industrial Materials*, 11th edn. New York: Wiley, 2004; 3229–3300.
- Phadke DS *et al.* Evaluation of batch-to-batch and manufacturer-to-manufacturer variability in the physical properties of talc and stearic acid. *Drug Dev Ind Pharm* 1994; 20: 859–871.
- Schmidt WF *et al.* Stearic acid solubility and cubic phase volume. *Chem Phys Lipids* 2006; 142(1–2): 23–32.
- Killen BU, Corrigan OI. Factors influencing drug release from stearic acid based compacts. *Int J Pharm* 2001; 228(1–2): 189–198.
- Qi XL *et al.* Preparation of tablets containing enteric-coated diclofenac sodium pellets. *Yao Xue Xue Bao* 2008; 43(1): 97–101.
- Food Chemicals Codex*, 6th edn. Bethesda, MD: United States Pharmacopeia, 2008; 927.

20 General References

- Allen LV. Featured excipient: capsule and tablet lubricants. *Int J Pharm Compound* 2000; 4(5): 390–392/404–405.
- European Directorate for the Quality of Medicines and Healthcare (EDQM). European Pharmacopoeia – State Of Work Of International Harmonisation. *Pharmeuropa* 2009; 21(1): 142–143. <http://www.edqm.eu/site/-614.html> (accessed 25 February 2009).
- Pilpel N. Metal stearates in pharmaceuticals and cosmetics. *Manuf Chem Aerosol News* 1971; 42(10): 37–40.
- Oxford University. Material safety data sheet: Stearic acid, 2009. http://msds.chem.ox.ac.uk/ST/stearic_acid.html (accessed 25 February 2009).
- ScienceLab.com, Inc. Material safety data sheet: Stearic acid, .2005.

21 Author

LV Allen Jr.

22 Date of Revision

25 February 2009.

recommended. Stearyl alcohol is not a fire hazard, although it will burn and may give off noxious fumes containing carbon monoxide.

16 Regulatory Status

Included in the FDA Inactive Ingredients Database (oral tablets, rectal topical, and vaginal preparations). Included in nonparenteral medicines licensed in the UK. Included in the Canadian List of Acceptable Non-medicinal Ingredients.

17 Related Substances

Cetostearyl alcohol; cetyl alcohol.

18 Comments

The EINECS number for stearyl alcohol is 204-017-6. The PubChem Compound ID (CID) for stearyl alcohol is 8221.

19 Specific References

- 1 Egan RR, Portwood O. Higher alcohols in skin lotions. *Cosmet Perfum* 1974; 89(3): 39–42.
- 2 Alexander P. Organic rheological additives. *Manuf Chem* 1986; 57(9): 49, 52.
- 3 Cao DY *et al.* Preparation of tetramethylpyrazine phosphate pulsed-release tablets. *Chin J New Drugs* 2005; 14(6): 723–726.
- 4 Cao QR *et al.* Photoimages and the release characteristics of lipophilic matrix tablets containing highly water-soluble potassium citrate with high drug loadings. *Int J Pharm* 2007; 339(1–2): 19–24.
- 5 Kaiho F *et al.* Application of fatty alcohols to pharmaceutical dosage forms. *Yakuzaigaku* 1984; 44: 99–102.
- 6 Tanabe K *et al.* Effect of additives on release of ibuprofen from suppositories. *Yakuzaigaku* 1988; 48: 262–269.
- 7 Passerini N *et al.* Controlled release of verapamil hydrochloride from waxy microparticles prepared by spray congealing. *J Control Release* 2003; 88(2): 263–275.
- 8 Liggins RT, Burt HM. Paclitaxel loaded poly(L-lactic acid) microspheres: properties of microspheres made with low molecular weight polymers. *Int J Pharm* 2001; 222(1): 19–33.
- 9 Takahashi Y *et al.* Trial for transdermal administration of sulfonylureas. *J Pharm Soc Japan* 1997; 117: 1022–1027.
- 10 Weller PJ. Stearyl alcohol. Kibbe AH, ed. *Handbook of Pharmaceutical Excipients*, 3rd edn. London and Washington, DC: Pharmaceutical Press and American Pharmaceutical Association, 2000; 537–538.
- 11 Gaul LE. Dermatitis from cetyl and stearyl alcohols. *Arch Dermatol* 1969; 99: 593.
- 12 Fisher AA. Contact dermatitis from stearyl alcohol and propylene glycol. *Arch Dermatol* 1974; 110: 636.
- 13 Black H. Contact dermatitis from stearyl alcohol in Metosyn (flucanide) cream. *Contact Dermatitis* 1975; 1: 125.
- 14 Cronin E. *Contact Dermatitis*. Edinburgh: Churchill Livingstone, 1980; 808.
- 15 Yesudian PD, King CM. Allergic contact dermatitis from stearyl alcohol in Efudix cream. *Contact Dermatitis* 2001; 45: 313–314.
- 16 Lewis RJ, ed. *Sax's Dangerous Properties of Industrial Materials*, 11th edn. New York: Wiley, 2004; 2758.

20 General References

- Barry BW. Continuous shear, viscoelastic and spreading properties of a new topical vehicle, FAPG base. *J Pharm Pharmacol* 1973; 25: 131–137.
- Cognis. Product literature: *Spezial C18 Pharma*, 2004.
- Cognis. Product literature: *Drug-Delivery Agents* – Pharmaline, 2008.
- Japan Pharmaceutical Excipients Council. *Japanese Pharmaceutical Excipients Directory* 1996. Tokyo: Yakuji Nippo, 1996; 527.
- Madan PL *et al.* Microencapsulation of a waxy solid: wall thickness and surface appearance studies. *J Pharm Sci* 1974; 63: 280–284.
- Rowe RC. A quantitative assessment of the reactivity of the fatty alcohols with cetrimide using immersion calorimetry. *J Pharm Pharmacol* 1987; 39: 50–52.
- Sasol. *Product literature: Sasol olefins and surfactants*, 2005.
- Schott H, Han SK. Effect of inorganic additives on solutions of nonionic surfactants II. *J Pharm Sci* 1975; 64: 658–664.
- Wan LSC, Poon PKC. The interfacial activity of sodium lauryl sulfate in the presence of alcohols. *Can J Pharm Sci* 1970; 5: 104–107.

21 Author

RT Guest.

22 Date of Revision

12 February 2009.

Sucralose

1 Nonproprietary Names

USP-NF: Sucralose

2 Synonyms

Splenda; sucralosa; sucralosum; *SucraPlus*; TGS; 1',4',6'-trichloro-galactosucrose; 4,1',6'-trichloro-4,1',6'-trideoxy-galacto-sucrose.

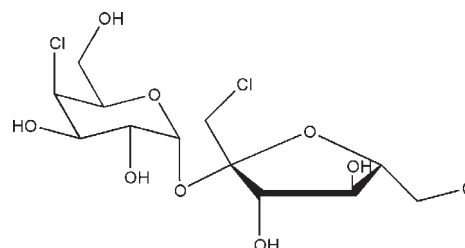
3 Chemical Name and CAS Registry Number

1,6-Dichloro-1,6-dideoxy-β-D-fructofuranosyl-4-chloro-4-deoxy-α-D-galactopyranoside [56038-13-2]

4 Empirical Formula and Molecular Weight

C₁₂H₁₉Cl₃O₈ 397.64

5 Structural Formula



6 Functional Category

Sweetening agent.

Greek characters (α , β , γ etc.), numerical prefixes (50-, 1,2- etc.) and prefixes such as *para*, *ortho*, *O*-, *N*-, *D*-, *L*- etc. are excluded from alphabetization; page numbers in **bold** refer to monograph titles.

905 (mineral hydrocarbons), 447

A-17, 306

A-46, 307

ABIL, 233

ABIL 20, 234

Abrasives, calcium phosphate

dibasic anhydrous, 94

dibasic dihydrate, 97

Absolute alcohol, 18

Absorbable gelatin, 278

Absorption enhancers, vitamin E polyethylene

glycol succinate, 764

Acacia, 1, 33, 147, 300

Acacia gum, 1

Acaciae gummi, 1

Accelerate, 121

Acconon, 542

Ac-Di-Sol, 206–207

Ace K, 3

Aceite de alazor, 610

Aceite de cartamo, 610

Aceite de coco, 184

Aceite de soja, 682

Aceloquat CPB, 158

Acesulfame K, 3

Acesulfame potassium, 3, 29, 606, 609

aspartame synergy, 50

sweetness *vs.* sucrose, 3

with sodium cyclamate, 644

Acesulfamum kalicum, 3

Acetate

brown, 82

gray, 82

Acetate of lime, 82

(Acetato-O)phenylmercury, 492

Acetazolamide, 399

Acetdimethylamide, 241

Acetic acid, 6

(2-butenylidene), 672

calcium salt, 82

dilute, 6

Acetic acid, calcium salt, 82

Acetic acid, cellulose ester, 141

Acetic acid dimethylamide, 241

Acetic acid ethenyl ester, polymer with 1-

ethenyl-2-pyrrolidinone, 196

Acetic acid ethyl ester, 253

Acetic acid, ethylene ester polymer with ethane,

268

Acetic acid, glacial, 5

Acetic acid, sodium salt, 620

Acetic acid vinyl ester, polymer with 1-vinyl-2-

pyrrolidinone, 196

Acetic acid, zinc salt, 791

Acetic acid[(2*S*,3*S*,4*R*,5*R*)-4-acetoxy-2,5-

bis(acetoxymethyl)-2-

[[[(2*R*,3*R*,4*S*,5*R*,6*R*)-3,4,5-triacetoxy-6-

(acetoxymethyl)-2-

tetrahydropyranyl]oxy]-3-

tetrahydrofuran]ester, 707

Acetic ester, 253

Acetic ether, 253

Acetone, 7

Acetone chloroform, 166

Acetoneum, 7

Acetoxyethane, 253

Acetoxypheylmercury, 492

Acetyl cellulose, 141

Acetyl phthalyl cellulose, 143

Acetylated lanolin, 380

Acetylbutyl citrate, 8

Acetylcitric acid, tributyl ester, 8

Acetylcitric acid, tributyl ester, 8

Acetyldimethylamine, 241

Acetyltributyl citrate, 8, 10, 750, 756–757

Acetyltriethyl citrate, 9–10, 750, 756–757

Acid fosforico, 503

Acid sodium phosphate, 659

Acide phosphorique, 503

Acidi methacrylici et ethylis acrylatis

polymerisatum, 525

Acidi methacrylici et methylis methacrylatis

polymerisatum, 525

Acidicum penteticum, 480

Acidifying agents

adipic acid, 11

ammonium chloride, 42

citric acid monohydrate, 181

glacial acetic acid, 5

hydrochloric acid, 308

diluted, 309

lactic acid, 355

phosphoric acid, 503

propionic acid, 586

sulfuric acid, 719

tartaric acid, 731

Acido trimico, 739

Acidulants

fumaric acid, 276

lactic acid, 355

maleic Acid, 410

malic acid, 411

monobasic sodium phosphate, 659

phosphoric acid, 503

tartaric acid, 731

Acidum aceticum glaciale, 5

Acidum adipicum, 11

Acidum alginicum, 20

Acidum ascorbicum, 43

Acidum benzoicum, 61

Acidum boricum, 68

Acidum citricum anhydricum, 183

Acidum citricum monohydricum, 181

Acidum edeticum, 247

Acidum hydrochloridum concentratum, 308

Acidum hydrochloridum dilutum, 309

Acidum lacticum, 355

Acidum maleicum, 410

Acidum malicum, 411

Acidum oleicum, 466

Acidum palmiticum, 473

Acidum phosphoricum dilutum, 504

Acidum phosphorum concentratum, 503

Acidum sorbicum, 672

Acidum stearicum, 697

Acidum sulfuricum, 719

Acidum tartaricum, 731

Acifloctin, 11

Acinetten, 11

Aclame, 28

Acriflavine hydrochloride, 54

Acritamer, 110

Acryl-EZE, 525–526

Acryl-EZE MP, 526

Acrylic acid polymer, 110

Acrypol, 110–111

Actapulgit, 51

Activated alumina, 37

Activated aluminum oxide, 37

Activated attapulgit, 51

Actylol, 256

Acytol, 256

Adeps lanae, 378

Adeps lanae cum aqua, 380

Adeps lanae hydrogenatus, 379

Adeps neutralis, 722

Adeps solidus, 722

Adhesives

carbomers, 110

dextrin, 220

hypromellose, 327

poly(methylvinyl ether/maleic anhydride),

534

see also Mucoadhesives

Adilactetten, 11

Adipic acid, 11

Adju-Phos, 38

Adsorbent, magnesium carbonate, 397

Adsorbents

aluminum hydroxide adjuvant, 34

aluminum oxide, 37

aluminum phosphate adjuvant, 38

attapulgit, 51

bentonite, 53

cellulose, powdered, 136

colloidal silicon dioxide, 185

hectorite, 301

kaolin, 352

magnesium aluminum silicate, 393

microcrystalline cellulose, 129

pectin, 478

polycarbophil, 509

saponite, 612

tal, 728

Advantia, 329

Advantose 100, 422, 424

Advantose FS 95, 273

Aeropres, 307

Aeropres 17, 306

Aeropres 31, 306

Aeropres 108, 306

Aerosil, 185–186

Aerosil 130, 310

Aerosil R972, 309–310

Aerosol propellants *see* Propellants

Aerosol Solvent Extraction Systems (ASES),

carbon dioxide, 116

Aethylis acetas, 253

Aethylum aceticum, 253

Aethylum hydrobenzoicum, 270

Aextreff CT, 476

Afrodit, 612

Agar, 13

Japan, 13

Agar-agar, 13

Agar-agar flake, 13

Agar-agar gum, 13

Agaropectin, 13

Agarose, 13

Agidol, 75

Air displacement gases

carbon dioxide, 115

nitrogen, 461

- Airvol*, 564
Akofine, 762
Akosoft, 722
Akosol, 722
Akucell, 118
 Alabaster, 105
Alba, 14
Albagel, 53
Alberger, 637
Albucomm, 14
 Albumin, 14
 human, 14
 Albumin human solution, 14
 Albumin Solution, 14
 human, 14
Albuminar, 14
 Albumini humani solutio, 14
Albumisol, 14
Albuspan, 14
Albutein, 14
 Alcohol, 17
 absolute, 18
 dehydrated, 18–19
 denatured, 18
 dilute, 18–19
 Alcohol benzylicus, 64
 Alcohol cetylicus, 155
 Alcohol cetylicus et stearylicus, 150
 Alcohol denaturants
 denatonium benzoate, 217
 diethyl phthalate, 230
 sucrose octaacetate, 707
 Alcohol isopropylus, 346
 Alcohol miristilo, 456
 Alcohol oleicus, 468
 Alcohol stearylicus, 700
 Alcoholes adipis lanae, 382
 Alcoholia lanae, 382
 Alcoholic shellac solution, 618
 Alcolanum, 382
Alcotex, 564
Aldo MO, 288
 Aleuritic acid, 618
 Alfadex Betadex, 210
 Alfadexum, 210
 Algaroba, 146
 Algin, 83, 622
 Alginato calcico, 83
 Alginato sodico, 622
 Alginic acid, 20, 41, 84, 567, 595, 624
 Alginic acid, ammonium salt, 41
 Alginic acid, calcium salt, 83
 Alginic acid, potassium salt, 566
 Alginic acid, propylene glycol ester, 594
 Alginic acid, sodium salt, 622
Alhydrogel, 34
 Aliphatic polyesters, 23, 356, 516
 Alitame, 4, 28, 50, 606, 609, 644
 Alkalizing agents
 ammonia solution, 39
 calcium hydroxide, 91
 diethanolamine, 228
 monoethanolamine, 450
 potassium bicarbonate, 570
 potassium citrate, 574
 potassium hydroxide, 576
 sodium bicarbonate, 629
 sodium borate, 633
 sodium carbonate, 635
 sodium citrate dihydrate, 640
 sodium hydroxide, 648
 triethanolamine, 754
 Alkyl dimethyl benzyl ammonium chloride, 56
 Alkylbenzyl dimethyl ammonium chloride, 56
 Alkyl dimethyl (phenylmethyl) ammonium chloride, 56
 Alkyltrimethyl ammonium bromides, 153
 Allomaleic acid, 276
 Allomalenic acid, 276
 Allopurinol, 238
 All-*rac*- α -tocopherol, 31
 All-*rac*- α -tocopheryl acetate, 32
 Almond oil, 29, 109, 185, 200, 203, 259, 477, 611, 615
 refined, 30
 Almond oil, bitter, 29
 Almond Oil, Virgin, 29
 Alpha aluminum oxide, 37
 Alpha tocopherol, 31–32, 46, 765
 and ascorbyl palmitate, 31
 and lecithin, 31
 and linoleic acid, 31
 and methyl linolenate, 31
 natural, 32
 synthetic, 31
 see also Tocopherol
 (2*R*,4'*R*,8'*R*)-Alpha-tocopherol, 31
d-Alpha tocopheryl acetate, 32
d-Alpha tocopheryl acid succinate, 32
 Alpha-cellulose, 136
 Alpha-cycloamylose, 210
 Alpha-cyclodextrin, 210
 Alpha-dextrin, 210
Altalc, 728
 Alum, 567
 Alum flour, 567
 Alum meal, 567
 Alum potassium, 567
 Alumen, 567
 Alumina, 37
 activated, 37
 calcined, 37
 tabular, 37
 Alumina, calcined, 37
 Alumina, tabular, 37
 Aluminii hydroxidum hydricum ad
 adsorptionem, 34
 Aluminii magnesii silicas, 393
 Aluminium hydroxide adjuvant, 34
 Aluminium Hydroxide, Hydrated, for
 Adsorption, 34
 Aluminium hydroxyphosphate, 38
 Aluminium Magnesium Silicate, 393
 Aluminium oxyhydroxide, 34
 Aluminosilicic acid, 393
 Aluminum, dihydroxy (octadecanoate-O-), 35
 Aluminum distearate, 36
 Aluminum hydroxide, 400
 Aluminum hydroxide adjuvant, 34, 39
 Aluminum hydroxyphosphate, 38
 Aluminum magnesium salt, 393
 Aluminum magnesium silicate, 393
 Aluminum monobasic stearate., 36
 Aluminum monostearate, 35
 Aluminum oxide, 37
 activated, 37
 Aluminum oxide alumite, 37
 Aluminum oxyhydroxide, 34
 Aluminum phosphate, 38
 Aluminum phosphate adjuvant, 35, 38
 Aluminum potassium alum, 567
 Aluminum potassium disulfate, 567
 Aluminum potassium sulfate, 567
 Aluminum potassium sulfate anhydrous, 567
 Aluminum potassium sulfate dodecahydrate, 567
 Aluminum Potassium Sulfate Hydrate, 567
 Aluminum silicate, 271
 hydrated, 53, 55, 352–353
 hydrous, 352
 Aluminum stearate, 35–36
 Aluminum trioxide, 37
 Aluminum tristearate, 36
 Aluminum-saponite, 612
Amalty, 414
 Amberlite, 506
Amberlite IR-120, 505
Amberlite IRA-400, 505
Amberlite IRP-58, 505
Amberlite IRP-64, 505–506
Amberlite IRP-67, 505
Amberlite IRP-69, 505
Amberlite IRP-88, 504–505
 Ambroxol, 478
Amerchol CAB, 484
Amerchol L-101, 449
Ametox, 671
 Amfetamine sulfate, 396
 Amido, 685
 Amidon, 685
 Amilo, 685
 Amino Methacrylate Copolymer, 525
 Aminoacetic acid, 295
 2-aminoacetic acid, 295
 (3*S*)-3-Amino-4-[[[(1*S*)-1-benzyl-2-methoxy-2-oxoethyl]amino]-4-oxobutanoic acid, 48
 5-Amino-1,3-bis(2-ethylhexyl)hexahydro-5-methylpyrimidine, 304
 γ -Aminobutyric acid lactam, 600
 4-aminobutyric acid lactam, 600
 γ -aminobutyric lactam, 600
 γ -aminobutyrolactam, 600
 3-amino-*N*-(α -carboxyphenethyl)succinamic acid *N*-methyl ester, 48
 2-Amino-2-deoxy-(1,4)- β -D-glucopyranan, 159
 5-amino-1,3-di-(β -ethylhexyl)hexahydro-5-methylpyrimidine, 304
 Aminoethanoic acid, 295
 2-Aminoethanol, 450
 β -Aminoethyl alcohol, 450
 α -Aminoisocaproic acid, 387
 3-amino-*N*-(α -methoxycarbonylphenethyl)succinamic acid, 48
 α -Amino- γ -methylmercaptobutyric acid, 436
 2-amino-4-methylpentanoic acid, 387
 (2*S*)-2-Amino-4-methylsulfanylbutanoic acid, 436
 (5*S*)-2-amino-4-(methylthio)butanoic acid, 436
 2-amino-4-(methylthio)butyric acid, 436
 α -amino- γ -methylvaleric acid, 387
 2-amino-4-methylvaleric acid, 387
 Amiodarone, incompatibilities, sodium bicarbonate, 631
 Ammonia, 39
 Ammonia solution, 39–40, 43
 concentrated, 39
 dilute, 40
 strong, 39
 Ammonia water, 40
 stronger, 39
 Ammoniaca, 39
 Ammoniacum, 39
 Ammoniae solution concentrata, 39
 Ammonii chloridum, 42
 Ammonio Methacrylate Copolymer, 525
 Ammonio Methacrylate Copolymer Dispersion, 525
 Ammonio Methacrylate Copolymer (Type A), 525
 Ammonio Methacrylate Copolymer (Type B), 525
 Ammonio methacrylatis copolymerum, 525
 Ammonium alginate, 21, 41, 567
 Ammonium chloride, 42
 Ammonium muriate, 42
 Ammonium polymannuronate, 41
 Amorphous silica, synthetic, 185

- Amorphous wax, 775
 Amoxicillin, 353
 Ampicillin, 353
 Amygdalae oleum raffinatum, 30
 Amygdalae oleum virginale, 29
 Amylum, 685
 Amylum pregelificatum, 691
 Anatase, 743
 Anatase titanium dioxide, 741
 Anhydrite, 105
Anhydrous 60M, 359
 Anhydrous Calcium Hydrogen Phosphate, 94
 Anhydrous calcium sulfate, 105
 Anhydrous chlorbutol, 166
 Anhydrous citric acid, 183, 630
 Anhydrous dextrose, 224–225
 Anhydrous Dibasic Calcium Phosphate, 94
 Anhydrous dibasic sodium phosphate, 656
Anhydrous Direct Tableting (DT), 359
Anhydrous DT High Velocity, 359
 Anhydrous ethanol, 18
 Anhydrous ferric oxide, 340
 Anhydrous D-(+)-glucopyranose, 224
 Anhydrous glucose, 224
 Anhydrous gypsum, 105
Anhydrous Impalpable, 359
 Anhydrous Lactose, 359
 Anhydrous lactose, O-β-D-galactopyranosyl-(1→4)-β-D-glucopyranose, 362
 Anhydrous lanolin, 378
 Anhydrous monobasic sodium phosphate, 659
 Anhydrous Sodium Carbonate, 635
 Anhydrous sodium citrate, 642
 Anhydrous sodium propionate, 662
 Anhydrous sulfate of lime, 105
 Anhydrous trisodium citrate, 642
 Anionic emulsifying wax, 770
 see also Emulsifying wax, anionic
 Anionic surfactants *see* Surfactants, anionic
 Annalin, 107
 Antacid, calcium hydroxide, 91
 Antacids, 399
 aluminum phosphate adjuvant, 39
 magnesium carbonate, 397
 Antiadherents, leucine, 387
 Antibacterial agents
 chlorocresol, 169
 diazolidinyl urea, 338
 dimethyl sulfoxide, 240
 glacial acetic acid, 5
 imidurea, 337
 iodine/edetic acid, 247
 phenylmercuric acetate, 492
 phenylmercuric borate, 495
 phenylmercuric hydroxide, 496–497
 potassium sorbate, 579
 sodium hydroxide, 649
 sorbic acid, 579–580
 thymol, 739
 see also Antiseptics; Disinfectants; Preservatives
 Antibacterial preservatives *see* Antibacterial agents; Preservatives
 Antibrowning agents, sodium metabisulfite, 654
 Anticaking agents
 calcium phosphate, tribasic, 99
 calcium silicate, 101
 colloidal silicon dioxide, 185
 hydrophobic colloidal silica, 309
 magnesium oxide, 400
 magnesium silicate, 402
 magnesium trisilicate, 408
 talc, 728
 Anticapping agents *see* Cap locking preventatives
 Anticoagulants, citric acid monohydrate, 181
 Antidusting agents, polyethylene alkyl ethers, 537
 Antifoaming agents
 dimethicone, 233
 oleyl alcohol, 468
 polypropylene glycol 2000, 543
 simethicone, 619
 Antifungal agents
 benzoic acid, 61
 butylene glycol, 77
 butylparaben, 78
 chlorocresol, 168–169
 coconut oil, 184
 dimethyl sulfoxide, 240
 ethylparaben, 270
 glacial acetic acid, 5
 imidurea, 337
 methylparabens, 442
 phenylmercuric acetate, 492
 phenylmercuric borate, 495
 phenylmercuric hydroxide, 496–497
 potassium sorbate, 579
 propylparaben, 596
 sodium propionate, 661
 sodium thiosulfate, 671
 sporocides, chlorocresol, 169
 thymol, 739
 vanillin, 760
 see also Preservatives
 Antimicrobial preservatives *see* Antibacterial agents; Antifungal agents; Preservatives
 Antioxidants
 alpha tocopherol, 31, 109
 ascorbic acid, 43, 45
 ascorbyl palmitate, 46
 butylated hydroxyanisole, 73, 587
 butylated hydroxytoluene, 75, 587
 carbon dioxide, 115
 chelating agents, 247
 citric acid monohydrate, 181
 erythorbic acid, 250
 ethyl oleate, 259
 fumaric acid, 276
 malic acid, 411
 methionine, 436
 monothioglycerol, 454
 phosphoric acid, 503
 potassium metabisulfite, 577
 propionic acid, 586
 propyl gallate, 587, 589
 sodium ascorbate, 625
 sodium bisulfite, 655
 sodium formaldehyde sulfoxylate, 645
 sodium metabisulfite, 654–655
 sodium sulfite, 655, 669
 sodium thiosulfate, 671
 sulfur dioxide, 718
 synergists
 citric acid monohydrate, 181
 tartaric acid, 731
 thymol, 739
 tocopherol (*see* Antioxidants, alpha tocopherol)
 vitamin E, 33
 vitamin E polyethylene glycol succinate, 764
 see also Preservatives
 Antiseptics
 ammonium chloride, 42
 benzalkonium chloride, 56
 benzethonium chloride, 59
 bronopol, 70
 cetrimide, 152
 cetylpyridinium chloride, 157
 chlorhexidine, 162
 chloroxylonol, 176
 hexetidine, 304
 phenol, 485
 phenylmercuric acetate, 492
 phenylmercuric borate, 494
 phenylmercuric nitrate, 496
 thimerosal, 736
 thymol, 739
 Antiviral agents
 benzalkonium chloride, 56
 butylated hydroxytoluene, 75
 cellulose acetate phthalate (CAP), 144
 sodium hydroxide, 649
AnyCoat C, 327
Apifil, 780
 APM, 48
 Apple acid, 411, 413
 Apricot kernel oil PEG 300 esters, 557
Aptal, 168
Aquat, 330
Aquat AS-HF/HG, 330
Aquat AS-LF/LG, 330
Aquat AS-MF/MG, 330
 Aqua, 766
 Aqua ammonia, 39
 Aqua purificata, 766
Aquacoat cPD, 143
Aquacoat ECD, 262–263
Aqualon, 262
Aqualon CMC, 118
Aquasorb, 118
 Aqueous shellac solution, 618
 Arabic gum, 1
 D-arabino-2-hexulose, 273
 Araboascorbic acid, 250
 Arachidic acid
 cottonseed oil, 202
 peanut oil, 476
 sunflower oil, 721
 Arachidis oleum raffinatum, 476
 Arachis Oil, 476
 Arachis Oil, Refined, 476
Araldite 502, 225
Arbocel, 136
Arcton, 173
Arcton 22, 172
 Argilla, 352
Argobase EU, 485
Argowax, 382
Arlatone, 542
Arosol, 488
 Artificial almond oil, 29
 Artificial sweeteners *see* Sweetening agents
 Artificial vinegar, 6
 Asapic, 11
Ascend, 746
 Ascorbic acid, 43, 47, 251, 626
 incompatibilities
 sodium starch glycolate, 665
 sucrose, 706
 Ascorbic acid ethyl oleate, 259
 L-Ascorbic acid 6-hexadecanoate, 46
 L-Ascorbic acid monosodium salt, 625
 L-Ascorbic acid 6-palmitate, 46
 Ascorbyl palmitate, 45–46, 626
 and alpha tocopherol, 31
 Ascorbylis palmitas, 46
Aseptiform M, 441
Aseptiform P, 596
Ashacel, 262
 Aspartame, 29, 48, 461, 606, 609
 acesulfame potassium synergy, 50
 sweetness, *vs.* neotame, 460
 sweetness *vs.* sucrose, 48
 with saccharin, 607
 with saccharin sodium, 610
 Aspartame acesulfame, 50
 Aspartamum, 48

- Aspartyl phenylamine methyl ester, 48
 3-(L-aspartyl-D-alaninamido)-2,2,4,4-tetramethylthietane, 28
 L-aspartyl-D-alanine-N-(2,2,4,4-tetramethylthietan-3-yl)amide, 28
 N-L- α -Aspartyl-L-phenylalanine 1-methyl ester, 48
 L- α -Aspartyl-N-(2,2,4,4-tetramethyl-3-thietanyl)-D-alaninamide anhydrous, 28
 L- α -Aspartyl-N-(2,2,4,4-tetramethyl-3-thietanyl)-D-alaninamide hydrate, 28
 Aspasomes, 47
 Aspirin, 405
 Astringents
 calcium hydroxide, 91
 potassium alum, 567
 sodium borate, 634
 A-TAB, 94–96
 ATBC, 8
 ATEC, 10
Atlas G-695, 288
Attaclay, 51
Attacote, 51
Attagel, 51
Attapulgit, 51, 302, 396, 613
 activated, 51
 colloidal activated, 51
Attapulgit, 51
 Autism, 737
 Auxite, 612
Avatech, 445
Avedex, 220
Avicel CE-15, 132
Avicel CL-611, 134
Avicel PH, 129
Avicel RC-501, 134
Avicel RC-581, 134
Avicel RC-591, 134
Avicel RC/CL, 134
Avol, 155
Avolin, 236
 Azote, 461

 Bactericides *see* Antibacterial agents
 Bacteriostatic water for injection, 769
 Baking soda, 629–630
Baktol, 168
Balocel Sanaq, 132
Barcroft CS90, 88
Barcroft CX50, 88
Barcroft CZ50, 88
 Barrier creams, 777
 Basic Butylated Methacrylate Copolymer, 525
 Basic phenylmercury nitrate, 496
 Bassorin, 744
Bayferrox 105M, 340
Bayferrox 306, 340
Bayferrox 920Z, 340
 Beeswax, 780
 substitute for, 148
 Beeswax, White, 779
 Beeswax, Yellow, 780
 Beet sugar, 345, 703
 Behenic acid
 peanut oil, 476
 sunflower oil, 721
 Belite, 102
Benecel, 438
Benecel MHPC, 326
Beneo, 339
 Bengal gelatin, 13
 Bengal gum, 13
 Bengal isinglass, 13
 Benne oil, 614
Bentone 27, 302
Bentone 38, 302

