

MANNITOL

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SECTION 1: IDENTIFICATION

1.1 GHS Product identifier:

MANNITOL
D-Mannitol; Manna Sugar; E421
CAS: 69-65-8

Other means of identification:

Not relevant

1.2 Recommended use of the chemical and restrictions on use:

Relevant uses: Food/pharmaceutical bulking agent and sweetener (sugar alcohol), tablet excipient (diluent/filler), anti-caking agent, and diuretic/osmotic agent in pharmaceutical formulations. For industrial/commercial user only.
Uses advised against: All uses not specified in this section or in section 7.3.

1.3 Supplier's details:

SURAJ CHEMICALS
No 92, Govindappa Naicken Street, Shiva Complex, Chennai – 600001, Tamil Nadu, India
Tel: +91 - 7092722822, +91 - 9840284032 / +91 - 44 - 25393652, 42130281
Email: sales@surajchemicals.com | Website: www.surajchemicals.com
GST No: 33ACEPV8190L1ZZ

1.4 Emergency phone number:

Emergency Contact No: +91 - 7092722822, +91 - 9840284032

SECTION 2: HAZARDS IDENTIFICATION

2.1 Classification of the substance or mixture:

GHS:
Classification of this product has been carried out in accordance with the Globally Harmonized System of Classification and Labelling of Chemicals (GHS).

Not classified	Not a hazardous substance or mixture according to GHS criteria, based on available data
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Mannitol is a well-established, widely used food/pharma-grade ingredient with a long history of safe industrial handling and consumption. It is not classified as hazardous to health, physical hazards, or the environment under standard GHS criteria.

2.2 GHS label elements, including precautionary statements:

GHS: No signal word, pictogram or hazard statement is required under GHS classification criteria.

Hazard statements:

None assigned under GHS classification.

Precautionary statements:

P262: Do not get in eyes, on skin, or on clothing.
P264: Wash hands thoroughly after handling.
P270: Do not eat, drink or smoke when using this product.
P280: Wear protective gloves/eye protection as a general industrial hygiene precaution.
P305+P351+P338: IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.

2.3 Other hazards which do not result in classification:

Fine powder/dust of this product may cause mechanical/nuisance irritation to eyes, skin and the respiratory tract on prolonged or repeated contact; it is not considered a specific target organ toxicant. This substance is not identified as a PBT or vPvB substance.

SECTION 3: COMPOSITION / INFORMATION ON INGREDIENTS

3.1 Substances:

Chemical description: D-Mannitol – a naturally occurring sugar alcohol (hexitol)
In accordance with Annex 4.3.3 of the GHS, the product contains:

Identification	Chemical Name / Classification	Concentration
CAS: 69-65-8	Mannitol — Not classified	≥99.0% (food/pharma grade, typical)

To obtain more information on the hazards of the substances, consult sections 11, 12 and 16.

3.2 Mixtures:

Non-applicable

SECTION 4: FIRST AID MEASURES

4.1 Description of necessary first-aid measures:

This product is not classified as hazardous; standard first-aid practice should nonetheless be followed in case of accidental exposure. Seek medical attention if symptoms persist, showing this SDS.

By inhalation:

If dust inhalation causes discomfort, remove the person affected to fresh air and keep at rest.

By skin contact:

Remove contaminated clothing. Wash the affected area with plenty of soap and water.

By eye contact:

Rinse eyes thoroughly with clean water for several minutes, lifting upper and lower eyelids. Remove contact lenses if present and easy to do. Seek medical attention if irritation persists.

By ingestion/aspiration:

Rinse mouth with water. If a large quantity is accidentally swallowed and discomfort occurs, seek medical advice.

4.2 Most important symptoms/effects, acute and delayed:

No significant acute or delayed effects are expected under normal conditions of use. See sections 2 and 11.

4.3 Indication of immediate medical attention and special treatment needed, if necessary:

Not relevant – treat symptomatically.

SECTION 5: FIRE-FIGHTING MEASURES

5.1 Suitable extinguishing media:
Suitable: Water spray/fog, foam, dry chemical powder, carbon dioxide (CO₂).
Unsuitable: High-pressure water jet on bulk dust/powder accumulations (may disperse dust and increase explosion risk).

