

Safety Data Sheet (SDS)

Section 1: Identification of the substance or mixture and of the supplier

1.1. Product identifier

Product name	SmartEx®
Grade name	Plus
Substance name	D-Mannitol, Low Substituted Hydroxypropylcellulose and Polyvinyl Alcohol Granules

1.2. Supplier's details

Supplier's name	Shin-Etsu Chemical Co., Ltd.
Section	Organic Chemicals Division Cellulose & Pharmaceutical Excipients Department
Address	4-1, Marunouchi 1-chome, Chiyoda-ku, Tokyo 100-0005, Japan
Phone number	+81-3-6812-2441
FAX number	+81-3-6812-2443
Email address	metolose@shinetsu.jp
Emergency phone number	+81-3-6812-2441

1.3. Recommended use of the chemical and restrictions on use

Pharmaceutical excipient; filler, disintegrant, binder

Section 2: Hazards identification

Hazards identification according to GHS Japan

2.1. Classification of the substance or mixture

This substance or mixture is classified into any one of "Classification not possible", "Not classified" or "Not applicable" according to JIS (Japanese Industrial Standards) Z7252:2019 and JIS Z7253:2019.

2.2. Label elements

Not required

2.3. Other hazards which do not result in classification

WARNING: MAY FORM COMBUSTIBLE DUST CONCENTRATION IN AIR (DUST EXPLOSION HAZARD). KEEP AWAY FROM HEAT, SPARKS AND FLAME.

WARNING: KEEP AWAY FROM PEROXIDE (FIRE).

Caution: Spilled powder becomes slippery when wet.

Caution: May cause eye irritation.

Caution: May cause coughing or unpleasant feeling by dust ingestion or inhalation.

Section 3: Composition/information on ingredients

3.1. Substance or mixture Mixture

3.2. Information on ingredients

Common name	D-Mannitol	Low-Substituted Hydroxypropyl Cellulose	Polyvinyl Alcohol
Another name	Mannite	Cellulose, 2-hydroxypropyl ether	Poval PVA
Chemical structure			
CAS RN®	69-65-8	9004-64-2	25213-24-5
Concentration range	CBI*	CBI*	CBI*

* CBI: Confidential Business Information

Section 4: First-aid measures

4.1. Description of first-aid measures

- Inhalation Remove the person to fresh air and get medical attention.
- Skin contact Wash the contaminated area with soap and water sufficiently.
If irritation develops, get medical attention.
- Eye contact Flush eyes with plenty of fresh water while holding eyelids open.
Get immediate medical attention.
Remove contact lenses if they don't adhere.
- Ingestion Wash mouth with water and get medical attention.

4.2. Most important symptoms and effects, both acute and delayed

Nothing has been reported.

4.3. Indication of immediate medical attention and special treatment needed

Nothing particularly

Section 5: Fire-fighting measures

5.1. Suitable extinguishing media

Water, Water spray, Dry chemical powder, Sand, Carbon dioxide (CO₂)

5.2. Unsuitable extinguishing media

High pressure water jet

5.3. Specific hazards arising from the chemical

- May cause toxic and irritating gasses with fire.
 May cause dust explosion if dust clouds are generated near flame.

5.4. Specific extinguishing measure

Use suitable extinguishing media except for water if the combustion expands with water spray.

5.5. Special protective equipment for fire fighters

Use suitable breathing apparatus and chemical protective cloths.

Take special care if dry chemical powder or carbon dioxide is used for fire-fighting in closed space.

Section 6: Accidental release measures

6.1. Personal precautions, protective equipment and emergency procedures

6.1.1 Personal precautions

Take precautions to avoid eye contact and inhalation.

Spilled powder becomes slippery when wet.

6.1.2. Emergency procedures

Wear suitable protective equipment (see section 8 of the SDS).

Remove sources of ignition near the spillage area.

Prevent spillage to drains.

6.2. Environmental precautions

In case of small amount of the material spills, flush the remaining material with plenty of water.

In case of large amount of the material spills, do not wash into drain. Vacuum or sweep up spillage as much as possible then flush the remaining.

6.3. Methods for containment and cleaning up

Avoid dispersal of dust in the air.

Vacuum or sweep up spillage as much as possible into an appropriate containers using non-sparking tools then flush the remains with water.

6.4. Precautions for secondary disaster

Remove sources of ignition.

Prevent spillage to drains.

Section 7: Handling and storage

7.1. Precautions for safe handling

7.1.1. Technical requirements

This substance or mixture is flammable and has the hazards of dust explosion.

Keep away from heat, sparks and flame near this material. Don't permit grinding, welding, drilling or smoking near this material.

All equipment and operators should be sufficiently grounded.

Oxygen concentration should be decreased by nitrogen or inert gas in case of large storage tank (1.5 m in diameter or larger). Monitoring of the oxygen concentration is recommended.

General precautions outlined in the National Fire Protection Association's NFPA 654 "Standard for the Prevention of Fire and Dust Explosions from the Manufacturing, Processing, and Handling of Combustible Particulate Solids" and NFPA 77 "Recommended Practice on Static Electricity" are recommended.