 Bentonite, 53, 302, 353, 396, 613, 730
 methylparabens incompatibility, 443
 purified, 55
 saponite similarity, 613
 sol/gel preparation, 54
 Bentonite magma, 55
 Bentonitum, 53
 Benzalkonii chloridum, 56
 Benzalkonium chloride, 56, 60, 153, 498
 alternatives, thimerosal, 736
 synergists, 247
 Benzenecarboxylic acid, 61
 1,2-benzenedicarboxylate, 236
 Benzenedicarboxylic acid, 225
 dibutyl ester of, 225
 1,2-Benzenedicarboxylic acid bis(2-ethylhexyl) ester, 226
 Benzene-*o*-dicarboxylic acid di-*n*-butyl ester, 225
 1,2-Benzenedicarboxylic acid, diethyl ester, 230
 Benzenedicarboxylic acid dimethyl ester, 236
 1,2-Benzene-dicarboxylic acid dimethyl ester, 236
 Benzeneethanol, 490
 Benzeneformic acid, 61
 Benzenemethanol, 64
 Benzethonii chloridum, 59
 Benzethonium chloride, 58–59, 153
 1,2-Benzisothiazol-3(2 *H*)-one 1,1-dioxide, sodium salt, 608
 1,2-Benzisothiazol-3(2*H*)-one 1,1-dioxide, 605
 1,2-Benzisothiazolin-3-one 1,1-dioxide, 605
 1,2-Benzisothiazolin-3-one 1,1-dioxide, sodium salt, 608
 Benzoate of potash, 569
 Benzoate of soda, 627
 Benzocaine, incompatibilities, polyvinyl acetate phthalate, 563
 Benzoic acid, 61, 412, 570, 629, 761
 Benzoic acid benzyl ester, 66
 Benzoic acid phenylmethyl ester, 66
 Benzoic acid potassium salt, 569
 Benzoic acid sodium salt, 627
 Benzoic acid sulfimide, 605
 Benzoic sulfimide, 605
 Benzosulfimide, 605
 Benzyl alcohol, 64
 Benzyl benzoate, 66
 Benzyl carbinol, 490
 Benzyl phenylformate, 66
 Benzylbenzenecarboxylate, 66
 Benzyl-diethyl[(2,6-xylylcarbamo-lyl)methyl]ammonium benzoate anhydrous, 217
 Benzyl-diethyl[(2,6-xylylcarbamo-lyl)methyl]ammonium benzoate monohydrate, 217
 Benzyl-dimethyl-[2-[2-(*p*-1,1,3,3-tetramethylbutylphenoxy)ethoxy]ethyl]ammonium chloride, 59
 Benzylis benzoas, 66
 Benzylmethanol, 490
Bergabest, 429
 Beta tocopherol, 32–33
 Beta-carotene, 193
 Beta-cycloamylose, 210
 Betadex, hydroxypropyl, 315
 Beta-dextrin, 210
 Betadexum, 210
 BHA, 73
 BHT, 75
 Binding agents
 acacia, 1
 agar, 13
 alginic acid, 20, 22
 calcium carbonate, 86
 calcium lactate, 92
 carbomers, 110
 carboxymethylcellulose sodium, 119
 carrageenan, 122
 cellulose acetate phthalate, 144
 ceratonia, 146
 chitosan, 159
 copovidone, 197
 corn starch and pregelatinized starch, 200
 cottonseed oil, 202
 dextrans, 218
 dextrin, 220
 dextrose, 222
 ethylcellulose, 262
 gelatin, 278
 glyceryl behenate, 286
 guar gum, 298
 hydrogenated vegetable oil type I, 762
 hydroxyethyl cellulose, 311
 hydroxyethylmethyl cellulose, 314
 hydroxypropyl cellulose, 318
 low-substituted, 322
 hydroxypropyl starch, 325
 hypromellose, 326
 inulin, 339
 lactose, 364
 liquid glucose, 282
 magnesium aluminum silicate, 393
 maltodextrin, 418
 maltose, 423
 methylcellulose, 438
 microcrystalline cellulose, 130
 pectin, 479
 poloxamer, 507
 polycarbophil, 509
 polydextrose, 513
 polyethylene oxide, 522
 polymethacrylates, 526
 povidone, 581
 sodium alginate, 622
 starch, 685
 pregelatinized, 691
 stearic acid, 697
 sucrose, 703
 sunflower oil, 721
 tricaprylin, 751
 vitamin E polyethylene glycol succinate, 764
 zein, 790
 Bioabsorbables, aliphatic polyesters, 23
 Bioadhesives
 glyceryl monooleate, 289
 hypromellose, 326
 polycarbophil, 509
 Bioadhesives *see also* Adhesives; Mucoadhesives
 Biocompatibles
 aliphatic polyesters, 23
 sulfobutylether β -cyclodextrin, 714
 Biodegradable materials
 aliphatic polyesters, 23, 27
 biodegradable polymers, 23, 27
 glyceryl monostearate, 291
 glyceryl palmitostearate, 293
 phospholipids, 499
 poly-DL-(lactic acid), 515
Biopure 100, 337
Bio-sorb, 695
N,N-bis[2-[bis(carboxymethyl)amino]ethyl], 480
 2-[Bis[2-(bis(carboxymethyl)amino)ethyl]amino]acetic acid, 480
N,N-bis[2-[bis(carboxymethyl)amino]ethyl]glycine, 480
 Bis(*n*-butyl)sebacate, 227
 1,6-bis[*N'*-(*p*-Chlorophenyl)-*N*⁵-biguanido]hexane, 162
N,N'-bis(4-chlorophenyl)-3,12-diimino-2,4,11,13-tetraazatetradecanediimidamide, 162

- 2,6-bis(1,1-dimethylethyl)-4-methylphenol, 75
 Bis(2-ethylhexyl) phthalate, 226
 Bis(2-ethylhexyl) sodium sulfosuccinate, 244
 1,4-Bis(2-ethylhexyl) sulfosuccinate, calcium salt, 246
 1,3-bis(β-ethylhexyl)-5-methyl-5-aminohexahydropyrimidine, 304
 1,3-bis(2-Ethylhexyl)-5-methylhexahydro-5-pyrimidinamine, 304
 1,3-bis(2-ethylhexyl)-5-methylhexahydropyrimidin-5-ylamine, 304
 Bis(hydroxyethyl)amine, 228
 Bismuth nitrate, and glycerin, 285
 Bisodium carbonate, 635
 2,3-bis[[*(Z)*]-octadec-9-enoyl]oxypropyl (*Z*)-octadec-9-enoate, 757
Bitrex, 217
 Bitter almond oil, 29
Bitterguard, 217
 Bittering agents, sucrose octaacetate, 707
 BKC, 56
 Black magnetic oxide, 340
 Black oxide, precipitated, 340
 Black rouge, 340
Blanose, 118
 Bleached wax, 779
Blonde, 616
 Blood sugar, 222
 Boletic acid, 276
 Bolus alba, 352
 Boracic acid, 68
 Boraic acid, 68
 Borax, 633
 fused, 634
 Borax decahydrate, 633
 Borax glass, 634
 Boric acid, 68, 285, 634
 Boric acid disodium salt, 633
Borofax, 68
 Boron trihydroxide, 68
 Bourbonal, 261
 Bovine serum albumin, 16
 Bovine spongiform encephalopathy (BSE), 180, 280
 Brazil wax, 772
Brij, 536
Brij 72, 537
Brij 97, 537
 British gum, 220
Bromat, 152
Bromocet, 158
 2-Bromo-2-nitro-1,3-propanediol, 70
 β-bromo-β-nitrotrimethyleneglycol, 70
 Bronopol, 70
 synergists, 247
 Brookite, 743
 Brookite titanium dioxide, 741
 Brown acetate, 82
 Brucine, 217
 BSE *see* Bovine Spongiform Encephalopathy
 Buffering agents
 adipic acid, 11
 ammonia solution, 39
 boric acid, 68
 calcium carbonate, 86
 calcium hydroxide, 91
 calcium lactate, 92
 calcium phosphate, tribasic, 99
 citric acid monohydrate, 181
 dibasic sodium phosphate, 656
 diethanolamine, 228
 glycine, 295
 maleic Acid, 410
 malic acid, 411
 methionine, 436
 monobasic sodium phosphate, 659
 monoethanolamine, 450
 monosodium glutamate, 452
 phosphoric acid, 503
 potassium citrate, 574
 sodium acetate, 620
 sodium bicarbonate, 630
 sodium borate, 633
 sodium carbonate, 635
 sodium citrate dihydrate, 640
 sodium hydroxide, 648
 sodium lactate, 650
 triethanolamine, 754
 Bulking agents
 cellulose, powdered, 136
 glycine, 295
 mannitol, 425
 see also Diluents (tablet/capsule)
Bulls Eye Shellac, 616
Buminate, 14
 Butane, 306
 Butane 1,2,3,4-tetrol, 251
 1,4-butanedicarboxylic acid, 11
 1,3-Butanediol, 77
 Butane-1,3-diol; 1,3-butylene glycol, 77
 (2*R*,3*S*)-Butane 1,2,3,4-tetrol, 251
 1,2,3,4-butanetetrol, 251
 Butenedioic acid, 276
 2-Butenedioic acid, 667
 (*E*)-2-Butenedioic acid, 276
 (*Z*)-2-butenedioic acid, 410
 (2-butenylidene) acetic acid, 672
 Butyl ester of poly(methylvinyl ether-co-maleic anhydride), 534
 Butyl Hydroxybenzoate, 78
 Butyl α-hydroxypropionate, 257
n-Butyl lactate, 257
 Butyl Parahydroxybenzoate, 78
 Butyl phthalate, 225
 Butyl sebacate, 227
 Butylated hydroxyanisole, 73, 76, 587
 and ethyl oleate, 259
 Butylated hydroxytoluene, 74–75, 379, 382, 412, 587
 and hydrous lanolin, 380
 Butylene glycol, 77
 Butylhydroxyanisole, 73
 Butylhydroxyanisolum, 73
 Butyl-4-hydroxybenzoate, 78
 Butyl-4-hydroxybenzoate sodium salt, 80
 Butylhydroxytoluene, 75
 Butylhydroxytoluenum, 75
 Butylis parahydroxybenzoas, 78
 Butylparaben, 78, 272, 444, 598, 600
 and methylcellulose, 440
 see also Parabens
 Butylparaben sodium, 80
 γ-butyrolactam, 600
Byco, 278
 BZT, 59
 C-97, 43
 C-1297, 383
 CA33, 83
Cab-O-Sil, 185
Cab-O-Sil M-5P, 185–186
Cachalot, 155, 700
 Caffeine, 760
 Calc algin, 83
Cal-Carb 4450 PG, 88
Cal-Carb 4457, 88
Cal-Carb 4462, 88
Calchem H-102, 109
Calchem IVO-114, 682
 Calcii acetate, 82
 Calcii carbonas, 86
 Calcii chloridum dihydricum, 89
 Calcii chloridum hexahydricum, 89
 Calcii hydrogenophosphas anhydricus, 94
 Calcii hydrogenophosphas dihydricus, 96
 Calcii hydroxidum, 91
 Calcii lactas pentahydricus, 92
 Calcii stearas, 103
 Calcii sulfas dihydricus, 105
 Calcii sulfas hemihydricus, 107
 Calcinated magnesite, 400
 Calcined gypsum, 107
 Calcined magnesia, 400
 Calcined soda, 635
 Calcitonin, 647
 Calcium acetate, 82
 Calcium acetate monohydrate, 83
 Calcium alginate, 21, 41, 83, 567, 624
 Calcium and sodium salts of poly(methylvinyl ether-co-maleic anhydride), 534
 Calcium ascorbate, 626
 Calcium bis(2-hydroxypropanoate) pentahydrate, 92
 Calcium carbonate, 86
 precipitated, 86
 Calcium carbonate (1 : 1), 86
 Calcium carboxymethylcellulose, 117
 Calcium cellulose glycolate, 117
 Calcium chloride, 89
 Calcium chloride anhydrous, 89
 Calcium Chloride Dihydrate, 89
 Calcium Chloride Hexahydrate, 89
 Calcium Chloride Hydrate, 89
 Calcium cyclamate, 644
 Calcium diacetate, 82
 Calcium dilactate, 92
 Calcium diorthosilicate, 102
 Calcium dipropionate, 662
 Calcium disodium edetate, 248
 Calcium disodium ethylenediaminetetraacetate, 248
 Calcium disodium (ethylenedinitrilo)tetraacetate, 248
 Calcium distearate, 103
 Calcium DTPA, 481
 Calcium hydrate, 91
 Calcium hydrogen orthophosphate dihydrate, 96
 Calcium Hydrogen Phosphate, 96
 Calcium Hydrogen Phosphate, Anhydrous, 94
 Calcium Hydrogen Phosphate Dihydrate, 96
 Calcium hydrosilicate, 101
 Calcium hydroxide, 91
 Calcium hydroxide phosphate, 99
 Calcium lactate, 92
 Calcium lactate (1:2) hydrate, 92
 Calcium lactate (1:2) pentahydrate, 92
 Calcium lactate anhydrous, 92
 Calcium Lactate Hydrate, 92
 Calcium lactate monohydrate and trihydrate, 92
 Calcium Lactate Pentahydrate, 92
 Calcium metasilicate, 101
 Calcium monohydrogen phosphate, 94
 Calcium monohydrogen phosphate dihydrate, 96
 Calcium monosilicate, 101
 Calcium *N*-cyclohexylsulfamate dihydrate, 644
 Calcium octadecanoate, 103
 Calcium orthophosphate, 94, 99
 Calcium pentetate, 481
 Calcium Phosphate, 99
 dibasic anhydrous, 98, 101, 107
 dibasic dihydrate, 96, 101, 107
 precipitated, 99
 secondary, 94, 96
 tertiary, 99
 tribasic, 96, 98, 107

- Calcium phosphate, dibasic anhydrous, 94
 Calcium phosphate, dibasic dihydrate, 96
 Calcium phosphate, tribasic, 99
 Calcium polycarboxophil, 511
 Calcium polymannuronate, 83
 Calcium polysilicate, 101
 Calcium propionate, 662
 Calcium (2R)-, (2S)- and (2RS)-2-hydroxypropanoates pentahydrates, 92
 Calcium salt, silicic acid, 101
 Calcium silicate, 101, 409
 Calcium sorbate, 674
 Calcium stearate, 103, 405, 427, 699, 794
 Calcium sulfate, 96, 105
 anhydrous, 105
 dihydrate, 105
 dried, 107
 exsiccated, 107
 hemihydrate, 105, 107
 native, 105
 precipitated, 105
 Calcium sulfate dihydrate, 105
 Calcium sulfate hemihydrate, 107
 Calcium Sulphate Dihydrate, 105
 Calcium trisilicate, 102
 Calcium trisodium DTPA, 481
 Calcium trisodium pentetate, 481
 Calcium/sodium salt mix, of poly(methylvinylether/maleic anhydride), 534
Calginate, 83
 C16-alkylpyridinium chloride, 157
Caloreen, 220, 222
Calstar, 98
Cal-Tab, 105
 Canary dextrin, 220
 Canbra oil, 108
Canderel, 48
Candex, 218
 Cane sugar, 703
 Canola oil, 30, 108, 185, 200, 203, 477, 611, 615, 684
 erucic acid content, 108
 oleic acid content, 109
 tocopherol content, 109
 CAP, 143
 'Cap locking' preventatives
 fructose, 273
 hydroxypropyl cellulose, low-substituted, 323
 sorbitol, 679
 xylitol, 786
Capmul GMO, 288
Capmul GMS-50, 290
 Capric acid, 384
 Caprinic acid, 384
 Caprylic acid, 1,2,3-propanetriyl ester, 751
 Caprylic acid triglyceride, 751
 Caprylic/capric triglyceride, 429
 Caprylocaproyl Macrogolglycerides, 557
 Caprylocaproyl Polyoxylglycerides, 557
 Caprynic acid, 384
CapsuLac, 364
 Capsule/tablet diluents *see* Diluents (tablet/capsule)
 Capsule/tablet disintegrants *see* Disintegrants (tablet/capsule)
 Capsule/tablet lubricants *see* Lubricants (tablet/capsule)
Captex 300, 429
Captex 355, 429
Captex 500, 748
Captex 8000, 751–752
Captex GTO, 757
Captisol, 714
 Caramania gum (hog gum), 745
 Caranda wax, 772
 Carbolic acid, 485
 Carbomer, 110, 511
 Carbomera, 110
 Carbomers, 110
 Carbon dioxide, 115, 462, 464
 Carbon dioxide *see also* Gas-forming agents
 Carbon dioxide-free water, 769
 Carbonate magnesium, 397
 Carbonei dioxidum, 115
 Carbonic acid, 590
 magnesium salt, mixture with magnesium hydroxide and magnesium hydrate, 399
 Carbonic acid calcium salt (1:1), 86
 Carbonic acid disodium salt, 635
 Carbonic acid gas, 115
 Carbonic acid, magnesium salt (1:1), 397
 Carbonic acid, magnesium salt (1:1), hydrate, 399
 Carbonic acid, magnesium salt (1:1), mixture with magnesium hydroxide and magnesium hydrate, 399
 Carbonic acid, magnesium salt anhydrous (1:1), 399
 Carbonic acid monopotassium salt, 570
 Carbonic acid monosodium salt, 629
 Carbonic anhydride, 115
Carbopol, 110
Carbopol 940, 110
Carbopol 941, 110
Carbopol 971P, 113
Carbopol 971P NF, 110
Carbopol 974P NF, 110
Carbopol ETD, 112
Carbopol Ultrez, 112
Carbose D, 118
Carbowax, 517
Carbowax Sentry, 517
 Carboxy polymethylene, 110
 Carboxybenzene, 61
 Carboxyethane, 586
 Carboxylic acid C, 384
 Carboxymethyl cellulose, 332
 Carboxymethyl starch, sodium salt, 663
 Carboxymethylamylum natricum, 663
 Carboxymethylcellulose, 789
 Carboxymethylcellulose calcium, 117, 121, 207
 Carboxymethylcellulose sodium, 118, 135, 207
 and microcrystalline cellulose, 132
 and microcrystalline cellulose, mixture, 134
 crosslinked, 206
 [(carboxymethyl)imino]bis(ethylenenitrilo) tetraacetic acid, 480
 [(o-Carboxyphenyl)thio]ethylmercury sodium salt, 736
 Carboxyvinyl polymer, 110
Cargill Dry, 418
Caridex, 222
 Carmellose Calcium, 117
 Carmellose Sodium, 118
 Carmellosum calcium, 117
 Carmellosum natricum, 118
 Carmellosum natricum conexum, 206
 Carnallite, 573
 Carnauba wax, 772
 Carob, extract of, 147
 Carob bean gum, 146
 Carob flour, 146
 Carob gum, 146
 β -Carotene, 193
 Carrageenan, 122
 and microcrystalline cellulose, 132
Carrisorb, 393
 Carthami oleum raffinatum, 610
 Cassava (tapioca) starch, 685, 690
 Castor oil, 126, 129, 185
 hydrogenated, 127–128, 185, 763
 hydrogenated polyoxyl, 542
 polyoxyethylene derivatives, 542
 polyoxyl, 542
 polyoxyl 35, 542
 polyoxyl 40 hydrogenated, 542–543
 Castor oil, hydrogenated, 128
 Castor Oil, Virgin, 126
Castorwax, 128
Castorwax MP 70, 128
Castorwax MP 80, 128
 Cathkinite, 612
 Cationic emulsifying wax, 778
 Cationic emulsifying wax *see* Emulsifying wax cationic
 Cationic surfactants *see* Surfactants, cationic
 Caustic potash, 576
 Caustic soda, 648
Cavamax W6 Pharma, 210
Cavamax W7 Pharma, 210
Cavamax W8 Pharma, 210
Cavasol W7, 315
Cavasol W7 HP, 316
Cavasol W7 HP Pharma, 316
Cavitron, 210
CCal-97, 626
*C*Dry* MD, 418
Cecavon, 793
 Cefazidime, 493
 Cefuroxime, 493
Celex, 129
 Cellacefate, 143
 Cellacephate, 143
Cellacol, 438
Cellactose 80, 374
Cellets, 129
Cellosize HEC, 311
Celluflex DBP, 225
 Cellulose, 129, 136
 crystalline, 129
 dispersible, 134
 hydroxyethyl, 311
 hydroxyethylmethyl, 314
 microcrystalline, 135, 138, 140, 332, 372
 and carboxymethylcellulose sodium, 132
 and carrageenan, 132
 and guar gum, 132
 powdered, 132, 136, 375
 silicified, microcrystalline, 132
 Cellulose acetate, 141, 145, 236, 332
 solvents, diethyl phthalate, 230
 Cellulose acetate benzene-1,2-dicarboxylate, 143
 Cellulose acetate hydrogen 1,2-benzenedicarboxylate, 143
 Cellulose acetate hydrogen phthalate, 143
 Cellulose acetate monophthalate, 143
 Cellulose acetate phthalate, 143, 332, 336, 562–563
 Cellulose acetate phthalate (CAP), compatible plasticizers, 144
 Cellulose acetate-butyrate, 236
 Cellulose acetophthalate, 143
 Cellulose acetylphthalate, 143
 Cellulose, carboxymethyl ether, calcium salt, 117
 Cellulose, carboxymethyl ether, sodium salt, 118
 crosslinked, 206
 Cellulose diacetate, 141
 Cellulose ethyl ether, 262
 Cellulose gel, 129
 Cellulose gum, 118
 modified, 206
 Cellulose, hydrogen 1,2-benzenedicarboxylate, 2-hydroxypropyl methyl ether, 333
 Cellulose hydroxyethyl ether, 311

- Cellulose, 2-hydroxyethyl methyl ester, 314
 Cellulose hydroxyethylate, 311
 Cellulose, hydroxypropyl ether, 317, 322
 Cellulose, 2-hydroxypropyl ether (low-substituted), 322
 Cellulose hydroxypropyl methyl ether, 326
 Cellulose, 2-hydroxypropyl methyl ether, acetate succinate, 330
 Cellulose, 2-hydroxypropylmethyl ether, acetate hydrogen butanedioate, 330
 Cellulose methyl ether, 438
 Cellulose, microcrystalline, 129
 Cellulose, microcrystalline and carboxymethylcellulose sodium, 134
 Cellulose phthalate hydroxypropyl methyl ether, 333
 Cellulose, powdered, 136
 Cellulose, silicified microcrystalline, 139
 Cellulose triacetate, 141
 Cellulosi acetas, 141
 Cellulosi acetas phthalas, 143
 Cellulosi pulvis, 136
 Cellulosum microcristallinum et carmellosum natricum, 134
Cel-O-Brandt, 118
Celphere, 129, 132
Celvol, 564
 Cenizas de soda, 635
Ceolus KG, 129
Cepacol, 157
Cepacol chloride, 157
 Cephadrine, 399
 Cera alba, 779
 Cera carnauba, 772
 Cera cetyla, 774
 Cera flava, 780
 Cera lanae, 378
 Cera mineralis alba, 148
 Ceratonia, 2, 146, 784
 Ceratonia extract, 147
 Ceratonia gum, 146
 Ceratonia siliqua, 146
 Ceratonia siliqua extract, 147
 Ceratonia siliqua gum, 146
 Ceresin, 148
 Ceresin wax, 148
 Ceresine, 148
 Ceresine wax, 148
*C*Eridex*, 251
 Cerin, 148
 Cerosin, 148
CertiSeal FC 300A, 616
Cetab, 152
Cetamium, 157
 Cetanol, 155
Cetapharm, 158
Cetasol, 158
Cetavlon, 152
 Cetearyl alcohol, 150
 Ceteth-N, 536
Cethylose, 118
 Cetomacrogol 1000, 536
 Cetomacrogol emulsifying ointment BP, 777
 Cetostearyl alcohol, 150, 156, 653, 701, 771, 778
 polyoxyethylene alkyl ethers, 548
 Cetostearyl Alcohol (Type A), Emulsifying, 770
 Cetostearyl Alcohol (Type B), Emulsifying, 770
Cetraol, 152
 Cetrimide, 58–60, 152, 164
 synergists, 247
 Cetrimide BP 1953, 153
 Cetrimide BP 1953, 153
 Cetrimide emulsifying wax, 778
 Cetrimidum, 152
 Cetrimonium bromide, 153
 Cetyl alcohol, 151, 155, 653, 701
 Cetyl esters wax, 774
 Cetyl pyridium chloride, 157
 Cetyl stearyl alcohol, 150
 Cetylacetic acid, 697
 Cetylic acid, 473
 Cetylpridini chloridum, 157
 Cetylpyridinium bromide, 158
 Cetylpyridinium chloride, 157
 Cetyltrimethylammonium bromide, 153
 Cevitamic acid, 43
 Ceylon isinglass, 13
 CFCs *see* Chlorofluorocarbons (CFCs)
 Chalk, precipitated, 86
 Chelating agents
 antioxidants, 247, 276
 citric acid monohydrate, 181
 disodium edetate, 242
 Edetate calcium disodium, 249
 edetic acid, 247
 fumaric acid, 276
 malic acid, 411
 maltol, 422
 pentetic acid, 480
 sodium edetate, 249
 trisodium edetate, 249
 Chelation therapy, 249
 Cheshire gum, 146
 Chewable tablet formulations
 mannitol, 424
 microcrystalline cellulose and guar gum, 132
 xylitol, 786
 see also Medicated confectionery bases
 China clay, 352
 Chinese isinglass, 13
 Chinese Restaurant Syndrome, 452–453
 Chinese seasoning, 452
 Chitin, deacetylated, 159
 Chitosan, 159, 479
 Chitosan Hydrochloride, 159
 Chitosani hydrochloridum, 159
 Chlorbutanol, 166
 Chlorbutol, 166
 Chloretone, 166
 Chlorhexidine, 162
 and surfactants, 164
 Chlorhexidine Acetate, 162, 164, 668
 Chlorhexidine cream BP, 777
 Chlorhexidine Diacetate, 162, 164
 Chlorhexidine digluconate, 165
 Chlorhexidine Digluconate Solution, 162
 Chlorhexidine Dihydrochloride, 162, 165
 Chlorhexidine gluconate, 164–165
 Chlorhexidine Gluconate Solution, 162
 Chlorhexidine Hydrochloride, 162, 164–165
 Chlorhexidini acetas, 164
 Chlorhexidini diacetat, 162
 Chlorhexidini digluconatis, 165
 Chlorhexidini digluconatis solutio, 162
 Chlorhexidini dihydrochloridum, 162
 Chlorhexidini hydrochloridum, 165
 Chloride of potash, 572
 Chlorobutanol, 166, 489, 491
 Chlorobutanol, Anhydrous, 166
 Chlorobutanolum anhydricum, 166
 Chlorocresol, 168, 178, 204
 4-chloro-*m*-cresol, 168
 Chlorocresolum, 168
 1-Chloro-1,1-difluoroethane, 171
 Chlorodifluoroethane (HCFC), 171
 Chlorodifluoromethane, 172
 with chlorodifluoroethane, 172
 4-Chloro-3,5-dimethylphenol, 176
 Chlorofluorocarbons (CFC), 173
 Chlorofluorocarbons (CFCs), 173, 733
 dichlorodifluoromethane, 173–175
 essential use status, 175
 dichlorotetrafluoroethane, 173–174
 essential use exemptions, 175
 Montreal Protocol, 175
 nomenclature, 175
 trichloromonofluoromethane, 173–174
 Chlorohydric acid, 308
 2-chloro-5-hydroxy-1,3-dimethylbenzene, 176
 1-chloro-4-hydroxy-2-methylbenzene, 168
 2-chloro-5-hydroxytoluene, 168
 2-chloro-5-hydroxy-*m*-xylene, 176
 4-chloro-3-methylphenol, 168
 Chlorophenoxyethanol, 489
 Chloropotassuril, 572
 Chloroquine, 478
 Chloroquine phosphate, 403, 408
 Chloroxylenol, 170, 176
 synergists, 247
 2-chloro-*m*-xylenol, 176
 Chlorphenamine maleate, 780
 Chlorpheniramine maleate, 321
 Chlorpromazine, 204
 Chlorure de sodium, 637
 Cholest-5-en-3 β -ol, 178
 Cholesterin, 178
 Cholesterol, 178, 379, 381, 383
 lanolin alcohols, 382
 Cholesterolum, 178
 Choline, 386
 Chondrus extract, 122
 CI 77499, 340
 Ciclosporin, 238, 259
 Cimetidine, 353
 Ciprofloxacin, 399
 incompatibilities, sodium bicarbonate, 631
Cirashine CS, 148
cis-butenedioic acid, 410
 9-*cis*,12-*cis*-linoleic acid, 389
cis,*cis*-9,12-octadecadienoic acid, 389
cis-ethene-1,2-dicarboxylic acid, 410
cis-1,2-ethylenedicarboxylic acid, 410
cis-maleic acid, 410
cis-9-octadecenoic acid, 466
cis-9-octadecen-1-ol, 468
Citation, 447
 Citrate of potash, 574
 Citric acid, 73, 183, 413, 570
 and polydextrose, 514
 anhydrous, 183, 630
 effervescent tablet formulations, 629
 sodium bicarbonate neutralization, 632
 Citric acid ethyl ester, 756
 Citric Acid Hydrate, 181
 Citric acid monohydrate, 181, 277, 642, 732
 Citric acid potassium salt, 574
 Citric acid, tributyl ester, 749
 Citric acid trisodium salt, 640
 Citric acid trisodium salt anhydrous, 642
Citroflex 2, 756
Citroflex 4, 749–750
Citroflex A-2, 10
Citroflex A-4, 8
Citrofol AI, 756
Citrosa, 458
 Citrus pectin, 478
 Clindamycin, 353
 Clinoenstatite, 403
 CMC calcium, 117
 CMC sodium, 118
 Coal tar, 450, 484
Coateric, 563
 Coating agents
 acetyltriethyl citrate, 10
 calcium carbonate, 86
 carboxymethylcellulose calcium, 117
 carboxymethylcellulose sodium, 119

- Coating agents (*cont.*)
 carnauba wax, 772
 cellulose acetate, 141
 cellulose acetate phthalate (CAP), 144
 ceresin, 148
 cetyl alcohol, 155
 chitosan, 159
 ethylcellulose, 262
 fructose, 273
 gelatin, 278
 glycerin, 283
 glyceryl behenate, 286
 glyceryl palmitostearate, 293
 hydroxyethyl cellulose, 311
 hydroxyethylmethyl cellulose, 314
 hydroxypropyl cellulose, 318
 hypromellose, 326
 hypromellose phthalate, 333
 isomalt, 343
 latex particles, 145
 liquid glucose, 282
 maltitol, 414
 maltodextrin, 418
 methylcellulose, 438
 microcrystalline wax, 775
 paraffin, 474
 poloxamer, 507
 polydextrose, 513
 polyethylene glycol, 518, 521
 polyethylene oxide, 522
 poly-DL-(lactic acid), 515
 polyvinyl acetate phthalate, 562
 polyvinyl alcohol, 564
 potassium chloride, model drug, 572
 povidone, 581
 shellac, 616
 shellac with stearic acid, 697
 sucrose, 282
 surface color agents, 189
 titanium oxide, 741, 743
 tributyl citrate, 749
 triethyl citrate, 756
 vanillin, 760
 white wax, 779
 xylitol, 786
 yellow wax, 780
 zein, 790
see also Film-forming agents; Lubricants (tablet and capsule)
- Coatsome, 499
 Cocoa butter, 725
 Cocois oleum raffinatum, 184
 Coconut butter, 184
 Coconut oil, 184, 431
 refined, 184
 Coconut oil PEG 1500 esters, hydrogenated, 557
 Coconut Oil, Refined, 184
 Colamine, 450
 Colemanite, 69
 Coliquifilm, 166
 Colloidal Anhydrous Silica, 185
 Colloidal cellulose, 134
 Colloidal silica, 185
 hydrophobic, 309
 Colloidal silicon dioxide, 139–140, 185, 310
 Collone HV, 770
 Collone NI, 777
 Colonic drug delivery
 chitosan, 159
 guar gum, 298
 Color index number 77891, 741
 Colorants, coloring agents, 189
 Coloring adjuvants, trehalose, 746
 Coloring agents, 189, 743
 calcium carbonate, 86
 classifications, 189
 iron oxides, 340
 lakes, 189
 see also Pigments
 Colza oil, 109
 low erucic acid, 108
 Colzao CT, 108
 Common salt, 637
 Compactrol, 105
 Complexing agents
 calcium acetate, 82
 hydroxypropyl betadex, 316
 poly(methylvinyl ether/maleic anhydride), 534
 sulfobutylether β -cyclodextrin, 714
 Compound Thymol Glycerin BP, 739
 Compressible starch, 691
 Compressible sugar, 706, 709, 712–713
 Compressible tablet excipients, lactose
 anhydrous, 359
 monohydrate and corn starch, 370
 spray dried, 376
 Compression aids, corn starch and
 pregelatinized starch, 200
 Compressuc, 709
 Comprima, 709
 Compritol 888 ATO, 286
 Concentrated ammonia solution, 39
 Concentrated hydrochloric acid, 308
 Confectionary glaze, 618
 Confectioner's sugar, 706, 710, 713
 Confectionery bases, medicated, sucrose, 703
 Confectionery bases, medicated *see* Medicated
 confectionery bases
 Contact lenses
 benzalkonium chloride, 57
 cetrimide, 152
 chlorhexidine, 162
 chlorobutanol, 167
 edetic acid, 247
 poloxamers, 507
 thimerosal, 736
 Controlled-release agents
 acetyltributyl citrate, 8
 acetyltriethyl citrate, 10
 alginic acid, 20, 22
 aliphatic polyesters, 23
 bentonite, 53, 55
 biodegradable polymers, 23
 carbomers, 110
 carrageenan, 122
 cellulose acetate, 141
 cellulose acetate phthalate with ethyl
 cellulose, 144
 ceratonia, 146–147
 cetyl alcohol, 155
 cetyl esters wax, 774
 chitosan, 159
 dibutyl sebacate, 227
 ethylcellulose, 263, 266
 glycerin monostearate, 290–291
 glyceryl behenate, 286
 glyceryl monooleate, 289
 glyceryl palmitostearate, 293
 guar gum, 298
 hydrogenated vegetable oil type I, 762
 hydroxypropyl betadex, 316
 hydroxypropyl cellulose, 318
 hypromellose, 326
 hypromellose acetate succinate, 330
 isopropyl palmitate, 350
 magnesium aluminum silicate, 393
 magnesium oxide, 401
 methylcellulose, 438
 microcrystalline wax, 775–776
 paraffin, 474
 peanut oil, 476
 polacrillin potassium, 505
 polycarbophil, 509
 polyethylene oxide, 522
 poly-DL-(lactic acid), 515
 polymethacrylates, 526
 potassium chloride, model drug, 572
 povidone, 585
 sesame oil, 614
 shellac, 616
 sodium bicarbonate, 630
 sodium chloride, 637
 starch, 690
 stearic acid, 697
 stearyl alcohol, 700
 talc, 728
 tributyl citrate, 749
 triethyl citrate, 756
 urethane hydrogels, 518
 white wax, 779
 yellow wax, 780–781
 zein, 790
 see also Enteric formulations/coating agents;
 Sustained-release agents
 Cooling agents, thymol, 739
 Copherol F1300, 31
 Copolymer of 1-vinyl-2-pyrrolidone and vinyl
 acetate in a ratio of 3:2 by mass, 196
 Copolymerum methacrylatis butylati basicum,
 525
 Copolyvidone, 196
 Copovidone, 196, 210
 Copovidonum, 196
 Copra oil, 184
 Cordycepic acid, 424
 Corn oil, 30, 109, 185, 199, 203, 477, 589,
 611, 615, 684, 722
 refined, 199
 Corn oil PEG 300 esters, 557
 Corn starch, 690, 710
 and lactose, monohydrate, mixture, 370
 sterilizable, 694–695
 Corn starch and pregelatinized starch, 200
 Corn sugar, 222
 Corn sugar gum, 782
 Corn syrup, 282
 Corn syrup solids, 420
 Cornmint oil, 434
 Corsodyl, 165
 CoSept B, 78
 CoSept E, 270
 CoSept M, 441
 CoSept P, 596
 Cosolvents *see* Solvents
 CoTran, 268–269
 CoTran 9702, 269
 CoTran 9705, 269
 CoTran 9706, 269
 CoTran 9715, 269
 CoTran 9716, 269
 CoTran 9726, 269
 CoTran 9728, 269
 Cotton oil, 202
 Cottonseed oil, 30, 109, 185, 200, 202, 477,
 589, 611, 615, 684, 722
 hydrogenated, 129, 762
 refined, 202
 C*Pharm, 220
 C*PharmDex, 222
 C*PharmDry, 418
 C*PharmGel, 685, 691
 C*PharmIsoMaltidex, 342
 C*PharmMaltidex, 414
 C*PharmMannidex, 424
 C*PharmSorbidex, 679
 C*PharmSweet, 282