5.2 Specific hazards arising from the chemical:
Not classified as flammable. As with most finely divided organic solids, dust suspended in air in sufficient concentration may present a combustible dust hazard in the presence of an ignition source. Combustion/thermal decomposition may generate oxides of carbon.

5.3 Special protective actions for fire-fighters:
Wear self-contained breathing apparatus (SCBA) and full protective clothing for significant fires. Avoid actions that generate or disperse combustible dust. Cool fire-exposed containers with water spray.

Additional provisions:
None beyond standard fire-fighting practice.

SECTION 6: ACCIDENTAL RELEASE MEASURES

6.1 Personal precautions, protective equipment and emergency procedures:
For non-emergency personnel:
Avoid generating dust. Use the personal protective equipment described in Section 8. Ensure adequate ventilation.

For emergency responders:
No special equipment beyond standard PPE (Section 8) is required for this non-hazardous product.

6.2 Environmental precautions:
Avoid large-scale discharge into drains or water courses, which may cause a local biological oxygen demand (BOD) load.

6.3 Methods and materials for containment and cleaning up:
Sweep up or vacuum (avoiding dust dispersion) and collect in a clean, dry, labelled container for recovery or disposal.

6.4 Reference to other sections:
See sections 8 and 13.

SECTION 7: HANDLING AND STORAGE

7.1 Precautions for safe handling:
A. General precautions for safe use:
Handle in accordance with good industrial/food-hygiene practice. Avoid generating dust. Use local exhaust ventilation where dust may be generated in bulk handling.

B. Technical recommendations for the prevention of fires and explosions:
Avoid accumulation of fine dust on surfaces and equipment. Use properly earthed equipment during bulk transfer to minimise static build-up. Mannitol is non-hygroscopic and generally stable; keep away from strong oxidising agents as a precaution.

C. Technical recommendations on general occupational hygiene:
Do not eat, drink or smoke while handling. Wash hands thoroughly after handling.

D. Technical recommendations to prevent environmental risks:
Avoid uncontrolled discharge to drains, soil or water courses.

7.2 Conditions for safe storage, including any incompatibilities:
A. Specific storage requirements:

Storage temperature	Cool, dry place, below 30°C
Relative humidity	Low humidity, in tightly closed containers
Recommended shelf life	Typically 36 months from date of manufacture in original sealed packaging

B. General conditions for storage:
Store in a cool, dry, well-ventilated place in tightly closed, moisture-proof packaging, away from direct sunlight, strong oxidisers and strong odours.

7.3 Specific end use(s):
Used as a food/pharma-grade sugar alcohol (polyol) sweetener and pharmaceutical excipient (bulking/diluent/anti-caking agent). Refer to product-specific technical data sheet for application guidance.

SECTION 8: EXPOSURE CONTROLS / PERSONAL PROTECTION

8.1 Control parameters:
No substance-specific occupational exposure limit (OEL) has been established under the Factories Act, 1948 (as amended), or by ACGIH/OSHA. As a general nuisance-dust guidance value, an airborne limit of 10 mg/m³ (inhalable fraction, TWA 8h) for particulates not otherwise classified (PNOC) may be applied as good practice – typical value, refer to current specification sheet.

8.2 Appropriate engineering controls:
Use local exhaust ventilation/dust collection at points of dust generation (bagging, bulk transfer, milling) to minimise airborne dust concentrations.

B. Respiratory protection:
Not normally required under good ventilation. For dusty operations, use a particulate filter mask (P1/P2 or equivalent).

C. Specific protection for the hands:
Protective gloves (nitrile or PVC) recommended for prolonged or repeated handling.

D. Eye and face protection:
Safety glasses with side shields recommended when handling powder.

E. Bodily protection:
Standard food-grade/industrial work clothing in line with applicable GMP/hygiene requirements.

F. Additional emergency measures:
Eyewash station and washing facilities should be available in the work area.

Environmental exposure controls:
No specific measures required beyond good housekeeping.