7.1.2. Precautions for safe handling

Handle material so as to minimize dust generation.

Avoid open flame, heat and sparks. No smoking nearby the material.

Read and understand SDS and other safety issues before use.

Avoid fall, put down and shock packages.

7.1.3. Contact evasion

Avoid contact with strong acid, strong base or strong oxidizing agents.

7.2. Conditions for safe storage, including any incompatibilities

7.2.1. Technical requirements

Keep dry. Store away from heat and sunlight.

Avoid contact with flame, heat and sparks during storage.

Use explosion proof designs to electrical facilities where acceptable.

In storing, follow all regulations in regards to this substance or mixture in your country or region.

7.2.2. Safety packaging material

Closed container with materials which can protect from absorbing moisture is recommended.

Section 8: Exposure controls/personal protection

8.1. Control parameters

Occupational Exposure Limits

The Japan society for occupational Health¹⁾; as other dust, class 3

Respirable dust 2 mg/m³

Total dust 8 mg/m³

ACGIH(2020)

TLV-TWA Not applicable

TLV-STEL Not applicable

OSHA PEL (29 CFR 1910.1000)

Respirable fraction 5 mg/m³

Total dust 15 mg/m³

8.2. Exposure controls

8.2.1. Technical requirements

Ventilation may be necessary to control air contaminates of working area under their exposure limits.

Safety shower and eye bath are required near the handling area.

Explosion proof is needed for electrical equipment and ventilation.

All equipment and operators should be sufficiently grounded.

All systems need to be closed for inert system and preventing powder leakage or ventilation system should be used.

Monitoring of the oxygen concentration is recommended when inert gas is used in the process.

8.2.2. Recommended personal protective equipment

Respiratory protection Use dust and mist respirator if needed.

Hand protection Chemical-resistant gloves are recommended.

Eye protection Safety goggles are needed.

Skin protection Use suitable safety clothing with anti-static effect.

Section 9: Physical and chemical properties

9.1. Information on basic physical and chemical properties

Appearance	White to yellowish white granulated powder
Odor	Odorless
Melting point/freezing point	Not available D-Mannitol: 166-169 °C ²⁾ Low-Substituted Hydroxypropyl Cellulose: Not applicable Polyvinyl Alcohol: 150-230 °C ³⁾
Initial boiling point and boiling range	Not applicable
Flammability (solid, gas)	Not available
Explosive limits	Not available (Minimum explosive dust concentration 70-80 g/m ³ as comparable product) Low-Substituted Hydroxypropyl Cellulose: Minimum explosive dust concentration 60-70 g/m ³ ⁴⁾ Polyvinyl Alcohol: Minimum explosive dust concentration 35 g/m ³ ³⁾
Flash point	Not applicable
Auto ignition temperature	Not available (400°C < (powder layer) as comparable product) Low-Substituted Hydroxypropyl Cellulose: 380-400°C (dust cloud), 280-290°C (powder layer) ⁴⁾ Polyvinyl Alcohol: 520°C (dust cloud), 440°C (powder layer) ³⁾
Decomposition temperature	Not available
pH	6.0-7.5 (10% aqueous suspension)
Viscosity	Not applicable
Solubility	This substance partially dissolves in water. This substance is poorly soluble in ethanol or pyridine. This substance is insoluble in diethyl ether.
Partition coefficient: n-octanol/water	Not available
Vapor pressure	Not applicable
Specific gravity	Not available
Bulk density	(Loose) 0.4-0.6 g/cm ³
Vapor density	Not applicable
Particle properties	Mean particle size (D ₅₀) Not more than 150 μm

Section 10: Stability and reactivity

10.1. Reactivity

Not applicable

10.2. Chemical stability

Stable under normal temperature and pressure.

10.3. Possibility of hazardous reactions

Dust explosion

Reacts with strong acid, strong bases, peroxides and strong oxidizing agents.

10.4. Conditions to avoid

Do not generate dust cloud when handling.

Avoid contact from heat, sparks or open flame.

10.5. Incompatible materials

Avoid contact with oxidizing agents.

10.6. Hazardous decomposition products

May form carbon monoxide, carbon dioxide, and other toxic gases when burning.

Section 11: Toxicological information

In this section, D-Mannitol ²⁾, Low-Substituted Hydroxypropyl Cellulose ^{5) 6)}, Polyvinyl Alcohol ³⁾ are abbreviated as MA, LH and PVA, respectively.

