

16 Regulatory Status

GRAS listed. Butane, isobutane, and propane are accepted for use as food additives in Europe. Included in the FDA Inactive Ingredients Database (aerosol formulations for topical application). Included in nonparental medicines licensed in the UK. Included in the Canadian Natural Health Products Ingredients Database.

17 Related Substances

Dimethyl ether.

18 Comments

Although hydrocarbon aerosol propellants are relatively inexpensive, nontoxic, and environmentally friendly (since they are not damaging to the ozone layer and are not greenhouse gases), their use is limited by their flammability. While hydrocarbon propellants are primarily used in topical aerosol formulations, it is possible that butane may also be useful in metered-dose inhalers as a replacement for chlorofluorocarbons.

Various blends of hydrocarbon propellants that have a range of physical properties suitable for different applications are commercially available, e.g. A-46 (*Aeropres*) is a commonly used mixture for aerosol foams and consists of about 85% isobutane and 15% propane. The number following the letter denotes the approximate vapor pressure of the blend or mixture.

Specifications for butane, isobutane, and propane are contained in the *Food Chemicals Codex* (FCC).⁽³⁾

The PubChem Compound IDs (CIDs) for butane, isobutane, and propane are 7843, 6360, and 6334 respectively.

19 Specific References

- 1 Sciarra JJ. Pharmaceutical aerosols. In: Banker GS, Rhodes CT, eds. *Modern Pharmaceutics*, 3rd edn. New York: Marcel Dekker, 1996: 547–574.
- 2 Dalby RN. Prediction and assessment of flammability hazards associated with metered-dose inhalers containing flammable propellants. *Pharm Res* 1992; 9: 636–642.
- 3 *Food Chemicals Codex*, 7th edn. Bethesda, MD: United States Pharmacopeia, 2010: 115, 529, 865.

20 General References

- Johnson MA. *The Aerosol Handbook*, 2nd edn. Caldwell: WE Dorland, 1982: 199–255, 335–361.
- Randall DS. Solving the problems of hydrocarbon propellants. *Manuf Chem Aerosol News* 1979; 50(4): 43, 44, 47.
- Sanders PA. *Handbook of Aerosol Technology*, 2nd edn. New York: Van Nostrand Reinhold, 1979: 36–44.
- Sciarra JJ. Pharmaceutical aerosols. In: Lackman L et al. eds. *The Theory and Practice of Industrial Pharmacy*, 3rd edn. Philadelphia: Lea and Febiger, 1986: 589–618.
- Sciarra CJ, Sciarra JJ. Aerosols. In: *Remington: The Science and Practice of Pharmacy*, 21st edn. Philadelphia, PA: Lippincott Williams and Wilkins, 2005: 1000–1017.
- Sciarra JJ. Aerosol suspensions and emulsions. In: Lieberman H et al. eds. *Pharmaceutical Dosage Forms: Disperse Systems*, 2nd edn, 2. New York: Marcel Dekker, 1996: 319–356.

21 Authors

CJ Sciarra, JJ Sciarra.

22 Date of Revision

1 March 2012.

Hydrochloric Acid

1 Nonproprietary Names

BP: Hydrochloric Acid

JP: Hydrochloric Acid

PhEur: Hydrochloric Acid, Concentrated

USP–NF: Hydrochloric Acid

2 Synonyms

Acidum hydrochloridum concentratum; chlorohydric acid; concentrated hydrochloric acid; E507.

3 Chemical Name and CAS Registry Number

Hydrochloric acid [7647-01-0]

4 Empirical Formula and Molecular Weight

HCl 36.46

5 Structural Formula

See Section 4.

6 Functional Category

Acidulant.

7 Applications in Pharmaceutical Formulation or Technology

Hydrochloric acid is widely used as an acidulant, in a variety of pharmaceutical and food preparations (see Section 16). It may also be used to prepare dilute hydrochloric acid; see Section 17.

8 Description

Hydrochloric acid occurs as a clear, colorless, fuming aqueous solution of hydrogen chloride, with a pungent odor.

The JP XV specifies that hydrochloric acid contains 35.0–38.0% w/w of HCl; the PhEur 7.4 specifies that hydrochloric acid contains 35.0–39.0% w/w of HCl; and the USP35–NF30 specifies that hydrochloric acid contains 36.5–38.0% w/w of HCl.

See also Section 9.

9 Pharmacopeial Specifications

See Table I.

10 Typical Properties

Acidity/alkalinity pH = 0.1 (10% v/v aqueous solution)

Boiling point 110°C (constant boiling mixture of 20.24% w/w HCl)

Density $\approx 1.18 \text{ g/cm}^3$ at 20°C

Table I: Pharmacopeial specifications for hydrochloric acid.

Test	JP XV	PhEur 7.4	USP35–NF30
Identification	+	+	+
Characters	+	+	—
Appearance of solution	—	+	—
Residue on ignition	≤1.0 mg	—	≤0.008%
Residue on evaporation	—	≤0.01%	—
Bromide or iodide	+	—	+
Free bromine	+	—	+
Free chlorine	+	≤4 ppm	+
Sulfate	+	≤20 ppm	+
Sulfite	+	—	+
Arsenic	≤1 ppm	—	—
Heavy metals	≤5 ppm	≤2 ppm	≤5 ppm
Mercury	≤0.04 ppm	—	—
Assay (of HCl)	35.0–38.0%	35.0–39.0%	36.5–38.0%

Freezing point $\approx -24^{\circ}\text{C}$

Refractive index $n_{\text{D}}^{20} = 1.342$ (10% v/v aqueous solution)

Solubility Miscible with water; soluble in diethyl ether, ethanol (95%), and methanol.

11 Stability and Storage Conditions

Hydrochloric acid should be stored in a well-closed, glass or other inert container at a temperature below 30°C . Storage in close proximity to concentrated alkalis, metals, and cyanides should be avoided.

12 Incompatibilities

Hydrochloric acid reacts violently with alkalis, with the evolution of a large amount of heat. Hydrochloric acid also reacts with many metals, liberating hydrogen.

13 Method of Manufacture

Hydrochloric acid is an aqueous solution of hydrogen chloride gas produced by a number of methods including: the reaction of sodium chloride and sulfuric acid; the constituent elements; as a by-product from the electrolysis of sodium hydroxide; and as a by-product during the chlorination of hydrocarbons.

