

DMV-Fonterra Excipients

The ingredients of success



Document : Material Safety Data Sheet (MSDS)
Product : Lactose monohydrate
Brand name : HMS Lactose impalpable grade
Issue date : 20 November 2009
Edition No. : 1

(Based on Regulation (EC) no. 1907/2006 (REACH) Article 31, Annex II)

1. Identification of the substance/preparation and of the company/undertaking

1.1 Identification of the substance preparation:

Product name : Lactose monohydrate
Synonyms :
Milk sugar
alpha-lactose
alpha-Lactose Monohydrate
alpha-D-lactose monohydrate
alpha-D-(+)-Lactose Monohydrate
4 -O-alpha-D-Glucopyranosyl-D-glucose
4 -O-beta-D-Galactopyranosyl-alpha-D-glucose
4 -O-alpha-D-Glucopyranosyl-D-glucopyranose
4 -O-alpha-D-Glucopyranosyl-D-Glucose
4 -O-alpha-Glucopyranosyl-D-glucose monohydrate
4 -O -beta-Galactopyranosyl-D-glucose

CAS No.	: 64044-51-5	NFPA code	: N.D.
EC index No.	: N.A.	Molecular weight	: 360,3
EINECS No.	: 200-559-2	Formula	: $C_{12}H_{22}O_{11} \cdot H_2O$
RTECS No.	: OD9625000		

1.2 Use of the substance/preparation:

- Pharmaceutical industry: component

1.3 Company/undertaking identification:

DMV-Fonterra Excipients GmbH & Co. KG
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1.4. Emergency telephone:

+31 413 37 22 22

2. Hazards identification

- Not classified as dangerous in compliance with Directive 67/548/EEC and/or Directive 1999/45/EC

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3. Composition/information on ingredients

Hazardous ingredients	CAS No. EINECS/ELINCS No.	Conc.(%)	Hazards (R-phrases)	Hazard symbol
Lactose monohydrate	64044-51-5 200-559-2	100	-	-

4. First aid measures

4.1 After inhalation:

- Move the victim into fresh air
- Respiratory problems: consult a doctor/medical service

4.2. Skin contact:

- Rinse with water
- Take victim to a doctor if irritation persists

4.3. Eye contact:

- Rinse with water
- Do not apply neutralizing agents
- Take victim to an ophthalmologist if irritation persists

4.4 After ingestion:

- Rinse mouth with water
- If you feel unwell: consult a doctor/medical service

5. Fire fighting measures

5.1 Suitable extinguishing media:

- Water spray
- Polyvalent foam
- ABC powder
- Carbon dioxide

5.2 Unsuitable extinguishing media:

- No data available

5.3 Special exposure hazards:

- Dust is explosive with air
- Upon combustion CO and CO₂ are formed

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5.4 Instructions:

- No specific fire fighting instructions required

5.5 Special protective equipment for fire-fighters:

- Heat/fire exposure: Self-contained breathing apparatus
- In case of dust production: Self-contained breathing apparatus

6. Accidental release measures

6.1 Personal precautions:

See heading 8.2/13

6.2 Environmental precautions:

- Contain released substance in suitable containers
- Plug the leaks, cut off the supply
- Knock down dust cloud/dilute dust cloud with water spray

6.3. Methods for cleaning up:

- Prevent dust cloud formation
- Shovel solid spill into closable drums
- Powdered form: do not use compressed air for pumping over spills
- Clean contaminated surfaces with an excess of water
- Wash clothing and equipment after handling

7. Handling and storage

7.1 Handling:

- Observe normal hygiene standards
- Avoid raising dust
- Remove contaminated clothing immediately
- Clean contaminated clothing

7.2 Storage:

- Keep container tightly closed
- Meet the legal requirements
- Keep away from: heat sources, ignition sources, oxidizing agents

Storage temperature : 5-25 C° at max. Rh of 70%

Storage life : See QA documentation

Materials for packaging

- materials to be avoided : no data available

7.3 Specific use(s):

- See information supplied by the manufacturer for the identified use(s)

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8. Exposure controls/Personal protection:

8.1 Exposure limit values:

8.1.1 Occupational exposure :

No limits are known for lactose monohydrate.