Acute toxicity (Oral)	Not classified as mixture MA: LD ₅₀ =17300 mg/kg (rat) Not classified, LH: LD ₅₀ >15000 mg/kg (mouse) Not classified, PVA: LD ₅₀ >2000 mg/kg (rat) Not classified
Acute toxicity (Dermal)	Not classified as mixture MA: Classification not possible, LH: LD ₅₀ >5000 mg/kg (rabbit) Not classified, PVA: LD ₅₀ >2000 mg/kg (rat) Not classified
Acute toxicity (Dust)	Classification not possible MA: Classification not possible, LH: Classification not possible, PVA: Classification not possible
Skin corrosion /irritation	Not classified as mixture MA: Classification not possible, LH: Not classified (rabbit), PVA: Not classified (rabbit)
Serious eye damage /eye irritation	Classification not possible MA: Classification not possible, LH: Classification not possible, PVA: Not classified (rabbit)
Respiratory sensitization	Classification not possible MA: Classification not possible, LH: Classification not possible, PVA: Classification not possible
Skin sensitization	Classification not possible

	MA: Classification not possible, LH: Classification not possible, PVA: Classification not possible
Germ cell mutagenicity	Not classified as mixture MA: Classification not possible, LH: Classification not possible, PVA: Not classified (hamster, house mouse)
Carcinogenicity	Not classified as mixture MA: Classification not possible, LH: Classification not possible, PVA: Not classified (rat)
Reproductive toxicity	Not classified as mixture MA: Classification not possible, LH: Not classified (rat), PVA: Classification not possible
Specific target organ toxicity (Single exposure)	Classification not possible MA: Classification not possible, LH: Classification not possible, PVA: Classification not possible
Specific target organ toxicity (Repeated exposure)	Not classified as mixture MA: Classification not possible, LH: Not classified (rat), PVA: Classification not possible
Aspiration Hazard	Classification not possible MA: Classification not possible, LH: Classification not possible, PVA: Classification not possible

Section 12: Ecological Information

In this section, D-Mannitol ²⁾, Low-Substituted Hydroxypropyl Cellulose, Polyvinyl Alcohol ³⁾ are abbreviated as MA, LH and PVA, respectively.

Acute aquatic toxicity	Classification not possible MA: Classification not possible, LH: Classification not possible, PVA: Classification not possible
Chronic aquatic toxicity	Classification not possible MA: Classification not possible, LH: Classification not possible, PVA: Classification not possible
Degradation for organic chemicals	No information available
Bioaccumulation potential	No information available
Mobility in soil	No information available
Hazardous to the ozone layer	Classification not possible. The substances controlled by the annex of the Montreal Protocol are not contained.

Section 13: Disposal considerations

13.1. Disposal of this material

Contact a licensed professional waste disposal service.

13.2. Disposal of contaminated packages

Follow all federal, state and local environmental regulations.

Remove whole remaining material from the container prior to dispose.

Section 14: Transport information

UN Number	Not applicable
UN Proper shipping name	Not applicable
Transport hazard class	Not applicable in accordance with the UN Model Regulations
Packing group	Not applicable
Environmental hazards	Not applicable
Special precautions for user	Secure package containers to prevent falling and damage. If the material is released in large quantities on transporting, take emergency procedures to prevent disasters and call the nearest fire station and related organization.
Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code	Not applicable
Transport according to the U.S. department of transportation (DOT)	This material is not hazardous as defined by 49 CFR 171.8.

Section 15: Regulatory information

All components of this product are not listed on followings:

Substances restricted under REACH Annex XVII

Authorization List of REACH Annex XIV

Candidate List of SVHCs (Substances of Very High Concern)

All components of this product are listed on the following inventories:

Japanese ENCS (Existing and New Chemical Substances) inventory

United States TSCA (Toxic Substances Control Act) inventory

Canadian DSL (Domestic Substances List)

IECSC (Inventory of Existing Chemical Substances Produced or Imported in China)

KECI (Korean Existing Chemicals Inventory)

TCSI (Taiwan Chemical Substance Inventory)

PICCS (Philippines Inventory of Chemicals and Chemical Substances)

AICS (Australian Inventory of Chemical Substances)

NZIoC (New Zealand Inventory of Chemicals)

Section 16: Other information

16.1. Revision date

Refer to the header information.

16.2. Reference

- 1) Journal of Occupational Health 2019; 61(5): 170-202, the Japan Society for Occupational Health.
- 2) SDS from supplier
- 3) SDS from supplier
- 4) To prevent dust explosion of cellulose derivatives, Shin-Etsu Chemical Co., Ltd., Aug. 2007
(<http://www.metolose.jp/sds/>)
- 5) WHO Food Additive, Vol.26
- 6) Journal of the American College of Toxicology, Vol.5 (3), (1986)

16.3. Remarks

The information in this SDS is written in good faith, but no warranty is given, to what it is expressed or implied, herein. To the best of our knowledge, the information contained in this SDS is accurate, however, Shin-Etsu Chemical Co., Ltd. does not assume any liability whatever for the accuracy or completeness of the information contained herein. Final determination of suitability to any material is the sole responsibility of the user. All materials may present unknown hazards and should be used in caution. Although certain hazards are described, we cannot guarantee that these are the only hazards that exist. Also it is impossible for Shin-Etsu Chemical Co., Ltd. to check up on all regulatory information on this material in unspecified countries or regions. Therefore, we request users to take responsibility for investigating the necessary information.

This SDS is written following JIS (Japanese Industrial Standards) Z7252:2019 and JIS Z7253:2019.

JIS Z7252:2019: Classification of chemicals based on “Globally Harmonized System of Classification and Labelling of Chemicals (GHS)”

JIS Z7253:2019: Hazard communication of chemicals based on GHS-Labeling and Safety Data Sheet (SDS)