14 Safety

When used diluted, at low concentration, hydrochloric acid is not usually associated with any adverse effects. However, the concentrated solution is corrosive and can cause severe damage on contact with the eyes and skin, or if ingested.

LD₅₀ (mouse, IP): 1.4 g/kg⁽¹⁾

LD₅₀ (rabbit, oral): 0.9 g/kg

15 Handling Precautions

Caution should be exercised when handling hydrochloric acid, and suitable protection against inhalation and spillage should be taken. Eye protection, gloves, face mask, apron, and respirator are recommended, depending on the circumstances and quantity of hydrochloric acid handled. Spillages should be diluted with copious amounts of water and run to waste. Splashes on the skin and eyes should be treated by immediate and prolonged washing with large amounts of water and medical attention should be sought. Fumes can cause irritation to the eyes, nose, and respiratory system;

prolonged exposure to fumes may damage the lungs. In the UK, the recommended short-term workplace exposure limit for hydrogen chloride gas and aerosol mists is 8 mg/m^3 (5 ppm). The long-term exposure limit (8-hour TWA) is 2 mg/m^3 (1 ppm).⁽²⁾

16 Regulatory Status

GRAS listed. Accepted for use as a food additive in Europe. Included in the FDA Inactive Ingredients Database (dental solutions; epidural injections; IM, IV, and SC injections; inhalations; ophthalmic preparations; oral solutions; nasal, otic, rectal, and topical preparations). Included in parenteral and nonparenteral medicines licensed in the UK. Included in the Canadian Natural Health Products Ingredients Database.

17 Related Substances

Dilute hydrochloric acid.

Dilute hydrochloric acid

Synonyms Acidum hydrochloridum dilutum; diluted hydrochloric acid.

Density $\approx 1.05\text{ g/cm}^3$ at 20°C

Comments The JP XV and PhEur 7.4 specify that dilute hydrochloric acid contains 9.5–10.5% w/w of HCl and is prepared by mixing 274 g of hydrochloric acid with 726 g of water. The USP35–NF30 specifies 9.5–10.5% w/v of HCl, prepared by mixing 226 mL of hydrochloric acid with sufficient water to make 1000 mL.

18 Comments

In pharmaceutical formulations, dilute hydrochloric acid is usually used as an acidulant in preference to hydrochloric acid. It is used intravenously in the management of metabolic alkalosis, and orally for the treatment of achlorhydria. Hydrochloric acid is also used therapeutically as an escharotic.⁽³⁾

The PhEur 7.4 also contains a specification for hydrochloric acid, dilute; see Section 17. A specification for hydrochloric acid is contained in the *Food Chemicals Codex* (FCC).⁽⁴⁾

The EINECS number for hydrochloric acid is 231-595-7. The PubChem Compound ID (CID) for hydrochloric acid is 313.

19 Specific References

- 1 Lewis RJ, ed. *Sax's Dangerous Properties of Industrial Materials*, 11th edn. New York: Wiley, 2004; 1980.
- 2 Health and Safety Executive. *EH40/2005: Workplace Exposure Limits*. Sudbury: HSE Books, 2011. www.hse.gov.uk/pubns/priced/eh40.pdf (accessed 12 April 2012).
- 3 Sweetman S, ed. *Martindale: The Complete Drug Reference*, 37th edn. London: Pharmaceutical Press, 2009; 2322.
- 4 *Food Chemicals Codex*, 7th edn. Bethesda, MD: United States Pharmacopeia, 2010.

20 General References

Japan Pharmaceutical Excipients Council. *Japanese Pharmaceutical Excipients Directory 1996*. Tokyo: Yakuji Nippo, 1996: 228.

21 Authors

ME Fenton, PJ Sheskey.

22 Date of Revision

12 April 2012.

Sodium Hydroxide

1 Nonproprietary Names

BP: Sodium Hydroxide
JP: Sodium Hydroxide
PhEur: Sodium Hydroxide
USP–NF: Sodium Hydroxide

2 Synonyms

Caustic soda; E524; lye; natrii hydroxidum; soda lye; sodium hydrate.

3 Chemical Name and CAS Registry Number

Sodium hydroxide [1310-73-2]

4 Empirical Formula and Molecular Weight

NaOH 40.00

5 Structural Formula

See Section 4.

6 Functional Category

Alkalizing agent.

7 Applications in Pharmaceutical Formulation or Technology

Sodium hydroxide is widely used in pharmaceutical formulations to adjust the pH of solutions.⁽¹⁾ It can also be used to react with weak acids to form salts.

8 Description

Sodium hydroxide occurs as a white or nearly white fused mass. It is available in small pellets, flakes, sticks, and other shapes or forms. It is hard and brittle and shows a crystalline fracture. Sodium hydroxide is very deliquescent and on exposure to air it rapidly absorbs carbon dioxide and water.

9 Pharmacopeial Specifications

See Table I.

Table I: Pharmacopeial specifications for sodium hydroxide.

Test	JP XV	PhEur 7.4	USP35–NF30
Identification	+	+	+
Characters	—	+	—
Appearance of solution	+	+	—
Insoluble substances	—	—	+
and organic matter			
Sodium carbonate	≤2.0%	≤2.0%	—
Sulfates	—	≤50 ppm	—
Chlorides	≤0.05%	≤50 ppm	—
Iron	—	≤10 ppm	—
Mercury	+	—	—
Heavy metals	≤30 ppm	≤20 ppm	≤30 ppm
Potassium	+	—	+
Assay (total alkali calculated as NaOH)	≥95.0%	97.0–100.5%	95.0–100.5%

10 Typical Properties

Acidity/alkalinity

pH ≈ 12 (0.05% w/w aqueous solution);
pH ≈ 13 (0.5% w/w aqueous solution);
pH ≈ 14 (5% w/w aqueous solution).

Melting point 318°C

Solubility see Table II.

Table II: Solubility of sodium hydroxide.

Solvent	Solubility at 20°C unless otherwise stated
Ethanol	1 in 7.2
Ether	Practically insoluble
Glycerin	Soluble
Methanol	1 in 4.2
Water	1 in 0.9
	1 in 0.3 at 100°C

11 Stability and Storage Conditions

Sodium hydroxide should be stored in an airtight nonmetallic container in a cool, dry place. When exposed to air, sodium hydroxide rapidly absorbs moisture and liquefies, but subsequently becomes solid again owing to absorption of carbon dioxide and formation of sodium carbonate.

