



Document	: Material Safety Data Sheet (MSDS)
Product	: Lactose HMS Impalpable
Product Description	: Lactose monohydrate
Product code	: 42034 (EU) / 42610 (NZ)
Document no.	: PD-0317
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(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	
EC index No.	:	N.A.	
EINECS No.	:	200-559-2	NFPA code : N.D.
RECS No.	:	OD9625000	Molecular weight : 360,3
			Formula : $C_{12}H_{22}O_{11} \cdot H_2O$

1.2 Use of the substance/preparation:

- Pharmaceutical industry: component

1.3 Company/undertaking identification:

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1.4. Emergency telephone:

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2. Hazards identification

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

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. Firefighting measures

5.1 Suitable extinguishing media:

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

5.2 Unsuitable extinguishing media:

- No data available

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5.3 Special exposure hazards:

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

5.4 Instructions:

- No specific firefighting 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

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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. Relative Humidity (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)

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

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d) Skin protection

- Protective clothing

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

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/m ³
Specific conductivity	:	N.D.	pS/m
LEL	:	60	g/m ³
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

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12.2. Mobility:

- Volatile organic compounds (VOC) : 0%
 - No data available
- For other physiochemical properties see heading 9

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

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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

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

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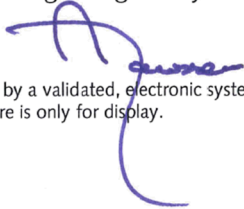
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16. Other information

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Abbreviations used:

N.A. = NOT APPLICABLE
N.D. = NOT DETERMINE

Name : Armand M. Janssen
Job title : Manager Regulatory Affairs
Signature : 

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