- Cream bases *see* Ointment bases
Cremao CS-34, 722
Cremao CS-36, 722
Cremophor, 542–543, 548
Cremophor 410, 542
Cremophor A, 536, 548
Cremophor A25, 537
Cremophor CO 40, 542
Cremophor CO 455, 542
Cremophor EL, 542–543
Cremophor ELP, 542, 544
Cremophor RH 40, 542–544
Cremophor RH 410, 542
Cremophore CO 40, 542
Cresol, 170, 203–205
Cresylic acid, 203–205
Cresylol, 203
Creta preparada, 86
Cristal G, 697
Cristal S, 697
Crodacid, 697
Crodacol C70, 155
Crodacol C90, 155
Crodacol C95, 155
Crodacol CS90, 150
Crodacol S95, 700
Crodamol EO, 259
Crodamol GTCC-PN, 429
Crodamol SS, 774
Croderol, 283
Crodex A, 770
Crodex C, 778
Crodex N, 777
Crodolene, 466
Croduret, 128
Croscarmellose sodium, 118, 206
Crospopharm, 208
Crospovidone, 198, 208, 585
Crospovidonum, 208
Crossential 094, 466
Crosslinked carboxymethylcellulose sodium, 206
Crosslinked povidone, 208
Crosslinking agents, calcium lactate, 92
Crotylidene acetic acid, 672
Crude olive-pomace oil, 471
Cryogel, 278
Cryoprotectants
 albumin, 15
 dimethyl sulfoxide, 238
 see also Freeze-drying stabilizers
Crystal Gum, 220, 222
Crystallac, 616
Crystalline cellulose, 129
Crystalline maltose, 423–424
Crystallization modifiers, raffinose, 603
Crystalllose, 608
Cristol carbonate, 635
CTAB, 153
Culminal MC, 438
Culminal MHEC, 314
Cumotocopherol, 33
Cutina CP, 774
Cutina GMS, 290
Cutina HR, 128
Cyclamate, 644
Cyclamate sodium, 643
Cyclamic acid, 644
Cyclan, 644
Cyclic methylethylene carbonate, 590
Cyclic oligosaccharide, 210
Cyclic propylene carbonate, 590
Cyclic propylene ester, 590
Cycloamylose, 210
 alpha-cycloamylose, 210
 beta-cycloamylose, 210
Cyclodextrin, 210–211, 716
β-Cyclodextrin, 2-hydroxypropyl ether, 315
β-Cyclodextrin sulfobutylether, sodium salt, 714
Cyclodextrins, 210, 316
 alpha-cyclodextrin, 210
Cycloglucan, 210
Cyclogol 1000, 536
Cycloheptaamylose, 210
Cycloheptaglukan, 210
Cyclohexaamylose, 210
Cyclohexanesulfamic acid, 644
Cyclohexanesulfamic acid calcium salt, 644
N-cyclohexylsulfamic acid, 644
Cyclohexylsulfamic acid calcium salt, 644
Cyclohexylsulfamic acid monosodium salt, 643
Cyclomaltoheptose, 210
Cyclomaltohexose, 210
Cyclomaltooctose, 210
Cyclomethicone, 215, 234, 620
Cyclonette Wax, 770
Cyclooctaamylose, 210
Cyclopolydimethylsiloxane, 215
p-cymen-3-ol, 739
3-*p*-cymenol, 739
Cysteine hydrochloride, 71

Dalpac, 75
DBP, 225
DBS, 227
DEA, 228
Deacetylated chitin, 159
Deacetylchitin, 159
De-aerated water, 769
Deasit PC, 103
Decanedioic acid, dibutyl ester, 227
Decanoic acid, 384
Decoic acid, 384
Decyclic acid, 384
n-decylic acid, 384
DEHP, 226
Dehydrated alcohol, 18–19
Delayed-release agents *see* Colonic drug delivery; Controlled-release agents; Enteric formulations/coating agents
Delta tocopherol, 32–33
 see also Tocopherol
Deltan, 238
Demarone, 793
Denatonium benzoate, 217
Denatured alcohol, 18–19
Denaturing agents
 methanol, 19
 methyl isobutyl ketone, 19
Dendritic salt, 639
1-Deoxy-1-(ethylamino)-D-glucitol, 432
(2S)-7-[[6-O-(6-Deoxy-α-L-mannopyranosyl)-β-D-glucopyranosyl]oxy]-2,3-dihydro-5-hydroxy-2-(3-hydroxy-4-methoxyphenyl)-4H-1-benzopyran-4-one, 459
1-[4-[[2-O-(6-Deoxy-α-L-mannopyranosyl)-β-D-glucopyranosyl]oxy]-2,6-dihydroxyphenyl]-3-(3-hydroxy-4-methoxyphenyl)propan-1-one, 458
1-[4-[[2-O-6-deoxy-α-L-mannopyranosyl)-β-D-glycopyranosyl]oxy]-2,6-dihydroxyphenyl]-3-(3-hydroxy-4-methoxyphenyl), 458
1-Deoxy-1-(methylamino)-D-glucitol, 431
DEP, 230
Dervacid, 697
Descote, 400
Desiccants, calcium sulfate, anhydrous, 105
Desiccants, calcium chloride, 89
Destab, 86, 105, 397
Detergents
 polyethylene alkyl ethers, 537
 sodium lauryl sulfate, 651
 see also Surfactants; Wetting agents
Dextrates, 218, 222, 224, 420
Dextrimaltose, 222
Dextrin, 220, 224, 282, 420, 690
 alpha-dextrin, 210
 beta-dextrin, 210
 see also Cyclodextrins
Dextrinum, 220
Dextrinum album, 220
Dextrofin, 222
Dextrose, 219, 222, 275, 282, 514
 anhydrous, 224–225
 invert sugar, 706
 monohydrate, 225
 sweetness *vs.* fructose, 273
 see also Polydextrose
Dextrose anhydrous, 224
Dextrose equivalent (DE) values, definition, 420
Dextrose solutions, 225
1,2-Diacyl-*sn*-glycero-3-phosphocholine, 385
Diagnostic aids, inulin, 339
Dialuminum dipotassium sulfate, 567
Diazepam, 396, 398
Diazolidinyl urea, 338
Dibasic anhydrous calcium phosphate, 94
Dibasic calcium phosphate, 94
Dibasic Calcium Phosphate Dihydrate, 96
Dibasic Calcium Phosphate Hydrate, 96
Dibasic dihydrate calcium phosphate, 96
Dibasic magnesium stearate, 404
Dibasic potassium phosphate, 658
Dibasic sodium phosphate, 656, 660
Dibasic sodium phosphate dihydrate, 656
Dibasic sodium phosphate dodecahydrate, 656
Dibasic sodium phosphate heptahydrate, 656
Dibasic sodium phosphate hydrate, 656
Dibasic sodium phosphate monohydrate, 656
Dibasic zinc stearate, 793
Dibutyl benzene 1,2-dicarboxylate, 225
Dibutyl 1,2-benzenedicarboxylate, 225
Dibutyl decanedioate, 227
Dibutyl ester, decanedioic acid, 227
Dibutyl ester of 1,2-benzenedicarboxylic acid, 225
Dibutyl 1,8-octanedicarboxylate, 227
Dibutyl phthalate, 225, 231, 237
Dibutyl sebacate, 227
Dibutylated hydroxytoluene, 75
2,6-di-*tert*-butyl-*p*-cresol, 75
3,5-di-*tert*-butyl-4-hydroxytoluene, 75
Dibutylis phthalas, 225
2,6-Di-*tert*-butyl-4-methylphenol, 75
Dibutyl-*o*-phthalate, 225
Di-Cafos, 96, 98
Di-Cafos AN, 94, 96
Dicalcium orthophosphate, 94, 96
Dicalcium silicate, 102
Dicarbomethoxy zinc, 791
1,6-Dichloro-1,6-dideoxy-β-D-fructofuranosyl-4-chloro-4-deoxy-α-D-galactopyranoside, 701
Dichlorodifluoromethane, 173–175, 304, 734
 essential use status, 175
 Montreal Protocol, 175
1,6-di(4'-chlorophenyl)diguano(hexane), 162
Dichlorotetrafluoroethane, 173–174, 304, 734
 Montreal Protocol, 175
1,2-Dichloro-1,1,2,2-tetrafluoroethane, 173
Diclofenac, 238
D-2,3-didehydro-*erythro*-hexono-1,4-lactone, 250
2,3-didehydro-L-*threo*-hexono-1,4-lactone, 43
Dietary supplements
 calcium phosphate, tribasic, 99
 glycine, 295

- Dietary supplements (*cont.*)
 linoleic acid, 389
 Diethanolamine, 228, 451, 755
 Diethyl benzene-1,2-dicarboxylate, 230
 Diethyl phthalate, 226, 230, 237, 562
 Diethylene glycol monopalmitostearate, 268
 Diethylene glycol palmitostearate, 268
 Diethyleneglycoli monopalmitostearas, 268
 Diethylenetriamine pentaacetic acid, 480
 Diethylenetriamine-*N,N,N',N',N''*-pentaacetic acid, 480
 (diethylenetrinitrilo)pentaacetic acid, 480
 Di(2-ethyl-hexyl)phthalate, 226
 Diethylis phthalas, 230
 Diethylolamine, 228
 1,1-Difluoro-1-chloroethane, 171
 Difluorochloromethane, 172
 Difluoroethane, 303, 734
 with chlorodifluoroethane, 172
 1,1-Difluoroethane, 232
 Difluoroethane (HFC), 232
 Digoxin, 353
 (±)-3,4-Dihydro-2,8-dimethyl-2-(4,8,12-trimethyltridecyl)-2*H*-1-benzopyran-6-ol, 33
 (Dihydrogen borato)phenylmercury, 494
 1,2-dihydro-2-ketobenzisulfonazole, 605
 2,3-dihydro-3-oxobenzisulfonazole, 605
 2-(1,3-Dihydro-3-oxo-5-sulfo-2*H*-indol-2-ylidene)-2,3-dihydro-3-oxo-1*H*-indole-5-sulfonic acid disodium salt, 193
 4,5-Dihydro-5-oxo-1-(4-sulfophenyl)-4-[(4-sulfophenyl)azo]-1*H*-pyrazole-3-carboxylic acid trisodium salt, 195
 9,10-dihydro-3,5,6,8-tetrahydroxy-7-[2-hydroxy-5-(2-hydroxyethyl)phenyl]-9,10-dioxo-1,2-anthracenedicarboxylic acid, 618
 (±)-3,4-dihydro-2,5,7,8-tetramethyl-2-(4,8,12-trimethyltridecyl)-2*H*-1-benzopyran-6-ol, 31
 (±)-3,4-Dihydro-2,5,7,8-tetramethyl-2-(4,8,12-trimethyltridecyl)-2*H*-1-benzopyran-6-ol acetate, 32
 (±)-3,4-dihydro-2,5,8-trimethyl-2-(4,8,12-trimethyltridecyl)-2*H*-1-β-benzopyran-6-ol, 33
 Dihydroxyaluminum monostearate, 35
 1,3-dihydroxybutane, 77
 (2*R*,3*R*)-2,3-dihydroxybutane-1,4-dioic acid, 731
 L-(+)-2,3-dihydroxybutanedioic acid, 731
 [R-(*R*^{*},*R*^{*})]-2,3-Dihydroxybutanedioic acid, 731
 2,2'-dihydroxydiethylamine, 228
 3,5-dihydroxy-4-(3-hydroxy-4-methoxyhydrocinnamoyl)phenyl-2-*O*-(6-deoxy-α-L-mannopyranosyl)-β-D-glucopyranoside, 458
 3,5-dihydroxy-4-[3-(3-hydroxy-4-methoxyphenyl)propionyl]phenyl-2-*O*-(6-deoxy-α-L-mannopyranosyl)-β-D-glucopyranoside, 458
 1,2-Dihydroxypropane, 592
 2,3-dihydroxypropyl docosanoate, 286
 2,3-dihydroxypropyl octadecanoate, 290
 2,3-dihydroxysuccinic acid, 731
 Diiron trioxide, 340
 Diisobutylphenoxyethoxyethyl dimethyl benzyl ammonium chloride, 59
 Diluent (tablet/capsule)
 lactose, monohydrate and povidone, 373
 lactose, monohydrate and powdered cellulose, 374
 Diluents (dry powder inhalers)
 inhalation lactose, 362
 lactose, 364
 mannitol, 424
 Diluents (liquids)
 maltitol, 414
 sunflower oil, 721
 Diluents (medicated powders), starch,
 sterilizable maize, 695–696
 Diluents (tablet/capsule)
 ammonium alginate, 41
 calcium carbonate, 86, 88
 calcium lactate, 92
 calcium phosphate
 dibasic anhydrous, 94
 dibasic dihydrate, 96
 tribasic, 99
 calcium silicate, 101
 calcium sulfate, 105
 cellulose
 powdered, 136
 silicified microcrystalline, 139
 cellulose acetate, 141
 compressible sugar, 709
 confectioner's sugar, 710
 corn starch and pregelatinized starch, 200
 dextrates, 218
 dextrin, 220
 dextrose, 222
 erythritol, 251
 ethylcellulose, 262
 fructose, 273
 fumaric acid, 276
 glyceryl palmitostearate, 293
 inhalation lactose, 362
 isomalt, 343
 kaolin, 352
 lactitol, 357
 lactose, 364
 anhydrous, 359
 monohydrate and corn starch, 370
 monohydrate and microcrystalline cellulose, 371
 spray dried, 376
 magnesium carbonate, 397
 magnesium oxide, 400
 maltodextrin, 418
 maltose, 422
 mannitol, 424
 medium-chain triglycerides, 429
 microcrystalline cellulose, 129
 polydextrose, 513
 polymethacrylates, 526
 simethicone, 619
 sodium alginate, 622
 sodium chloride, 637, 639
 sorbitol, 679
 starch, 685
 pregelatinized, 691
 sterilizable maize, 695–696
 sucrose, 703
 sugar spheres, 712
 sulfobutylether β-cyclodextrin, 714
 talc, 728
 tragacanth, 744
 trehalose, 746
 xylitol, 786
 Dilute acetic acid, 6
 Dilute alcohol, 18–19
 Dilute ammonia solution, 40
 Dilute ethanol, 19
 Dilute hydrochloric acid, 309
 Dilute phosphoric acid, 504
 Dilute sulfuric acid, 720
 Diluted glycerin solutions, 285
 Diluted hydrochloric acid, 309
 Diluted phosphoric acid, 504
 Dimethicone, 216, 233, 620
 Dimethyl 1,2-benzenedicarboxylate, 236
 Dimethyl benzeneorthodicarboxylate, 236
 Dimethyl carbinol, 346
 Dimethyl ether, 235, 307
 Dimethyl ketone, 7
 Dimethyl oxide, 235
 Dimethyl phthalate, 226, 231, 236
 Dimethyl sulfoxide, 238
 Dimethyl sulphoxide, 238
 Dimethylacetamide, 241
 Dimethylacetamidum, 241
 Dimethylacetone amide, 241
 Dimethylamide acetate, 241
 3-(3,3-Dimethylbutylamino)-*N*-(α-carboxyphenethyl)succinamic acid methyl ester, 460
 (3*R*)-3-(3,3-Dimethylbutylamino)-4-[[[(2*R*)-1-methoxy-1-oxo-3-phenylpropan-2-yl]amino]-4-oxobutanoic acid, 460
N-[*N*-(3,3-dimethylbutyl)-L-α-aspartyl]-L-phenylalanine 1-methyl ester, 460
 3,5-dimethyl-4-chlorophenol, 176
 Dimethyl-β-cyclodextrin, 213, 716
 Dimethylcyclopolsiloxane, 215
 1,1-dimethylethyl-4-methoxyphenol, 73
 Dimethylformaldehyde, 7
 Dimethylis sulfoxidum, 238
 Dimethylmethane, 306
N-[2-(2,6-dimethylphenyl)amino]-2-oxoethyl-*N,N*-diethylbenzenemethanaminium benzoate monohydrate, 217
 Dimethylpolysiloxane, 233
 Dimethylsilicone fluid, 233
 Dimethylsiloxane, 233
N,N-Dimethyl-*N*-[2-[4-(1,1,3,3-tetramethylbutyl)phenoxy]ethoxy]ethyl benzene-methanaminium chloride, 59
 5,8-dimethyltolcol, 33
 Dimeticone, 233
 Dimeticonum, 233
 Dimexide, 238
 Dinatrii edetas, 242
 Dinatrii phosphas anhydricus, 656
 Dinatrii phosphas dihydricus, 656
 Dinatrii phosphas dodecahydricus, 656
 Dinitrogen monoxide, 463
 Dinitrogen oxide, 463
 Dinitrogenii oxidum, 463
 1,3-Di(octanoyloxy)propan-2-yl octanoate, 751
 Dioctyl calcium sulfosuccinate, 246
 Dioctyl phthalate, 226
 Dioctyl potassium sulfosuccinate, 246
 Dioctyl sodium sulfosuccinate, 244
 Diolamine, 228
 Dioxotitanium, 741
 Di-Pac, 709
 Dipotassium dichloride, 572
 Dipotassium edathamil, 248
 Dipotassium edetate, 248
 Dipotassium ethylenediaminetetraacetate, 248
 Dipotassium hydrogen orthophosphate, 658
 Dipotassium hydrogen phosphate, 658
 Dipotassium phosphate, 658
 Dipotassium pyrosulfite, 577
 Dipotassium salt, 577
 Direct compacting sucrose, 709
 Directly compressible sucrose, 709
 Disinfectants
 alcohol, 17
 benzalkonium chloride, 56
 benzethonium chloride, 59
 benzyl alcohol, 64
 cetrimide, 152
 cetylpyridinium chloride, 157
 chlorhexidine, 162
 chlorocresol, 168

- chloroxylenol, 176
 cresol, 203–204
 isopropyl alcohol, 346
 phenol, 485
 phenoxyethanol, 488
 phosphoric acid, 504
 potassium metabisulfite, 577
 povidone-iodine, 585
 propylene glycol, 592
 sodium borate, 633
 sodium hydroxide, 649
 thymol, 739
see also Antibacterial agents
- Disintegrants**
 hydroxypropyl starch, 325
 lactose, monohydrate and corn starch, 370
- Disintegrants (tablet/capsule)**
 alginic acid, 20
 calcium alginate, 83
 carboxymethylcellulose calcium, 117
 carboxymethylcellulose sodium, 119
 cellulose, powdered, 136, 138
 chitosan, 159
 colloidal silicon dioxide, 185–186
 corn starch and pregelatinized starch, 200
 croscarmellose sodium, 206
 crospovidone, 208
 docusate sodium, 244
 glycine, 295
 guar gum, 298
 hydroxypropyl cellulose, 318
 low-substituted, 322
 magnesium aluminum silicate, 393
 methylcellulose, 438
 microcrystalline cellulose, 129
 polacrillin potassium, 504
 povidone, 581
 sodium alginate, 622
 sodium starch glycolate, 663
 starch, 685
 pregelatinized, 691
- Disodium carbonate, 635
 Disodium disulfite, 654
 Disodium edetate, 242, 247–248
 Disodium Edetate Hydrate, 242
 Disodium EDTA, 242
 Disodium ethylenediaminetetraacetate, 242
 Disodium ethylenediaminetetraacetate dihydrate, 242
 Disodium hydrogen citrate, 640
 Disodium hydrogen phosphate, 656
 anhydrous, 656
 Disodium Hydrogen Phosphate Dihydrate, 656
 Disodium Hydrogen Phosphate Dodecahydrate, 656
 Disodium 5,5'-indigotin disulfonate, 193
 Disodium phosphate, 656
 Disodium Phosphate, Anhydrous, 656
 Disodium Phosphate Dihydrate, 656
 Disodium Phosphate Dodecahydrate, 656
 Disodium pyrosulfite, 654
 Disodium sulfite, 669
 Disodium tetraborate anhydrous, 634
 Disodium tetraborate decahydrate, 633
 Disodium thiosulfate, 671
 Disodium thiosulfate pentahydrate, 671
- Dispersing agents**
 aluminum oxide, 37
 cellulose, microcrystalline and carboxymethylcellulose sodium, 134
 diethanolamine, 228
 ethylene glycol palmitostearate, 267
 glycerin monostearate, 290
 hypromellose, 326
 hypromellose acetate succinate, 330
- lecithin, 385
 phospholipids, 499
 poloxamers, 507–508
 polyethylene alkyl ethers, 537
 poly(methylvinyl ether/maleic anhydride), 534
 polyoxyethylene sorbitan fatty acid esters, 550
 sorbitan esters, 675
- Dissolution enhancer, macrogol 15
 hydroxystearate, 391
- Dissolution enhancers**
 calcium carbonate, 86
 crospovidone, 208, 210
 cyclodextrins, 211
 fructose, 273
 hydroxypropyl betadex, 316
 hypromellose, 326
 oleyl alcohol, 468
 polyoxylglycerides, 558
 povidone, 581
see also Solubilizing agents
- Dissolution-enhancing agents, sulfobutylether β -cyclodextrin, 714
- Dissolvine*, 247
 Distilled water, 769
 Disulfurous acid, 577
 Disulfurous acid, disodium salt, 654
DI-TAB, 96, 98
 DL-Dilactide homopolymer, 515
 DL-dilactide polymer, 515
 DL-3,6-dimethyl-1,4-dioxane-2,5-dione homopolymer, 515
DL-erythro-9,10,16-Trihydroxyhexadecanoic acid, 618
 DL-PLA, 515
 DMA, 241
 DMAC, 241
 DM- β -CD, 213
 DME, 235
 DMP, 236
 DMSO, 238
Dobendan, 157
 Docosanoic acid, diester with glycerin, 286
 Docosanoic acid, 2,3-dihydroxypropyl ester, 286
 Docosanoic acid, monoester with glycerin, 286
 Docosanoic acid, triester with glycerin, 286
 Docusate calcium, 246
 Docusate potassium, 246
 Docusate sodium, 244
 Dodecanoic acid, 383
 Dodecoic acid, 383
 Dodecyl alcohol hydrogen sulfate, sodium salt, 651
 Dodecyl gallate, 589
 Dodecyl sodium sulfate, 651
 Dodecyl 3,4,5-trihydroxybenzoate, 589
 Dodecylis gallas, 589
 Dodecylsulfate sodium salt, 651
 Dodecyltrimethylammonium bromide, 153
 Dolomite, 398
 DOP, 226
 Double-dressed, white maize starch, 695
Dow Corning 245 Fluid, 215
Dow Corning 246 Fluid, 215
Dow Corning 345 Fluid, 215
Dow Corning Q7-2243 LVA, 619
Dow Corning Q7-2587, 619
Dow Corning Q7-9120, 233
Dowanol EPh, 488
 Dracrylic acid, 61
Drakeol, 445
 Dried calcium sulfate, 107
 Dried gypsum, 107
 Dried Sodium Carbonate, 635
- Drierite*, 105
 Dry ice, 115
 DSS, 244
 DTAB, 153
 DTPA, 480
 DTPAN, 481
 Duodecyclic acid, 383
 Dusting powders
 absorbable, 695
 chlorhexidine salts, 162
 starch-derivative, 695
 talc, 728
 zinc stearate, 793
- Dygminu aliejus, rafinuotas, 610
Dymel, 173
Dymel 134a/P, 733
Dymel 142b, 171
Dymel 152a, 232
Dymel 227 ea/P, 303
Dymel A, 235
 Dypingite, 399
Dyriel 22, 172
Dytol R-52, 456
- 1E-2-[6-[[amino-[[amino-[(4-chlorophenyl)amino]methylidene]amino]methylidene]amino]hexyl]-1-[amino-[(4-chlorophenyl)amino]methylidene]guanidine, 162
- Ear wax softeners, 30
 Earth wax, 148
 Earlnut oil, 476
Eastacryl, 525
Eastacryl 30 D, 526
Eastman DMP, 236
ECG 505, 117
Eco-Lac, 355
 Edathamil, 247
 Edathamil calcium disodium, 248
 Edathamil dipotassium, 248
 Edathamil disodium, 242
Edenor, 697
Edenor C14 98-100, 455
Edenor C16 98-100, 473
 Edetate calcium disodium, 247–248
 Edetate dipotassium, 248
 Edetate Disodium, 242
 Edetate sodium, 249
 Edetate trisodium, 249
 Edetic acid, 244, 247
 and thimerosal, 737
 dipotassium salt, 248
 tetrasodium salt, 249
 trisodium salt, 249
 Edetic acid calcium, disodium salt, 248
 Edetic acid calcium disodium salt, 248
 Edetic acid dipotassium salt, 248
 Edetic acid, disodium salt, 242
 Edetic acid tetrasodium salt, 249
 Edetic acid trisodium salt, 249
 EDTA, 247
 EDTA calcium, 248
 EDTA dipotassium, 248
 EDTA tetrasodium, 249
 EDTA trisodium, 249
Effer-Soda, 629
- Effervescent tablet formulations
 citric acid, anhydrous, 181
 citric acid monohydrate, 181
 dextrates, 218
 fumaric acid, 276
 potassium bicarbonate, 570
 sodium bicarbonate, 629–630, 636
 sodium carbonate, 635
 sodium citrate dihydrate, 640
 tartaric acid, 731
- Egg lecithin, 385

- Egg yolk lecithin, 385
 Eglumine, 432
 Elaic acid, 466
Elaol, 225
Elcema, 136
Elfan 240, 651
Elvanol, 564
Embanox BHT, 75
Embanox tocopherol, 33
Emcocel, 129
Emcompress, 96, 98
Emcompress Anhydrous, 94, 96
EmCon CO, 126
Emdex, 218
Emeressence 1160, 488
Emerest 2316, 350
Emersol, 466, 697
Emersol 140, 473
Emersol 143, 473
Emersol 310, 389
Emersol 315, 389
 Emollients
 almond oil, 30
 aluminum stearate, 35
 canola oil, 108
 castor oil, 126
 ceratonia extract, 147
 cetostearyl alcohol, 150
 cetyl alcohol, 155
 cetyl esters wax, 774
 cholesterol, 178
 coconut oil, 184
 cottonseed oil, 202
 cyclomethicone, 215
 dibutyl sebacate, 228
 dimethicone, 233
 ethylene glycol palmitostearate, 267
 glycerin, 283
 glycerin monostearate, 290
 glyceryl monooleate, 289
 glyceryl monostearate, 292
 isopropyl myristate, 348
 isopropyl palmitate, 350
 lanolin, 379
 lecithin, 385
 light mineral oil, 447
 medium-chain triglycerides, 429
 mineral oil, 445
 mineral oil and lanolin alcohols, 449
 myristyl alcohol, 456
 octyldodecanol, 465
 oleyl alcohol, 468
 petrolatum, 482
 petrolatum and lanolin alcohols, 484
 safflower glycerides, 611
 safflower oil, 610
 soybean oil, 683
 stearyl alcohol, 700
 sunflower oil, 721–722
 tricaprylin, 751
 triolein, 757
 xylitol, 786
 zinc acetate, 791
Empilan KB, 536
Empilan KM, 536
Emprove, 424
Emulgade 1000NI, 777
Emulgen, 536
 Emulsifying agents, ammonium alginate, 41
 Emulsifying agent, capric acid, 384
 Emulsifying agents
 acacia, 1
 agar, 13
 anionic emulsifying wax, 771
 calcium alginate, 83
 calcium stearate, 103
 carbomers, 110
 carboxymethylcellulose calcium, 117
 carrageenan, 122
 cetostearyl alcohol, 150
 cetyl alcohol, 155
 cholesterol, 178
 diethanolamine, 228
 ethylene glycol palmitostearate, 267
 glycerin monostearate, 290
 glyceryl monooleate, 289
 hectorite, 301
 hydroxypropyl cellulose, 318
 hydroxypropyl starch, 325
 hypromellose, 326
 lanolin, 378
 hydrous, 380
 lanolin alcohols, 382
 lauric acid, 383
 lecithin, 385
 linoleic acid, 389
 medium-chain triglycerides, 429
 methylcellulose, 438
 mineral oil and lanolin alcohols, 449
 monobasic sodium phosphate, 659
 monoethanolamine, 450
 myristic acid, 455
 nonionic emulsifying wax, 777
 octyldodecanol, 465
 oleic acid, 466
 oleyl alcohol, 468
 palmitic acid, 473
 pectin, 478
 phospholipids, 499
 poloxamer, 507
 poloxamers, 508
 polycarbophil, 509
 polyoxyethylene alkyl ethers, 536
 polyoxyethylene castor oil derivatives, 542
 polyoxyethylene sorbitan fatty acid esters, 550
 polyoxyethylene stearates, 555
 polyoxylglycerides, 558
 potassium alginate, 566
 propylene glycol alginate, 594
 safflower glycerides, 611
 saponite, 612
 self-emulsifying glyceryl monostearate, 292
 sodium borate, 633
 sodium citrate dihydrate, 640
 sodium lactate, 650
 sodium lauryl sulfate, 651
 sorbitan esters, 675
 stearic acid, 697
 sunflower oil, 721
 tragacanth, 744
 triethanolamine, 754
 vitamin E polyethylene glycol succinate, 764
 xanthan gum, 782
 Emulsifying ointment BP, 771
 Emulsifying Wax, 770, 777
 anionic, 770–771, 778
 incompatibilities, quaternary ammonium compounds, 771
 with white soft paraffin, 771
 cationic, 778
 cetrimide emulsifying wax, 778
 incompatibilities, anionic surfactants/drugs, 778
 nomenclature, 772, 778
 nonionic, 541, 771, 777
 cetomacrogol emulsifying wax, 777
 phenol, 777
 quaternary ammonium compounds, 777
 surfactants, 772, 778
 Emulsifying wax BP, 772, 778
 Emulsifying wax USP, 772, 778
 Emulsion stabilizers
 cellulose, microcrystalline and carboxymethylcellulose sodium, 134
 colloidal silicon dioxide, 185
 hydrophobic colloidal silica, 309
 hypromellose, 326
 myristyl alcohol, 456
 phospholipids, 499
 polyethylene glycol, 518
 poly(methylvinyl ether/maleic anhydride), 534
 zinc acetate, 791
Encapsin, 210
 Encapsulating agents, shellac, 616
 Enstatite, 403
 Enteric formulations/coating agents
 acetyltributyl citrate, 8
 carbomers, 110
 cellulose acetate phthalate, 144
 colonic drug delivery, 298
 guar gum, 298
 hypromellose acetate succinate, 330
 hypromellose phthalate, 333
 polymethacrylates, 526
 polyvinyl acetate phthalate, 562
 potassium chloride, model drug, 572
 shellac, 616
 Sureteric, 562
 tributyl citrate, 749
 triethyl citrate, 756
 triolein, 757
 white wax, 779
 zein, 790
 see also Controlled-release agents
Entonox, 464
Equal, 48
Ergoplast FDB, 225
 Erucic acid
 canola oil, 108
 colza oil, 108
 rapeseed oil, 108–109
 Erycorbin, 250
 Erythorbic acid, 45, 250
 Erythorbic acid sodium salt, 251
 Erythrite, 251
 Erythritol, 251
 Erythritolum, 251
 Erythroglucin, 251
 D-erythro-hex-2-enoic acid, 250
 D-erythro-hex-2-enoic acid sodium salt, 251
 D-erythro-3-ketohexonic acid lactone, 250
 Erythromycin stearate, 403, 408
 Essential oils, 247, 443
 solubilizing agents
 polyethylene alkyl ethers, 537
 polyoxyethylene castor oil derivatives, 543
 polyoxyethylene sorbitan fatty acid esters, 550
 Esterifying agents, propionic acid, 586
Esterwax NF, 777
Estol IPM, 348
 Ethal, 155
 Ethanecarboxylic acid, 586
 N,N'-1,2-Ethanediylbis[N-(carboxymethyl)glycine], 247
 N,N'-1,2-ethanediylbis[N-(carboxymethyl)glycine] dipotassium salt, 248
 N,N'-1,2-ethanediylbis[N-(carboxymethyl)glycine] tetrasodium salt, 249
 N,N'-1,2-ethanediylbis[N-(carboxymethyl)glycine] trisodium salt, 249
 Ethanoic acid, 5