SECTION 9: PHYSICAL AND CHEMICAL PROPERTIES

Appearance	
Physical state at 20°C	Solid (crystalline powder/granules)
Color	White
Odor	Odourless
Odour threshold	Not established
Volatility	

Boiling point	Non-applicable (solid)
Vapour pressure at 20°C	Negligible
Evaporation rate	Not relevant (solid)
Product Description	
Molecular formula	C6H14O6
Molecular weight	182.17 g/mol
Bulk density	Typical value – refer to current specification sheet
Bulk density (typical)	Typical value – refer to current specification sheet
Solubility in water	Soluble in water (≈180 g/L at 20°C); slightly soluble in ethanol
Partition coefficient n-octanol/water	Typical value – refer to current specification sheet
Melting point/freezing point	166–168°C
Flammability	
Flash Point	Non-applicable (solid)
Flammability (solid, gas)	Not classified as flammable
Autoignition temperature	Not established
Lower / Upper flammability limit	Not established
Particle Characteristics	
Median particle size	Typical value – refer to current specification sheet

Values are typical for commercial food/pharma-grade Mannitol and may vary within specification tolerances.

9.2 Other information:

Explosive properties	Not classified; fine dust may present a combustible-dust hazard under specific conditions
Oxidising properties	Not classified
Corrosive to metals	Not corrosive
Decomposition temperature	Decomposes above approximately 290°C
Surface tension	Not relevant (solid)
Refraction index	Not relevant

SECTION 10: STABILITY AND REACTIVITY

10.1 Reactivity:

No reactivity hazards are known under normal conditions of storage, handling and use. May react with strong oxidising agents, generating heat.

10.2 Chemical stability:

Chemically stable under the indicated conditions of storage, handling and use.

10.3 Possibility of hazardous reactions:

Under the specified conditions, hazardous reactions are not expected.

10.4 Conditions to avoid:

Shock/Friction	Contact with Air	Increase in Temperature	Sunlight	Humidity
Not applicable	Not applicable	Avoid prolonged exposure to high temperature	Avoid prolonged direct exposure	Avoid contact with moisture (caking/degradation)

10.5 Incompatible materials:

Strong Oxidisers	Strong Acids/Alkalis	Moisture
Avoid contact	No significant reactivity expected; avoid prolonged contact	Avoid prolonged exposure (hygroscopic/caking tendency)

10.6 Hazardous decomposition products:

None under normal conditions of storage and use. Thermal decomposition at high temperature may generate oxides of carbon.

SECTION 11: TOXICOLOGICAL INFORMATION

11.1 Information on toxicological effects:

This substance has a long history of safe use in the food/pharmaceutical sector. Based on available data, the classification criteria for the health hazard classes below are not met.

A. Ingestion (acute effect):

Acute toxicity classification criteria are not met based on available data. LD50 oral (rat): >20,000 mg/kg (practically non-toxic; widely used as a food/pharma excipient)

B. Inhalation (acute effect):

Not classified. Inhalation of dust in high concentration may cause mechanical irritation of the respiratory tract.

C. Contact with skin and eyes (acute effect):

Not classified. Prolonged or repeated contact with dust may cause mild, transient mechanical irritation.

D. CMR effects (carcinogenicity, mutagenicity, reproductive toxicity):

Classification criteria for carcinogenicity, mutagenicity and reproductive toxicity are not met based on available data. IARC: Not listed.

E. Sensitizing effects:

Classification criteria for respiratory or skin sensitisation are not met based on available data.

F. Specific target organ toxicity (STOT) – single exposure:

Classification criteria are not met based on available data.

G. Specific target organ toxicity (STOT) – repeated exposure:

Classification criteria are not met based on available data.

H. Aspiration hazard:

Classification criteria are not met based on available data.

Product-specific toxicological information:

Identification	Acute Toxicity	Genus
Mannitol CAS: 69-65-8	LD50 oral (rat): >20,000 mg/kg (practically non-toxic; widely used as a food/pharma excipient)	Rat (oral)

SECTION 12: ECOLOGICAL INFORMATION

Not classified as hazardous to the aquatic environment based on available data.

12.1 Toxicity:

Acute Toxicity	Species	Genus
LC50: >100 mg/L (96h) – low toxicity (typical value)	Non-applicable	Fish
EC50: >100 mg/L (48h) – low toxicity (typical value)	Non-applicable	Crustacean (Daphnia)

12.2 Persistence and degradability:

Expected to be readily biodegradable, consistent with its food/pharma-grade composition and history of use.

12.3 Bioaccumulative potential:

Not expected to bioaccumulate, based on its physicochemical properties.

12.4 Mobility in soil:

Koc	Henry	Dry Soil	Moist Soil
Low (water-soluble)	Negligible	Moderate mobility	Moderate mobility

12.5 Results of PBT and vPvB assessment:

This substance does not meet the PBT/vPvB criteria.