12 Incompatibilities

Sodium hydroxide is a strong base and is incompatible with any compound that readily undergoes hydrolysis or oxidation. It will react with acids, esters, and ethers, especially in aqueous solution.

13 Method of Manufacture

Sodium hydroxide is manufactured by electrolysis of brine using inert electrodes. Chlorine is evolved as a gas at the anode and hydrogen is evolved as a gas at the cathode. The removal of chloride and hydrogen ions leaves sodium and hydroxide ions in solution. The solution is dried to produce the solid sodium hydroxide.

A second method uses the Kellner–Solvay cell. Saturated sodium chloride solution is electrolyzed between a carbon anode and a flowing mercury cathode. In this case the sodium is produced at the cathode rather than the hydrogen because of the readiness of sodium to dissolve in the mercury. The sodium–mercury amalgam is then exposed to water and a sodium hydroxide solution is produced.

14 Safety

Sodium hydroxide is widely used in the pharmaceutical and food industries and is generally regarded as a nontoxic material at low concentrations. At high concentrations it is a corrosive irritant to the skin, eyes, and mucous membranes.

LD₅₀ (mouse, IP): 0.04 g/kg⁽²⁾

LD₅₀ (rabbit, oral): 0.5 g/kg

15 Handling Precautions

Observe normal handling precautions appropriate to the quantity and concentration of material handled. Gloves, eye protection, a respirator, and other protective clothing should be worn.

Sodium hydroxide is a corrosive irritant to the skin, eyes, and mucous membranes. The solid and solutions cause burns, often with deep ulceration. It is moderately toxic on ingestion and harmful on inhalation.

In the UK, the workplace exposure limit for sodium hydroxide has been set at 2 mg/m³ short-term.⁽³⁾

16 Regulatory Status

GRAS listed. Accepted for use as a food additive in Europe. Included in the FDA Inactive Ingredients Database (dental preparations; injections; inhalations; nasal, ophthalmic, oral, otic, rectal, topical, and vaginal preparations). Included in nonparenteral and parenteral medicines licensed in the UK. Included in the Canadian Natural Health Products Ingredients Database.

17 Related Substances

Potassium hydroxide.

18 Comments

Sodium hydroxide is most commonly used in solutions of fixed concentration. Sodium hydroxide has some antibacterial and antiviral properties and is used as a disinfectant in some applications.⁽⁴⁻⁶⁾

A specification for sodium hydroxide is contained in the *Food Chemicals Codex* (FCC).⁽⁷⁾

The EINECS number for sodium hydroxide is 215-185-5. The PubChem Compound ID (CID) for sodium hydroxide is 14798.

19 Specific References

- 1 Zhan X, *et al.* Improved stability of 25% vitamin C parenteral formulation. *Int J Pharm* 1998; 173: 43-49.
- 2 Lewis RJ, ed. *Sax's Dangerous Properties of Industrial Materials*, 11th edn. New York: Wiley, 2004: 3254-3255.
- 3 Health and Safety Executive. *EH40/2005: Workplace Exposure Limits*. Sudbury: HSE Books, 2011. <http://www.hse.gov.uk/pubns/priced/eh40.pdf> (accessed 29 February 2012).
- 4 Brown P, *et al.* Sodium hydroxide decontamination of Creutzfeldt-Jakob disease virus. *N Engl J Med* 1984; 320: 727.
- 5 Gasser G. Creutzfeldt-Jakob disease [letter]. *Br Med J* 1990; 300: 1523.
- 6 Perkowski CA. Operational aspects of bioreactor contamination control. *J Parenter Sci Technol* 1990; 44: 113-117.
- 7 *Food Chemicals Codex*, 7th edn. Bethesda, MD: United States Pharmacopeia, 2010: 941.

20 General References

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21 Author

AH Kibbe.

22 Date of Revision

2 March 2012.

Sodium Lactate

1 Nonproprietary Names

BP: Sodium Lactate Solution

PhEur: Sodium Lactate Solution

USP-NF: Sodium Lactate Solution

2 Synonyms

E325; 2-hydroxypropanoic acid monosodium salt; *Lacolin*; lactic acid monosodium salt; lactic acid sodium salt; natrii lactatis solutio; *Patlac*; *Purasal*; *Ritalac* NAL; sodium α -hydroxypropionate.

3 Chemical Name and CAS Registry Number

Sodium lactate [72-17-3]

4 Empirical Formula and Molecular Weight

C₃H₅NaO₃ 112.06

5 Structural Formula

The PhEur 7.4 and USP35-NF30 describe sodium lactate solution as a mixture of the enantiomers of sodium 2-hydroxypropanoate in approximately equal proportions.

6 Functional Category

Antimicrobial preservative; buffering agent; emulsifying agent; flavoring agent; humectant.

7 Applications in Pharmaceutical Formulation or Technology

Sodium lactate is widely used in cosmetics,^(1,2) food products, and pharmaceutical applications including parenteral and topical formulations.

8 Description

Sodium lactate occurs as a clear, colorless, slightly syrupy liquid. It is odorless, or has a slight odor with a characteristic saline taste. It is hygroscopic.

9 Pharmacopeial Specifications

See Table I.

10 Typical Properties

Acidity/alkalinity pH = 7 for an aqueous solution.

Boiling point 112°C

Hygroscopicity Very hygroscopic.

Melting point 17°C with decomposition at 140°C.

Solubility Miscible with ethanol (95%), and with water.

Specific gravity 1.31–1.34

11 Stability and Storage Conditions

Sodium lactate should be stored in a well-closed container in a cool, dry place. Sodium lactate is combustible and decomposes upon heating.