- Ethanol, 17–19
 anhydrous, 18
 dilute, 19
 Ethanol (96%), 17
 Ethanol (96 per cent), 17
 Ethanolamine, 450
 Ethanolic acid, 5
 Ethanolum (96 per centum), 17
 1,2-ethenedicarboxylic acid, 276
 Ethenol, homopolymer, 564
 1-Ethenyl-2-pyrrolidinone homopolymer, 208, 581
 Ethiops iron, 340
Ethispheres, 129
Ethocel, 262
 Ethol, 155
Ethosperse, 536
 3-Ethoxy-4-hydroxybenzaldehyde, 261
 Ethoxylated fatty acid esters, 554
 Ethyl acetate, 253
 Ethyl Acrylate and Methyl Methacrylate Copolymer Dispersion, 525
 Ethyl alcohol, 17
 Ethyl benzene-1,2-dicarboxylate, 230
 Ethyl cellulose, with cellulose acetate phthalate, 144
 Ethyl citrate, 756
 Ethyl ethanoate, 253
 Ethyl gallate, 589
 Ethyl hydroxide, 17
 Ethyl Hydroxybenzoate, 270
 Ethyl 4-hydroxybenzoate potassium salt, 272
 Ethyl 4-hydroxybenzoate sodium salt, 272
 Ethyl α -hydroxypropionate, 256
 Ethyl lactate, 256
 Ethyl linoleate, 389
 Ethyl maltol, 257, 422
 Ethyl (2-mercaptobenzoato-S)-mercury, sodium salt, 736
 Ethyl 9-octadecenoate, 259
 Ethyl oleate, 259, 467
 Ethyl Parahydroxybenzoate, 270
Ethyl parasept, 270
 Ethyl phthalate, 230
 2-Ethyl pyromeconic acid, 257
 Ethyl (sodium o-mercaptobenzoato)mercury, 736
 Ethyl 3,4,5-trihydroxybenzoate, 589
 Ethyl vanillin, 261, 761
Ethylan, 536
 Ethylcellulose, 262, 315, 329, 332, 440
 compatible plasticizers, 266
 Ethylcellulosum, 262
 Ethylene fluoride, 232
 Ethylene glycol monopalmitate, 268
 Ethylene Glycol Monopalmitostearate, 267
 Ethylene glycol monostearate, 268
 Ethylene glycol palmitostearate, 267
 Ethylene glycol stearate, 268
 Ethylene glycol stearates, 267
 Ethylene glycoli monostearas, 268
 Ethylene vinyl acetate, 268
 Ethylene vinyl acetate copolymer, 268
 Ethylenebis(iminodiacetic acid), dipotassium salt, 248
 Ethylenebis(iminodiacetic acid) dipotassium salt, 248
 Ethylenebis(iminodiacetic acid) tetrasodium salt, 249
 Ethylenediaminetetraacetic acid, 247
 calcium disodium chelate, 248
 dipotassium salt, 248
 tetrasodium salt, 249
 trisodium salt, 249
 Ethylenediaminetetraacetic acid calcium disodium chelate, 248
 Ethylenediaminetetraacetic acid dipotassium salt, 248
 Ethylenediaminetetraacetic acid, disodium salt, 242
 Ethylenediaminetetraacetic acid tetrasodium salt, 249
 Ethylenediaminetetraacetic acid trisodium salt, 249
 [(ethylenedinitrilo)tetraacetato]calcate(2-) disodium, 248
 (ethylenedinitrilo)tetraacetic acid, 247
 dipotassium salt, 248
 tetrasodium salt, 249
 (ethylenedinitrilo)tetraacetic acid dipotassium salt, 248
 (ethylenedinitrilo)tetraacetic acid tetrasodium salt, 249
 (ethylenedinitrilo)tetraacetic acid trisodium salt, 249
 Ethyleneglycol monophenyl ether, 488
 Ethyleneglycoli monopalmitostearas, 267
 Ethylene/vinyl acetate copolymer, 268
 Ethyleni glycoli stearas, 268
 Ethylformic acid, 586
 Ethylformic acid, sodium salt, hydrate, 661
 N-ethylglucamine, 432
 Ethylhydroxy cellulose, 311
 Ethyl-4-hydroxybenzoate, 270
 2-Ethyl-3-hydroxy-4H-pyran-4-one, 257
 Ethyl-2-hydroxypropionate, 256
 Ethyl-2-hydroxypropionate, 256
 Ethylic acid, 5
 Ethylis acetate, 253
 Ethylis oleas, 259
 Ethylis parahydroxybenzoas, 270
 Ethyl[2-mercaptobenzoato(2-)-O,S]-mercurate(1-) sodium, 736
 Ethylolamine, 450
 Ethylose, 311
 Ethylparaben, 80, 270, 444, 598, 600
see also Parabens
 Ethylparaben potassium, 272
 Ethylparaben sodium, 272
 Ethylprotal, 261
 Ethylprotocatechuic aldehyde, 261
 Ethyl-S-(–)-2-hydroxypropionate, 256
Etocas, 542
Eudragit, 525
Eudragit E, 525–526
Eudragit FS, 525–526
Eudragit L, 525–526
Eudragit L 30 D-55, 526
Eudragit L 30D, 562
Eudragit L 100-55, 526
Eudragit NE 30 D, 526
Eudragit NE 40 D, 526
Eudragit NM 30 D, 526
Eudragit RL, 525–526
Eudragit RS, 401, 525–526
Eudragit S, 525–526
Eumulgine, 542
Eurylon, 685
Eutanol G PH, 465
 EVA, 268
 EVA copolymer, 268
 EVM, 268
Excelacs 3-Circles, 616
Excelacs 3-Stars, 616
Explocel, 206
Explosol, 663
Explotab, 663
Explotab CLV, 665
Explotab Low pH, 665
 Expressed almond oil, 29
 Exsiccated calcium sulfate, 107
 Exsiccated sodium sulfite, 669
 Extended-release agents *see* Sustained-release agents
Extra AS, 697
Extra P, 697
Extra S, 697
Extra ST, 697
 Extra virgin olive oil, 471
 Extract of carob, 147
 Extractants, propylene glycol, 592
 Famotidine, 742
Fancol, 128
 Fatty acid esters, ethoxylated, 554
 FD&C blue #2, 193
 FD&C yellow #6, 194–195
 Fecule, 685
 β -fenethylalcohol, 490
 β -fenylethanol, 490
Fermine, 236
 Ferric ferrous oxide, 340
 Ferric hydrate, 340
 Ferric hydroxide, 340
 Ferric hydroxide oxide, 340
 Ferric oxide
 anhydrous, 340
 hydrated, 340
 Ferric oxide hydrated, 340
 Ferroan saponite, 612
 Ferrosioferric oxide, 340
Ferroxide 78P, 340
Ferroxide 88P, 340
Ferroxide 212P, 340
Ferroxide 226P, 340
Ferroxide 510P, 340
Fibrocel, 129
 Fillers *see* Diluents (tablet/capsule)
 Film-forming agents
 ammonium alginate, 41
 chitosan, 159
 chlorpheniramine maleate, 321
 copovidone, 197
 dibutyl phthalate, 225
 dibutyl sebacate, 227
 diethyl phthalate, 230
 dimethyl phthalate, 236
 ethyl lactate, 256
 ethylcellulose, 263
 gelatin, 278
 hydroxyethyl cellulose, 311
 hydroxypropyl cellulose, 318, 321
 hypromellose, 326
 hypromellose acetate succinate, 330
 maleic acid, 411
 maltodextrin, 418
 opacifiers, calcium carbonate, 86
 polydextrose, 513
 polyethylene glycol, 518, 521
 polyethylene oxide, 523
 polymethacrylates, 526
 poly(methylvinyl ether/maleic anhydride), 534
 polyvinyl acetate phthalate, 562
 shellac, 616
 starch, 690
 triethyl citrate, 756
 vanillin, 760
see also Coating agents
 Fine virgin olive oil, 471
Finetose, 422
Finetose F, 422
Finlac DC, 357–358
Finmalt L, 416
Finmfix, 118
 Fixatives, perfume, diethyl phthalate, 230
Flavinol, 739

- Flavor enhancer, neohesperidin dihydrochalcone, 458
- Flavor enhancers
- acesulfame potassium, 3
 - aspartame, 48
 - citric acid monohydrate, 181
 - dibutyl sebacate, 227
 - ethyl maltol, 257
 - ethylcellulose, 263
 - fructose, 273
 - maltol, 421
 - monosodium glutamate, 452
 - neohesperidin dihydrochalcone, 458
 - neotame, 460
 - saccharin, 605
 - saccharin sodium, 608
 - sodium cyclamate, 643
 - thaumatin, 735
 - trehalose, 746
 - xylitol, 786
- Flavoring agent, capric acid, 384
- Flavoring agents
- adipic acid, 11
 - n*-butyl lactate, 257
 - confectioner's sugar, 710
 - denatonium benzoate, 217
 - dibutyl sebacate, 227
 - ethyl acetate, 253
 - ethyl lactate, 256
 - ethyl maltol, 257
 - ethyl vanillin, 261
 - ethylcellulose, 262
 - fumaric acid, 276
 - leucine, 387
 - malic acid, 411
 - maltol, 421
 - menthol, 433
 - methionine, 436
 - monosodium glutamate, 452
 - phosphoric acid, 503
 - propionic acid, 587
 - sodium acetate, 620
 - sodium lactate, 650
 - sodium propionate, 661
 - tartaric acid, 731
 - thymol, 739
 - triethyl citrate, 756
 - vanillin, 760
- Flolys*, 282
- FlowLac* 90, 376
- FlowLac* 100, 376
- Fluidamid R444P*, 695
- Fluorocarbon 134a, 733
- Fluorocarbon emulsifying agents, poloxamer, 507
- Foaming agents
- hypromellose, 326
 - polyethylene alkyl ethers, 537
- Folic acid, 403, 408
- Forlan* 500, 484
- Formaldehyde, 398
- Formaldehyde hydrosulfite, 645
- Formaldehyde sodium sulfoxylate, 645
- Formaldehydesulfoxylic acid sodium salt, 645
- Forsterite, 403
- Freeze-drying stabilizers/carriers
- albumin, 15
 - lactose
 - anhydrous, 359
 - monohydrate, 364
 - mannitol, 424
 - sodium bicarbonate, 630
 - trehalose, 746
 - see also* Cryoprotectants
- French chalk, purified, 728
- Freon*, 173
- Frigen*, 173
- Frigen* 22, 172
- Frigen* 134a, 733
- Fructamyl*, 273
- Fructofin*, 273
- β -D-Fructofuranosyl-O- α -D-galactopyranosyl-(1 $\rightarrow$ 6)- α -D-glucopyranoside, anhydrous, 603
- β -D-Fructofuranosyl-O- α -D-galactopyranosyl-(1 $\rightarrow$ 6)- α -D-glucopyranoside pentahydrate, 603
- β -D-fructofuranosyl- α -D-glucopyranoside, 703
- D-(–)-fructopyranose, 273
- Fructose, 224, 273
- furanose form, 275
 - high-fructose syrup, 275
 - invert sugar, 706
 - liquid, 275
 - powdered, 275
 - pyranose form, 275
 - sweetness *vs.* dextrose, 273
 - sweetness *vs.* sucrose, 273, 275
 - with povidone, 273
 - with silicon dioxide, 275
- Fructosum, 273
- Fruit sugar, 273
- Fruitose*, 273
- Frutafit*, 339
- Fujicalin*, 94–96
- Fumaric acid, 183, 276, 411, 413, 732
- Fumaric acid, octadecyl ester, sodium salt, 667
- Fumed silica, 185
- Fumed silicon dioxide, 185
- Fuming sulfuric acid, 720
- Fungicides *see* Antifungal agents
- Fused borax, 634
- Fused sodium borate, 634
- G, 295
- Galactomannan, 146
- Galactomannan polysaccharide, 298
- Galactomannans, guar gum, 298
- 4-O-(β -D-Galactopyranosyl)-D-glucitol, 357
- 4-O-(β -D-Galactopyranosyl)-D-glucitol dihydrate, 357
- 4-O-(β -D-Galactopyranosyl)-D-glucitol monohydrate, 357
- O- β -D-Galactopyranosyl-(1 $\rightarrow$ 4)- β -D-glucopyranose, 359
- O- β -D-Galactopyranosyl-(1 $\rightarrow$ 4)- α -D-glucopyranose monohydrate, 364, 376
- β -galactosido-sorbitol, 357
- Galactosol*, 298
- galenIQ*, 342
- Gallic acid propyl ester, 587
- Galzin*, 792
- Gamma aluminum oxide, 37
- Gamma Cyclodextrin, 210
- Gamma tocopherol, 32–33
- Gantrez*, 534
- Gantrez AN-119*, 534
- Garantose*, 605
- Gas-forming agents
- potassium bicarbonate, 570
 - sodium bicarbonate, 630
- Gelatin, 33, 278, 427
- absorbable, 278
 - hard capsules, 278, 762
 - plasticizers
 - glycerin, 283
 - mannitol, 424
 - sorbitol, 679
- Gelatin sponge, 278
- Gelatina, 278
- Gelatine, 278
- Gelcarin*, 122
- Geleol*, 290
- Gelling agents
- aluminum stearate, 35
 - carbomers, 113
 - carboxymethylcellulose sodium, 119
 - carrageenan, 122
 - chitosan, 159
 - colloidal silicon dioxide, 186
 - gelatin, 278
 - glyceryl monooleate, 289
 - glyceryl palmitostearate, 293
 - guar gum, 299–300
 - hydroxyethyl cellulose, 314
 - pectin, 478
 - polyethylene alkyl ethers, 537
 - polyethylene glycol, 518
 - polyethylene oxide, 523
 - polymethacrylates, 526
 - propylene carbonate, 590
 - sodium ascorbate, 625
 - sorbitol, 680
 - xanthan gum, 782
 - zinc acetate, 791
 - see also* Hydrogels; Stiffening agents; Thickening agents; Viscosity-increasing agents
- Gelosa, 13
- Gelose, 13
- Gelsorb*, 393
- Gelucire* 44/14, 557
- Gelucire* 50/13, 557
- Gelvitol*, 564
- Gendorf 450, 608
- Genetron*, 173
- Genetron* 134a, 733
- Genetron* 142b, 171
- Genetron* 152a, 232
- Genoplast B*, 225
- Genu*, 122, 478
- Germall* 115, 337
- Germall* II, 338
- Ghassoulite*, 301
- Gifu Shellac GBN-PH*, 616
- Gifu Shellac Pearl-811*, 616
- Gingelly oil, 614
- Gingili oil, 614
- Ginseng, Korean red, 422
- Glacial acetic acid, 5
- Glaze, pharmaceutical, 618
- Glycerol, 283
- Glidants
- calcium phosphate, tribasic, 99
 - cellulose, powdered, 136
 - colloidal silicon dioxide, 185
 - hydrophobic colloidal silica, 309
 - magnesium oxide, 400
 - magnesium silicate, 402
 - magnesium trisilicate, 408
 - silicon dioxide, 275
 - talc, 728
- Glipizide, 432
- Glucens, substituted, 160
- Glucidex*, 418
- D-Glucitol, 679
- Glucodry*, 418
- Glucomalt*, 282
- D-(+)-Glucopyranose, anhydrous, 224
- D-(+)-glucopyranose monohydrate, 222
- α -D-Glucopyranoside, 1,3,4,6-tetra-O-acetyl- β -D-fructofuranosyl-, tetraacetate, 707
- α -D-glucopyranosyl- β -D-fructofuranoside, 703
- 4-O- α -D-Glucopyranosyl-D-glucitol, 414
- 4-O- α -D-Glucopyranosyl- β -D-glucopyranose anhydrous, 422
- 4-O- α -D-Glucopyranosyl- β -D-glucopyranose monohydrate, 422

- α -D-glucopyranosyl- α -D-glucopyranoside, 746
 4-O- α -D-glucopyranosyl- β -D-glucose, 422
 1-O- α -D-glucopyranosyl-D-mannitol dihydrate (1,1-GPM), 342
 6-O- α -D-glucopyranosyl-D-sorbitol (1,6-GPS), 342
 Glucosaccharonic acid, 250
 Glucose, 222
 and polydextrose, 514
 anhydrous, 224
 liquid, 222, 224, 424
 Glucose, liquid, 282
 Glucose Monohydrate, 222
 Glucose syrup, 282
 hydrogenated, 416
 4-(α -D-glucosido)-D-glucose, 422
 (α -D-glucosido)- α -D-glucoside, 746
 Glucosum liquidum, 282
 Glucosum monohydricum, 222
 Glucosweet, 282
 Gluside, 605
 soluble, 608
 Glutamic acid monosodium salt, 452
 Glutamic acid monosodium salt monohydrate, 452
 Glutamic acid, sodium salt, 452
 Gly, 295
 Glycerides
 almond oil, 29
 hydrogenated vegetable, 722
 Glycerin, 283, 592, 725
 concentrated, 283
 Glycerin monostearate, 290
 Glycerin palmitostearate, 293
 Glycerin solutions, diluted, 285
 Glycerin tricaprilate, 751
 Glycerine, 283
 Glycerine monostearate, 290
 Glycerol, 283
 Glycerol (85 per cent), 285
 Glycerol behenate, 286
 Glycerol Dibehenate, 286
 Glycerol Mono-oleate, 288
 Glycerol monostearate, 290
 Glycerol Monostearate 40–55, 290
 Glycerol palmitostearate, 293
 Glycerol phosphatides, 499
 Glycerol stearate, 290
 Glycerol triacetate, 748
 Glycerol tricaprilate, 751
 Glycerol trielaidate, 757
 Glycerol trioctanoate, 751
 Glyceroli dibehenas, 286
 Glyceroli mono-oleas, 288
 Glyceroli monostearas, 290
 Glycerol-1-oleate, 288
 Glycerolum, 283
 Glyceryl behenate, 286, 294
 Glyceryl dibehenate, 286
 Glyceryl monobehenate, 286
 Glyceryl monooleate, 288, 292
 Glyceryl monostearate, 268, 289–290, 294
 self-emulsifying, 292
 Glyceryl Monostearate 40–55, 290
 Glyceryl palmitostearate, 268, 287, 292–293
 Glyceryl stearate, 290
 Glyceryl triacetate, 748
 Glyceryl tribehenate, 286
 Glyceryl tricaprilate, 751
 Glyceryl tricaprilate/caprinate, 429
 Glyceryl triisooctanoate, 752
 Glyceryl trioctanoate, 751
 Glyceryl trioleate, 757
 Glyceryl tris-2-ethylhexanoate, 752
 Glyceryl-tri-(12-hydroxystearate), 128
 Glycine, 295, 480
 Glycine hydrochloride, 296
 Glycinium, 295
 Glycinum, 295
 Glycoamin, 295
 Glycocoll, 295
 Glycofurol, 297
 Glycofurol 75, 297
 Glycolixir, 295
 Glycoll, 295
 Glycolys, 663
 Glycolys LM, 665
 Glycolys Low pH, 665
 Glycolys LV, 665
 Glycon, 466
 Glycon G-100, 283
 Glykocellan, 118
 Glypesin, 304
 GMS, 290
 Goat's thorn, 744
 Gohsenol, 564
 Gomenoleo oil, 470
 Gomme de caroube, 146
 Gossypol, 202
 Gossypose, 603
 Grain alcohol, 17
 GranuLac, 364
 Granulating agents
 copovidone, 197
 hypromellose, 326
 isomalt, 343
 liquid glucose, 282
 maltitol, 414
 polydextrose, 513
 sucrose, 703
 vitamin E polyethylene glycol succinate, 764
 Grape sugar, 222
 Gray acetate, 82
 Griffithite, 612
 Grindsted, 122, 782
 Groco, 466
 Groundnut oil, 476
 GS-Ceresin, 148
 Guar acetate, 300
 Guar acetate phthalate, 300
 Guar flour, 298
 Guar Galactomannan, 298
 Guar galactomannanum, 298
 Guar gum, 2, 298, 300, 784
 and microcrystalline cellulose, 132
 oxidized, 300
 Guar phthalate, 300
 L-gulo-D-mannoglycuronan, 20
 Gum acacia, 1
 Gum arabic, 1
 Gum benjamin, 744
 Gum dragon, 744
 Gum tragacanth, 744
 Gummi africanum, 1
 Gummi arabicum, 1
 Gummi mimosae, 1
 Gypsum, 105
 calcined, 107
 dried, 107
 Halite, 639
 HallStar CO-1695, 155
 HallStar GMO, 288
 HallStar GMS, 290
 HallStar IPM-NF, 348
 Halocarbon 152a, 232
 Halofantrine, 399
 Halon, 173
 Haloperidol, 760
 Hampshire glycine, 295
 Hard Fat, 722
 Hard fat suppository bases, 431, 722
 additives, 722–723
 chemical reactivity, 723
 melting characteristics, 723
 rheology, 723
 Hard fat triglyceride esters, 722
 Hard water, 769
 Hard wax, 474
 alternatives, 762
 Hardening agents (suppositories)
 hydrogenated vegetable oil, 762
 stearic acid, 697
 Hatcol DBP, 225
 HCFC 22, 172
 HCFC 142b, 171
 HCFCs
 HCFC 22, 172
 HCFC 142b, 171
 see also Hydrochlorofluorocarbons (HCFCs)
 HD-Eutanol V PH, 468
 HE cellulose, 311
 Heavy kaolin, 352
 Heavy liquid petrolatum, 445
 Heavy magnesium carbonate, 397
 Heavy magnesium oxide, 400
 Heavy mineral oil, 445
 HEC, 311
 2-HE- β -CD, 213
 Hectabrite AW, 301
 Hectabrite DP, 301
 Hector clay, 301
 Hectorite, 301, 613
 Helianthi annui oleum raffinatum, 721
 Hellulosum microcrystallinum, 129
 Hematite, 340
 HEMC, 314
 1-heptadecanecarboxylic acid, 697
 Heptafluoropropane, 734
 1,1,1,2,3,3,3-Heptafluoropropane, 303
 Heptafluoropropane (HFC), 303
 Hermesetas, 605
 Hesperetin-7-rutinoside, 459
 Hesperidin, 459
 Hesperitin 7-rhamnoglucoside, 459
 Hest TC, 751
 Hetastarch, 311
 Hexadecanoic acid, 473
 Hexadecanoic acid isopropyl ester, 350
 Hexadecanoic acid 1-methylethyl ester, 350
 Hexadecanoic acid sodium salt, 473
 Hexadecan-1-ol, 155
 1-hexadecanol, 155
 n-hexadecanoic acid, 473
 n-hexadecyl alcohol, 155
 Hexadecylic acid, 473
 Hexadecylpyridinium chloride, 157
 1-hexadecylpyridinium chloride, 157
 1-Hexadecylpyridinium chloride monohydrate, 157
 Hexadecyltrimethylammonium bromide, 152–153
 Hexadecyltrimethylammonium hydroxide, 152
 Hexadecylpyridinium bromide, 158
 Hexadienic acid, 672
 Hexadienoic acid, 672
 2,4-hexadienoic acid, 672
 (E,E)-Hexa-2,4-dienoic acid, 672
 2,4-hexadienoic acid (E,E)-potassium salt, 579
 2,4-Hexadienoic acid potassium salt, 579
 Hexahydrothymol, 433
 1,1'-hexamethylene-bis[5-(p-chlorophenyl)biguanide], 162
 1,1'-hexamethylenebis[5-(4-chlorophenyl)biguanide] diacetate, 164
 1,1'-hexamethylenebis[5-(4-chlorophenyl)biguanide] digluconate, 165

- 1,1'-hexamethylenebis[5-(4-chlorophenyl)biguanide]dihydrochloride, 165
- Hexamic acid, 644
- Hexanedioic acid, 11
- 1,6-hexanedioic acid, 11
- 1,2,3,4,5,6-hexanehexol, 679
- Hexaplast M/B*, 225
- Hexetidine, 304
- Hexetidinum, 304
- Hexigel*, 304
- Hexocil*, 304
- Hexoral*, 304
- Hextril*, 304
- HFA227, 303
- HFA 134a, 733
- HFC227, 303
- HFC 152a, 232, 733
- HFCs
- HFC 134a, 733
 - HFC 152a, 232
 - HFC227, 303
- see also* Hydrofluorocarbons (HFCs)
- Hibiclen*, 165
- Hibiscrub*, 165
- Hibitane*, 165
- Hibitane diacetate*, 164
- Hidroksipropilbetadeksas, 315
- High-fructose syrup, 275
- Hochdisperses silicium dioxid, 185
- Hog gum (caramania gum), 745
- Hombitan FF-Pharma*, 741
- Hopper salt, 637
- HP-50, 336
- HP-55, 336
- HP-55S, 336
- HPMC, 326
- HPMCAS, 330
- HPMCP, 333
- HSA, 14
- Huile d'amande, 29
- Huile de carthame, 610
- Huile de colza, 108
- Huile de tournesol, 721
- Human Albumin Solution, 14
- Human serum albumin, 14
- normal, 14
- Humectants
- ammonium alginate, 41
 - butylene glycol, 77
 - cyclomethicone, 215
 - glycerin, 283
 - polydextrose, 513
 - propylene glycol, 592
 - sodium hyaluronate, 646
 - sodium lactate, 650
 - sorbitol, 679
 - tagatose, 727
 - trehalose, 746
 - triacetin, 748
 - triethanolamine, 754
 - xylitol, 786
- Hyaluronan, 646–647
- see also* Sodium hyaluronate
- Hyaluronate sodium, 646
- Hyaluronic acid, 647
- see also* Sodium hyaluronate
- Hyamine* 1622, 59
- Hyamine* 3500, 56
- Hydagen* CAT, 756
- Hydoxipropylbetadex, 315
- Hydrated aluminum silicate, 352
- Hydrated ferric oxide, 340
- Hydrated lime, 91
- Hydrazine yellow, 195
- Hydrocarbons (HC), 236, 306
- Hydrochloric acid, 308
- concentrated, 308
 - dilute, 309
- Hydrochloric Acid, Concentrated, 308
- Hydrochlorofluorocarbons (HCFCs)
- chlorodifluoroethane, 171
 - nomenclature, 175
- Hydrocortisone, 51
- Hydrofluoroalkanes (HFAs), tetrafluoroethane, 733
- Hydrofluorocarbons (HFCs)
- difluoroethane, 232
 - heptafluoropropane, 303
 - tetrafluoroethane, 733
- Hydrofol*, 473
- Hydrofol acid* 1255, 383
- Hydrofol acid* 1295, 383
- Hydrogels
- hydroxyethyl cellulose, 314
 - sodium alginate, 622
 - urethane, 518
- Hydrogen oxide, 766
- Hydrogen phosphate, 503
- Hydrogen sulfate, 719
- Hydrogenated castor oil, 128, 763
- Hydrogenated coconut oil PEG 1500 esters, 557
- Hydrogenated cottonseed oil, 762
- Hydrogenated glucose syrup, 416
- Hydrogenated isomaltulose, 342
- Hydrogenated lanolin, 379–380
- Hydrogenated maltose, 414
- Hydrogenated Oil, 762
- Hydrogenated palatinose, 342
- Hydrogenated palm oil, 762
- Hydrogenated palm oil PEG 1500 esters, 557
- Hydrogenated palm/palm kernel oil PEG 300 esters, 557
- Hydrogenated soybean oil, 762
- Hydrogenated vegetable glycerides, 722
- Hydrogenated vegetable oil, 431, 762
- type I, 129, 203, 762
 - type II, 763
 - applications, 763
- Hydrogenated vegetable oil, type II, 763
- Hydrogenated wool fat, 379
- α -Hydro- ω -hydroxypoly(oxy-1,2-ethanediyl), 517
- α -Hydro- ω -hydroxypoly(oxyethylene)poly(oxypropylene) poly(oxyethylene) block copolymer, 506
- Hydroksipropylbetadeksi, 315
- Hydromagnesite, 397
- 2-hydroperfluoropropane, 303
- Hydrophobic Colloidal Anhydrous Silica, 309
- Hydrophobic colloidal silica, 188, 309
- Hydrous lanolin, 379–380
- Hydrous magnesium calcium silicate, 728
- Hydrous magnesium silicate, 728
- Hydroxyaluminum distearate, 36
- Hydroxyaluminum tristearate, 36
- 4-Hydroxy-*m*-anisaldehyde, 760
- Hydroxybenzene, 485
- 4-hydroxybenzoic acid butyl ester, 78
- 4-hydroxybenzoic acid ethyl ester, 270
- 4-hydroxybenzoic acid methyl ester, 441
- 4-hydroxybenzoic acid propyl ester, 596, 599
- Hydroxybutanedioic acid, 411
- (R)-(+)-Hydroxybutanedioic acid, 413
- (RS)-($\pm$)-Hydroxybutanedioic acid, 411
- (S)-(-)-hydroxybutanedioic acid, 413
- 2-hydroxy-1,4-butanedioic acid, 411
- 3-hydroxy-*p*-cymene, 739
- 1-hydroxy-1,2-ethanedicarboxylic acid, 411
- 4-hydroxy-3-ethoxybenzaldehyde, 261
- β -hydroxyethyl benzene, 490
- Hydroxyethyl cellulose, 266, 311, 315, 321, 329, 332, 440
- 2-hydroxyethyl cellulose ether, 311
- 2-hydroxyethyl ester stearic acid, 268
- Hydroxyethyl ether cellulose, 311
- Hydroxyethyl methylcellulose, 314
- β -hydroxyethyl phenyl ether, 488
- Hydroxyethyl starch, 311
- 4-O-(2-Hydroxyethyl)-1-O-[2,5,7,8-tetramethyl-2-(4,8,12-trimethyltridecyl)-3,4-dihydrochromen-6-yl]butanedioate, 764
- β -hydroxyethylamine, 450
- 2-hydroxyethylamine, 450
- Hydroxyethylcellulose, 311
- Hydroxyethylcellulosum, 311
- 2-Hydroxyethyl- β -cyclodextrin, 213, 716
- 2-Hydroxyethyl-12-hydroxyoctadecanoate, 391
- Hydroxyethylmethyl cellulose, 266, 314, 324, 329, 440
- Hydroxyethylmethylcellulose, 314
- 3-hydroxy-2-ethyl-4-pyrone, 257
- Hydroxylapatite, 99–100
- Hydroxylpropyl starch, 325
- p*-hydroxy-*m*-methoxybenzaldehyde, 760
- 4-Hydroxy-3-methoxybenzaldehyde, 760
- (3S,4S,5R)-2-(hydroxymethyl)oxane-2,3,4,5-tetrol, 727
- 3-Hydroxy-2-methyl-4 *H* -pyran-4-one, 421
- 3-hydroxy-1-methyl-4-isopropylbenzene, 739
- 3-Hydroxy-2-methyl-(1,4-pyran), 421
- 3-hydroxy-2-methyl-4-pyrone, 421
- N*-(hydroxymethyl)-*N*-(1,3-dihydroxymethyl-2,5-dioxo-4-imidazolidinyl)-*N'*-(hydroxymethyl)urea, 338
- (2R,3R,4S,5R,6R)-2-(Hydroxymethyl)-6-[(2R,3R,4S,5R,6R)-3,4,5-trihydroxy-6-(hydroxymethyl)oxan-2-yl]oxy-oxane-3,4,5-triol anhydrous, 746
- (2R,3R,4S,5R,6R)-2-(Hydroxymethyl)-6-[(2R,3R,4S,5R,6R)-3,4,5-trihydroxy-6-(hydroxymethyl)oxan-2-yl]oxy-oxane-3,4,5-triol dihydrate, 746
- 12-Hydroxyoctadecanoic acid polymer with α -hydro- ω -hydroxypoly(oxy-1,2-ethanediyl), 391
- 1-hydroxy-2-phenoxyethane, 488
- 2-hydroxypropane 1,2,3-tricarboxylic acid, 183
- 2-hydroxy- β -1,2,3-propanetricarboxylic acid, 183
- 2-hydroxypropane-1,2,3-tricarboxylic acid monohydrate, 181
- 2-Hydroxy-1,2,3-propanetricarboxylic acid triethyl ester, 756
- 2-Hydroxy-1,2,3-propanetricarboxylic acid tripotassium salt anhydrous, 574
- 2-Hydroxy-1,2,3-propanetricarboxylic acid tripotassium salt monohydrate, 574
- 2-hydroxypropanoic acid, 355
- 2-hydroxypropanoic acid, calcium salt, 92
- 2-hydroxypropanoic acid ethyl ester, 256
- 2-hydroxypropanoic acid monosodium salt, 650
- 2-hydroxypropanol, 592
- α -hydroxypropionic acid, 355
- 2-Hydroxypropionic acid, 355
- (R)-(-)-2-Hydroxypropionic acid, 355
- (RS)-($\pm$)-2-Hydroxypropionic acid, 355
- (S)-(+)-2-Hydroxypropionic acid, 355
- Hydroxypropyl alginate, 594
- Hydroxypropyl betadex, 315, 716
- Hydroxypropyl cellulose, 314, 317, 324, 329, 332
- low-substituted, 314, 321
- Hydroxypropyl cellulose, low-substituted, 322
- 2-hydroxypropyl cyclomaltoheptaose, 315
- 2-hydroxypropyl ether (low-substituted) cellulose, 322

