

Hypromellose (4000 mPa.s)

Safety Data Sheet

252328

according to Regulation (EC) No. 1907/2006 (REACH) with its amendment Regulation (EU) 2015/830

Version: 3.0

Date of issue: 07/08/2014 Revision date 14/08/2019

Supersedes 20/03/2017

SECTION 1: Identification of the substance/mixture and of the company/undertaking

1.1. Product identifier

Product form : Substance
 Substance name : Hypromellose (4000 mPa.s)
 CAS-No. : 9004-65-3
 Product code : 252328
 Synonyms : Hydroxypropylmethylcellulose
 Product group : Raw material

1.2. Relevant identified uses of the substance or mixture and uses advised against

1.2.1. Relevant identified uses

Industrial/Professional use spec : Industrial
 For professional use only
 Use of the substance/mixture : Thickener. Binder. Film-forming properties.
 Use of the substance/mixture : Exipient

1.2.2. Uses advised against

No additional information available

1.3. Details of the supplier of the safety data sheet

Supplier

Duchefa Farma BV
 A. Hofmanweg 71
 2031BH Haarlem - Nederland
 T +31(0)23-5319093
farma@duchefa.nl - www.duchefa-farma.com

1.4. Emergency telephone number

Emergency number : Supplier contact information:
 +31(0)23-5319093 (M-F 09:00-17:00)
 +31(0)6-30109355 (outside office hours)

Country	Organisation/Company	Address	Emergency number	Comment
United Kingdom	Guy's & St Thomas' Poisons Unit Medical Toxicology Unit, Guy's & St Thomas' Hospital Trust	Avonley Road SE14 5ER London	+44 20 7188 7188	

SECTION 2: Hazards identification

2.1. Classification of the substance or mixture

Classification according to Regulation (EC) No. 1272/2008 [CLP]

Not classified

Adverse physicochemical, human health and environmental effects

No additional information available

2.2. Label elements

According to EC directives or the corresponding national regulations there is no labelling obligation for this product.

2.3. Other hazards

No additional information available

SECTION 3: Composition/information on ingredients

3.1. Substances

Substance type : Mono-constituent

Name	Product identifier	%	Classification according to Regulation (EC) No. 1272/2008 [CLP]
Hypromellose (4000 mPa.s)	(CAS-No.) 9004-65-3	100	Not classified

Full text of H-statements: see section 16

3.2. Mixtures

Not applicable

SECTION 4: First aid measures

4.1. Description of first aid measures

- First-aid measures general : Never give anything by mouth to an unconscious person. If you feel unwell, seek medical advice (show the label where possible).
- First-aid measures after inhalation : Allow affected person to breathe fresh air. Allow the victim to rest.
- First-aid measures after skin contact : Wash skin with mild soap and water.
- First-aid measures after eye contact : Rinse immediately with plenty of water. Obtain medical attention if pain, blinking or redness persists. Remove contact lenses, if present and easy to do. Continue rinsing.
- First-aid measures after ingestion : Rinse mouth.

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

- Symptoms/effects : Not expected to present a significant hazard under anticipated conditions of normal use.

4.3. Indication of any immediate medical attention and special treatment needed

Treat symptomatically.

SECTION 5: Firefighting measures

5.1. Extinguishing media

- Suitable extinguishing media : Foam. Dry powder. Carbon dioxide. Water spray. Sand.
- Unsuitable extinguishing media : Do not use a heavy water stream.

5.2. Special hazards arising from the substance or mixture

- Explosion hazard : May form flammable/explosive vapour-air mixture.
- Hazardous decomposition products in case of fire : On burning: release of harmful/irritant gases/vapours e.g.: carbon monoxide - carbon dioxide.

5.3. Advice for firefighters

- Precautionary measures fire : In order to rule out potential electrostatic discharge production, the system must be adequately grounded.
- Firefighting instructions : Use water spray or fog for cooling exposed containers. Exercise caution when fighting any chemical fire. Prevent fire fighting water from entering the environment.
- Protection during firefighting : Do not enter fire area without proper protective equipment, including respiratory protection.

SECTION 6: Accidental release measures

6.1. Personal precautions, protective equipment and emergency procedures

6.1.1. For non-emergency personnel

- Emergency procedures : Evacuate unnecessary personnel.

6.1.2. For emergency responders

- Protective equipment : Equip cleanup crew with proper protection.
- Emergency procedures : Ventilate area.

