

Safety Data Sheet (SDS)

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

1.1. Product identifier

| | |
|-----------------|---|
| Product name | HPMCP |
| Grade name | HP-50, HP-55, HP-55S |
| Compendial name | Hypromellose Phthalate (NF) |
| Substance name | Hydroxypropyl Methylcellulose Phthalate |

1.2. Supplier's details

| | |
|------------------------|--|
| Supplier's name | Shin-Etsu Chemical Co., Ltd. |
| Section | Organic Chemicals Division Cellulose & Pharmaceutical Excipients Department |
| Address | 6-1, Ohtemachi 2-chome, Chiyoda-ku, Tokyo, 100-0004, Japan |
| Phone number | +81-3-3246-5261 |
| FAX number | +81-3-3246-5372 |
| Email address | metolose@shinetsu.jp |
| Emergency phone number | +81-3-3246-5261 |

1.3. Recommended use of the chemical and restrictions on use

Pharmaceutical excipient: enteric coating agent

Section 2: Hazards identification

2.1. Classification of the substance or mixture

This mixture is classified into any one of "Classification not possible" "Not classified" or "Not applicable."

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.

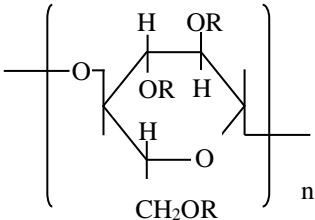
Caution: May cause coughing or unpleasant feeling by dust ingestion or inhalation.

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Section 3: Composition/information on ingredients

3.1. Substance or mixture Substance

3.2. Information on ingredients

| | |
|---------------------|--|
| Common name | Hydroxypropyl Methylcellulose Phthalate |
| Chemical name | Cellulose, 2-hydroxypropyl methyl ether, hydrogen benzene-1,2-dicarboxylate |
| Chemical structure |  <p>R: - H, -CH₃, - CH₂CH(OH)CH₃, - COC₆H₄COOH</p> |
| CAS RN [®] | 9050-31-1 |
| Concentration range | Not less than 95% |

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, don 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 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 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(2018)

TLV-TWA Not applicable

STEL Not applicable

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

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|---|---|
| Appearance | White to off white flake or powder |
| Odor | Odorless or slight odor |
| pH | Not available |
| Melting point/freezing point | Not applicable |
| Initial boiling point and boiling range | Not applicable |
| Flash point | Not applicable |
| Evaporation rate | Not applicable |
| Flammability (solid, gas) | Not available |
| Explosive limits | Minimum explosive dust concentration 85 g/m ³ ²⁾ (Minimum explosive dust concentration 30 g/m ³ as Methylcellulose) ³⁾ |
| Vapor pressure | Not applicable |
| Vapor density | Not applicable |
| Specific gravity | Not available |
| Bulk density | (Loose) about 0.2-0.4 g/cm ³ |
| Solubility | This substance is insoluble in water, acetonitrile and ethanol (99.5%). This substance dissolves in methanol/dichloromethane (1:1) and 1N NaOH aqueous solution and to be viscous solution. |
| Partition coefficient: n-octanol/water | Not available |
| Auto ignition temperature | Not available (360°C (dust cloud), 340°C (powder layer) as Methylcellulose) ³⁾ |
| Decomposition temperature | Not available |
| Viscosity | Not applicable |

Section 10: Stability and reactivity

10.1. Reactivity

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

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

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|--|--|
| Acute toxicity (Oral) | Not classified: LD50>15000 mg/kg (rat) (Kitagawa et al., 1970) ⁴⁾ |
| Acute toxicity (Dermal) | Classification not possible |
| Acute toxicity (Dust) | Classification not possible |
| Skin corrosion /irritation | Classification not possible |
| Serious eye damage /eye irritation | Classification not possible |
| Respiratory sensitization | Classification not possible |
| Skin sensitization | Classification not possible |
| Germ cell mutagenicity | Classification not possible |
| Carcinogenicity | Classification not possible |
| Reproductive toxicity | Not classified: (rat, mouse) (Itoh & Toida, 1972) ⁵⁾ |
| Specific target organ toxicity (Single exposure) | Classification not possible |
| Specific target organ toxicity (Repeated exposure) | Not classified: (rat) (Kitagawa et al., 1973) ⁶⁾ |
| Aspiration Hazard | Classification not possible |

Section 12: Ecological Information

| | |
|-----------------------------------|--|
| Acute aquatic toxicity | Classification not possible |
| Chronic aquatic toxicity | Classification not possible |
| Bioaccumulation potential | No information available |
| Degradation for organic chemicals | BOD ₅ : not more than 5 mg-O ₂ /L (JIS K0102 21) as hydroxypropyl methylcellulose |
| Hazardous to the ozone layer | Classification not possible |

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 |

Section 15: Regulatory information

This material is not hazardous as defined by 49CFR 172.101 by the U.S. department of transportation.

This substance is not classified as hazardous according to Regulation (EC) No 1272/2008 (CLP).

This substance is listed in current US National Formulary, European Pharmacopoeia and Japanese Pharmacopoeia.

Section 16: Other information

16.1. Reference

- 1) Journal of Occupational Health 2017: 59(5):153-185, the Japan Society for Occupational Health.
- 2) Journal of the Society of Powder Technology, Japan Vol.32, No.1, 4-9, 1995
- 3) Technical Recommendations of Research Institute of Industrial safety, Ministry of Labour Research Institute of Industrial Safety Japan, Rev., Mar. 1988
- 4) Kitagawa et al., Acute and Subacute Toxicities of HPMCP. Pharmacometrics 1970; 4:1017-1025
- 5) Itoh et al., Studies on the teratogenicity of a New Enteric coating materials, Hydroxypropyl Methylcellulose Phthalate(HPMCP) in Rats and Mice. J Med Soc Toho-univ 1972; 19,453-461
- 6) Kitagawa et al., Chronic toxicity of HPMCP in rats. Pharmacometrics 1973; 7: 689-701

16.2. 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) Z7252:2014 and JIS Z7253:2012.

JIS Z7252:2014: Classification of chemicals based on “Globally Harmonized System of Classification and Labelling of Chemicals (GHS)

JIS Z7253:2012: Hazard communication of chemicals based on GHS-Labelling and Safety Data Sheet (SDS)