8.1.2 Sampling methods

- No data available

8.2 Exposure controls:

8.2.1 Occupational exposure controls:

- Work under local exhaust/ventilation

Personal protective equipment:

a) Respiratory protection:

- In case of dust production: dust mask with filter type P1

b) Hand Protection:

- Gloves of a suitable material

c) Eye protection:

- Safety glasses

- In case of dust production: protective goggles

d) Skin protection

- Protective clothing

8.2.2 Environmental exposure controls: see headings 6.2, 6.3 and 13

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9. Physical and chemical properties

9.1 General information:

Appearance (at 20°C) : Solid / Dry chemical powder
Odour : None
Colour : White to slightly yellow powder

9.2 Important health, safety and environmental information:

pH value (at %) : N.D.
Boiling point/boiling range : N.D. °C
Oxidising properties : N.D.
Vapour pressure (at 20°C) : N.D. hPa
Vapour pressure (at 50°C) : N.D. hPa
Relative density (at 20°C) : N.D.
Water solubility : 15 g/100 ml at 10 °C
Soluble in : N.D.
1.5 g / 10 g water
Relative vapour density : N.D.
Viscosity (at °C) : N.D. mPas
Partition coefficient n-octanol/water : N.D.
Evaporation rate
ratio to butyl acetate : N.D.
ratio to ether : N.D.

9.3 Other information:

(See also Explanatory Document on Explosion Data)

Melting point/melting range : N.D. °C
Auto-ignition point : N.D. °C
Saturation concentration : N.D. g/m³
Specific conductivity : N.D. pS/m
LEL : 60 g/m³
P_{max} : 7.2 bara
K_{st} : 24 bar.m/s
MOE/MIE : 1000 mJ
MOT/MIT : 470 °C
SMOUL : 350 °C
Dust Explosion Class : 1

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10. Stability and reactivity

10.1 Conditions to avoid:

- No data available

10.2 Materials to avoid:

- Keep away from: heat sources, ignition sources, oxidizing agents

10.3 Hazardous decomposition products:

- Upon combustion CO and CO₂ are formed

11. Toxicological information

11.1 Acute toxicity:

No data available

11.2 Chronic toxicity:

No data available

11.3 Routes of exposure:

Ingestion, inhalation, eye and skin

11.4 Acute effects/symptoms:

AFTER EYE CONTACT

- Slight irritation

11.5 Chronic effects:

- Not listed in carcinogenicity class (IRAC,EC,TLV,MAK)
- Not listed in mutagenicity class (EC,MAK)
- Not classified as toxic to reproduction (EC)

12. Ecological information

12.1 Ecotoxicity:

- No data available
- Effect on waste water purification : no data available

12.2. Mobility:

- Volatile organic compounds (VOC) : 0%
- No data available

For other physiochemical properties see heading 9

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12.3 Persistence and degradability:

No data available

12.4 Bioaccumulative potential:

No data available

12.5 Results of PBT assessment:

- No data available

12.6 Other adverse effects:

-Effect on the ozone layer : Not dangerous for the ozone layer (Council Regulation (EC) 2037/2000, PB 29/09/2000)

13. Disposal considerations

13.1 Provisions relating to waste:

- Waste material code (75/442/EEC, Council Decision 2001/118/EC, O.J. L47 of 16/2/2001): 02 05 99 (wastes not otherwise specified)

13.2 Disposal methods:

- Remove to an authorized waste treatment plant

13.3 Packaging:

- No data available

14. Transport information

14.1 Classification of a substance in compliance with UN Recommendations

No data available

14.2 ADR (transport by road)

No data available

14.3 RID (transport by rail)

No data available

14.4 ADNR (transport by inland waterways)

No data available

14.5 IMDG (maritime transport)

No data available

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14.6 ICAO (air transport)
No data available

14.7 Special precautions : Not restricted for any mode of internal transport

15. Regulatory information

15.1 EU Legislation:

Not classified as dangerous in compliance with Directive 67/548/EEC and/or Directive 1999/45/EC

15.2 National provisions:

No data available

16. Other information

The information provided on this SDS is correct to the best of our knowledge, information and belief at the date of its publication. The information given is designed only as a guidance for safe handling, use, processing, storage, transportation, disposal and release and is not to be considered as a warranty or quality specification. The information relates only on the specific material designated and may not be valid for such material used in combination with any other material or in any process, unless specified in the text.

Abbreviations used:

N.A. = NOT APPLICABLE
N.D. = NOT DETERMINED

Name : Dipl.-Ing. Astrid Stockrahm
Job title: Manager Quality Assurance & Regulatory Affairs
Signature :



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