- Hydroxypropyl methylcellulose, 326
 Hydroxypropyl methylcellulose benzene-1,2-dicarboxylate, 333
 2-hydroxypropyl methylcellulose phthalate, 333
 Hydroxypropyl starch, 325, 690
 pregelatinized, 325
 Hydroxypropyl starch-methyl methacrylate (HS-MMA), 325
 Hydroxypropylbetadexum, 315
 Hydroxypropyl-betadex, 213, 315
 Hydroxypropylbetadexum, 315
 Hydroxypropylcellulose, 317
 Hydroxypropylcellulose, 317
 3-Hydroxypropyl- β -cyclodextrin, 316, 716
 2-hydroxypropyl- β -cyclodextrin, 315
 12-hydroxystearic acid polyethylene glycol copolymer, 391
 Hydroxysuccinic acid, 411
 2-hydroxysuccinic acid, 411
 6-hydroxy-5-[(4-sulfophenyl)azo]-2-naphthalenesulfonic acid disodium salt, 194
 α -hydroxytoluene, 64, 203
 butylated, 379–380, 382
 3-hydroxytoluene, 204–205
 Hyetellose, 311
 Hyfatol 16-95, 155
 Hyfatol 16-98, 155
 Hyfatol 18-95, 700
 Hyfatol 18-98, 700
 Hygum TP-1, 122
 Hylon, 685
 Hymetellose, 314
 Hy-Phi, 466
 Hyprolose, 317
 Hyprolose, low-substituted, 322
 Hypromellose, 314–315, 321, 326, 332, 336, 440
 Hypromellose acetate succinate, 329–330
 Hypromellose phthalate, 145, 329, 332–333, 563
 film coat splitting, 333, 335
 plasticizers, 333
 Hypromellosi phthalas, 333
 Hypromellose, 326
 HyQual, 35, 103, 793
 HyQual Aluminum Monostearate NF Fine Powder, 36
 HyQual Aluminum Monostearate NF Powder, 36
 Hystrene, 697
 Hystrene 9016, 473
 Hystrene 9512, 383
 Ibuprofen, 156
 Ichthammol, 450, 484
 Icing sugar, 710
 Idoxuridine, 238
 Imidazolidinyl urea, 337
 Imidurea, 337
 and methylparabens, 442
 synergists, 247
 2,2'-Iminobisethanol, 228
 2,2'-iminodiethanol, 228
 Imperial, 728
 Implantable drug delivery systems
 aliphatic polyesters, 23
 gelatin, 278
 glyceryl monostearate, 291
 Improved Kelmar, 566
 Impruvol, 75
 Imwitor 191, 290
 Imwitor 900, 290
 Imwitor 948, 288
 Indigo blue, soluble, 193
 Indigo carmine, 193
 Indigotine, 193
 Industrene, 466, 697
 Industrene 4516, 473
 Industrial methylated spirit, 19
 Inhalac, 362
 Inhalation lactose, 362
 Inhalers
 dry powder diluents/carrier, lactose, anhydrous, 359
 dry powder diluents/carriers
 inhalation lactose, 362
 mannitol, 424
 Inhalers, dry powder diluents/carrier, *see also* Metered-dose inhalant formulations
 Inipol DS, 11
 Insect repellents
 dibutyl phthalate, 226
 dimethyl phthalate, 236
 Instagel, 278
 Instant Pure-Cote, 690
 Instastarch, 691
 Intense sweeteners *see* Sweetening agents
 Intracol, 739
 Inulin, 339
 Invert sugar, 706
 Iodine, 247
 Ionol CP, 75
 IPA, 346
 Irish moss extract, 122
 Iron hydrate, 340
 Iron hydroxide, 340
 Iron hydroxide oxide, 340
 Iron (II, III) oxide, 340
 Iron (III) oxide, anhydrous, 340
 Iron (III) oxide monohydrate, yellow, 340
 Iron oxide, 340, 721
 Iron oxide black, 340
 Iron oxide red, 340
 Iron oxide yellow, 340
 Iron oxides, 189, 193, 340
 Iron oxides (Fe, 340
 Isceon, 173
 Isceon 22, 172
 Isceon 134a, 733
 Isinglas
 Bengal, 13
 Ceylon, 13
 Chinese, 13
 Japan, 13
 Isoarachidyl alcohol, 465
 D-isoascorbic acid, 250
 Isobutane, 306
 Isomalt, 342
 with polydextrose, 513
 IsoMaltidex 16500, 342
 Isomaltulose, hydrogenated, 342
 Isomaltum, 342
 Isopropanol, 346
 Isopropyl alcohol, 18, 346
 Isopropyl cresol, 739
 Isopropyl ester of myristic acid, 348
 Isopropyl hexadecanoate, 350
 Isopropyl lanolate, 380
 Isopropyl metacresol, 739
 Isopropyl myristate, 348, 351
 Isopropyl palmitate, 349–350
 Isopropyl-*m*-cresol, 739
 6-isopropyl-*m*-cresol, 739
 Isopropylis myristas, 348
 Isopropylis palmitas, 350
 2-isopropyl-5-methylcyclohexanol, 433
 2-isopropyl-5-methylphenol, 739
 Isopropylmyristat, 348
 Isopropylpalmitat, 350
 Isotrehalose, 747
 Isotron, 173
 Isovitamin C, 250
 Jaguar gum, 298
 Japan agar, 13
 Japan isinglass, 13
 Jarcol 1-20, 465
 Jeechem, 542
 Jeechol ODD, 465
 Jeweller's borax, 634
 Jinjili oil, 614
 Kainite, 573
 Kali disulfis, 577
 Kalii chloridum, 572
 Kalii citras, 574
 Kalii hydrogenocarbonas, 570
 Kalii hydroxidum, 576
 Kalii sorbas, 579
 Kalinite, 567
 Kalipol 32, 659
 Kalium benzoat, 569
 Kalium hydroxydatum, 576
 Kaltostat, 83
 Kaolin, 55, 62, 302, 352, 396, 613
 heavy, 352
 light, 352
 light (natural), 352
 Kaolin, Heavy, 352
 Kaolinite, 352–353
 Kaolinosis, 353
 Kaolinum ponderosum, 352
 Karstenite, 105
 Karvol, 740
 Katchung oil, 476
 Katemfe, 735
 KC Flock, 136
 Kelacid, 20
 Kelcoloid, 594
 Kelcosol, 622
 Keldent, 782
 Keltone, 622
 Keltose, 41
 Keltrol, 782
 Kemilub, 793
 Kemira AFDC, 741
 Kemistab EC-F, 103
 Kemsol, 238
 Kemstrene, 283
 Keoflo ADP, 695
 Kessco CA, 155
 Kessco EO, 259
 Kessco GMO, 288
 Kessco GMS, 290
 Kessco IPM 95, 348
 Kessco IPP, 350
 Ketoprofen, 294
 β -ketopropane, 7
 2-ketopyrrolidine, 600
 Kimiloid, 594
 Klea 134a, 733
 Kleptose, 210
 Kleptose HPB, 315
 Klinit, 786
 Klucel, 317
 Kodaflex DBP, 225
 Kodaflex DBS, 227
 Kodaflex DEP, 230
 Kodaflex DMP, 236
 Kolatin, 278
 Kollicoat MAE, 525
 Kollicoat MAE 30 DP, 526
 Kollicoat MAE 100 P, 526
 Kollidon, 581
 Kollidon CL, 208
 Kollidon CL-M, 208
 Kollidon VA 64, 196, 198

- Kortacid* 1895, 697
Koster Keunen Ceresine, 148
Kronos 1171, 741
Krystar, 273
- Labrafac* CC, 429
Labrafac Lipo, 429
Labrafil M1944CS, 557
Labrafil M2125CS, 557
Labrasol, 557
 Lac, 616
 Lac dye, 618
 Lacca, 616
 Laccaic acid B, 618
Lacolin, 650
 Lactic acid, 27, 93, 355, 516, 651
 racemic, 355
 DL-lactic acid, 355
 Lactic acid butyl ester, 257
 Lactic acid, calcium salt, 92
 D-lactic acid-L copolymer, 515
 Lactic acid ethyl ester, 256
 Lactic acid homopolymer, 515
 Lactic acid monosodium salt, 650
 D,L-lactic acid polymer, 515
 Lactic acid sodium salt, 650
 D-lactide-L-lactide copolymer, 515
 DL-lactide polymer, 515
 Lactil, 357
 Lactite, 357
 Lactitol, 357
 sweetness *vs.* sucrose, 358
 with lactose, 357
 with polydextrose, 513
 Lactitol Monohydrate, 357
 Lactitol monohydricum, 357
 Lactobiosit, 357
Lactochem, 364
Lactohale, 362
 γ -lactone, 250
Lactopress Anhydrous, 359
Lactopress Anhydrous 250, 359
Lactopress Spray-Dried, 376
Lactopress Spray-Dried 250, 376
 Lactose, 276, 364, 376
 anhydrous, 359, 363, 368, 377
 inhalation, 361–362, 368, 377
 monohydrate, 361, 363–364, 370, 372–373, 375, 377
 and corn starch, 368
 and microcrystalline cellulose, 368
 and povidone, 368
 and powdered cellulose, 368
 spray dried, 361, 368, 376
 with lactitol, 357
 Lactose, anhydrous, 359
 Lactose Hydrate, 364
 Lactose, inhalation, 362
 Lactose, monohydrate, 364
 Lactose, monohydrate and corn starch, 370
 Lactose, monohydrate and microcrystalline cellulose, 371
 Lactose, monohydrate and povidone, 373
 Lactose, monohydrate and powdered cellulose, 374
 Lactose monohydrate, O- β -D-galactopyranosyl-(1 $\rightarrow$ 4)- α -D-glucopyranose monohydrate, 362
 Lactose, spray-dried, 376
 Lactosit, 357
 Lactosum anhydricum, 359
 Lactosum monohydricum, 364
Lacty, 357
 Laevulose, 273
 Lakes (coloring agents), 189
 Lampante virgin olive oil, 471
- Lanalcolum, 382
Lanette, 770
Lanette 16, 155
Lanette 18, 700
Lanette O, 150
Lanette SX, 770
Lanette Wax KS, 456
 Lanolin, 180, 378, 381, 383
 acetylated, 380
 anhydrous, 378
 hydrogenated, 379–380
 hydrous, 379–380, 383
 liquid, 380
 modified, 379–380
 purified, 378
 water-soluble, 380
 Lanolin alcohols, 180, 379, 381–382, 449–450, 484–485
 and mineral oil, 448, 485
 and petrolatum, 450, 483–484
 and white soft paraffin, 484
 and yellow soft paraffin, 484
 mineral oil and, 449
 Lanolin alcohols ointment, 485
 Lanolin anhydrous, 378
 Lanolin hydrous, 180, 380
 Lanolin oil, 380
 Lanolin wax, 380
 Lanolina, 378
 Lansoprazole, 398
Laponite, 301
 Larixinic acid, 421
 Latex particle coating agents, 145
 Lattosio, 359
 Laughing gas, 463
 Laureth-N, 536
 Lauric acid, 383, 455, 457, 473
 Lauromacrogol, 536
 Laurostearic acid, 383
 Lauroyl Macrogolglycerides, 557
 Lauroyl Polyoxylglycerides, 557
 Lauryl gallate, 589
 Lauryl sodium sulfate, 651
 Lauryl sulfate, sodium salt, 651
 N-lauryl-N,N,N-trimethylammonium bromide, 153
 Layor carang, 13
 Leavening agents, potassium bicarbonate, 570
 Lecithin, 385, 501
 and alpha tocopherol, 31
 solvents, glycerin monostearate, 290
 unpurified, 387
 vegetable, 385
 Leinoleic acid, 389
Lemol, 564
 Leu, 387
 Leucine, 387–388
 DL-leucine, 387
 Leucinum, 387
 Levofloxacin, incompatibilities, sodium bicarbonate, 631
 Levomenthol, 435
 Levomentholum, 435
 Levulose, 273
Lexalt L, 355
Lexgard B, 78
Lexol IPM-NF, 348
Lexol IPP-NF, 350
LH-21, 323
LH-22, 323
LH-31, 323
LH-32, 323
LH-B1, 323
L-HPC, 322
 Lichenic acid, 276
 Licianite, 612
- Ligalub*, 288
 Light Anhydrous Silicic Acid, 185
 Light kaolin, 352
 Light kaolin (natural), 352
 Light liquid petrolatum, 447
 Light magnesium oxide, 400
 Light mineral oil, 447, 475, 483
 Light spar, 105
 Light white mineral oil, 447
 Lignocaine benzyl benzoate, 217
 Lignoceric acid, peanut oil, 476
 Lime
 acetate of, 82
 hydrated, 91
 precipitated carbonate of, 86
 slaked, 91
 sulfate of, 107
 Lime acetate, 82
 Lime pyrolignite, 82
 Lincomycin, 353
 Linoleic acid, 389
 and almond oil, 29
 and alpha tocopherol, 31
 and corn oil, 199
 and cottonseed oil, 202
 castor oil, 126
 peanut oil, 476
 sunflower oil, 721
 9,12-linoleic acid, 389
 Linoleic acid ethyl ester, 389
 Linolenic acid
 and corn oil, 199
 canola oil, 109
 Linoleoyl Macrogolglycerides, 557
 Linoleoyl Polyoxylglycerides, 557
 Linolic acid, 389
Lion, 352
Lipex 107, 682
Lipex 108, 108
Lipex 200, 682
Lipex 204, 108
Lipo GMS, 290
Lipocol, 542
Lipocol C, 155
Lipocol S, 700
Lipocol S-DEO, 700
Lipoid, 499
Lipolan, 380
Liponate IPP, 350
Liponate SPS, 774
Liponic 70-NC, 679
Liponic 76-NC, 679
Liposyn II, 611
Lipovol CAN, 108
Lipovol CO, 126
Lipovol HS-K, 762
Lipovol SES, 614
Lipowax P, 777
Lipoxol, 517
 Liquefied phenol, 487
 Liquid fructose, 275
 Liquid Glucose, 282
 Liquid lanolin, 380
 Liquid Maltitol, 416
 Liquid paraffin and lanolin alcohols, 449
 Liquid petrolatum, 445
 heavy, 445
Lissolamine V, 152
Litesse, 513
 Locust bean gum, 146
 Locust tree extract, 147
 Loperamide, 51
Lorol C14-95, 456
LoSalt, 573
 Low erucic acid colza oil, 108
 Low erucic acid rapeseed oil, 108

- Low Substituted Hydroxypropylcellulose, 322
 Low-substituted hydroxypropyl cellulose, 322
 Low-substituted hypromellose, 322
Loxanol V, 456
LSC 5050, 385
LSC 6040, 385
 Lubricants (general)
 canola oil, 108
 hydroxyethyl cellulose, 311
 lauric acid, 383
 leucine, 387
 mineral oil, 446
 octyldodecanol, 465
 poloxamers, 507
 polyvinyl alcohol, 564
 sodium hyaluronate, 646
 talc, 728
 tricaprylin, 751
 Lubricants (surgeons'/exam gloves)
 sterilizable maize starch, 695–696
 triethanolamine, 754
 Lubricants (tablet/capsule)
 calcium stearate, 103
 glycerin monostearate, 290
 glyceryl behenate, 286
 glyceryl palmitostearate, 293
 hydrogenated castor oil, 128
 hydrogenated vegetable oil type I, 762
 light mineral oil, 447
 magnesium lauryl sulfate, 653
 magnesium stearate, 404, 418
 medium-chain triglycerides, 429
 mineral oil, 445
 myristic acid, 455
 palmitic acid, 473
 poloxamer, 507
 polyethylene glycol, 517
 sodium benzoate, 627
 sodium chloride, 637
 sodium lauryl sulfate, 651
 sodium stearyl fumarate, 667
 stearic acid, 691, 697
 talc, 728
 zinc stearate, 793
 see also Coating agents
 Lubricants (tablet/capsule)potassium benzoate, 569
Lubritab, 762
 Lucianite, 612
Ludipress LCE, 373
Lunac P-95, 473
Lustre Clear, 132
Lutrol, 506, 508
Lutrol E, 517
Luviskol, 198
Luviskol VA, 196
Luviskol VA 64, 198
Luzenac Pharma, 728
Lycadex PF, 222
Lycasin 80/55, 416
Lycasin 80/55 (Roquette), 416
Lycasin HBC, 416
Lycatab C, 691
Lycatab DS, 420
Lycatab DSH, 418
Lycatab PGS, 691
 Lye, 648
 Lyophilization see Freeze-drying stabilizers/
 carriers
D-lyxo-Hexulose, 727–728
 Macrogol 15 hydroxystearate, 391
 Macrogol 400, 517
 Macrogol 1500, 517
 Macrogol 4000, 517
 Macrogol 6000, 517
 Macrogol 20000, 517
 Macrogol Cetostearyl Ether, 536
 Macrogol ethers, 536
 Macrogol Lauryl Ether, 536
 Macrogol Oleyl Ether, 536
 Macrogol stearate 400, 554
 Macrogol stearates, 554
 Macrogol Stearyl Ether, 536
 Macrogola, 517
 Macrogolglyceridum caprylocaprates, 557
 Macrogolglyceridum laurates, 557
 Macrogolglyceridum linoleates, 557
 Macrogolglyceridum oleates, 557
 Macrogolglyceridum stearates, 557
 Macrogolglycerol Hydroxystearate, 542
 Macrogolglycerol Ricinoleate, 542
 Macrogolglyceroli hydroxystearas, 542
 Macrogolglyceroli ricinoleas, 542
 Macrogoli 15 hydroxystearas, 391
 Macrogoli aether cetostearyllicus, 536
 Macrogoli aether laurilicus, 536
 Macrogoli aether oleicus, 536
 Macrogoli aether stearyllicus, 536
 Macrogols, 517
Magcal, 400
Magchem 100, 400
MagGran CC, 86
Maglite, 400
Magnabrite, 393
 Magnesia, 400
 calcined, 400
 Magnesia monoxide, 400
 Magnesia usta, 400
 Magnesii oxidum leve, 400
 Magnesii oxidum ponderosum, 400
 Magnesii stearas, 404
 Magnesii subcarbonas levis, 397
 Magnesii subcarbonas ponderosus, 397
 Magnesii trisilicas, 408
 Magnesite, 399
 calcinated, 400
 Magnesium aluminosilicate, 393
 Magnesium aluminum silicate, 51, 55, 302,
 353, 393, 403, 405, 409, 613, 730, 782,
 784
 activated attapulgite, 51
 and propylparaben, 597
 hydrated, 51
 saponite, 612
 Magnesium aluminum silicate, colloidal, 393
 Magnesium aluminum silicate, complex
 colloidal, 393
 Magnesium calcium silicate, hydrous, 728
 Magnesium carbonate, 397, 573
 anhydrous, 399
 heavy, 397
 light, 397
 normal, 399
 Magnesium carbonate anhydrous, 397, 399
 Magnesium carbonate hydroxide, 399
 Magnesium carbonate, normal hydrate, 399
 Magnesium distearate, 404
 Magnesium hydrogen metasilicate, 728
 Magnesium lauryl sulfate, 653
 Magnesium mesotrisilicate, 408
 Magnesium metasilicate, 403
 Magnesium octadecanoate, 404
 Magnesium orthosilicate, 403
 Magnesium oxide, 400, 696
 heavy, 400
 light, 400
 Magnesium Oxide, Heavy, 400
 Magnesium Oxide, Light, 400
 Magnesium salt, 393
 Magnesium silicate, 402, 409, 730
 hydrous, 728
 synthetic, 402
 Magnesium stearate, 105, 404, 418, 427, 691,
 699, 794
 crystalline forms, 405
 dextrates, 218
 incompatibilities, 531
 Magnesium trisilicate, 55, 396, 403, 408, 730
 and propylparaben, 597
 anhydrous, 409
 methylparabens incompatibility, 443
 preservative inactivation, 408
 Magnesium trisilicate anhydrous, 409
 Magnetite, 340
Magnyox, 400
Magsil Osmanthus, 728
Magsil Star, 728
 Maize oil, 199
 refined, 199
 Maize starch, 690
 sterilizable, 690, 695
Majsao CT, 199
Malbit, 414
Maldex, 418
Maldex G, 418
 Maleic acid, 410
 Maleinic acid, 410
 Malic acid, 183, 277, 411, 413, 732
 DL-malic acid, 411
 Malt sugar, 422
*Malta*Gran*, 418
Maltisorb, 414
Maltisorb 75/75, 416
Maltisweet 3145, 416
Maltit, 414
 Maltitol, 414, 416–417
 with polydextrose, 513
 Maltitol, Liquid, 416
 Maltitol solution, 416, 681
 Maltitol syrup, 416
 Maltitolum, 414
 Maltitolum liquidum, 416
 Maltobiose, 422
 Maltodextrin, 222, 418, 690
 Maltodextrinum, 418
Maltodiase, 422
 Maltol, 257–258, 421
 Maltose, 282, 422
 crystalline, 423–424
 dextrimaltose, 222
 hydrogenated, 414
Maltose HH, 422
Maltose HHH, 422
 Maltose Hydrate, 422
Maltosweet, 418
Maltrin, 418, 420
Maltrin QD, 418
 Manna sugar, 424
 D-mannite, 424
 Mannitol, 253, 424, 681
 recommended lubricants, 427
 sweetness vs. xylitol, 789
 vs. sorbitol, 427
 Mannitolum, 424
Mannogem, 424
Mantrolac HP-55, 333
Mantrolac R-49, 616
Mantrolac R-52, 616
Manucol Ester, 594
Mapeg, 542
Mapico Black EC, 340
Mapico Yellow EC, 340
Mapolose, 438
Marcoat 125, 616
 Margarine, oleomargarine, 721
Marine Colloids, 122
Marlosol, 554

- Marlowet, 536, 542
 Marmag, 400
 Massa Estarinum, 722
 Massupol, 722
 Masurf Emulsifying Wax NF, 777
 Matrix-forming agents, shellac, 616
 Maydis amylum, 685
 Maydis oleum raffinatum, 199
 Maydol, 199
 MCC Sanaq, 129
 MCT, 751
 MCT oil, 429
 Mebeverine hydrochloride, 403, 408
 Medicated confectionery bases
 polydextrose, 513
 sucrose, 703
 see also Chewable tablet formulations
 Medilave, 157
 Medium-chain triglycerides, 429, 725, 752, 763
 plastics incompatibility, 430
 Medophyll, 739
 Meerscham, 403
 Meglumin, 431
 Meglumina, 431
 Meglumine, 431
 Megluminum, 431
 Melbiose, 604
 Melitose, 603
 Melitriose, 603
 Melojel, 685
p-menthan-3-ol, 433
 3-*p*-menthanol, 433
 Menthol, 433–435, 740
 racemic, 433–434
 Menthol, Racemic, 433
 Mentholum racemicum, 433
 Menthomenthol, 433
 Mentoli, 433
 Mentolis, 433
 1-Mercaptoglycerol, 454
 1-mercapto-2,3-propanediol, 454
 Mercuriphenyl nitrate, 496
 Mercuriothiolate, 736
 Merigel, 691
 Meritena, 685, 695
 Meritol, 679
 Merkur, 481
 Merphenyl nitrate, 496
 meso-erythritol, 251
 meso-xylitol, 786
 Metaboric acid, 68
 Metacetic acid, 586
 meta-cresol, 204
 Metagin, 441
 Metallac, 793
 Metaupon, 466
 Metered-dose inhalant formulations, 174
 CFC-free, 733
 heptafluoropropane, 303
 tetrafluoroethane, 733–734
 see also Inhalers, dry powder diluents/
 carriers; Propellants
 Methacrylic Acid Copolymer, 525
 Methacrylic Acid Copolymer Dispersion, 525
 Methacrylic acid, methyl ester, 532
 Methacrylic acid polymer with divinylbenzene,
 506
 Methacrylic acid polymer with divinylbenzene,
 potassium salt, 504
 Methacrylic Acid–Ethyl Acrylate Copolymer
 (1 : 1), 525
 Methacrylic Acid–Ethyl Acrylate Copolymer
 (1 : 1) Dispersion 30 per cent, 525
 Methacrylic Acid–Methyl Methacrylate
 Copolymer (1 : 1), 525
 Methacrylic Acid–Methyl Methacrylate
 Copolymer (1 : 2), 525
 Methaform, 166
 Methane carboxylic acid, 5
 Methanebis[N,N' (5-ureido-2,4-
 diketotetrahydroimidazole)-N,N'-
 dimethylol], 337
 Methanesulfonic acid, 645
 Methanol, 19
 Methionine, 436–437
 Methioninum, 436
 Methocel, 326, 329, 438
 Methocel E Premium LV, 327
 Methocel ELVP, 327
 Methopectin, 478
 3-methoxy-4-hydroxybenzaldehyde, 760
 Methoxymethane, 235
 Methyl 4-hydroxybenzoate, soluble, 444
 Methyl *N*-L- α -aspartyl-L-phenylalaninate, 48
 Methyl benzene-1,2-dicarboxylate, 236
 Methyl carbinol, 17
 Methyl cellulose, 314
 Methyl Chemosept, 441
 Methyl ether, 235
 Methyl ethylene glycol, 592
 Methyl glycol, 592
 Methyl hydroxy propionate, 257
 Methyl Hydroxybenzoate, 441
 Methyl 4-hydroxybenzoate potassium salt, 444
 Methyl 4-hydroxybenzoate sodium salt, 444
 Methyl hydroxypropylcellulose, 326
 Methyl isobutyl ketone, 19
 Methyl lactate, 257
 Methyl linoleate, 389
 Methyl linolenate, 31
 Methyl methacrylate, 532
 Methyl methacrylate polymer, 533
 Methyl 2-methylpropenoate, 532
 Methyl 9-octadecanoate, 260
 Methyl oleate, 260
 Methyl Parahydroxybenzoate, 441
 Methyl Parasept, 441
 Methyl pectin, 478
 Methyl pectinate, 478
 Methyl polysiloxane, 233
 2-methyl pyromeconic acid, 421
 Methylacetic acid, 586
 Methylacetic acid, sodium salt, hydrate, 661
 1-methylamino-1-deoxy-D-glucitol, 431
 Methylated spirit, industrial, 19
 1-methylazacyclopentan-2-one, 601
N-methyl- γ -butyrolactam, 601
 Methylcellulose, 266, 314–315, 324, 329, 332,
 427, 438
 alternatives, guar gum, 298
 Methylcellulose propylene glycol ether, 326
 Methylcellulosum, 438
 3-methyl-4-chlorophenol, 168
 6-methyl-3,4-dihydro-1,2,3-oxathiazin-4(3*H*)-
 one-2,2-dioxide potassium salt, 3
 $\pm$ -4-Methyl-1,3-dioxolan-2-one, 590
 Methylidopa, 760
N,N'-Methylenebis[N'-(3-(hydroxymethyl)-2,5-
 dioxo-4-imidazolidinyl]urea], 337
 1,1'-methylenebis[3-(3-(hydroxymethyl)-2,5-
 dioxo-4-imidazolidinyl]urea], 337
 1-Methylethyl hexadecanoate, 350
 1-Methylethyl tetradecanoate, 348
N-methylglucamine, 431
N-methyl-D-glucamine, 431
 Methyl-4-hydroxybenzoate, 441
 Methylhydroxyethylcellulose, 314
 Methylhydroxyethylcellulosum, 314
 1-methyl-3-hydroxy-4-isopropylbenzene, 739
 Methylhydroxypropylcellulose phthalate, 333
 2-methyl-3-hydroxy-4-pyrone, 421
 Methylis parahydroxybenzoas, 441
 5-methyl-2-isopropylphenol, 739
 (1*R*,2*S*,5*R*)-(-)-5-methyl-2-(1-
 methylethyl)cyclohexanol, 435
 (1*R*,2*R*,5*R*)-(+)-5-methyl-2-(1-
 methylethyl)cyclohexanol, 433
 (1*S*,2*R*,5*S*)-(+)-5-methyl-2-(1-
 methylethyl)cyclohexanol, 435
 5-methyl-2-(1-methylethyl) phenol, 739
 4-methylnorvaline, 387
 6-Methyl-1,2,3-oxathiazin-4(3*H*)-one-2,2-
 dioxide potassium salt, 3
 4-methyl-2-oxo-1,3-dioxolane, 590
 Methylparaben, 80, 272, 337, 441, 598, 600
 and hydroxypropyl cellulose, 320
 and methylcellulose, 440
 and propylene glycol, 442–443
 and propylparaben, 596
 see also Parabens
 Methylparaben potassium, 444
 Methylparaben sodium, 444
 Methylphenol, 203
 3-methylphenol, 204–205
 2-methylpropane, 306
 2-methyl-2-propenoic acid polymer with
 divinylbenzene, 506
 2-Methyl-2-propenoic acid polymer with
 divinylbenzene, potassium salt, 504
 Methylprotocatechuic aldehyde, 760
N-methyl- α -pyrrolidinone, 601
 1-Methyl-2-pyrrolidinone, 601
N-Methylpyrrolidone, 601
N-methylpyrrolidone, 601
 Methylsulfoxide, 238
 γ -methylthio- α -aminobutyric acid, 436
 8-methyltolcol, 33
 Methyltrimethylene glycol, 77
 Metolose, 326, 438
 Mexpectin, 478
 Meyprodor, 298
 Meyprofin, 298
 Meyprofleur, 146
 Meyprogat, 298
 MHEC, 314
 MHPC, 326
 Micol, 152
 Micro-Cel, 101
 Microcel 3E-150, 136
 Microcelac 100, 371
 Microcrystalline, wax, 149
 Microcrystalline cellulose, 129
 and carboxymethylcellulose sodium, 132
 and carrageenan, 132
 and guar gum, 132
 lactose, monohydrate, mixture, 371
 silicified, 132
 Microcrystalline Cellulose and
 Carboxymethylcellulose Sodium, 134
 Microcrystalline Cellulose and Carmellose
 Sodium, 134
 Microcrystalline cellulose and carrageenan, 132
 Microcrystalline cellulose and guar gum, 132
 Microcrystalline cellulose spheres, 713
 Microcrystalline wax, 475, 775, 780–781
 Micromite, 86
 Miglyol 808, 751–752
 Miglyol 810, 429
 Miglyol 812, 429
 Milk acid, 355
 Milk sugar, 359
 Mineral jelly, 481
 Mineral oil, 445, 448–450, 483, 485
 and lanolin alcohols, 448
 heavy, 445
 light, 447, 475, 483
 light white, 447