Appendix II: List of Monographs by Functional Category

Acidifying agent *see* Acidulant

Acidulant

Acetic Acid, Glacial, 5
Adipic Acid, 13
Ammonium Chloride, 44
Ascorbic Acid, 45
Citric Acid Monohydrate, 192
Fumaric Acid, 312
Hydrochloric Acid, 349
Lactic Acid, 404
Maleic Acid, 460
Malic Acid, 462
Phosphoric Acid, 565
Propionic Acid, 662
Sulfuric Acid, 822
Tartaric Acid, 834

Adsorbent

Albumin, 17
Aluminum Hydroxide Adjuvant, 35
Aluminum Oxide, 38
Aluminum Phosphate Adjuvant, 40
Attapulgit, 53
Bentonite, 55
Calcium Silicate, 107
Carboxymethylcellulose Calcium, 123
Carboxymethylcellulose Sodium, 125
Cellulose, Microcrystalline, 138
Cellulose, Powdered, 144
Colloidal Silicon Dioxide, 196
Hectorite, 342
Kaolin, 401
Magnesium Aluminum Silicate, 443
Magnesium Carbonate, 446
Polycarbophil, 573
Saponite, 697

Adsorbing agent *see* Adsorbent

Aerosol propellant

Carbon Dioxide, 121
Chlorodifluoroethane (HCFC), 183
Chlorofluorocarbons (CFC), 184
Difluoroethane (HFC), 259
Dimethyl Ether, 262
Heptafluoropropane (HFC), 344
Hydrocarbons (HC), 347
Nitrogen, 517
Nitrous Oxide, 519
Tetrafluoroethane (HFC), 836

Air displacement

Carbon Dioxide, 121
Nitrogen, 517

Alcohol denaturant

Denatonium Benzoate, 235
Sucrose Octaacetate, 807

Alkalizing agent

Ammonia Solution, 41
Calcium Hydroxide, 96
Diethanolamine, 252
Monoethanolamine, 505
Potassium Bicarbonate, 642
Potassium Citrate, 646
Potassium Hydroxide, 648
Sodium Bicarbonate, 717
Sodium Borate, 721
Sodium Carbonate, 722
Sodium Citrate Dihydrate, 728

Sodium Hydroxide, 737

Triethanolamine, 859

Tromethamine, 865

Anionic surfactant

Docusate Sodium, 275
Phospholipids, 561
Sodium Lauryl Sulfate, 740

Antiadherent, Leucine, 438

Antiadhesive agent *see* Antiadherent

Anticaking agent

Calcium Phosphate, Tribasic, 105
Calcium Silicate, 107
Colloidal Silicon Dioxide, 196
Hydrophobic Colloidal Silica, 351
Magnesium Oxide, 450
Magnesium Silicate, 452
Talc, 831

Antifoaming agent

Dimethicone, 261
Simethicone, 704

Antimicrobial preservative

Acetone Sodium Bisulfite, 9
Alcohol, 19
Benzalkonium Chloride, 58
Benzethonium Chloride, 61
Benzoic Acid, 63
Benzyl Alcohol, 66
Boric Acid, 71
Bronopol, 73
Butylated Hydroxyanisole, 76
Butylene Glycol, 80
Butylparaben, 82
Calcium Acetate, 87
Calcium Chloride, 94
Calcium Lactate, 97
Cetrimide, 162
Cetylpyridinium Chloride, 168
Chlorhexidine, 173
Chlorobutanol, 177
Chlorocresol, 180
Chloroxylenol, 187
Cresol, 220
Edetic Acid, 279
Ethylparaben, 304
Glycerin, 322
Hexetidine, 345
Imidurea, 383
Isopropyl Alcohol, 393
Methylparaben, 496
Monothioglycerol, 509
Pentetic Acid, 542
Phenol, 547
Phenoxyethanol, 550
Phenylethyl Alcohol, 552
Phenylmercuric Acetate, 554
Phenylmercuric Borate, 556
Phenylmercuric Nitrate, 558
Potassium Benzoate, 640
Potassium Metabisulfite, 649
Potassium Nitrate, 652
Potassium Sorbate, 655
Propionic Acid, 662
Propyl Gallate, 664
Propylene Glycol, 668
Propylparaben, 676

Propylparaben Sodium, 679

Sodium Acetate, 706

Sodium Benzoate, 714

Sodium Borate, 721

Sodium Lactate, 738

Sodium Metabisulfite, 743

Sodium Propionate, 750

Sodium Sulfite, 761

Sorbic Acid, 765

Sulfur Dioxide, 820

Thimerosal, 840

Zinc Oxide, 902

Antioxidant

Acetone Sodium Bisulfite, 9
Alpha Tocopherol, 32
Ascorbic Acid, 45
Ascorbyl Palmitate, 48
Butylated Hydroxyanisole, 76
Butylated Hydroxytoluene, 78
Citric Acid Monohydrate, 192
Dodecyl Gallate, 277
Erythorbic Acid, 282
Fumaric Acid, 312
Malic Acid, 462
Mannitol and Sorbitol, 481
Monothioglycerol, 509
Octyl Gallate, 522
Potassium Metabisulfite, 649
Propionic Acid, 662
Propyl Gallate, 664
Sodium Ascorbate, 711
Sodium Formaldehyde Sulfoxylate, 733
Sodium Metabisulfite, 743
Sodium Sulfite, 761
Sodium Thiosulfate, 763
Sulfur Dioxide, 820
Thymol, 843
Vitamin E Polyethylene Glycol Succinate, 872

Bioadhesive material

Carbomer, 116
Chitosan, 170
Guar Gum, 339
Polycarbophil, 573
Poly(methyl vinyl ether/maleic anhydride), 598

Biocompatible material, Aliphatic Polyesters, 26

Biodegradable material

Aliphatic Polyesters, 26
Glyceryl Palmitostearate, 334
Maltodextrin, 468
Phospholipids, 561
Polydextrose, 579

Bitter flavoring agent, Sucrose Octaacetate, 807

Bittering agent *see* Alcohol denaturant

Buffer *see* Buffering agent

Buffering agent

Acetic Acid, Glacial, 5
Adipic Acid, 13
Boric Acid, 71
Calcium Carbonate, 91
Calcium Lactate, 97
Calcium Phosphate, Tribasic, 105