6.2. Environmental precautions

Prevent entry to sewers and public waters. Notify authorities if liquid enters sewers or public waters.

6.3. Methods and material for containment and cleaning up

- Methods for cleaning up : On land, sweep or shovel into suitable containers. Minimise generation of dust. Store away from other materials.

6.4. Reference to other sections

Reference to other sections (8, 13).

SECTION 7: Handling and storage

7.1. Precautions for safe handling

- Additional hazards when processed : Take precautionary measures against static discharges. Dust may form explosive mixture in air.
- Precautions for safe handling : Wash hands and other exposed areas with mild soap and water before eating, drinking or smoking and when leaving work. Provide good ventilation in process area to prevent formation of vapour.
- Hygiene measures : Handle in accordance with good industrial hygiene and safety practice.

7.2. Conditions for safe storage, including any incompatibilities

- Storage conditions : Keep container closed when not in use. Store in a dry place.
- Incompatible products : Strong bases. Strong acids. oxidising substances.
- Incompatible materials : Sources of ignition. No open flames. No smoking. Sparks.
- Storage temperature : 15 - 25 °C

7.3. Specific end use(s)

Pharmaceutical industry.

SECTION 8: Exposure controls/personal protection

8.1. Control parameters

No additional information available

8.2. Exposure controls

Appropriate engineering controls:

Good ventilation of the workplace required. Technical measures and appropriate working operations should have priority over the use of personal protective equipment.

Personal protective equipment:

Avoid all unnecessary exposure.

Hand protection:

No specific measures are necessary

Eye protection:

Safety glasses (to European standard EN 166 or equivalent)

Skin and body protection:

Protective clothing (with elasticated cuffs and closed neck)

Respiratory protection:

Dust production: dust mask with filter type P1

Other information:

Do not eat, drink or smoke during use.

SECTION 9: Physical and chemical properties

9.1. Information on basic physical and chemical properties

Physical state	: Solid
Appearance	: Powder.
Colour	: White to off-white.
Odour	: odourless.
Odour threshold	: No data available
pH	: No data available
Relative evaporation rate (butylacetate=1)	: No data available
Melting point	: No data available
Freezing point	: No data available
Boiling point	: No data available
Flash point	: No data available
Auto-ignition temperature	: No data available
Decomposition temperature	: No data available
Flammability (solid, gas)	: Non flammable.
Vapour pressure	: No data available
Relative vapour density at 20 °C	: No data available
Relative density	: No data available
Solubility	: Soluble in water.
Log Pow	: No data available
Viscosity, kinematic	: No data available
Viscosity, dynamic	: No data available
Explosive properties	: No data available

Safety Data Sheet

according to Regulation (EC) No. 1907/2006 (REACH) with its amendment Regulation (EU) 2015/830

Oxidising properties : No data available

Explosive limits : No data available

9.2. Other information

No additional information available

SECTION 10: Stability and reactivity

10.1. Reactivity

Stable under normal conditions.

10.2. Chemical stability

Stable at normal conditions. zie rubriek 7.

10.3. Possibility of hazardous reactions

No additional information available

10.4. Conditions to avoid

Avoid temperature above. 130 °C. Use special care to avoid static electric charges.

10.5. Incompatible materials

Strong acids. Strong bases. Strong oxidizing agents.

10.6. Hazardous decomposition products

Carbon monoxide. Carbon dioxide.

SECTION 11: Toxicological information

11.1. Information on toxicological effects

Acute toxicity : Not classified

Hypromellose (4000 mPa.s) (9004-65-3)	
LD50 dermal rabbit	> 5000 mg/kg
Additional information	For similar substances LD50, Rat> 10,000 mg / kg

Skin corrosion/irritation : Not classified

Additional information : Based on available data, the classification criteria are not met

Serious eye damage/irritation : Not classified

Additional information : Based on available data, the classification criteria are not met
May cause eye irritation

Respiratory or skin sensitisation : Not classified

Additional information : Based on available data, the classification criteria are not met

Germ cell mutagenicity : Not classified

Based on available data, the classification criteria are not met

Carcinogenicity : Not classified

Additional information : Based on available data, the classification criteria are not met

Reproductive toxicity : Not classified

Additional information : Based on available data, the classification criteria are not met

STOT-single exposure : Not classified

Additional information : Based on available data, the classification criteria are not met

STOT-repeated exposure : Not classified

Additional information : Based on available data, the classification criteria are not met

Aspiration hazard : Not classified
 Additional information : Based on available data, the classification criteria are not met
 Potential adverse human health effects and symptoms : Based on available data, the classification criteria are not met.

