



Mannitol and Sorbitol, Coprocessed

1 Nonproprietary Names

None adopted.

2 Synonyms

Compressol S; Compressol SM.

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

Direct compression excipient.

7 Applications in Pharmaceutical Formulation or Technology

Coprocessed mannitol and sorbitol is used in direct compression of tablets with high active loading and/or with actives that are difficult to compress as it has good flow and compressibility properties.^(1,2) The coprocessed mixture with its improved functionality has been used in tableting of moisture-sensitive active substances as it has a lower hygroscopicity than standard sorbitol.⁽¹⁻⁷⁾

Mannitol and sorbitol coprocessed mixture has a pleasant taste and favorable mouthfeel, making it especially suitable for chewable tablets.^(1,2)

8 Description

Coprocessed mannitol and sorbitol occurs as a white to off-white fine powder with a smooth mouthfeel.

9 Pharmacopeial Specifications

Both mannitol and sorbitol are listed as separate monographs in the BP, JP, PhEur, and USP-NF, but the combination is not listed. See Mannitol, and Sorbitol.

10 Typical Properties

Density (tapped) 0.5–0.65 g/cm³ for *Compressol SM*⁽⁸⁾

Loss on drying ≤1% for *Compressol SM*⁽⁸⁾

Particle size distribution

≤10% of the powder is retained on the 60-mesh screen

≤18% goes through the 325-mesh screen (for *Compressol SM*)⁽⁸⁾

Solubility Soluble in water (for *Compressol SM*)⁽⁹⁾

Total polyols 96–101% (for *Compressol SM*)⁽⁸⁾

11 Stability and Storage Conditions

Protect from excessive temperatures and humidity. Store in a tightly closed container.

12 Incompatibilities

See Mannitol, and Sorbitol. The coprocessed mixture may react with strong acids or oxidizing agents.⁽⁴⁾ Upon decomposition, this

product emits carbon monoxide, carbon dioxide, and/or low-molecular-weight hydrocarbons.

13 Method of Manufacture

Mannitol and sorbitol coprocessed mixture is manufactured by a proprietary process.

14 Safety

Coprocessed mannitol and sorbitol is a nonflammable white powder.⁽⁴⁾ Eye contact may produce slight irritation. No skin irritation can be expected from single short-term exposure to this product. Prolonged or repeated contact may produce some irritation. Ingestion of large amounts may produce gastrointestinal disturbances including a laxative action. Overexposure to dusts may produce irritation of the respiratory system.

See also Mannitol, and Sorbitol.

15 Handling Precautions

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

Accumulation of airborne dust may present an explosion hazard in the presence of an ignition source. Avoid breathing dusts from this material.⁽⁴⁾ Avoid contact with the eyes, and wash thoroughly after handling.

16 Regulatory Status

Mannitol and sorbitol is a coprocessed mixture of two materials both of which are GRAS listed and accepted for use as a food additive in Europe. See Mannitol, and Sorbitol.

Mannitol GRAS listed. Accepted for use as a food additive in Europe. Included in the FDA Inactive Ingredients Database (IP, IM, IV, and SC injections; infusions; buccal, oral and sublingual tablets, powders and capsules; ophthalmic preparations; topical solutions). Included in nonparenteral and parenteral medicines licensed in the UK. Included in the Canadian Natural Health Products Ingredients Database.

Sorbitol GRAS listed. Accepted for use as a food additive in Europe. Included in the FDA Inactive Ingredients Database (intra-articular and IM injections; nasal; oral capsules, solutions, suspensions, syrups and tablets; rectal, topical, and vaginal preparations). Included in parenteral and nonparenteral medicines licensed in the UK. Included in the Canadian Natural Health Products Ingredients Database.

17 Related Substances

Mannitol; sorbitol.

18 Comments

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19 Specific References

- 1 SPI Pharma Inc. Technical bulletin: *Compressol SM, Co-processed polyol*, January 2009.
- 2 SPI Pharma Inc. Technical bulletin: *Compressol S, Co-processed polyol*, September 2007.
- 3 Bolhuis GK, et al. Polyols as filler-binders for disintegrating tablets prepared by direct compaction. *Drug Dev Ind Pharm* 2009; 35(6): 671–677.
- 4 Patel RP, Bhavsar M. Directly compressible materials via co-processing. *Int J PharmTech Res* 2009; 1(3): 745–753.