- Citric Acid Monohydrate, 192
 Glycine, 336
 Hydroxyethylpiperazine Ethane Sulfonic Acid, 357
 Lysine Hydrochloride, 441
 Maleic Acid, 460
 Malic Acid, 462
 Meglumine, 485
 Methionine, 490
 Monosodium Glutamate, 507
 Phosphoric Acid, 565
 Potassium Citrate, 646
 Potassium Metaphosphate, 651
 Potassium Phosphate, Dibasic, 653
 Sodium Acetate, 706
 Sodium Borate, 721
 Sodium Carbonate, 722
 Sodium Citrate Dihydrate, 728
 Sodium Lactate, 738
 Sodium Phosphate, Dibasic, 746
 Sodium Phosphate, Monobasic, 748
 Tromethamine, 865
- Cationic surfactant
 Benzalkonium Chloride, 58
 Cetrimide, 162
 Cetylpyridinium Chloride, 168
 Phospholipids, 561
- Chelating agent *see* Complexing agent
- Coating agent
 Carboxymethylcellulose Calcium, 123
 Castor Oil, Hydrogenated, 135
 Cellaburate, 137
 Cellulose Acetate, 150
 Cellulose Acetate Phthalate, 152
 Ceresin, 157
 Cetyl Alcohol, 164
 Chitosan, 170
 Colophony, 200
 Corn Syrup Solids, 216
 Ethylcellulose, 295
 Ethylene Glycol and Vinyl Alcohol Grafted Copolymer, 300
 Gelatin, 317
 Glucose, Liquid, 321
 Glycerol Behenate, 326
 Glycerol Palmitostearate, 334
 Hydroxyethyl Cellulose, 353
 Hydroxyethylmethyl Cellulose, 356
 Hydroxypropyl Cellulose, 361
 Hypromellose, 371
 Hypromellose Acetate Succinate, 375
 Hypromellose Phthalate, 378
 Isomalt, 389
 Maltitol, 464
 Maltodextrin, 468
 Methylcellulose, 492
 Paraffin, 536
 Polydextrose, 577, 579
 Polyethylene Glycol, 582
 Polyethylene Oxide, 587
 Polyvinyl Acetate Dispersion, 631
 Polyvinyl Acetate Phthalate, 633
 Polyvinyl Alcohol, 635
 Povidone, 657
 Pullulan, 680
 Shellac, 701
 Starch, Modified, 787
 Sucrose, 803
 Sugar, Confectioner's, 813
 Titanium Dioxide, 845
 Wax, Carnauba, 880
 Wax, Microcrystalline, 884
 Wax, White, 887
 Wax, Yellow, 889
- Xylitol, 895
 Zein, 899
 Zinc Oxide, 902
- Color *see* Colorant
- Colorant
 Coloring Agents, 203
 Iron Oxides, 387
- Colored lake *see* Colorant; Pigment
- Complexing agent
 Calcium Acetate, 87
 Citric Acid Monohydrate, 192
 Cyclodextrins, 228
 Disodium Edetate, 273
 Ederic Acid, 279
 Fumaric Acid, 312
 Galactose, 315
 Hydroxypropyl Betadex, 359
 Malic Acid, 462
 Pentetic Acid, 542
 Poly(methyl vinyl ether/maleic anhydride), 598
 Potassium Citrate, 646
 Sodium Citrate Dihydrate, 728
 Sodium Phosphate, Dibasic, 746
 Sodium Phosphate, Monobasic, 748
 Sulfobutylether β -Cyclodextrin, 817
 Tartaric Acid, 834
 Trehalose, 851
- Controlled-release agent *see* Modified-release agent
- Cosolvent *see* Solvent
- Cryoprotectant, Albumin, 17
- Denaturant *see* Alcohol denaturant
- Desiccant
 Calcium Chloride, 94
 Calcium Sulfate, 111
- Detergent *see* Anionic surfactant; Cationic surfactant; Nonionic surfactant
- Direct compression excipient
 Cellulose, Microcrystalline, 138
 Corn Starch and Pregelatinized Starch, 214
 Fructose and Pregelatinized Starch, 311
 Isomalt, 389
 Lactitol, 406
 Lactose, Anhydrous, 408
 Lactose, Monohydrate and Corn Starch, 419
 Lactose, Monohydrate and Microcrystalline Cellulose, 420
 Lactose, Monohydrate and Povidone, 422
 Lactose, Spray-Dried, 425
 Maltodextrin, 468
 Mannitol and Sorbitol, 479
- Disinfectant *see* Antimicrobial preservative
- Dispersing agent
 Albumin, 17
 Aluminum Oxide, 38
 Cellulose, Microcrystalline and Carboxymethylcellulose Sodium, 142
 Hypromellose, 371
 Phospholipids, 561
 Poloxamer, 569
 Polyoxyethylene Alkyl Ethers, 601
 Polyoxyethylene Sorbitan Fatty Acid Esters, 617
 Sodium Carbonate, 722
 Sorbitan Esters (Sorbitan Fatty Acid Esters), 768
 Sucrose Stearate, 809
 Tricaprylin, 856
- Dry powder inhaler carrier
 Lactose, Anhydrous, 408
 Lactose, Inhalation, 411
 Lactose, Monohydrate, 413
- Dye *see* Colorant
- Emollient
 Almond Oil, 30
 Aluminum Monostearate, 37
 Butyl Stearate, 85
 Canola Oil, 114
 Castor Oil, 133
 Cetostearyl Alcohol, 159
 Cetyl Alcohol, 164
 Cetyl Palmitate, 166
 Cholesterol, 189
 Coconut Oil, 195
 Cyclomethicone, 232
 Decyl Oleate, 234
 Diethyl Sebacate, 258
 Dimethicone, 261
 Ethylene Glycol Stearates, 301
 Glycerin, 322
 Glycerol Monooleate, 329
 Glycerol Monostearate, 331
 Isopropyl Isostearate, 395
 Isopropyl Myristate, 396
 Isopropyl Palmitate, 398
 Lanolin, 428
 Lanolin Alcohols, 431
 Lanolin, Hydrous, 430
 Lecithin, 435
 Mineral Oil, 500
 Mineral Oil and Lanolin Alcohols, 504
 Mineral Oil, Light, 502
 Myristyl Alcohol, 512
 Octyldodecanol, 521
 Oleyl Alcohol, 526
 Palm Kernel Oil, 532
 Palm Oil, 533
 Petrolatum, 543
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 Polyoxyethylene Sorbitan Fatty Acid Esters, 617
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 Propylene Glycol Monolaurate, 674
 Safflower Oil, 694
 Squalane, 779
 Sunflower Oil, 824
 Tricaprylin, 856
 Triolein, 863
 Wax, Cetyl Esters, 882
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 Agar, 15
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 Calcium Alginate, 88
 Carbomer, 116
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 Cetyl Alcohol, 164
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 Glycerol Monostearate, 331
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 Hypromellose, 371
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 Lanolin Alcohols, 431
 Lanolin, Hydrous, 430
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 Lecithin, 435
 Linoleic Acid, 439
 Magnesium Oxide, 450
 Medium-chain Triglycerides, 482
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- Myristic Acid, 510
- Octyldodecanol, 521
- Oleic Acid, 524
- Oleyl Alcohol, 526
- Palm Oil, Hydrogenated, 535
- Palmitic Acid, 531
- Pectin, 540
- Phospholipids, 561
- Poloxamer, 569
- Polycarbophil, 573
- Polyoxyethylene Alkyl Ethers, 601
- Polyoxyethylene Castor Oil Derivatives, 608
- Polyoxyethylene Sorbitan Fatty Acid Esters, 617
- Polyoxyethylene Stearates, 622
- Polyoxyl 15 Hydroxystearate, 624
- Polyoxyglycerides, 627
- Potassium Alginate, 637
- Propylene Glycol Alginate, 671
- Propylene Glycol Dilaurate, 672
- Propylene Glycol Monolaurate, 674
- Saponite, 697
- Sodium Borate, 721
- Sodium Citrate Dihydrate, 728
- Sodium Lactate, 738
- Sodium Lauryl Sulfate, 740
- Sodium Stearate, 757
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- Starch, Modified, 787
- Stearic Acid, 796
- Sucrose Stearate, 809
- Tragacanth, 848
- Triethanolamine, 859
- Tromethamine, 865
- Vitamin E Polyethylene Glycol Succinate, 872
- Wax, Anionic Emulsifying, 879
- Wax, Nonionic Emulsifying, 885
- Xanthan Gum, 891
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- Emulsion stabilizing agent
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 - Carbomer, 116
 - Carrageenan, 129
 - Cellulose, Microcrystalline and Carboxymethylcellulose Sodium, 142
 - Ceresin, 157
 - Cetyl Palmitate, 166
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 - Ethylene Glycol Stearates, 301
 - Glyceryl Monooleate, 329
 - Glyceryl Monostearate, 331
 - Hydrophobic Colloidal Silica, 351
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- Enteric coating agent *see* Coating agent
- Extended-release agent *see* Modified-release agent
- Film-coating agent *see* Coating agent
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Film-forming agent