- white, 445
 Mineral oil and lanolin alcohols, 447, 449, 485
 Mineral oil, light, 447
 Mineral oils, 383
 Mineral soap, 53
 Mineral wax, 148
 Mineral white, 105
 Mipax, 236
 Mixed soybean phosphatides, 385
 MME, 532
 Modified cellulose gum, 206
 Modified lanolin, 379–380
 Modified starch dusting powder, 695
 Monestriol EN-A, 268
 Monobasic potassium phosphate, 660
 Monobasic sodium phosphate, 658–659
 Monobasic sodium phosphate dihydrate, 659
 Monobasic sodium phosphate monohydrate, 659
 Monobutyl/monoethyl ester mix, of
 poly(methylvinyl ether/maleic acid), 534
 Monocizer DBP, 225
 Monododecyl sodium sulfate, 651
 Monoester with 1,2,3-propanetriol, 290
 Monoethanolamine, 229, 450, 755
 Monoethyl ester, of poly(methylvinyl ether/
 maleic acid), 534
 Monoethyl/monobutyl ester mix, of
 poly(methylvinyl ether/maleic acid), 534
 Monohydrate, 364
 Monolan, 506
 Monolein, 288
 Monomuls 90-O18, 288
 Monoolein, 288
 Monoolein glycerol, 288
 Monopotassium carbonate, 570
 Monopotassium phosphate, 660
 Monosodium L-(+)-ascorbate, 625
 Monosodium carbonate, 629
 Monosodium glutamate, 452
 Monosodium L-glutamate monohydrate, 452
 Monosodium hydroxymethane sulfinate, 645
 Monosodium orthophosphate, 659
 Monosodium phosphate, 659
 Monostearin, 290
 Monothioglycerin, 454
 Monothioglycerol, 454
 Monthyle, 268
 Montmorillonite, 53, 393–394, 396
 Montreal Protocol, 175
 essential use exemptions, 175
 Morflex DBS, 227
 Morpan CHSA, 152
 Morphans, 152
 Mowiol, 564
 MP, 601
 MSG, 452
 Mucoadhesives
 chitosan, 159
 ethylcellulose backing membranes, 266
 glyceryl monooleate, 289
 hypromellose, 326
 polyethylene oxide, 522
 see also Adhesives; Bioadhesives
 Muriacite, 105
 Myacide, 70
 Mycose, 746
 Mylose, 282
 Myreth-N, 536
 Myristic acid, 202, 384, 455, 457, 473
 Myristic acid isopropyl ester, 348
 Myristic alcohol, 456
 Myristyl alcohol, 455–456
 Myristyltrimethylammonium bromide, 154
 Myritol, 429
 Myrj 45, 555
 Myvaplex 600P, 290
 Myvatex, 290
 NAA-160, 473
 Nacol 14-95, 456
 Nacol 14-98, 456
 Nacol 16-95, 155–156
 Nacol 18-98, 700
 Nacol 18-98P, 700
 Naproxen, 698
 National 78-1551, 691
 Native calcium sulfate, 105
 NatraTaste, 48
 Natrii acetat trihydricus, 620
 Natrii alginas, 622
 Natrii ascorbas, 625
 Natrii benzoas, 627
 Natrii carbonas anhydricus, 635
 Natrii chloridum, 637
 Natrii citras, 640
 Natrii cyclamas, 643
 Natrii dihydrogenophosphas dihydricus, 659
 Natrii disulfis, 654
 Natrii docusas, 244
 Natrii glutamas, 452
 Natrii hyaluronas, 646
 Natrii hydrogenocarbonas, 629
 Natrii hydroxidum, 648
 Natrii lactatis solutio, 650
 Natrii laurilsulfas, 651
 Natrii metabisulfis, 654
 Natrii propionas, 661
 Natrii stearylis fumaras, 667
 Natrii sulfis anhydricus, 669
 Natrii sulfis heptahydricus, 670
 Natrii tetraboras, 633
 Natrii thiosulfas, 671
 Natrium benzoicum, 627
 Natrium thiosulfuricum, 671
 Natrosol, 311
 Natural alpha tocopherol, 32
 Natural halite, 637
 Natural red 25, 618
 Natural trehalose, 746
 Naturlose, 727
 Neantine, 230
 Neobee M5, 429
 Neo-Fat, 466
 Neo-fat 12, 383
 Neo-fat 12–43, 383
 Neohesperidin DC, 458
 Neohesperidin DHC, 458
 Neohesperidin dihydrochalcone, 458
 and sodium cyclamate, 644
 Neohesperidin dihydrochalconum, 458
 Neohesperidine dihydrochalcone, 458
 Neomycin sulfate, 261
 Neosorb, 679, 681
 Neosorb P20/60, 680
 Neosorb P30/60, 680
 Neosorb P60, 680
 Neosorb P60W, 680
 Neosorb P100T, 680
 Neotame, 50, 460, 606, 609
 Neotocopherol, 33
 Neotrehalose, 747
 Nesatol, 429
 Neusilin, 393
 Nevulose, 273
 NF Lactose–315, 376
 NF Lactose–316 Fast Flo, 376
 NHDC, 458
 Nicardipine, incompatibilities, sodium
 bicarbonate, 631
 Nikkol, 542
 Ninol AA62 Extra, 383
 Nipabutyl, 78
 Nipacide PC, 168
 Nipacide PX, 176
 Nipagin A, 270
 Nipagin M, 441
 Nipagin P, 596
 Nipanox BHA, 73
 Nipanox BHT, 75
 Nipantiox 1-E, 73
 Nipasol M, 596
 Nipasol M Sodium, 599
 Nisso HPC, 317
 (nitrate-O)Phenylmercury, 496
 Nitratophenylmercury, 496
 2,2',2''-Nitrilotriethanol, 754
 Nitrogen, 116, 461, 464
 aerosol propellant, 115
 Nitrogen monoxide, 463
 Nitrogenium, 461
 Nitrogenol, 158
 Nitromethane, 503
 Nitrous oxide, 116, 462–463
 aerosol propellant, 115
 NMP, 601
 1-nonanecarboxylic acid, 384
 Nonionic emulsifying wax see Emulsifying wax,
 nonionic
 Nonionic surfactants see Surfactants, nonionic
 Nonoxynol 10, 541
 Non-pareil, 712
 Non-pareil seeds, 712
 Norfloxacin, 408
 Normal human serum albumin, 14
 Normal magnesium carbonate, 399
 Novata, 722
 Noveon AA-1, 509
 Noveon CA-1, 511
 Noveon CA-2, 511
 Novol, 468
 NSC-2752, 276
 Nu-Core, 712
 Nu-Pareil PG, 712
 Nut oil, 476
 Nu-Tab, 709
 NutraSweet, 48
 Nymcel ZSB, 118
 Nymcel ZSC, 117
 Nymcel ZSX, 206
 Ocenol, 468
 Octaacetylsucrose, 707
 9,12-octadecadienoic acid ethyl ester, 389
 9,12-Octadecadienoic acid, methyl ester, 389
 (Z,Z)-9,12-Octadecadienoic acid, 389
 Octadecanoic acid, 697, 699
 (Z)-9-Octadecenoic acid, 466
 Octadecanoic acid aluminum salt, 35
 Octadecanoic acid, calcium salt, 103
 Octadecanoic acid, 2,3-dihydroxypropyl ester
 mixed with 3-hydroxy-2-[(1-oxohexadecyl)-oxy] propyl
 octadecanoate, 293
 (Z)-9-Octadecenoic acid, ethyl ester, 259
 Octadecanoic acid, magnesium salt, 404
 (Z)-9-octadecenoic acid, methyl ester, 260
 Octadecanoic acid, monoester with 1,2,3-
 propanetriol, 290
 Octadecanoic acid zinc salt, 793
 n-octadecanol, 700
 1-Octadecanol, 700
 9,10-octadecenoic acid, 466
 9-Octadecenoic acid (Z), monoester with 1,2,3-
 propanetriol, 288
 9-octadecenoic acid-1,2,3-propanetriyl ester,
 757

- (Z)-9-Octadecen-1-ol, 468
 Octadecyl alcohol, 700
Octalbin, 14
 Octanoic acid, 751
n-octanoic acid glycerol triester, 751
 Octildodecanol, 465
Octoil, 226
 Octyl gallate, 589
 Octyl 3,4,5-trihydroxybenzoate, 589
 Octyldodecanol, 465
 2-octyl-1-dodecanol, 465
 Octyldodecanolum, 465
 2-octyldodecyl alcohol, 465
 Odor-enhancing agents, menthol, 433
OHS28890, 75
 Oil of vitriol, 719
 Ointment bases
 coconut oil, 184
 lanolin, 378
 hydrous, 380
 lanolin alcohols, 382
 paraffin, 474
 petrolatum, 482
 petrolatum and lanolin alcohols, 484
 poloxamer, 507
 polyethylene glycol, 517
 stearic acid, 697
 vitamin E polyethylene glycol succinate, 764
 Okenite, 101
Olea europaea oil, 470
 Oleaginous vehicles
 almond oil, 30
 canola oil, 108
 castor oil, 126
 corn oil (maize), 199
 cottonseed oil, 202
 ethyl oleate, 259
 isopropyl myristate, 348
 isopropyl palmitate, 350
 light mineral oil, 447
 mineral oil, 445
 myristyl alcohol, 456
 olive oil, 470
 peanut oil, 476
 safflower oil, 610
 sesame oil, 614
 soybean oil, 682
 Oleic acid, 260, 466, 469, 733
 almond oil, 29
 and corn oil, 199
 and cottonseed oil, 202
 canola oil, 109
 castor oil, 126
 peanut oil, 476
 sunflower oil, 721–722
 Oleic acid, ethyl ester, 259
 Oleic alcohol, 468
 Olein, 757
 Oleinic acid, 466
 Oleo alcohol, 468
 Oleo de amêndoas, 29
 Oleol, 468
 Oleomargarine, 721
 Oleoyl Macroglycerides, 557
 Oleoyl Polyoxylglycerides, 557
 Oleum, 720
 Oleum cacao, 725
 Oleum cocois, 184
 Oleum helianthi, 721
 Oleum neutrale, 429
 Oleum olivae, 470
 Oleum ricini, 126
 Oleum theobromatis, 725
 Oleum vegetable tenue, 429
 Oleyl alcohol, 468
 Oleyl oleate, 469
 Oligofructose, 339
 Oligosaccharides, cyclic, 210
 Olio di mandorla, 29
 Olivae oleum raffinatum, 470
 Olive oil, 185, 470
 alternatives, rapeseed oil, 109
 extra virgin, 471
 fine virgin, 471
 lampante virgin, 471
 pure, 470
 refined, 470
 virgin, 471
 Olive Oil, Refined, 470
 Olive-pomace oil, 471–472
 Opacifying agents, calcium carbonate, 86
 Opacifying agent, ceresin, 148
 Opacifying agents
 aluminum stearate, 35
 calcium silicate, 101
 coloring agents, 189
 ethylene glycol palmitostearate, 267
 octyldodecanol, 465
 titanium oxide, 741
 zinc acetate, 791
 zinc stearate, 793
Opadry, 329
Opaglos R, 616
Opaseal, 562
Optim, 283
Orafti, 339
Oraldene, 304
 Organic bases, meglumine, 431
 [Orthoborato(3-)-O]-phenylmercurate(2-)
 dihydrogen, 494
 Orthoboric acid, 68
 Orthophosphoric acid, 503
 Oryzae amylum, 685
 Osmotic agents, sulfobutylether β -cyclodextrin,
 714
 Overloading syndrome, 203
 Ovolecithin, 385
 3-oxo-L-gulofuranolactone, enol form, 43
 3-oxo-L-gulofuranolactone 6-palmitate, 46
 3-oxo-L-gulofuranolactone sodium enolate, 625
 2-[(1-oxohexadecyl)-oxy]-1,3-propanediyl
 dioctadecanoate and 1,2,3-propane triol,
 293
 2-oxopyrrolidine, 600
 Oxybenzene, 485
 Oxybismethane, 235
 Oxycellulose, 311
Oxymag, 400
 Oxypropylated cellulose, 317, 322
 Ozokerite
 purified, 148
 substitute for, 148
 P-22, 172, 303
 P-152a, 232
 Padil, 295
Pal Sweet, 48
Pal Sweet Diet, 48
Palatinit, 342
Palatinol A, 230
Palatinol C, 225
Palatinol M, 236
 Palatinose, hydrogenated, 342
Palatone, 421
 Palm kernel oil PEG 300 esters, hydrogenated,
 557
 Palm oil, 109
 hydrogenated, 762
 Palm oil PEG 1500 esters, hydrogenated, 557
 Palmitic acid, 318, 384, 455, 457, 473
 almond oil, 29
 and corn oil, 199
 and cottonseed oil, 202
 castor oil, 126
 peanut oil, 476
 purified stearic acid, 699
 sunflower oil, 721
 Palmitic acid isopropyl ester, 350
 Palmitic acid sodium salt, 473
 Palmitin, 473
 Palmityl alcohol, 155
 Palygorskite, 51
 Palygorskite, 51
Pamolyn, 389
Panasate 800, 751
 Parabens, 337, 403
 antimicrobial activity, and chain length, 442
 incompatibilities
 methylcellulose, 440
 nonionic surfactants, 443
 phenylethyl alcohol, 491
 poloxamer, 507
 polyethylene alkyl ethers, 537
 polyethylene glycols, 520
 polysorbates, 551
 paraben paradox, 444
 synergists, 247
 see also Butylparaben; Ethylparaben;
 Methylparaben; Propylparaben
 Paracetamol, 403, 408, 478
 Parachlorometacresol, 168
 Parachlorometaxyleneol, 176
 Paraffin, 447–448, 474, 483, 485, 776, 780–
 781
 anhydrous ointment bases, 771
 hard, 474
 light liquid, 447
 liquid, 445
 and lanolin alcohols, 449
 synthetic, 475
 white soft, 483
 and anionic emulsifying wax, 771
 yellow soft, 481
 Paraffin, Hard, 474
 Paraffin, Liquid, 445
 Paraffin oil, 445
 Paraffin wax, 474, 775
 substitute for, 148
 Paraffin, Yellow Soft, 481
 Paraffinum durum, 474
 Paraffinum liquidum, 445
 Paraffinum perliquidum, 447
 Paraffinum solidum, 474
 Parasepiolite, 403
 Parasept, 599
Paselli MD10 PH, 418
Patlac, 650
Patlac LA, 355
 P-142b, 171
 PCMC, 168
 PCMX, 176
 PDLA, 515
 PEA, 490
 Peanut oil, 30, 109, 185, 200, 203, 259, 476,
 611, 615, 682, 684, 722
Pearl, 685
Pearl Steric, 697
 Pearling agents, ethylene glycol palmitostearate,
 267
Pearlitol, 424
Peceol, 288
 Pectin, 478
 Pectina, 478
 Pectinic acid, 478
 PEG, 517
 PEG 400 caprylic/capric glycerides, 557
 PEG fatty acid esters, 554
 PEG see Poly(ethylene glycol)

- PEG stearates, 554
 Peglicol-5-oleate, 557
Pemulen, 110
 Penetration enhancers
 alcohol, 17
 dimethyl sulfoxide, 238–239
 glyceryl monooleate, 289
 glycofurool, 297
 isopropyl myristate, 348
 isopropyl palmitate, 350
 lanolin, 379
 light mineral oil, 448
 linoleic acid, 389
 menthol, 433
 myristic acid, 455
 myristyl alcohol, 456
 oleic acid, 466
 oleyl alcohol, 468
 palmitic acid, 473
 polyoxyethylene alkyl ethers, 536
 polyoxylglycerides, 558
 pyrrolidone, 600
 sodium lauryl sulfate, 651
 thymol, 739
 tricaprylin, 751, 753
 triolein, 757
 see also Transdermal delivery agents
 Penicillin V, 299
 Pentacarboxymethyl diethylenetriamine, 480
 Pentacin, 481
 1-pentadecanecarboxylic acid, 473
 1,3-pentadiene-1-carboxylic acid, 672
 (3S,4S,5R)-1,3,4,5,6-pentahydroxyhexan-2-one, 727
 Pentasodium DTPA, 481
 Pentasodium pentetate, 481
 Pentetate calcium trisodium, 481
 Pentetate pentasodium, 481
 Pentetate zinc trisodium, 481
 Pentetic acid, 480
Pentonium, 56
 PEO see Poly(ethylene oxide)
 Peppermint camphor, 433
 Peppermint oil, 434
Perfectamyl, 685
 Perfume fixatives, diethyl phthalate, 230
 Periclast, 400
Permulgin D, 777
 Persian tragacanth, 744
 Petrohol, 346
 Petrolatum, 447–448, 475, 481, 484–485
 and lanolin alcohols, 382, 450, 483–484
 and wool alcohols, 484
 light liquid, 447
 white, 483, 485
 yellow, 485
 Petrolatum and lanolin alcohols, 383, 484
 Petrolatum and wool alcohols, 484
 Petroleum ceresin, 775
 Petroleum jelly, 481
 white, 483
 Petroleum wax (microcrystalline), 775
 PH-adjusting agents
 ammonia solution, 39
 diethanolamine, 228
 glacial acetic acid, 6
 meglumine, 432
 sodium citrate dihydrate, 640
 sodium hydroxide, 648
 see also Acidifying agents; Alkalizing agents;
 Buffering agents
Pharma-Carb, 86
Pharmacel, 129
Pharmacel XL, 206
 Pharmaceutical glaze, 618
Pharmacoat, 326–327
Pharma-Gel, 691
Pharmasolve, 601
Pharmasorb, 393
Pharmatose, 364
Pharmsorb Regular, 51
Phe-Mer-Nite, 496
 Phenethanol, 490
 Phenic acid, 485
 Phenobarbital sodium, 398
 Phenol, 204, 450, 484–485
 incompatibilities
 carbomers, 112
 nonionic emulsifying wax, 777
 poloxamer, 507
 polyoxyethylene castor oil derivatives, 544
 liquefied, 487
 Phenolium, 485
Phenoxen, 488
Phenoxetol, 488
 Phenoxyethanol, 167, 488
 2-Phenoxyethanol, 488
 Phenoxyethanolium, 488
 β -phenoxyethyl alcohol, 488
 Phenoxypropanol, 489
 1-Phenoxypropan-2-ol, 489
Phenyl Cellosolve, 488
 Phenyl hydrate, 485
 Phenyl hydroxide, 485
 L-phenylalanine, N-[N-(3,3-dimethylbutyl)-L- α -aspartyl]-1-methyl ester, 460
 Phenylcarbinol, 64
 Phenylcarboxylic acid, 61
 2-Phenylethanol, 169, 490
 2-Phenylethanol, 490
 Phenylethyl alcohol, 167, 490
 2-phenylethyl alcohol, 490
 Phenylformic acid, 61
 Phenylhydrargyri acetate, 492
 Phenylhydrargyri boras, 494
 Phenylhydrargyri nitras, 496
 Phenylic acid, 485
 Phenylic alcohol, 485
 Phenylmercuriborate, 494
 Phenylmercuric acetate, 492, 494–496, 498, 738
 Phenylmercuric borate, 492–494, 496, 498, 738
 Phenylmercuric hydroxide, 494, 496
 Phenylmercuric metaborate, 494
 Phenylmercuric nitrate, 247, 492–496, 738
 Phenylmercuric orthoborate, 494
 Phenylmercury acetate, 492
 Phenylmercury borate, 494
 Phenylmercury nitrate, 496
 Phenylmethanol, 64
 Phenylmethyl benzoate, 66
 Phenytol, 353
Phosal 53 MCT, 385
 Phosphatides, 499
 mixed soybean, 385
 Phosphatidic acid, 499
 Phosphatidylcholine, 385, 499
 Phosphatidylethanolamine, 499
 Phosphatidylglycerol, 499
 Phosphatidylinositol, 499
 Phosphatidylserine, 499
 Phosphoglycerides, 499
PhosphoLipid, 499
 Phospholipids, 499
 solvents, glycerin monostearate, 290
 soybean, 385
Phospholipon 100 H, 385
 Phosphoric acid, 503
 dilute, 504
 diluted, 504
 Phosphoric acid calcium salt (1 : 1), 94, 99
 Phosphoric acid calcium salt (1 : 1) dihydrate, 96
 Phosphoric Acid, Concentrated, 503
 Phosphoric acid, disodium salt, 656
 Phosphoric acid, monosodium salt, 659
 Phosphorite, 657
 Photostabilizers, vanillin, 760
Phthalavin, 562
 Phthalic acid, 562–563
 Phthalic acid dibutyl ester, 225
 Phthalic acid diethyl ester, 230
 Phthalic acid dimethyl ester, 236
 Phthalic acid methyl ester, 236
 Phycite, 251
 Pigment black 11, 340
 Pigment red 101, 340
 Pigment white 6, 741
 Pigment yellow 42, 340
 Pigments, 189
 classifications, 189
 dispersing agents, glycerin monostearate, 290
 titanium oxide, 741, 743
 see also Coloring agents
 Pirotine, 612
 Pisi amyllum, 685
Plasbumin, 14
Plasdone, 581
Plasdone S-630, 196, 198
 Plasma albumin, 14
 Plaster of Paris, 105, 107
 Plasticizers
 acetyltributyl citrate, 8, 756
 acetyltriethyl citrate, 10, 756
 benzyl benzoate, 67
 cellulose acetate phthalate compatible, 144–145
 chlorbutanol, 166
 dextrin, 220
 dibutyl phthalate, 225
 dibutyl sebacate, 227
 diethyl phthalate, 230
 dimethyl phthalate, 236
 glycerin, 283
 glycerin monostearate, 290
 hypromellose phthalate compatible, 333
 mannitol, 424
 mineral oil and lanolin alcohols, 449
 palmitic acid, 318
 petrolatum and lanolin alcohols, 484
 polyethylene glycol, 517
 polymethacrylate compatible, 533
 polyvinyl acetate phthalate, 562
 propylene glycol, 592
 pyrrolidone, 600
 sorbitol, 679
 stearic acid, 318
 triacetin, 748
 tributyl citrate, 749, 756
 triethanolamine, 754
 triethyl citrate, 756
 PLGA see Poly(L-lactide-co-glycolide)
Pluracare, 508
Plurafac, 536
Pluriol E, 517
Pluronic, 506, 508
Pluronic F-68, 508
 PMA, 492
 PMAC, 492
 PMAS, 492
 PMB, 494
 PMMA, 533
 PMN, 496
 Polacrillin, 506
 Polacrillin potassium, 504
 Polacrillin resin, 505
 Polacrillinum kalii, 504
Polargel, 53

- Polawax*, 777
 Polishing agents
 yellow wax, 780
 see also Coating agents
 Poloxalkol, 506
 Poloxamer, 506
 Poloxamer 188, 507
 Poloxamer 338, 507
 Poloxamer 407, 507
 Poloxamera, 506
 Poloxamers, 506
 nomenclature, 508
 Poloxyl 8 stearate, 554
 Poly (RS)-2-hydroxypropanoic acid, 515
 Polyacrylate Dispersion (30 per cent), 525
 Polyacrylatis dispersio 30 per centum, 525
 Polyacrylic acid, 110
 Poly(alcohol vinyllic), 564
 Poly- β -(1,4)-2-Amino-2-deoxy-D-glucose, 159
 Polycarophil, 113, 509
Polycizer DBP, 225
 Polydextrose, 224, 513, 789
 Polydextrose A, 513
 Polydextrose K, 513
 Polydextrose *see also* Dextrose
 Poly(dimethylsiloxane), 233
 Polydimethylsiloxane-silicon dioxide mixture, 619
 Poly(DL-lactide), 515
 Polyesters, aliphatic, 23
 Polyethoxylated castor oil, 542
 Polyethylene glycol, 392, 517, 524, 553, 556, 725
 incompatibilities, sorbitol, 680
 Polyethylene glycol 660 12-hydroxystearate, 391
 Polyethylene glycol distearate, 554
 Polyethylene glycol monocetyl ether, 536
 Polyethylene glycol monolauryl ether, 536
 Polyethylene glycol monooleyl ether, 536
 Polyethylene glycol monostearyl ether, 536
 Poly(ethylene glycol) (PEG), 516
 Polyethylene glycol stearate, 554
 Polyethylene glycol stearates, 554
 Polyethylene glycol-15-hydroxystearate, 391
 Polyethylene oxide, 521-522
 Poly(ethylene oxide) (PEO), 516
 Poly(ethylene-co-vinyl acetate), 268
 Polyethylene-propylene glycol copolymer, 506
 Polyfructose, 339
 Poly-(1,4- β -D-glucopyranosamine), 159
 β -1,4-poly-D-glucosamine, 159
 D,L-poly(lactic acid), 515
 Polylactic acids, 356
 Polylactide, 515
 Polylactide acetyltributyl citrate, 9
 Poly(L-lactide-co-glycolide) (PLGA), 516
Polylin No. 515, 389
 Polymannuronic acid, 20
 Polymeric methacrylates, 525
 Polymers, biodegradable, aliphatic polyesters, 23, 27
 Polymers acrylic acid *see* Carbomer
 Polymethacrylates, 525, 563
 compatible plasticizers, 533
 Poly(methyl methacrylate), 532-533
 Poly(methyl vinyl ether/maleic anhydride), 534
 Poly(methylvinyl ether/maleic acid), 534
 Poly(methylvinyl ether/maleic anhydride), 534
Polyox, 522
 Polyoxiante, 522
 Polyoxirane, 522
 Poly[1-(2-oxo-1-pyrrolidinyl)ethylene], 581
 Poly(oxy-1,2-ethanediyl) α -hydro- ω -hydroxyoctadecanoate, 554
 Polyoxyethylene, 522
 Polyoxyethylene 8 stearate, 554
 Polyoxyethylene alkyl ethers, 521, 536, 548, 778
 nomenclature, 536
 Polyoxyethylene castor oil derivatives, 542
 Polyoxyethylene glycol, 517
 Polyoxyethylene glycol 400 stearate, 554
 Polyoxyethylene glycol stearates, 554
 Polyoxyethylene lauryl alcohol ether, 536
 Polyoxyethylene sorbitan fatty acid esters, 521, 549, 678
 Polyoxyethylene stearates, 521, 548, 554, 699
 nomenclature, 554
 Polyoxyethylene-polyoxypropylene copolymer, 506
 Polyoxyl 10 Oleyl Ether, 536
 Polyoxyl 20 Cetostearyl Ether, 536
 Polyoxyl 35 castor oil, 542
 Polyoxyl 40 hydrogenated castor oil, 543
 Polyoxyl 40 Stearate, 554
 Polyoxyl lanolin, 380
 Polyoxyl Lauryl Ether, 536
 Polyoxyl Stearyl Ether, 536
 Polyoxylglycerides, 557
 Poly[oxy(1-methyl-2-oxo-1,2-ethanediyl)], 515
Polyplasdone XL, 208
Polyplasdone XL-10, 208
 Polypropylene glycol 2000, 543
 Polysaccharide B-1459, 782
 Polysorbate 20, 549
 Polysorbate 40, 549
 Polysorbate 60, 549
 Polysorbate 80, 443, 549
 Polysorbates, incompatibilities, phenylethyl alcohol, 491
 Polysorbatum 20, 60, and 80, 549
 Polythiazide, 760
 Polyvidone, 581
Polyvinol, 564
 Polyvinyl acetate phthalate, 145, 562
 Polyvinyl alcohol, 564
 Poly(vinyl alcohol) (PVA), 516
 Polyvinylpolypyrrolidone, 208
 Polyvinylpyrrolidone, 581
 Poly(vinylpyrrolidone) (PVP), 516
 Poly(1-vinylpyrrolidone-co-vinyl acetate), 196
 Polyvinylpyrrolidone-vinyl acetate copolymer, 196
 Poorly crystalline boehmite, 34
 Porcelain clay, 352
 Potash alum, 567
 Potash lye, 576
 Potassium acid carbonate, 570
 Potassium acid phosphate, 660
 Potassium acid sulfite, 578
 Potassium alginate, 21, 41, 84, 566, 624
 Potassium alum, 567
 Potassium aluminum sulfate (1:1:2), 567
 Potassium aluminum sulfate-12-hydrate, 567
 Potassium benzoate, 62, 569, 629
 Potassium bicarbonate, 570, 632
 Potassium biphosphate, 660
 Potassium 1,4-bis(2-ethylhexyl) sulfosuccinate, 246
 Potassium bisulfite, 578
 Potassium bisulphite, 578
 Potassium chloride, 572, 639
 Potassium citrate, 574
 anhydrous, 575
 monohydrate, 575
 Potassium dihydrogen orthophosphate, 660
 Potassium (E,E)-hexa-2,4-dienoate, 579
 Potassium (E,E)-sorbate, 579
 Potassium ethyl hydroxybenzoate, 272
 Potassium hydrate, 576
 Potassium Hydrogen Carbonate, 570
 Potassium hydrogen sulfite, 578
 Potassium hydroxide, 92, 576, 649
 Potassium metabisulfite, 577, 655, 718
 Potassium Metabisulphite, 577
 Potassium methyl hydroxybenzoate, 444
 Potassium 6-methyl-2,2-dioxo-oxathiazin-4-olate, 3
 Potassium monochloride, 572
 Potassium myristate, 455-457
 Potassium phosphate, 658
 dibasic, 658
 monobasic, 660
 Potassium polymannuronate, 566
 Potassium propionate, 662
 Potassium propyl hydroxybenzoate, 598
 Potassium pyrosulfite, 577
 Potassium salt trihydrate, 569
 Potassium sorbate, 579, 674
 Povidone, 198, 210, 373, 427, 581
 and fructose, 273
 and lactose, monohydrate, mixture, 373
 crosslinked, 208
 incompatibilities, polyvinyl acetate phthalate, 563
 Povidone-iodine, 585
 Povidonum, 581
Poviphar, 581
 Powdered cellulose, 132, 136
 and lactose, monohydrate, mixture, 374
 Powdered fructose, 275
 Powdered sugar, 710
 Powdered talc, 728
 Powdered tragacanth, 745
 Precipitated calcium phosphate, 99
 Precipitated calcium sulfate, 105
 Precipitated carbonate of lime, 86
 Precipitated chalk, 86
Precirol ATO 5, 293
 Pregelatinised Starch, 691
 Pregelatinized starch, 88, 665, 690-691, 696
 and corn starch, mixture, 200
Prejel, 691
 Preservatives
 alcohol, 17
 benzalkonium chloride, 56
 benzethonium chloride, 59-60
 benzoic acid, 61
 benzyl alcohol, 64
 boric acid, 68
 bronopol, 70
 butylated hydroxyanisole, 73
 butylene glycol, 77
 butylparaben, 78, 80
 calcium acetate, 82
 calcium chloride, 89
 calcium lactate, 92
 carbon dioxide, 115
 cationic, and bentonite, 54
 cetrimide, 152
 cetylpyridinium chloride, 157
 chlorhexidine, 162
 chlorobutanol, 166
 chlorocresol, 168-169
 chloroxylenol, 176
 citric acid monohydrate, 181
 cresol, 203-204
 dimethyl ether, 236
 ethylparaben, 270-271
 glycerin, 283
 hexetidine, 304
 imidurea, 337
 inactivation by magnesium trisilicate, 408
 isopropyl alcohol, 346
 lactic acid, 355
 methylparaben, 337, 441
 monothioglycerol, 454