12.6 Other adverse effects:

Excessive discharge of concentrated material may locally increase biological oxygen demand (BOD) in water courses.

SECTION 13: DISPOSAL CONSIDERATIONS

13.1 Disposal methods:

Dispose of waste/residues in accordance with local, state and national regulations. Empty packaging completely before disposal/recycling. Avoid discharge of concentrated product directly into drains or water courses. Refer to national and local regulations on waste management.

SECTION 14: TRANSPORT INFORMATION

Transport of dangerous goods by land (ADR 2023 / RID 2023):

14.1 UN number	Not assigned – non-dangerous goods
14.2 UN proper shipping name	Non-applicable
14.3 Transport hazard class(es)	Not regulated
14.4 Packing group	N/A
14.5 Environmental hazard	No
14.6 Special precautions for user	Non-hazardous for transport; physico-chemical properties: see section 9
14.7 Transport in bulk (Annex II MARPOL 73/78, IBC Code)	Not relevant

Transport of dangerous goods by sea (IMDG 41-22):

14.1 UN number	Not assigned – non-dangerous goods
14.2 UN proper shipping name	Non-applicable
14.3 Transport hazard class(es)	Not regulated
14.4 Packing group	N/A
14.5 Marine pollutant	No
14.6 Special precautions for user	Non-hazardous for transport
14.7 Transport in bulk (Annex II MARPOL 73/78, IBC Code)	Not relevant

Transport of dangerous goods by air (IATA/ICAO 2024):

14.1 UN number	Not assigned – non-dangerous goods
14.2 UN proper shipping name	Non-applicable
14.3 Transport hazard class(es)	Not regulated
14.4 Packing group	N/A
14.5 Environmental hazard	No
14.6 Special precautions for user	Non-hazardous for transport
14.7 Transport in bulk (Annex II MARPOL 73/78, IBC Code)	Not relevant

SECTION 15: REGULATORY INFORMATION

15.1 Safety, health and environmental regulations specific for the product in question:

Permitted as a food additive (INS 421) under the Food Safety and Standards Authority of India (FSSAI) regulations, subject to applicable use-level limits. It is recommended to use the information included in this safety data sheet as data used in a risk evaluation of local circumstances.

Other legislation:

Food Safety and Standards Act, 2006, and the Food Safety and Standards (Food Products Standards and Food Additives) Regulations, 2011, and amendments thereto, as applicable to food-grade use
The Factories Act, 1948 (Act No. 63 of 1948), as amended by the Factories (Amendment) Act, 1987 (Act 20 of 1987)
Manufacture, Storage and Import of Hazardous Chemicals Rules, 1989 (not applicable – product not classified as hazardous)

SECTION 16: OTHER INFORMATION

Legislation related to safety data sheets:

This safety data sheet has been designed in accordance with Annex 4 – Guidance on the preparation of Safety Data Sheets of the Globally Harmonized System of Classification and Labelling of Chemicals (GHS).

Texts of the legislative phrases mentioned in sections 2 and 3:

Not applicable – no GHS hazard statements are assigned to this product.

This SDS is provided to support safe industrial handling, storage, and transport, notwithstanding the product's non-hazardous classification.

Advice related to training:

Minimal training is recommended to familiarise staff with good handling/storage practice and with this safety data sheet.

Principal bibliographical sources:

Published GHS classification databases and standard commercial safety data references for Mannitol (CAS 69-65-8); Food Safety and Standards Authority of India (FSSAI) guidance, where applicable to food-grade use.

Abbreviations and acronyms:

ADR: European agreement concerning the international carriage of dangerous goods by road | IMDG: International maritime dangerous goods code | IATA: International Air Transport Association | ICAO: International

The information contained in this safety data sheet is based on sources, technical knowledge and current legislation, without being able to guarantee its accuracy. This information cannot be considered a guarantee of the properties of the product; it is simply a description of the security requirements. The occupational methodology and conditions for users of this product are not within Suraj Chemicals' awareness or control, and it is ultimately the responsibility of the user to take the necessary measures to obtain the legal requirements concerning the manipulation, storage, use and disposal of chemical products. The information on this safety data sheet only refers to this product, which should not be used for needs other than those specified.

END OF SAFETY DATA SHEET