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- Chitosan, 170
- Colophony, 200
- Copovidone, 211
- Ethylene Glycol and Vinyl Alcohol Grafted Copolymer, 300
- Gelatin, 317
- Hydroxypropyl Cellulose, 361
- Hypromellose, 371
- Hypromellose Acetate Succinate, 375
- Polymethacrylates, 591
- Poly(methyl vinyl ether/maleic anhydride), 598
- Polyvinyl Acetate Dispersion, 631
- Polyvinyl Acetate Phthalate, 633
- Polyvinyl Alcohol, 635
- Povidone, 657
- Pullulan, 680
- Pyroxylin, 682
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- Flavor enhancer
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 - Ethyl Maltol, 290
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 - Neohesperidin Dihydrochalcone, 514
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 - Trehalose, 851
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- Flavoring agent
 - Adipic Acid, 13
 - Denatonium Benzoate, 235
 - Ethyl Acetate, 286
 - Ethyl Lactate, 288
 - Ethyl Maltol, 290
 - Ethyl Vanillin, 293
 - Fructose, 308
 - Fumaric Acid, 312
 - Leucine, 438
 - Malic Acid, 462
 - Maltol, 471
 - Menthol, 487
 - Methionine, 490
 - Monosodium Glutamate, 507
 - Phenylethyl Alcohol, 552
 - Sodium Acetate, 706
 - Sodium Lactate, 738
 - Tartaric Acid, 834
 - Thymol, 843
 - Vanillin, 868
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- Foam preventing agent *see* Antifoaming agent
- Foam stabilizer *see* Foam stabilizing agent
- Foam stabilizing agent, Propylene Glycol Alginate, 671
- Freeze-drying agent *see* Lyophilization aid
- Friction-reducing agent *see* Lubricant
- Gas flushing agent *see* Air displacement
- Gel thickening agent *see* Gelling agent
- Gelling agent
 - Agar, 15
 - Aluminum Monostearate, 37
 - Carrageenan, 129
 - Ceresin, 157
 - Gelatin, 317
 - Glyceryl Monooleate, 329
 - Glyceryl Palmitostearate, 334
 - Pectin, 540
 - Polycarbophil, 573
 - Polyoxyethylene Alkyl Ethers, 601
 - Potassium Alginate, 637

Sodium Stearate, 757

Xanthan Gum, 891

Zinc Acetate, 900

Glidant

- Cellulose, Powdered, 144
- Colloidal Silicon Dioxide, 196
- Hydrophobic Colloidal Silica, 351
- Magnesium Oxide, 450
- Magnesium Silicate, 452
- Magnesium Trisilicate, 458
- Sodium Stearate, 757
- Talc, 831
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Humectant

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- Butylene Glycol, 80
- Corn Syrup Solids, 216
- Cyclomethicone, 232
- Dipropylene Glycol, 271
- Glycerin, 322
- Polydextrose, 577
- Propylene Glycol, 668
- Sodium Hyaluronate, 735
- Sodium Lactate, 738
- Sorbitol, 772
- Trehalose, 851
- Triacetin, 853
- Xylitol, 895

Lubricant

- Canola Oil, 114
- Mineral Oil, 500
- Octyldodecanol, 521
- Polyvinyl Alcohol, 635
- Sodium Hyaluronate, 735
- Starch, Sterilizable Maize, 794
- Tricaprylin, 856

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Lyophilization aid

- Dextran, 237
- Glycine, 336
- Inulin, 385
- Lactose, Anhydrous, 408
- Lactose, Monohydrate, 413
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- Aliphatic Polyesters, 26
- Carrageenan, 129
- Colophony, 200
- Ethylcellulose, 295
- Gelatin, 317
- Shellac, 701