- parabens, 337
 alkyl chain length, 442
 pentetic acid, 480
 phenol, 485
 phenoxyethanol, 488–489
 phenylethyl alcohol, 490
 phenylmercuric acetate, 492
 phenylmercuric borate, 494–495
 phenylmercuric nitrate, 496–498
 potassium benzoate, 569
 potassium metabisulfite, 577
 potassium sorbate, 579–580
 propionic acid, 586
 propyl gallate, 588
 propylene glycol, 592
 propylparaben, 337, 596–597
 propylparaben sodium, 599
 sodium acetate, 620
 sodium benzoate, 627
 sodium borate, 633
 sodium lactate, 650
 sodium metabisulfite, 654
 sodium propionate, 661
 sodium sulfite, 669
 sorbic acid, 672
 sulfobutylether- β -cyclodextrin, 714
 sulfur dioxide, 718
 synergists, edetic acid, 247–248
 thimerosal, 736
 xanthan gum incompatibility, 783
 xylitol, 786
 see also Antibacterial agents; Antifungal agents; Antioxidants
Pretiox AV-01-FG, 741
Pricerine, 283
 Primary sodium phosphate, 659
Primellose, 206
Primogran W, 220
Primojel, 663
 Printing inks, pharmaceutical, shellac, 616
Priolene, 466
Priolube 1408, 288
PrismaLac, 364
Pristacin, 157
Pristerene, 697
ProBenz PG, 569
Pro-Bumin, 14
Procipient, 238–239
Procol, 536
Profoam, 594
Progallin P, 587
Proguanil, 408
ProKote LSC, 385
 Prolamins, zein, 790
 Promethazine hydrochloride, 672
Pronova, 594
 Propagin, 596
Propal, 350
 Propan-1-ol, 347
 Propan-2-ol, 346
 Propane, 306
 Propane-1,2,3-triol, glycerin solutions, 285
 Propane-1,2-diol, 592
 1,2-Propanediol, 592
 Propane-1,2-diol alginate, 594
 1,2-propanediol cyclic carbonate, 590
 1,2,3-Propanetricarboxylic acid, 2-acetyloxy, tributyl ester, 8
 1,2,3-Propanetricarboxylic acid, 2-acetyloxy, triethyl ester, 10
 1,2,3-Propanetricarboxylic acid, 2-hydroxy, tributyl ester, 749
 Propane-1,2,3-triol, 283
 1,2,3-propanetriol, 283
 1,2,3-propanetriol octadecanoate, 290
 1,2,3-Propanetriol triacetate, 748
 1,2,3-propanetriyl ester, 751
 1,2,3-propanetriyl tris((*E*)-9-octadecenoate), 757
 Propanoic acid, 586, 662
 Propanoic acid, calcium salt, 662
 Propanoic acid 2-hydroxy butyl ester, 257
 Propanoic acid, 2-hydroxy-, calcium salt (2:1), hydrate, 92
 Propanoic acid 2-hydroxy-ethyl ester, 256
 RS-propanoic acid, 2-hydroxy-, homopolymer, 515
 Propanoic acid, potassium salt, 662
 Propanoic acid, sodium salt, anhydrous, 662
 Propanoic acid, zinc salt, 662
 Propan-2-ol, 346–347
 2-propanol, 346
 2-Propanone, 7, 458
 Propellant 22, 172, 303
 Propellant 11(trichloromonofluoromethane), 173
 Propellant 12 (dichlorodifluoromethane), 173, 175
 Propellant 114 (dichlorotetrafluoroethane), 173, 175
 Propellant 152a, 232, 733
 Propellant 142b, 171
 Propellants
 butane, 306
 carbon dioxide, 115–116
 chlorodifluoroethane, 171
 chlorodifluoromethane, 172
 chlorofluorocarbons (CFCs), 173–174
 difluoroethane, 232
 dimethyl ether, 235
 fluorocarbon nomenclature, 175
 heptafluoropropane, 303
 hydrocarbons, 306
 isobutane, 306
 nitrogen, 115, 461
 nitrous oxide, 115, 463
 propane, 306
 solubility enhancers, polyoxyl 40
 hydrogenated castor oil, 543
 tetrafluoroethane, 733–734
 2-propenylacrylic acid, 672
 Propionic acid, 586, 662
 Propionic acid, calcium salt, 662
 Propionic acid, potassium salt, 662
 Propionic acid, sodium salt, anhydrous, 661
 Propionic acid, sodium salt, hydrate, 661
 Propionic acid, zinc salt, 662
 Propyl alcohol, 347
Propyl Aseptofom, 596
 Propyl butex, 596
Propyl Chemosept, 596
 Propyl gallate, 200, 587
 ethyl oleate, 259
 Propyl hydride, 306
 Propyl Hydroxybenzoate, 596
 Propyl 4-hydroxybenzoate potassium salt, 598
 Propyl 4-hydroxybenzoate, sodium salt, 599
 Propyl Parahydroxybenzoate, 596
Propyl Parasept, 596
 Propyl 3,4,5-trihydroxybenzoate, 587
 Propylene carbonate, 590–591
 1,2-propylene carbonate, 590
 Propylene glycol, 77, 592, 595
 and methylparabens, 442–443
 Propylene glycol alginate, 21, 41, 84, 567, 593–594, 624
 Propylenglycol, 592
 Propylic alcohol, 347
 Propylis gallas, 587
 Propylis parahydroxybenzoas, 596
 Propylis parahydroxybenzoas natricus, 599
 Propylparaben, 80, 272, 444, 596, 600
 and hydroxypropyl cellulose, 320
 and methylcellulose, 440
 and methylparabens, 442
 see also Parabens
 Propylparaben potassium, 598
 Propylparaben sodium, 598–599
Proserum, 14
ProSolv, 139
Protachem, 542
Protachem GMS-450, 290
Protachem IPP, 350
Protachem MST, 774
Protacid, 20
Protalan anhydrous, 378
Protalan M-16, 449
Protalan M-26, 449
Protanal, 594, 622
 Protoenstatite, 403
Pruv, 667
 Pseudoacetic acid, 586
 Pseudoboehmite, 34
Purac 88 PH, 355
Puracal, 92
Puracal PP, 93
Purasal, 650
Purasolv BL, 257
Purasolv EL, 256
Purasolv ML, 257
 Pure olive oil, 470
Pure-Bind, 690
Pureco 76, 184
Pure-Coat, 690
Pure-Dent, 685
Pure-Dent B851, 695
Pure-Gel, 690
Pure-Set, 690
 Purified bentonite, 55
 Purified egg yolk PC, 499
 Purified French chalk, 728
 Purified lanolin, 378
 Purified ozokerite, 148
 Purified stearic acid, 699
 Purified water, 766, 769
Purity 21, 685
Purity 826, 685
Purtalc, 728
 PVA, 564
 PVA see Poly(vinyl alcohol)
 PVAP, 562
 PVP, 581
 PVP see Poly(vinylpyrrolidone)
 PVP/VA, 196
 PVP/VA copolymer, 196
PX 104, 225
Pyrisept, 157
 Pyroacetic ether, 7
 Pyroborax, 634
 2-Pyrol, 600
 α -pyrrolidinone, 600
 2-Pyrrolidinone, 600
 Pyrrolidone, 600
 2-pyrrolidone, 600
 Pyrrolidonum, 600

Quammonium, 152
 Quassin, 217
 Quaternary ammonium compounds
 benzalkonium chloride, 56
 benzethonium chloride, 59
 cetrimide, 152
 imidurea, 337
 incompatibilities
 anionic emulsifying wax, 771
 nonionic emulsifying wax, 777
 talc, 729
 Quaternium 18-hectorite, 302

- R-227, 303
 Racementhol, 433
 Racemic lactic acid, 355
 Racemic menthol, 433–434
 Raffinerad, 610
 Raffinose, 603
Raftiline, 339
Rapae oleum raffinatum, 108
 Rape oil, 109
 Rapeseed oil, 109
 alternatives, olive oil, 109
 erucic acid, 108–109
 Rapeseed Oil, Refined, 108
 Rayon, 748
RC Plasticizer DBP, 225
 Red ferric oxide, 340
 Refined almond oil, 30
 Refined coconut oil, 184
 Refined corn oil, 199
 Refined cottonseed oil, 202
 Refined olive-pomace oil, 471
 Refined sugar, 703
 Refined sunflower oil, 721
 Refined wax, 780
 Refined wool fat, 378
 Refrigerant 22, 172
 Refrigerant 152a, 232, 733
 Refrigerant 142b, 171
 Refrigerants
 dimethyl ether, 235
 refrigerant 22, 172
 refrigerant 134a, 733
 refrigerant 142b, 171
 refrigerant 152a, 232
 tetrafluoroethane, 733
Rehydragel, 34
Rehydraphos, 38
Renex, 536
Repeftal, 236
 Resorcinol, 450, 484
Respitose, 362
RH 60, 543
 Rheology modifiers, carbomers, 110
Rhodiarome, 261
Rhodicare S, 782
Rhodigel, 782
Rhovanyl, 760
 Riboflavin, 51
*Rice*Trin*, 418
Ricini oleum hydrogenatum, 128
Ricini oleum virginale, 126
 Ricinoleic acid, 126
 Ricinoleum, 126
Ricinus communis, 126
 Ricinus oil, 126
Rimso-50, 238
Rita CA, 155
Rita GMS, 290
RITA HA C-1-C, 646
Rita IPM, 348
Rita IPP, 350
Rita SA, 700
Ritaceti, 774
Ritachol 2000, 777
Ritachol SS, 774
Ritalac NAL, 650
Ritawax, 382
Ritoleth, 536
Ritox, 536
 Rock alum, 567
 Rock salt, 637
Roclys, 282
Roferose, 222
Rofetan GTC, 751–752
Rongalite, 645
Roquette (Lycasin 80/55), 416
Ross Ceresine Wax, 148
 Rubbing alcohol, 346
 Rubefacients, ammonia solution, 40
 Rutile, 743
 Rutile titanium dioxide, 741

SA-99, 625
 Sacarina, 605
 Sacarina, 605
 Sacchari sphaerae, 712
 Saccharin, 29, 605, 609
 and sodium cyclamate, 643
 insoluble, 605
 soluble, 608
 sweetness *vs* neohesperidin dihydrochalcone, 458
 sweetness *vs* sucrose, 605
 Saccharin ammonium, 606–607
 Saccharin calcium, 606–607
 Saccharin insoluble, 605
 Saccharin sodium, 29, 606, 608
 sweetness *vs* sucrose, 608
 Saccharin Sodium Hydrate, 608
 Saccharinum, 605
 Saccharinum natricum, 608
 Saccharose, 703
 Saccharosonic acid, 250
 Saccharum, 703
 Saccharum lactis, 359
SacheLac, 364
 Safflorolja, 610
 Safflower glycerides, 611
 Safflower oil, 610
 refined, 610
 Safflower Oil, Refined, 610
 Safflower oil (unhydrogenated), 610
 Saflonoljy puhdistettu, 610
 Sal ammoniac, 42
 Sal de Vichy, 629
 Salicylic acid, 412
 Saline, 637
 Salmiac, 42
 Salt, 637
Sanacel, 136
Sanacel Pharma, 136
Sancel-W, 136
Sanecta, 48
 Saponite, 302, 393–394, 396, 612
 SAS, 185
 Sassolite, 69
Satialgine H8, 20
 Satin spar, 105
 Satinite, 105
 (SBE), 714
 SBE7- β -CD, 714
 Scabies, treatment of, 67
 Schardinger dextrin, 210
 SCMC, 118
 SDS, 651
 SDS (sodium dodecyl sulfate), 651
 Sea salt, 637
SeaSpem PF, 122
 Sebacic acid, 276
 Secondary calcium phosphate, 94, 96
 Secondary sodium phosphate, 656
 Sec-propyl alcohol, 346
Sedaform, 166
 Selenite, 105
 Self-emulsifying glyceryl monostearate, 292
 Semisynthetic glycerides, 722
Sentry, 233
Sentry Simethicone, 619
Sepifilm SN, 616
 Sepiolite, 403
Sepistab ST 200, 692, 694
Sepistab ST200, 691, 694
Seprison, 158
 Sequestering agents
 calcium acetate, 82
 citric acid, 73
 citric acid monohydrate, 181
 dibasic sodium phosphate, 656
 hydroxypropyl betadex, 316
 monobasic sodium phosphate, 659
 pentetic acid, 480
 phosphoric acid, 503
 potassium citrate, 574
 sodium citrate dihydrate, 640
 tartaric acid, 731
Sequestrene AA, 247
Sequestrene NA3, 249
Sequestrene NA4, 249
 Serum albumin, 14
 Sesame oil, 30, 109, 185, 200, 203, 477, 611, 614, 684, 722
 refined, 614
 Sesame Oil, Refined, 614
 Sesami oleum raffinatum, 614
SHCa-1, 301
 Shellac, 562–563, 616
 purified, 616
 white, 616
 with stearic acid, 697
 Shellac ammonium salt, 618
 Shellactypes of, 616
Shogun CT, 682
Sicovit B80, 340
Sicovit B85, 340
Sicovit R30, 340
Sicovit Y10, 340
 Silane, dichloro-dimethyl-, reaction products
 with silica, 309
 Silica, 185
 colloidal, 185
 hydrophobic, 309
 fumed, 185
 Silica, Colloidal Anhydrous, 185
 Silica colloidalis anhydrica, 185
 Silica dimethyl silylate, 309
 Silica, Hydrophobic Colloidal, 309
 Silica hydrophobica colloidalis, 309
 Silica sol, 185
 Silicic acid, 393
 Silicic acid, calcium salt, 101
 Silicic acid, magnesium salt, 402
 Silicic acid, magnesium salt (1:2), hydrate, 408
 Silicic acid, silylated, 309
 Silicic anhydride, 185
 Silicified microcrystalline cellulose, 132, 139
 Silicon dioxide
 and fructose, 275
 colloidal, 139–140, 185
 fumed, 185
 Silicon dioxide colloidal, 185
 Silicon dioxide fumed, 185
 Silicon dioxide, silanated, 309
 Silicones, cyclomethicone, 215
 Silicosis, 353
Silkolene, 481
 Siloxanes, 215
 dimethicone, 233
Sim 90, 352
 Simethicone, 216, 233–234, 619
 Simeticone, 619
 Simeticonum, 619
Simulsol, 542
Sirius, 445
 Skin-penetration enhancers *see* Penetration enhancers; Transdermal delivery agents
 Slaked lime, 91
 SLS, 651
Snow White, 105, 481

- Soap clay, 53
 Soapstone, 728
 Sobenate, 627
 Soda ash, 635
 Soda calcined, 635
 Soda lye, 648
 Sodii benzoas, 627
 Sodium acetate, 5, 83, 620, 708
 Sodium acetate anhydrous, 620
 Sodium Acetate Hydrate, 620
 Sodium Acetate Trihydrate, 620
 Sodium Acetate Trihydrates, 620
 Sodium acid carbonate, 629
 Sodium acid sulfite, 654
 Sodium alginate, 21, 41, 84, 567, 595, 622
 methylparabens incompatibility, 443
 Sodium ascorbate, 45, 47, 625
 Sodium benzoate, 62, 570, 627
 alternatives to, 569
 Sodium benzoic acid, 627
 Sodium baborate decahydrate, 633
 Sodium bicarbonate, 571, 629, 636
 alternatives, potassium bicarbonate, 570
 citric acid neutralization, 632
 tartaric acid neutralization, 632
 Sodium biphosphate, 659
 Sodium 1,4-bis(2-ethylhexyl) sulfosuccinate, 244
 Sodium 1,4-bis[(2-ethylhexyl)oxy]-1,4-dioxobutane-2-sulfonate, 244
 Sodium bisulfite, 655
 Sodium borate, 69, 633
 fused, 634
 Sodium borate anhydrous, 634
 Sodium bromide, 153
 Sodium butyl hydroxybenzoate, 80
 Sodium calciumedate, 248
 Sodium carbonate, 635
 Sodium Carbonate, Anhydrous, 635
 Sodium carbonate decahydrate, 635–636
 Sodium carbonate monohydrate, 635–636
 Sodium carboxymethyl guar, 300
 Sodium carboxymethyl starch, 663
 Sodium carboxymethylcellulose, 118
 Sodium cellulose glycolate, 118
 Sodium chloride, 573, 637
 Sodium Citrate, 640
 Sodium citrate anhydrous, 642
 Sodium citrate dihydrate, 183, 640
 Sodium Citrate Hydrate, 640
 Sodium citrate tertiary, 640
 Sodium cyclamate, 29, 606, 643
 and saccharin, 643
 sweetness *vs.* sucrose, 643
 with acesulfame potassium, 644
 with saccharin sodium, 644
 Sodium cyclohexanesulfamate, 643
 Sodium N-cyclohexylsulfamate, 643
 Sodium dihydrogen orthophosphate, 659
 Sodium dihydrogen phosphate, 659
 anhydrous, 659
 Sodium Dihydrogen Phosphate Dihydrate, 659
 Sodium Dihydrogen Phosphate Monohydrate, 659
 Sodium dioctyl sulfosuccinate, 244
 Sodium dodecyl sulfate, 651
 Sodium DTPA, 481
 Sodium edetate, 248–249
 Sodium (E,E)-hexa-2,4-dienoate, 674
 Sodium erythorbate, 251
 Sodium ethanoate, 620
 Sodium ethyl hydroxybenzoate, 272
 Sodium ethylmercurithiosalicylate, 736
 Sodium formaldehyde sulfoxylate, 645
 Sodium formaldehyde sulfoxylate dihydrate, 645
 Sodium L-glutamate, 452
 Sodium glutamate monohydrate, 452
 Sodium glycinate, 296
 Sodium hexadecanoate, 473
 Sodium hyaluronate, 646
 Sodium hydrate, 648
 Sodium hydrogen L-(+)-2-aminoglutarate monohydrate, 452
 Sodium Hydrogen Carbonate, 629
 Sodium hydrogen sulfite, 655
 Sodium hydroxide, 92, 577, 648
 Sodium hydroxymethane sulfinate, 645
 Sodium hydroxymethylsulfinate, 645
 Sodium α -hydroxypropionate, 650
 Sodium hyposulfite, 671
 Sodium indigotin disulfonate, 193
 Sodium iodide, 639
 Sodium lactate, 93, 356, 650
 Sodium Lactate Solution, 650
 Sodium laurate, 384
 Sodium Laurilsulfate, 651
 Sodium lauryl sulfate, 151, 651, 771
 and cationic surfactants, 652
 Sodium Lauryl Sulphate, 651
 Sodium metabisulfite, 578, 654, 670, 718
 Sodium Metabisulphite, 654
 Sodium methanalsulfoxylate, 645
 Sodium methyl hydroxybenzoate, 444
 Sodium monododecyl sulfate, 651
 Sodium monolauryl sulfate, 651
 Sodium monostearyl fumarate, 667
 Sodium myristate, 455–457
 Sodium nitrite, sodium ascorbate, 625
 Sodium o-benzosulfimide, 608
 Sodium orthophosphate, 656
 Sodium palmitate, 473
 Sodium phosphate
 dibasic, 656, 660
 monobasic, 658–659
 secondary, 656
 tribasic, 658
 Sodium phosphate, dibasic, 656
 Sodium phosphate, monobasic, 659
 Sodium polymannuronate, 622
 Sodium propanoate hydrate, 661
 Sodium propionate, 587, 661
 anhydrous, 662
 Sodium propionate hydrate, 661
 Sodium 4-propoxycarbonylphenolate, 599
 Sodium Propyl Hydroxybenzoate, 599
 Sodium Propyl Parahydroxybenzoate, 599
 Sodium pyroborate, 634
 Sodium pyroborate decahydrate, 633
 Sodium Pyrosulfite, 654
 Sodium salt, 599
 Sodium sorbate, 674
 Sodium starch glycolate, 663, 690
 Sodium stearyl fumarate, 667
 Sodium subsulfite, 671
 Sodium sulfate, 654
 Sodium sulfinomethanolate, 645
 Sodium sulfite, 654–655, 669, 718
 anhydrous, 669
 dried, 669
 exsiccated, 669
 heptahydrate, 670
 Sodium sulfite heptahydrate, 670
 Sodium sulphate, anhydrous, 669
 Sodium tetraborate anhydrous, 634
 Sodium tetraborate decahydrate, 633
 Sodium thiosulfate, 671
 Sodium thiosulfate anhydrous, 671
 Sodium Thiosulfate Hydrate, 671
 Sodium thiosulfate pentahydrate, 671
 Sodium Thiosulphate, 671
 Sodium/calcium salt mix, of poly(methylvinyl ether/maleic anhydride), 534
 Sodothiol, 671
 Soft water, 769
 Soft White, 481
 Softisan 154, 762
 Soiae oleum raffinatum, 682
 Soja bean oil, 682
 Solactol, 256
 Solani amyllum, 685
 Solbrol A, 270
 Solbrol M, 441
 Solbrol P, 596
 Solka-Floc, 136
 Solkane 134a, 733
 Solkane 142b, 171
 Solkane 152a, 232
 Solkane 227, 303
 Solubility-enhancing agents *see* Dispersing agents
 Solubilizing agent, macrogol 15 hydroxystearate, 391
 Solubilizing agents
 anionic emulsifying wax, 771
 benzalkonium chloride, 56
 benzethonium chloride, 59
 benzyl alcohol, 64
 benzyl benzoate, 67
 cetylpyridinium chloride, 157
 cyclodextrins, 211
 glycerin monostearate, 290
 hydroxypropyl betadex, 316
 hypromellose, 326
 inulin, 339
 lecithin, 385
 meglumine, 432
 nonionic emulsifying wax, 777
 phospholipids, 499
 poloxamer, 507
 polyoxyethylene alkyl ethers, 536
 polyoxyethylene castor oil derivatives, 542
 polyoxyethylene sorbitan fatty acid esters, 550
 polyoxyethylene stearates, 555
 polyoxylglycerides, 558
 povidone, 581
 pyrrolidone, 600
 sodium bicarbonate, 630
 sorbitan esters, 675
 starch, 690
 stearic acid, 697
 sulfobutylether β -cyclodextrin, 714
 tricaprylin, 751, 753
 triolein, 757
 vitamin E polyethylene glycol succinate, 764
 see also Dissolution enhancers; Solvents; Surfactants; Wetting agents
 Soluble gluside, 608
 Soluble indigo blue, 193
 Soluble methyl hydroxybenzoate, 444
 Soluble propyl hydroxybenzoate, 599
 Soluble saccharin, 608
 Solugel, 278
 Soluphor P, 600
 Solutab, 206
 Solutol HS 15, 391
 Solvanom, 236
 Solvarone, 236
 Solvent, acetone, 7
 Solvents
 albumin, 15
 alcohol, 17
 almond oil, 30
 benzyl alcohol, 64
 benzyl benzoate, 67
 butylene glycol, 77
 carbon dioxide, 115
 castor oil, 126

Solvents (*cont.*)

- corn oil (maize), 199
- cottonseed oil, 202
- dibutyl phthalate, 225
- diethyl phthalate, 230
- dimethyl ether, 235
- dimethyl phthalate, 236
- dimethyl sulfoxide, 238
- dimethylacetamide, 241
- ethyl acetate, 253
- ethyl lactate, 256
- ethyl oleate, 259
- glycerin, 283
- glycofurol, 297
- isopropyl alcohol, 346
- isopropyl myristate, 348
- isopropyl palmitate, 350
- light mineral oil, 447
- medium-chain triglycerides, 429
- methyl lactate, 257
- mineral oil, 445
- monoethanolamine, 450
- octyldodecanol, 465
- olive oil, 470
- peanut oil, 476
- polyethylene glycol, 517
- polyoxyl 35 castor oil, 542
- propylene carbonate, 590–591
- propylene glycol, 592
- pyrrolidone, 600
- safflower oil, 610
- sesame oil, 614
- soybean oil, 682
- sunflower oil, 721
- triacetin, 748
- tricaprylin, 751
- triethanolamine, 754
- triethyl citrate, 756
- triolein, 757
- water, 766
- water-miscible, 592
- see also* Solubilizing agents
- Sorbic acid, 337, 580, 672
- (*E,E*)-sorbic acid, 672
- Sorbic acid potassium salt, 579
- Sorbistat K*, 672
- Sorbitab*, 679
- Sorbitab SD 250*, 680
- Sorbitab SD 500*, 680
- Sorbitan, esters monodecanoate (sorbitan monolaurate), 675
- Sorbitan diisostearate, 678
- Sorbitan dioleate, 678
- Sorbitan esters (sorbitan fatty acid esters), 553, 675
- Sorbitan Laurate, 675, 678
- Sorbitan monolaurate (sorbitan, esters monodecanoate), 675
- Sorbitan Monooleate, 675
- Sorbitan Monopalmitate, 675
- Sorbitan Monostearate, 675
- Sorbitan Oleate, 675, 678
- Sorbitan Palmitate, 675, 678
- Sorbitan sesquiolate, 678
- Sorbitan Sesquioleate, 675, 733
- Sorbitan sesquisteate, 678
- Sorbitan Stearate, 675, 678
- Sorbitan triisostearate, 678
- Sorbitan Trioleate, 675, 678, 733
- Sorbitan tristearate, 678
- Sorbite, 679
- Sorbitol, 253, 415–417, 427, 679
- and polydextrose, 514
- incompatibilities
 - methylparabens, 443
 - polyethylene glycols, 680
 - vs.* mannitol, 427
- Sorbitol Instant*, 679
- Sorbitol Special*, 681
- Sorbitolum, 679
- Sorbo*, 681
- Sorbogem*, 679
- SorboLac*, 364
- Soya bean oil, 682
- Soya lecithin, 733
- Soya oil, refined, 682
- Soyabean oil, 682
- Soya-Bean Oil, Refined, 682
- Soybean lecithin, 385
- Soybean oil, 30, 109, 185, 200, 203, 477, 611, 615, 682, 722
 - hydrogenated, 762
- Soybean phosphatides, mixed, 385
- Soybean phospholipids, 385
- Sparfloxacin, 399
- Spectracel*, 327
- Spermaceti, synthetic, 774
- Spermaceti wax, 775
- Spermaceti wax replacement, 774
- Speziol C16 Pharma*, 155
- Speziol C16-18 Pharma*, 150
- Speziol C18 Pharma*, 700
- Speziol TPGS Pharma*, 764
- SpheroLac*, 364
- Sphingomyelin, 499
- Spirit of hartshorn, 39
- Splenda*, 701
- Sporocides, chlorocresol, 169
- Spres B820*, 691
- SSB 55 Pharma*, 616
- SSB 56 Pharma*, 616
- SSB 57 Pharma*, 616
- SSB Aquagold*, 616
- St. John's bread, 146
- Stabilizers, glyceryl monooleate, 289
- Stabilizing agent
 - ceresin, 148
 - macrogol 15 hydroxystearate, 391
- Stabilizing agents
 - acacia, 1
 - agar, 13
 - albumin, 14
 - alginic acid, 20
 - aluminum stearate, 35
 - ammonium alginate, 41
 - ascorbic acid, 43
 - ascorbyl palmitate, 46
 - bentonite, 53
 - butylated hydroxytoluene, 75
 - calcium alginate, 83
 - calcium stearate, 103
 - carboxymethylcellulose calcium, 117
 - carboxymethylcellulose sodium, 119
 - carrageenan, 122
 - cellulose, microcrystalline and carboxymethylcellulose sodium, 134
 - ceratonia, 146
 - colloidal silicon dioxide, 185
 - cyclodextrins, 211
 - diethanolamine, 228
 - edetates, 247
 - ethylcellulose, 263
 - ethylene glycol palmitostearate, 267
 - glycerin monostearate, 290
 - guar gum, 298
 - hectorite, 301
 - hydroxypropyl betadex, 316
 - hydroxypropyl cellulose, 318
 - hypromellose, 326
 - inulin, 339
 - invert sugar, 706
 - lauric acid, 383
 - lecithin, 385
 - magnesium aluminum silicate, 393
 - mineral oil and lanolin alcohols, 449
 - monoethanolamine, 450
 - pectin, 478
 - pentetic acid, 480
 - phospholipids, 499
 - polacrillin potassium, 505
 - poloxamer, 507
 - polyvinyl alcohol, 564
 - potassium alginate, 566
 - potassium chloride, 572
 - povidone, 581
 - propyl gallate, 588
 - propylene glycol, 592
 - propylene glycol alginate, 594
 - raffinose, 603
 - sodium acetate, 620
 - sodium alginate, 622
 - sodium borate, 633
 - sodium stearyl fumarate, 668
 - sorbitol, 679
 - stearyl alcohol, 700
 - sulfobutylether β -cyclodextrin, 714
 - tagatose, 727
 - trehalose, 746
 - triethanolamine, 755
 - white wax, 779
 - xanthan gum, 782
 - xylitol, 786
 - yellow wax, 780
 - zinc acetate, 791
- Stachyose, 604
- Staflax DBP*, 225
- STA-Lite*, 513
- Standamul G*, 465
- StarCap 1500*, 200, 694
- Starch, 201, 370, 420, 427, 665, 685, 694, 696, 713
 - compressible, 691
 - corn, 685, 690
 - sterilizable, 694–695
 - maize, 685, 690
 - sterilizable, 690, 694–695
 - modified, dusting powder, 695
 - pea, 685
 - potato, 685
 - pregelatinized, 88, 201, 665, 690–691, 696
 - rice, 685
 - sterilizable maize, 690, 694–695
 - wheat, 685
- Starch 1500 G*, 691–692
- Starch 1500 LM*, 694
- Starch carboxymethyl ether, sodium salt, 663
- Starch gum, 220
- Starch, pregelatinized, 691
- Starch, sterilizable maize, 695
- Starch sugar, 222
- Starch syrup, 282
- Starch-derivative dusting powder, 695
- Star-Dri*, 418, 420
- Starfol Wax CG*, 774
- StarLac*, 370
- Stearalkonium hectorite, 302
- Steareth-20, 536
- Steareth-N, 536
- Stearic acid, 105, 318, 384, 405, 455, 457, 473, 556, 562, 691, 697, 794
 - and corn oil, 199
 - and cottonseed oil, 202
 - castor oil, 126
 - peanut oil, 476
 - polyethoxylated, 554
 - purified, 699
 - sunflower oil, 721
- Stearic acid aluminum dihydroxide salt, 35

- Stearic acid aluminum salt, 35
 Stearic acid, calcium salt, 103
 Stearic acid, magnesium salt, 404
 Stearic acid, monoester with glycerol, 290
 Stearic acid zinc salt, 793
 Stearic monoglyceride, 290
 Stearol, 700
 Stearoyl Macrogolglycerides, 557
 Stearoyl Polyoxylglycerides, 557
 Stearyl alcohol, 151, 156, 700
 Steatite, 728
 Stenol, 700
 Stepan GMO, 288
 Stepan GMS, 290
 Stepan IPM, 348
 Stepan IPP, 350
 Stereophanic acid, 697
 Sterile water
 for inhalation, 769
 for injection, 769
 for irrigation, 769
 Sterile water for inhalation, 769
 Sterile water for injection, 769
 Sterile water for irrigation, 769
 Sterilizable corn starch, 695
 Sterilizable maize starch, 690, 695
 Sterilizing agents
 potassium metabisulfite, 577
 see also Disinfectants
 Sterisil, 304
 SteriSol, 304
 Sternpur, 385
 Sterogenol, 158
 Sterotex, 762
 Sterotex HM, 762
 Sterotex K, 129, 763
 Stiffening agent, ceresin, 148
 Stiffening agents
 anionic emulsifying wax, 771
 carnauba wax, 773
 cetyl alcohol, 155
 cetyl esters wax, 774
 dextrin, 220
 hydrogenated castor oil, 128
 microcrystalline wax, 775
 nonionic emulsifying wax, 777
 paraffin, 474
 stearyl alcohol, 700
 white wax, 779
 yellow wax, 780
 see also Gelling agents; Thickening agents;
 Viscosity-increasing agents
 Strese & Hofmann's Hectorite, 301
 Stronger ammonia water, 39
 Substituted glucens, 160
 Sucaryl, 644
 Sucaryl calcium, 644
 Sucaryl sodium, 608
 Succinylsulfathiazole, 261
 Sucralfate, 403, 408
 Sucralosa, 701
 Sucralose, 606, 609, 701
 Sucralosum, 701
 SucraPlus, 701
 Sucre de gélatine, 295
 Sucrose, 224, 275, 282, 604, 702–703, 708,
 710, 712–713
 alternatives to see Sweetening agents
 direct compacting, 709
 directly compressible, 709
 sweetness
 vs. acesulfame potassium, 3
 vs. aspartame, 48
 vs. fructose, 273, 275
 vs. lactitol, 358
 vs. maltitol, 414
 vs. neohesperidin dihydrochalcone, 458
 vs. neotame, 460
 vs. saccharin, 605
 vs. saccharin sodium, 608
 vs. xylitol, 789
 vs. artificial sweetening agents, 607, 609
 see also Sugar
 Sucrose octaacetate, 707
 Sucrose see Sucrose
 Sucrose syrup, 416
 Sucticide, 152
 Sugar, 703
 alternatives to see Sweetening agents
 compressible, 706, 709, 712–713
 confectioner's, 706, 710, 713
 icing, 710
 powdered, 710
 refined, 703
 see also Sucrose
 Sugar coating adjuncts, 710
 sucrose, 703–704
 Sugar, compressible, 709
 Sugar, confectioner's, 710
 Sugar seeds, 712
 Sugar spheres, 706, 710, 712
 Sugar-free lozenges, 513
 Sugartab, 710
 Suglets, 712
 Sukor, 458
 Sulfate of lime, 107
 anhydrous, 105
 Sulfinylbismethane, 238
 o-sulfobenzimide, 605
 o-sulfobenzoic acid imide, 605
 Sulfo-butanedioic acid 1,4-bis(2-ethylhexyl)
 ester, sodium salt, 244
 Sulfobutylether β -cyclodextrin, 213, 316, 714
 Sulfobutylether- β -cyclodextrin, sodium salt, 714
 1-p-sulphophenylazo-2-naphthol-6-sulfonic acid
 disodium salt, 194
 Sulfosuccinic acid 1,4-bis(2-ethylhexyl) ester S-
 sodium salt, 244
 Sulfothiorine, 671
 Sulfur dioxide, 718
 Sulfuric acid, 719
 dilute, 720
 fuming, 720
 Sulfuric acid aluminum potassium salt (2 : 1 : 1)
 dodecahydrate, 567
 Sulfuric acid monododecyl ester, sodium salt,
 651
 Sulfuric acid monododecyl ester sodium salt
 (1 : 1), 651
 Sulfur(IV) oxide, 718
 Sulfurous acid disodium salt, 669
 Sulfurous anhydride, 718
 Sulfurous oxide, 718
 Sulphinylbismethane, 238
 Sulphuric Acid, 719
 Sunett, 3
 Sunflower oil, 185, 200, 203, 477, 611, 615,
 684, 721
 refined, 721
 Sunflowerseed oil, 721
 Sunmalt, 422
 Sunmalt S, 422
 Sunrose, 118
 Sunscreens, 722
 Sunset yellow FCF, 193–194
 Super Hartolan, 382
 Super Refined Crodamol IPM, 348
 Super Refined Crodamol IPP, 350
 Superiore, 728
 SuperTab 11SD, 376
 SuperTab 14SD, 376
 SuperTab 21AN, 359
 SuperTab 22AN, 359
 SuperTab 30GR, 364
 Suppocire, 722
 Suppository bases, 521, 763
 agar, 13
 factors affecting drug release, 722
 hard fat, 431, 722
 additives, 722–723
 chemical reactivity, 723
 melting characteristics, 723
 rheology, 723
 poloxamer, 507
 polyethylene glycol, 517
 Suppository bases, hard fat, 722
 Supronic, 506
 Surelease, 262–263
 Sureteric, 562
 Surfactant, nonionic, macrogol 15
 hydroxystearate, 391
 Surfactants
 alcohol, 17
 and emulsifying waxes, 772, 778
 anionic
 and self-emulsifying glyceryl monooleate,
 289
 docusate sodium, 244
 emulsifying wax BP, 772, 778
 phospholipids, 499
 sodium lauryl sulfate, 651
 cationic
 benzethonium chloride, 59
 cetrimide, 152
 cetylpyridinium chloride, 157
 phospholipids, 499
 sodium lauryl sulfate incompatibility, 652
 xanthan gum incompatibility, 783
 chlorhexidine activity, 164
 lauric acid, 383
 myristyl alcohol, 456
 nonionic
 and butylparaben, 80
 and ethylparaben, 271
 and methylparaben, 443
 and propylparaben, 597
 and sorbic acid, 672–673
 emulsifying wax USP, 772, 778
 glyceryl monooleate, 289
 phospholipids, 499
 polyoxyethylene alkyl ethers, 536
 polyoxyethylene castor oil derivatives,
 542
 polyoxyethylene sorbitan fatty acid esters,
 550
 polyoxyethylene stearates, 554
 polyoxylglycerides, 558
 polysorbate 80, 443
 sorbitan esters, 675
 triethyl citrate, 756
 vitamin E polyethylene glycol succinate, 764
 see also Solubilizing agents; Wetting agents
 Surgical spirit, 19
 Suspending agents
 acacia, 1
 agar, 13
 alginic acid, 20
 bentonite, 53
 calcium stearate, 103
 carbomers, 110
 carboxymethylcellulose calcium, 117
 carboxymethylcellulose sodium, 119
 carrageenan, 122
 cellulose, powdered, 136
 cellulose, microcrystalline and
 carboxymethylcellulose sodium, 134
 ceratonia, 146
 colloidal silicon dioxide, 185