SECTION 12: Ecological information

12.1. Toxicity

No additional information available

12.2. Persistence and degradability

Hypromellose (4000 mPa.s) (9004-65-3)	
Persistence and degradability	Not biodegradable.
Biochemical oxygen demand (BOD)	0 g O ₂ /g substance

12.3. Bioaccumulative potential

Hypromellose (4000 mPa.s) (9004-65-3)	
Bioaccumulative potential	No bioconcentration is expected, as a result of the relatively high molecular weight (MW greater than 1000).

12.4. Mobility in soil

No additional information available

12.5. Results of PBT and vPvB assessment

No additional information available

12.6. Other adverse effects

Additional information : Avoid release to the environment.

SECTION 13: Disposal considerations

13.1. Waste treatment methods

Product/Packaging disposal recommendations : Dispose in a safe manner in accordance with local/national regulations.
 Ecology - waste materials : Avoid release to the environment.

SECTION 14: Transport information

In accordance with ADR / RID / IMDG / IATA / ADN

ADR	IATA
14.1. UN number	
Not applicable	Not applicable
14.2. UN proper shipping name	
Not applicable	Not applicable
14.3. Transport hazard class(es)	
Not applicable	Not applicable
Not applicable	Not applicable
14.4. Packing group	
Not applicable	Not applicable
14.5. Environmental hazards	
Dangerous for the environment : No	Dangerous for the environment : No
No supplementary information available	

Safety Data Sheet

according to Regulation (EC) No. 1907/2006 (REACH) with its amendment Regulation (EU) 2015/830

14.6. Special precautions for user

- Overland transport

No data available

- Air transport

No data available

14.7. Transport in bulk according to Annex II of Marpol and the IBC Code

Not applicable

SECTION 15: Regulatory information

15.1. Safety, health and environmental regulations/legislation specific for the substance or mixture

15.1.1. EU-Regulations

No REACH Annex XVII restrictions

Hypromellose (4000 mPa.s) is not on the REACH Candidate List

Hypromellose (4000 mPa.s) is not on the REACH Annex XIV List

15.1.2. National regulations

No additional information available

15.2. Chemical safety assessment

No chemical safety assessment has been carried out

SECTION 16: Other information

Indication of changes:

1.4	Emergency telephone	Modified	Added additional information
7.1	Hygiene measures	Added	
7.2	Storage temperature	Modified	
7.2	Storage temperature	Modified	
8.2	Hand protection	Modified	Specified material, thickness, et cetera of gloves
8.2	Eye protection	Modified	

Abbreviations and acronyms:

SDS	Safety Data Sheet
RID	Regulations concerning the International Carriage of Dangerous Goods by Rail
REACH	Registration, Evaluation, Authorisation and Restriction of Chemicals Regulation (EC) No 1907/2006
IMDG	International Maritime Dangerous Goods
IATA	International Air Transport Association
ADR	European Agreement concerning the International Carriage of Dangerous Goods by Road
ADN	European Agreement concerning the International Carriage of Dangerous Goods by Inland Waterways
CLP	Classification Labelling Packaging Regulation; Regulation (EC) No 1272/2008

Hypromellose (4000 mPa.s)

252328

Safety Data Sheet

according to Regulation (EC) No. 1907/2006 (REACH) with its amendment Regulation (EU) 2015/830

- Data sources : REGULATION (EC) No 1272/2008 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 16 December 2008 on classification, labelling and packaging of substances and mixtures, amending and repealing Directives 67/548/EEC and 1999/45/EC, and amending Regulation (EC) No 1907/2006.
- Other information : **DISCLAIMER OF LIABILITY** The information in this SDS was obtained from sources which we believe are reliable. However, the information is provided without any warranty, express or implied, regarding its correctness. REACH Disclaimer:
This information is based on current knowledge. Consistency of data in the SDS with CSR is considered, as far as the information is available at the time of compilation (cfr Revision date and Version number).

SDS EU (REACH Annex II) ducheafa oude logo

This information is based on our current knowledge and is intended to describe the product for the purposes of health, safety and environmental requirements only. It should not therefore be construed as guaranteeing any specific property of the product.