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- Acacia, 1
- Adipic Acid, 13
- Agar, 15
- Alginate, 23
- Aliphatic Polyesters, 26
- Calcium Alginate, 88
- Carbomer, 116
- Carrageenan, 129
- Castor Oil, Hydrogenated, 135
- Cellulose, 137
- Cellulose Acetate, 150
- Ceratonin, 155
- Colophony, 200
- Copovidone, 211
- Glyceryl Behenate, 326
- Glyceryl Monooleate, 329
- Glyceryl Monostearate, 331
- Glyceryl Palmitostearate, 334
- Hydroxypropyl Betadex, 359

- Hydroxypropyl Cellulose, 361
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 Polacrilin Potassium, 567
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 Polymethacrylates, 591
 Polyoxylglycerides, 627
 Polyvinyl Acetate Dispersion, 631
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 Sodium Alginate, 708
 Sodium Hyaluronate, 735
 Sodium Lauryl Sulfate, 740
 Sodium Stearate, 757
 Starch, Modified, 787
 Sucrose Stearate, 809
 Vegetable Oil, Hydrogenated, 870
 Wax, Microcrystalline, 884
 Wax, White, 887
 Wax, Yellow, 889
 Xanthan Gum, 891
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- Modified-release coating agent *see* Coating agent
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 Glyceryl Monooleate, 329
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 Phospholipids, 561
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 Polyoxyethylene Alkyl Ethers, 601
 Polyoxyethylene Castor Oil Derivatives, 608
 Polyoxyethylene Sorbitan Fatty Acid Esters, 617
 Polyoxyethylene Stearates, 622
 Polyoxyl 15 Hydroxystearate, 624
 Polyoxylglycerides, 627
 Propylene Glycol Dilaurate, 672
 Propylene Glycol Monolaurate, 674
 Sorbitan Esters (Sorbitan Fatty Acid Esters), 768
 Sucrose Stearate, 809
 Tricaprylin, 856
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 Lanolin Alcohols, 431
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 Petrolatum and Lanolin Alcohols, 546
 Polyethylene Glycol, 582
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 Vitamin E Polyethylene Glycol Succinate, 872
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 Canola Oil, 114
 Castor Oil, 133
 Corn Oil, 213
 Cottonseed Oil, 218
 Ethyl Oleate, 291
 Isopropyl Myristate, 396
 Isopropyl Palmitate, 398
 Mineral Oil, 500
- Mineral Oil, Light, 502
 Myristyl Alcohol, 512
 Olive Oil, 528
 Peanut Oil, 537
 Safflower Oil, 694
 Sesame Oil, 698
 Soybean Oil, 776
- Opacifier
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 Calcium Carbonate, 91
 Calcium Silicate, 107
 Ceresin, 157
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 Zinc Acetate, 900
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 Penetration enhancer
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 Glycofurol, 338
 Isopropyl Myristate, 396
 Isopropyl Palmitate, 398
 Lauric Acid, 432
 Linoleic Acid, 439
 Myristic Acid, 510
 Oleic Acid, 524
 Oleyl Alcohol, 526
 Palmitic Acid, 531
 Polyoxyethylene Alkyl Ethers, 601
 Polyoxylglycerides, 627
 Propylene Glycol Monolaurate, 674
 Pyrrolidone, 684
 Sodium Lauryl Sulfate, 740
 Squalane, 779
 Thymol, 843
 Tricaprylin, 856
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 Petrolatum and Lanolin Alcohols, 546
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 Lanolin Alcohols, 431
 Lecithin, 435
 Oleyl Alcohol, 526
 Phospholipids, 561
 Poloxamer, 569
 Polymethacrylates, 591
 Polyoxyethylene Alkyl Ethers, 601
 Polyoxyethylene Castor Oil Derivatives, 608
 Polyoxyethylene Sorbitan Fatty Acid Esters, 617
 Polyoxyl 15 Hydroxystearate, 624
 Polyoxylglycerides, 627
 Povidone, 657
 Pyrrolidone, 684
 Sodium Lauryl Sulfate, 740
 Sorbitan Esters (Sorbitan Fatty Acid Esters), 768
 Stearic Acid, 796
 Sucrose Stearate, 809
 Sulfobutylether β -Cyclodextrin, 817
 Tricaprylin, 856
 Triolein, 863
 Vitamin E Polyethylene Glycol Succinate, 872
 Wax, Anionic Emulsifying, 879
 Wax, Nonionic Emulsifying, 885
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 Almond Oil, 30
 Benzyl Alcohol, 66
 Benzyl Benzoate, 69
 Butylene Glycol, 80
 Carbon Dioxide, 121
 Castor Oil, 133
 Corn Oil, 213
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 Dibutyl Phthalate, 249
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 Ethyl Acetate, 286
 Ethyl Lactate, 288
 Ethyl Oleate, 291
 Glycerin, 322
 Glyceryl Monostearate, 331
 Glycofurol, 338
 Isopropyl Alcohol, 393
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 Safflower Oil, 694
 Sesame Oil, 698
 Soybean Oil, 776
 Sunflower Oil, 824
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 Wax, Anionic Emulsifying, 879
 Wax, Cetyl Esters, 882
 Wax, Microcrystalline, 884
 Wax, Nonionic Emulsifying, 885
 Wax, White, 887
 Wax, Yellow, 889
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 Cationic surfactant; Nonionic surfactant
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 Acacia, 1
 Agar, 15
 Alginate Acid, 23
 Attapulgit, 53
 Bentonite, 55
 Carbomer, 116
 Carboxymethylcellulose Calcium, 123
 Carboxymethylcellulose Sodium, 125
 Carrageenan, 129
 Cellulose, Microcrystalline, 138
 Cellulose, Microcrystalline and
 Carboxymethylcellulose Sodium, 142
 Cellulose, Powdered, 144
 Ceratonin, 155
 Colloidal Silicon Dioxide, 196
 Corn Syrup Solids, 216
 Dextrin, 243
 Gelatin, 317
 Guar Gum, 339
 Hydrophobic Colloidal Silica, 351
 Hydroxyethyl Cellulose, 353
 Hydroxyethylmethyl Cellulose, 356
 Hydroxypropyl Cellulose, 361
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 Medium-chain Triglycerides, 482
 Methylcellulose, 492
 Phospholipids, 561
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 Polyoxyethylene Sorbitan Fatty Acid Esters,
 617
 Potassium Alginate, 637
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 Propylene Glycol Alginate, 671
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 Sorbitan Esters (Sorbitan Fatty Acid Esters),
 768
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 Tragacanth, 848
 Vitamin E Polyethylene Glycol Succinate,
 872
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 Sweetening agent
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 Aspartame, 50
 Corn Syrup Solids, 216
 Dextrose, 246
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 Galactose, 315
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 Glycerin, 322
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 Isomalt, 389
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 Sugar, Compressible, 811
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 Thaumatococcus, 838
 Trehalose, 851
 Xylitol, 895
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 Acacia, 1
 Agar, 15
 Alginic Acid, 23
 Attapulgit, 53
 Calcium Carbonate, 91
 Calcium Lactate, 97
 Carboxymethylcellulose Calcium, 123
 Carboxymethylcellulose Sodium, 125
 Ceratonin, 155
 Chitosan, 170
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 Copolydione, 211
 Corn Syrup Solids, 216
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 Glyceryl Behenate, 326
 Guar Gum, 339