Suspending agents (*cont.*)

dextrin, 220
gelatin, 278
guar gum, 298
hectorite, 301
hydrophobic colloidal silica, 309
hydroxyethyl cellulose, 311
hydroxyethylmethyl cellulose, 314
hydroxypropyl cellulose, 318
hypromellose, 326
kaolin, 352
magnesium aluminum silicate, 393
maltitol solution, 416
medium-chain triglycerides, 429
methylcellulose, 438
microcrystalline cellulose, 129
phospholipids, 499
polycarbophil, 509
polyethylene glycol, 518
polyoxyethylene sorbitan fatty acid esters, 550
potassium alginate, 566
povidone, 581
propylene glycol alginate, 594
saponite, 612
sesame oil, 614
sodium alginate, 622
sodium starch glycolate, 663
sorbitan esters, 675
sucrose, 703
tragacanth, 744
vitamin E polyethylene glycol succinate, 764
xanthan gum, 782

Sustained-release agents

acetyltributyl citrate, 8
agar, 13
alginic acid, 20
carbomers, 110
carnauba wax, 772
carrageenan, 122
cellulose acetate, 141
glycerin monostearate, 290
glyceryl monooleate, 289
glyceryl palmitostearate, 293
guar gum, 298
hydrogenated castor oil, 128
hydroxypropyl cellulose, 318
hypromellose, 326
hypromellose acetate succinate, 330
hypromellose phthalate, 333
mannitol, 424
methylcellulose, 438
oleyl alcohol, 468
peanut oil, 476
polacrilin potassium, 505
polyethylene oxide, 522
polyoxylglycerides, 558
polyvinyl alcohol, 564
sesame oil, 614
sodium acetate, 621
sodium alginate, 622
sodium hyaluronate, 646
stearic acid, 697
sugar spheres, 712
tributyl citrate, 749
triethyl citrate, 756
white wax, 779
xanthan gum, 782
yellow wax, 780
zein, 790

see also Controlled-release agents

Sustane, 75

Suva 134a, 733

Swanlac, 616

Sweet almond oil, 29

Sweet One, 3

Sweetening agents

acesulfame potassium, 3–4
alitame, 28
artificial *vs.* sucrose, 607, 644
aspartame, 48, 50
compressible sugar, 709
confectioner's sugar, 710
dextrose, 222
erythritol, 251
fructose, 273
glycerin, 283
glycine, 295
inulin, 339
isomalt, 343
lactitol, 357
liquid glucose, 282
maltitol, 414
maltitol solution, 416
maltose, 422
mannitol, 424
neohesperidin dihydrochalcone, 458
neotame, 460
relative sweetness, 275
saccharin, 605
saccharin sodium, 608–609
sodium cyclamate, 643
sorbitol, 679, 681
sucralose, 701
sucrose, 703
synergistic effects, 607, 609, 644
tagatose, 727
thaumatin, 735
trehalose, 746
xylitol, 786

Syloid 244 FP-BU, 188

Syloid 244FP, 188

Sylvine, 573

Sylvinite, 573

Sylvite, 573

Synaceti 116, 774

Synical CAS, 607

Synperonic, 506

Synpro, 35, 103, 793

Synpro 90, 404

Synpro Aluminum Monostearate NF, 36

Synpro Aluminum Monostearate NF Gellant, 36

Synthetic alpha tocopherol, 31

Synthetic amorphous silica, 185

Synthetic magnesium silicate, 402

Synthetic paraffin, 475

Synthetic spermaceti, 774

Syrupy phosphoric acid, 503

Tabfine D-100, 222

Table salt, 637

Tablet binders/binding agents *see* Binding agents

Tablet coating agents *see* Coating agents

Tablet film former *see* Film-forming agents

Tablet/capsule diluents *see* Diluents (tablet/capsule)

Tablet/capsule disintegrants *see* Disintegrants (tablet/capsule)

Tablet/capsule lubricants *see* Lubricants (tablet/capsule)

Tablets, chewable *see* Chewable tablet formulations; Medicated confectionery bases

Tabletose, 364

Tablitz, 691

Tablo, 663

Tabulose, 129

Tagatose, 606, 609, 727

Tagatosum, 727

Tagatoza, 727

Talc, 55, 175, 302, 396, 403, 409, 613, 728, 762

methylparabens incompatibility, 443

powdered, 728

purified, 728

Talcum, 728

Talha gum, 1

Talin, 735

Tangantangan, 126

Tannic acid, 13

Tapi, 418

Tapioca (cassava) starch, 690

Tartaric acid, 183, 277, 413, 570, 731

effervescent tablet formulations, 629

sodium bicarbonate neutralization, 632

Tartrazine, 193, 195

Taste-masking agents

alginic acid, 20

erythritol, 251

glyceryl palmitostearate, 293

Taumatina, 735

Taumatina, 735

Taxol, 542

Taylorite, 53

TBC, 749

TEA, 754

Tealan, 754

TEC, 756

Teel oil, 614

Tegin, 288, 290

Tegin 503, 290

Tegin 515, 290

Tegin 4100, 290

Tegin M, 290

Tego Alkanol 16, 155

Tego Alkanol 18, 700

Tego Alkanol 1618, 150

Tego Alkanol 6855, 150

Tego Carbomer, 110

Tegosept B, 78

Tegosept E, 270

Tegosept M, 441

Tegosept P, 596

Tegosoft M, 348

Tegosoft P, 350

Tegostearic, 697

Telfairic acid, 389

Tenox BHA, 73–74

Tenox BHT, 75

Tenox PG, 587

Terra alba, 105

tert-butyl-4-methoxyphenol, 73

2-*tert*-Butyl-4-methoxyphenol, 73

Tertiary calcium phosphate, 99

Tetracemate dipotassium, 248

Tetracemate tetrasodium, 249

Tetracemic acid, 247

Tetracemin, 249

Tetracycline, 353, 403, 408

n-tetradecanoic acid, 455

Tetradecanoic acid, 1-methylethyl ester, 348

n-tetradecanol-1, 456

1-tetradecanol, 456

n-tetradecyl alcohol, 456

Tetradecyltrimethylammonium bromide, 154

Tetrafluoroethane, 233, 303

1,1,1,2-Tetrafluoroethane, 733

Tetrafluoroethane (HFC), 733

Tetraglycol, 297

α -(tetrahydrofuran-2-yl)- ω -hydroxy-poly(oxyethylene), 297

α -[(Tetrahydro-2-furanyl)methyl]- ω -hydroxy-poly(oxy-1,2-ethanediyl), 297

Tetrahydrofurfuryl alcohol, 297

Tetrahydrofurfuryl alcohol polyethylene glycol ether, 297

- Tetrahydroxybutane, 251
 (+)-(2*R*,4'*R*,8'*R*)-2,5,7,8-Tetramethyl-2-(4',8',12'-trimethyltridecyl)-6-chromanyl acetate, 32
 (±)-(2*RS*,4'*RS*,8'*RS*)-2,5,7,8-Tetramethyl-2-(4',8',12'-trimethyltridecyl)-6-chroman-3-ol, 31
 (+)-(2*R*,4'*R*,8'*R*)-2,5,7,8-tetramethyl-2-(4',8',12'-trimethyltridecyl)-6-chroman-3-ol, 32
 (±)-(2*RS*,4'*RS*,8'*RS*)-2,5,7,8-tetramethyl-2-(4',8',12'-trimethyltridecyl)-6-chromanyl acetate, 32
 Tetrasodium edetate, 249
 Tetrasodium ethylenebis(iminodiacetate), 249
 Tetrasodium ethylenediaminetetraacetate, 249
Texapon K12P, 651
Texofor A, 536
 TGS, 701
 Thalin, 735
 Thaumatin, 606, 609, 735
 Thaumatine, 735
 Thaumatin, 735
 Thaumatin protein, 735
 Theobroma oil, 725, 771
 Therapeutic agents
 albumin, 14
 alginic acid, 20, 22
 almond oil, 30
 alpha tocopherol, 31
 aluminum hydroxide, 400
 aluminum hydroxide adjuvant, 35
 ammonia solution, 40
 ammonium chloride, 42
 anionic emulsifying wax, 771
 ascorbic acid, 43
 attapulgit, 51
 bentonite, 53
 benzethonium chloride, 60
 benzoic acid, 61
 benzyl alcohol, 64
 benzyl benzoate, 67
 butylated hydroxytoluene, 75
 calcium acetate, 82
 calcium alginate, 84
 calcium carbonate, 86
 calcium chloride, 89
 calcium hydroxide, 91
 calcium lactate, 92
 calcium sulfate, 105
 castor oil, 127
 cellulose acetate, 141
 cellulose acetate phthalate (CAP), 144
 cetrimide, 153
 chlorbutanol, 166
 chloroxylenol, 177
 citric acid monohydrate, 181
 coconut oil, 184
 cottonseed oil, 202
 dextrin, 220
 dextrose, 222
 dibasic sodium phosphate, 656
 diluted hydrochloric acid, 309
 dimethicone, 233
 dimethyl sulfoxide, 238–239
 docusate sodium, 244, 246
 edetic acid, 247
 fumaric acid, 276
 gelatin, 278
 glycerin, 283
 guar gum, 298
 hexetidine, 304
 hydrochloric acid, 308
 isopropyl alcohol, 346
 isopropyl myristate, 348
 kaolin, 352
 lactic acid, 355
 lactitol, 357
 lecithin, 386
 light mineral oil, 447
 macrogol 15 hydroxystearate, 392
 magnesium carbonate, 397
 magnesium oxide, 400
 magnesium silicate, 403
 magnesium trisilicate, 408
 malic acid, 411
 maltodextrin, 418
 maltol, 422
 mannitol, 424
 medium-chain triglycerides, 429
 menthol, 433
 methionine, 436
 methylcellulose, 438
 mineral oil, 446
 monobasic sodium phosphate, 659
 monoethanolamine, 450
 monothioglycerol, 454
 nitrous oxide, 463
 oleyl alcohol, 469
 olive oil, 470
 peanut oil, 476
 petrolatum, 482
 phenol, 485
 phosphoric acid, 503
 poloxamers, 507
 potassium benzoate, 569
 potassium bicarbonate, 570
 potassium chloride, 572
 potassium citrate, 574–575
 potassium hydroxide, 576
 propylene glycol, 593
 simethicone, 619–620
 sodium acetate, 621
 sodium alginate, 622
 sodium ascorbate, 625
 sodium bicarbonate, 629
 sodium carbonate, 635
 sodium citrate dihydrate, 641
 sodium hyaluronate, 647
 sodium lactate, 650
 sodium propionate, 661, 663
 sorbitol, 679
 soybean oil, 682–683
 sucrose, 704
 sulfuric acid, 719
 sunflower oil, 721
 thymol, 739
 titanium oxide, 741
 triethanolamine, 754
 trisodium edetate, 249
 vanillin, 760
 xylitol, 786
 zinc acetate, 791
 Thermal stabilizers
 colloidal silicon dioxide, 185
 hydrophobic colloidal silica, 309
 THFP, 297
 Thiamin (vitamin B1), 578
 Thickening agent, ceresin, 148
 Thickening agents
 agar, 13
 ammonium alginate, 41
 calcium alginate, 83
 calcium lactate, 92
 cellulose, powdered, 136
 cellulose, microcrystalline and carboxymethylcellulose sodium, 134
 colloidal silicon dioxide, 186
 dextrin, 220
 ethylcellulose, 263
 ethylene glycol palmitostearate, 267
 glyceryl behenate, 286
 hectorite, 301
 hydroxyethyl cellulose, 311
 hydroxyethylmethyl cellulose, 314
 hydroxypropyl cellulose, 318
 hydroxypropyl starch, 325
 hypromellose, 326
 methylcellulose, 438
 myristyl alcohol, 456
 octyldodecanol, 465
 pectin, 478
 polycarbophil, 509
 polyethylene glycol, 518
 polyethylene oxide, 522
 potassium alginate, 566
 starch, 685
 trehalose, 746
 xanthan gum, 782–783
 zinc stearate, 793
 see also Gelling agents; Stiffening agents;
 Viscosity-increasing agents
 Thimerosal, 247, 493, 495, 498, 736
Thimerosal Sigmaultra, 736
 Thin vegetable oil, 429
 Thioglycerin, 454
 1-thioglycerol, 454
 Thiomersal, 736
 Thiomersalate, 736
 Thiomersalum, 736
 Thiosulfuric acid disodium salt, 671
 Thiothixene, 760
 Thyme camphor, 739
 Thymic acid, 739
 Thymol, 435, 739
 Thymolum, 739
TIC Pretested, 594
 Timol, 739
 Timolol, 238, 579
Tioxide, 741
TiPure, 741
 Titanic anhydride, 741
 Titanii dioxide, 741
 Titanium dioxide, 189, 193, 196, 335, 741
 anatase, 741
 Titanium Oxide, 741
 TM-β-CD, 213
 Tobermorite, 101
 Tocofersolan, 764
 Tocopherol, 31–33
 (2*R*,4'*R*,8'*R*)-alpha-Tocopherol, 31
 alpha Tocopherol, 31–32, 46
 and ascorbyl palmitate, 31
 and lecithin, 31
 and linoleic acid, 31
 and methyl linolenate, 31
 natural, 32
 synthetic, 31
 d-alpha Tocopheryl acetate, 32
 d-alpha Tocopheryl acid succinate, 32–33
 and canola oil, 109
 beta Tocopherol, 32–33
 delta Tocopherol, 32–33
 (±)-α-tocopherol acetate, 32
 (+)-α-Tocopherol hydrogen succinate, 33
 Tocopherol polyethylene glycol succinate, 764
 dl-α-tocopherol succinate, 33
 α-tocopherol acetate, 32
 Tocopherols excipient, 32–33
 RRR-α-tocopherolum, 31
 Tocophersolan, 764
 d-α-tocopheryl acetate, 32
 d-α-tocopheryl acid succinate, 33
 D-α-tocopheryl polyethylene glycol 1000 succinate, 764
 Tolbutamide, 396
 α-toluenol, 64

- Tonicity agents
 dextrose, 222
 glycerin, 283
 hydroxypropyl betadex, 316
 mannitol, 424
 potassium chloride, 572
 sodium chloride, 637
Topanol, 75
 Tower rapeseed oil, 108
 Toxilic acid, 410
 TPGS, 764
 Trag, 744
 Tragacanth, 2, 146–147, 300, 744
 and acacia, 1
 and guar gum, 299
 methylparabens incompatibility, 443
 powdered, 745
 Tragacanth gum, 744
 Tragacantha, 744
 Tragant, 744
trans-butenedioic acid, 276
 Transdermal delivery agents
 acetyltributyl citrate, 9
 dimethyl sulfoxide, 238
 ethylene vinyl acetate, 268
 glyceryl monooleate, 289
 isopropyl myristate, 348
 isopropyl palmitate, 350
 light mineral oil, 448
 polymethacrylates, 526
 polyvinyl alcohol, 564
 sesame oil, 614
 sodium carboxymethyl guar, 300
 stearyl alcohol, 700
 see also Penetration enhancers
trans-1,2-ethylenedicarboxylic acid, 276
 Transmissible Spongiform Encephalopathy (TSE), 280
Treha, 746
 Trehalose, 746–747
 Trehalose dihydrate, 746
 Triacetin, 748
 Triacetinum, 748
 Triacetyl glycerine, 748
 Tribasic calcium phosphate, 99
 Tribasic sodium phosphate, 658
 Tribehenin, 286
 Tributyl Acetylcitrate, 8
 Tributyl citrate, 9–10, 749, 756–757
 Tributyl citrate acetate, 8
 Tributyl ester, citric acid, 749
 Tributyl 2-hydroxy-1,2,3-propanetricarboxylate, 749
 Tributylis acetyltras, 8
Tri-Cafos, 99
TRI-CAL WG, 99
 Tricalcii phosphas, 99
 Tricalcium diorthophosphate, 99
 Tricalcium orthophosphate, 99
 Tricalcium phosphate, 99
 Tricalcium silicon pentaoxide, 102
 Tricaprilin, 751
 Tricaprylin, 751
 Tricapryloglycerol, 751
 Tricaprylylglycerin, 751
 Trichloro-*tert*-butanol, 166
 β,β,β -trichloro-*tert*-butyl alcohol, 166
 Trichlorofluoromethane, 173
 1',4',6'-trichlorogalactosucrose, 701
 1,1,1-Trichloro-2-methyl-2-propanol, 166
 1,1,1-Trichloro-2-methyl-2-propanol hemihydrate, 166
 Trichloromonofluoromethane, 173–174
 Montreal Protocol, 175
 Trichloro-*t*-butyl alcohol, 166
 4,1',6'-trichloro-4,1',6'-trideoxy-galacto-sucrose, 701
 1,2,3-tri(*cis*-9-octadecenoyl)glycerol, 757
 Tricresol, 203
 1-tridecanecarboxylic acid, 455
 Trielaidin, 757
 Trielaidoylglycerol, 757
 Triethanolamine, 229, 451, 754
 Triethyl acetylcitrate, 10
 Triethyl citrate, 9–10, 750, 756
 Triethyl citrate acetate, 10
 Triethylis citras, 756
 Triethylolamine, 754
 Triglycerida saturata media, 429
 Triglyceride, caprylic/capric, 429
 Triglycerides, medium-chain, 429, 725, 752, 763
 Triglycerides, Medium-Chain, 429
 3,4,5-Trihydroxybenzoic acid propyl ester, 587
 Trihydroxyborene, 68
 9,10,16-trihydroxypalmitic acid, 618
 8,9,15-trihydroxypentadecane-1-carboxylic acid, 618
 Trihydroxypropane glycerol, 283
 Trihydroxytriethylamine, 754
 Triiron tetraoxide, 340
 Trimethyl- β -cyclodextrin, 213, 716
 N,N,N-trimethyldodecylammonium bromide, 153
 N,N,N-trimethylhexadecylammonium bromide, 153
 α -(Trimethylsilyl)- ω -methylpoly[oxy(dimethylsilylene)], 233
 N,N,N-trimethyl-1-tetradecanaminium bromide, 154
 Trimethyltetradecylammonium bromide, 152–153
 5,7,8-trimethyltocol, 31
 α -(Trimethylsilyl)- ω -methylpoly[oxy(dimethylsilylene)], mixture with silicon dioxide, 619
 Trioctanoin, 751
 Trioctonolglycerol, 751
 Triolein, 757
 Tripotassium citrate, 574
Trisept B, 78
 Tris(hydroxyethyl)amine, 754
 Trisodium calcium diethylenetriaminepentaacetate, 481
 Trisodium citrate, 640
 anhydrous, 642
 Trisodium edetate, 248–249
 Trisodium ethylenediaminetetraacetate, 249
 Trisodium 2-hydroxypropane-1,2,3-tricarboxylate dihydrate, 640
 Trisodium 2-hydroxy-1,2,3-propanetricarboxylic acid, 642
 Trisodium orthophosphate, 658
 Trisodium phosphate, 658
 Trisodium zinc diethylenetriaminepentaacetate, 481
Tri-Stat IU, 337
Tri-Sweet, 48
TRI-TAB, 99
 Tritici amyllum, 685
 Trolamine, 754
 Trolaminum, 754
Tronox, 741
 TSE see Transmissible Spongiform Encephalopathy
 TSP, 658
T-Wax, 777
Tylopur, 326
Tylopur MH, 314
Tylopur MHB, 314
Tylose, 438
Tylose CB, 118
Tylose H, 311
Tylose MB, 314
Tylose MGA, 118
Tylose MH, 314
Tylose MHB, 314
Tylose MO, 326
Tylose PHA, 311
 U-1149, 276
 Ultramarine blue
 and butylparaben, 80
 and ethylparaben, 271
 and propylparaben, 597
Ultrez, 112
 1-undecanecarboxylic acid, 383
Unihydag WAX-14, 456
Unimate GMS, 290
Unimate IPP, 350
Unimoll DB, 225
Unimoll DM, 236
Uniphen P-23, 78, 270, 441, 596
Uni-Pure, 685
Unipure LD, 691
Unipure WG220, 691
Unisept, 165
Unisept B, 78
 Urethane hydrogels, 518
 USAF EK-P-583, 276
USG Terra Alba, 105
 Vaccine adjuvants
 aluminum hydroxide adjuvant, 34
 aluminum phosphate adjuvant, 38
 mineral oil, 445
 VA/ethylene copolymer, 268
 Vanillal, 261
 Vanillic aldehyde, 760
 Vanillin, 261–262, 760
 Vanillinum, 760
Vanzan NF, 782
 Vaselineum album, 483
 Vaselineum flavum, 481
Veegum, 393
Veegum HS, 53
Vegarol 1695, 155
Vegarol 1898, 700
 Vegetable glycerides, hydrogenated, 722
 Vegetable lecithin, 385
 Vegetable oil
 hydrogenated, 431, 762
 type I, 129, 203, 762
 type II, 763
 thin, 429
 Vegetable oil, hydrogenated, 762
VEGS, 764
Veltol, 421
Veltol Plus, 257
Versene, 249
Versene Acid, 247
Versene CA, 248
Versene-9, 249
Versenex, 480
Vestimol C, 225
Vianol, 75
Vilvanolin CAB, 484
 Vinegar, artificial, 6
 Vinegar acid, 5
 Vinegar naphtha, 253
 Vinegar salts, 82
 Vinyl acetate, copolymer with 1-vinyl-2-pyrrolidinone, 196
 Vinyl acetate/ethylene copolymer, 268
 Vinyl alcohol polymer, 564
 1-Vinyl-2-pyrrolidinone, copolymer with vinyl acetate, 196

- 1-vinyl-2-pyrrolidinone homopolymer, 208
 1-vinyl-2-pyrrolidinone polymer, 581
 Virgin Almond Oil, 29
 Virgin Castor Oil, 126
 Virgin olive oil, 471–472
 Viricides *see* Antiviral agents
Viscarin, 122
Viscol, 438
 Viscosity-increasing agents
 acacia, 1
 agar, 13
 alginic acid, 20
 bentonite, 53
 carboxymethylcellulose calcium, 117
 carboxymethylcellulose sodium, 119
 carrageenan, 122
 ceratonia, 146
 cetostearyl alcohol, 150
 chitosan, 159
 colloidal silicon dioxide, 185
 cyclomethicone, 215
 ethylcellulose, 262
 gelatin, 278
 glycerin, 283
 guar gum, 298
 hectorite, 301
 hydrogenated vegetable oil type I, 762
 hydrophobic colloidal silica, 309
 hydroxyethyl cellulose, 311
 hydroxyethylmethyl cellulose, 314
 hydroxypropyl cellulose, 318
 hydroxypropyl starch, 325
 hypromellose, 326
 magnesium aluminum silicate, 393
 maltodextrin, 418
 methylcellulose, 438
 myristyl alcohol, 456
 polydextrose, 513
 polyethylene glycol, 518
 poly(methylvinyl ether/maleic anhydride), 534
 polyvinyl acetate phthalate, 562
 polyvinyl alcohol, 564
 potassium chloride, 572
 povidone, 581
 propylene glycol alginate, 594
 saponite, 612
 sodium alginate, 622, 624
 sodium chloride, 637
 starch, 690
 stearyl alcohol, 700
 sucrose, 703
 sulfobutylether β -cyclodextrin, 714
 tragacanth, 744
 xanthan gum, 147, 782–784
 see also Gelling agents; Stiffening agents; Thickening agents
Vitagel, 278
Vitagran, 86
 Vitamin C, 43
 Vitamin C palmitate, 46
 Vitamin C sodium, 625
 Vitamin E, 32–33
 Vitamin E polyethylene glycol 1000 succinate, 764
 Vitamin E polyethylene glycol succinate, 764
 Vitamin E TPGS, 764
 Vitamin F, 389
 Vitamins
 solubilizing agents
 polyoxyethylene castor oil derivatives, 542–543
 polyoxyethylene sorbitan fatty acid esters, 550
 vitamin A palmitate, 542–543
 vitamin A propionate, 543
 vitamin B1 (thiamin), 578
 vitamin C, 43, 450
 vitamin C palmitate, 46
 vitamin C sodium, 625
 vitamin D, 542
 vitamin E, 31–33
 vitamin E acetate, 542
 vitamin E polyethylene glycol 1000 succinate, 764
 vitamin E polyethylene glycol succinate, 764
 vitamin E TPGS, 764
 vitamin F, 389
 vitamin K1, 542
Vivapress Ca, 86
Vivapress Ca 740, 88
Vivapress Ca 800, 88
Vivapur, 129
Vivapur MCG 591 PCG, 134
Vivapur MCG 611 PCG., 134
Vivasol, 206
Vivastar P, 663
Vivastar PSF, 665
 Voelicherite, 100
 Volpo, 536
 Volpo N, 537
 Volpo N10, 536
 Vulvic acid, 383

Wacker HDK, 185
Waglinol 3/9280, 429
Waglinol 6014, 348
Waglinol 6016, 350
Walocel C, 118
 Warfarin, 353
 Warfarin sodium, 396
 Water, 766
 distilled, 769
 for injection, 769
 potable, 766
 purified, 766, 769
 Water for injection, 769
 Water for injection (WFI), 769
 Water softeners, edetic acid, 247
 Water-absorbing agents
 calcium chloride, 89
 carboxymethylcellulose calcium, 117
 carboxymethylcellulose sodium, 119
 Water-repelling agents
 dimethicone, 233
 simethicone, 619
 Water-soluble lanolin, 380
 Wax
 anionic emulsifying, 151, 653, 770, 778
 anionic emulsifying (*see* Emulsifying wax anionic)
 bleached, 779
 carnauba, 772
 ceresin, 148
 ceresine, 148
 cetyl esters, 774
 earth, 148
 hard, 474
 alternatives to, 762
 microcrystalline, 149, 475, 775, 780–781
 mineral, 148
 nonionic emulsifying, 541, 777
 refined, 780
 spermaceti, 775
 white, 149, 776, 779, 781
 white ceresin, 148
 white ozokerite, 148
 yellow, 149, 776, 779–780
 Wax, anionic emulsifying, 770
 Wax, carnauba, 772
 Wax, cetyl esters, 774
 Wax, microcrystalline, 775
 Wax, nonionic emulsifying, 777
 Wax, white, 779
 Wax, yellow, 780
Wecobee, 722
Wecoline 129S, 383
 Weisserton, 352
 Wetting agents
 benzalkonium chloride, 56
 benzethonium chloride, 59
 cetylpyridinium chloride, 157
 docusate sodium, 244
 glycine, 295
 hypromellose, 327
 phospholipids, 499
 poloxamer, 507
 polyoxyethylene alkyl ethers, 536
 polyoxyethylene castor oil derivatives, 542
 polyoxyethylene sorbitan fatty acid esters, 550
 polyoxyethylene stearates, 555
 sodium lauryl sulfate, 651
 sorbitan esters, 675
 tricaprylin, 751
 see also Solubilizing agents; Surfactants
 White Beeswax, 779
 White bole, 352
 White ceresin wax, 148
 White dextrin, 220
 White mineral oil, 445
 White ozokerite wax, 148
 White petrolatum, 483, 485
 White petroleum jelly, 483
 White soft paraffin, 483
 and anionic emulsifying wax, 771
 and lanolin alcohols, 484
 White soft paraffin and lanolin alcohols, 484
 White wax, 149, 776, 779, 781
 Whitfield's ointment, 61
 Whitlockite, 100
Wickenol 111, 350
 Wilkinite, 53
Wilzin, 792
Witcarb, 86
Witcizer 300, 225
Witepsol, 722
 Wood ether, 235
 Wool Alcohols, 382
 and petrolatum, 484
 Wool alcohols ointment, 485
 Wool Fat, 378
 hydrogenated, 379
 hydrous, 380
 refined, 378
 Wool Fat, Hydrous, 380
 Wool wax alcohols, 382

 Xanthan gum, 147, 300, 393, 782
 Xanthani gummi, 782
Xantural, 782
 Xilitol, 786
Xylifin, 786
Xylisorb, 786
 Xylit, 786
Xylitab, 786
Xylitab 100, 789
Xylitab 200, 789
Xylitab 300, 789
 Xylite, 786
 Xylitol, 253, 426, 681, 786
 cooling effect, 789
 sweetness *vs.* mannitol, 789
 sweetness *vs.* sucrose, 789
Xylitolo, 786
 Xylitolum, 786
Xylo-Mucine, 118
xylo-Pentane-1,2,3,4,5-pentol, 786

- p*-xylotocopherol, 33
- Yellow Beeswax, 780
- Yellow dextrin, 220
- Yellow ferric oxide, 340
- Yellow iron oxide, 340
- and butylparaben, 80
- and ethylparaben, 271
- and propylparaben, 597
- Yellow ochre, 340
- Yellow orange S, 194
- Yellow Petrolatum, 481, 485
- Yellow petroleum jelly, 481
- Yellow soft paraffin, and lanolin alcohols, 484
- Yellow soft paraffin and lanolin alcohols, 484
- Yellow wax, 149, 776, 779–780
- Yeso blanco, 107
- Zebedassite, 612
- Zein, 790
- Zenalb*, 14
- Zephex 134a*, 733
- Zephex 227 ea*, 303
- Zephiran*, 56
- Zerose*, 251
- Zinc acetate dihydricus, 791
- Zinc acetate, 791
- Zinc acetate anhydrous, 791
- Zinc Acetate Dihydrate, 791
- Zinc diacetate, 791
- Zinc distearate, 793
- Zinc DTPA, 481
- Zinc ethanoate, 791
- Zinc formaldehyde sulfoxylate, 646
- Zinc (II) acetate, 791
- Zinc octadecanoate, 793
- Zinc oxide, 285, 721
- Zinc pentetate, 481
- Zinc propionate, 662
- Zinc soap, 793
- Zinc stearate, 105, 405, 699, 793
- dibasic, 793
- Zinc trisodium pentetate, 481
- Zinci stearas, 793
- ZK-43649, 480