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 Hydroxyethylmethyl Cellulose, 356
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 Isomalt, 389
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 Methylcellulose, 492
 Polycarbophil, 573
 Polydextrose, 577
 Polyethylene Oxide, 587
 Polymethacrylates, 591
 Povidone, 657
 Pullulan, 680
 Sodium Alginate, 708
 Starch, 781
 Starch, Pregelatinized, 790
 Sucrose, 803
 Sugar, Compressible, 811
 Vegetable Oil, Hydrogenated, 870
 Vitamin E Polyethylene Glycol Succinate,
 872
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 Calcium Lactate, 97
 Calcium Phosphate, Dibasic Anhydrous, 99
 Calcium Phosphate, Dibasic Dihydrate, 102
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 366
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 419
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 Sodium Carbonate, 722
 Sodium Chloride, 725
 Sorbitol, 772
 Starch, 781
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 Starch, Pregelatinized, 790
 Sucrose, 803
 Sugar, Compressible, 811
 Sugar, Confectioner's, 813
 Sugar Spheres, 815
 Sulfobutylether β -Cyclodextrin, 817
 Sunflower Oil, 824
 Talc, 831
 Trehalose, 851
 Xylitol, 895
 Tablet and capsule disintegrant
 Alginic Acid, 23
 Calcium Alginate, 88
 Carboxymethylcellulose Calcium, 123
 Carboxymethylcellulose Sodium, 125
 Cellulose, Powdered, 144
 Chitosan, 170
 Colloidal Silicon Dioxide, 196
 Corn Starch and Pregelatinized Starch, 214
 Croscarmellose Sodium, 222
 Crospovidone, 225
 Glycine, 336
 Guar Gum, 339
 Hydroxypropyl Cellulose, Low-substituted, 366
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 Lactose, Monohydrate and Corn Starch, 419
 Magnesium Aluminum Silicate, 443
 Methylcellulose, 492
 Polacrillin Potassium, 567
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 Sodium Alginate, 708
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 Starch, 781
 Starch, Modified, 787
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 Calcium Stearate, 109
 Castor Oil, Hydrogenated, 135
 Glyceryl Behenate, 326
 Glyceryl Monostearate, 331
 Glyceryl Palmitostearate, 334
 Leucine, 438
 Magnesium Stearate, 454
 Mineral Oil, Light, 502
 Myristic Acid, 510
 Palm Oil, Hydrogenated, 535
 Palmitic Acid, 531
 Poloxamer, 569
 Polyethylene Glycol, 582
 Potassium Benzoate, 640
 Sodium Benzoate, 714
 Sodium Lauryl Sulfate, 740
 Sodium Stearate, 757
 Sodium Stearyl Fumarate, 759
 Stearic Acid, 796
 Sucrose Stearate, 809
 Talc, 831
 Vegetable Oil, Hydrogenated, 870
 Zinc Stearate, 904
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 Alginic Acid, 23
 Erythritol, 284
 Ethylcellulose, 295
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 Glyceryl Palmitostearate, 334
 Polydextrose, 577
 Sulfobutylether β -Cyclodextrin, 817
 Vanillin, 868
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 Tonicity agent
 Corn Syrup Solids, 216
 Dextrose, 246
 Glycerin, 322
 Hydroxypropyl Betadex, 359
 Mannitol, 475
 Potassium Chloride, 643
 Sodium Chloride, 725
 Transdermal delivery component
 Butylene Glycol, 80
 Cellulose Acetate, 150
 Dipropylene Glycol, 271
 Ethylene Vinyl Acetate, 303
 Isopropyl Myristate, 396
 Isopropyl Palmitate, 398
 Poly(methyl vinyl ether/maleic anhydride), 598
 Vaccine adjuvant
 Aluminum Hydroxide Adjuvant, 35
 Aluminum Phosphate Adjuvant, 40
 Mineral Oil, 500
 Potassium Alum, 639
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 Viscosity-increasing agent
 Acacia, 1
 Agar, 15
 Alginic Acid, 23
 Aluminum Monostearate, 37
 Ammonium Alginate, 42
 Attapulgit, 53
 Bentonite, 55
 Calcium Alginate, 88
 Calcium Lactate, 97
 Carbomer, 116
 Carboxymethylcellulose Calcium, 123
 Carboxymethylcellulose Sodium, 125
 Carrageenan, 129
 Cellulose, Microcrystalline and Carboxymethylcellulose Sodium, 142
 Cellulose, Powdered, 144
 Ceratonin, 155
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 Cetostearyl Alcohol, 159
 Cetyl Palmitate, 166
 Chitosan, 170
 Colloidal Silicon Dioxide, 196
 Corn Syrup Solids, 216
 Cyclomethicone, 232
 Ethylcellulose, 295
 Gelatin, 317
 Glyceryl Behenate, 326
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 Myristyl Alcohol, 512
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 Palm Oil, Hydrogenated, 535
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 Polycarbophil, 573
 Polydextrose, 577
 Polyethylene Oxide, 587
 Poly(methyl vinyl ether/maleic anhydride), 598
 Polyoxyethylene Alkyl Ethers, 601
 Polyvinyl Alcohol, 635
 Potassium Alginate, 637
 Propylene Glycol Alginate, 671
 Pullulan, 680
 Saponite, 697
 Sodium Alginate, 708
 Starch, 781
 Starch, Modified, 787
 Sucrose, 803
 Sugar, Confectioner's, 813
 Sulfobutylether β -Cyclodextrin, 817
 Tragacanth, 848
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