

1. Product and Company Identification

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Product Name LACTOSE MONOHYDRATE AR
Part Number RXSOL-60-6604-780

Company Details:

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2. Composition / Information on ingredients

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Substance / Preparation : LACTOSE (MONOHYDRATE)

CAS No :10039-26-6

Substance.

Contains no other components or impurities which will influence the classification of the product.

3. Hazards Identification

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3.1. Classification of the substance or mixture

Classification EC 67/548 or EC 1999/45

Not classified.

Hazard Class and Category Code(s), Regulation (EC) No 1272/2008 (CLP)

Not classified.

3.2. Label elements

Labelling EC 67/548 or EC 1999/45

Not classified.

Not classified.

3.3. Other hazards

Other hazards : The substance does not fulfil the criteria to be identified as PBT substance or vPvB substance according to Annex XIII of Regulation REACH.

4. First Aid Measures

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4.1. Description of first aid measures

Inhalation : Assure fresh air breathing. Allow the victim to rest.

Skin contact : Remove affected clothing and wash all exposed skin area with mild soap and water, followed by warm water rinse.

Eye contact : Rinse immediately with plenty of water. Obtain medical attention if pain, blinking or redness persist.

Ingestion : Obtain emergency medical attention. Rinse mouth. Do NOT induce vomiting.

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

Symptoms relating to use : 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

General information : Never give anything by mouth to an unconscious person. If you feel unwell, seek medical advice (show the label where possible).

5. Fire-fighting Measures

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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.

Surrounding fires : Use water spray or fog for cooling exposed containers.

5.2. Special hazards arising from the substance or mixture

Hazardous combustion products : Under fire conditions, hazardous fumes will be present.

5.3. Advice for fire-fighters

Protection against fire : Do not enter fire area without proper protective equipment, including respiratory protection.

Special procedures : Exercise caution when fighting any chemical fire. Avoid (reject) fire-fighting water to enter environment.

6. Accidental Release Measures

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6.1. Personal precautions, protective equipment and emergency procedures

For emergency responders : Equip cleanup crew with proper protection.

Ventilate area.

For non-emergency personnel : Evacuate unnecessary personnel.

6.2. Environmental precautions

Environmental precautions : Prevent entry to sewers and public waters. Notify authorities if product enters sewers or public waters.

6.3. Methods and material for containment and cleaning up

Clean up methods : On land, sweep or shovel into suitable containers. Minimize generation of dust. Store away from other materials.

6.4. Reference to other sections

See section 8. Exposure controls/personal protection

7. Handling and Storage

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7.1. Precautions for safe handling

Handling : Wash hands and other exposed areas with mild soap and water before eat, drink or smoke and when leaving work.

Technical protective measures : Provide good ventilation in process area to prevent formation of vapour.

7.2. Conditions for safe storage, including any incompatibilities

Storage : Keep only in the original container in a cool, well ventilated place. Keep container closed when not in use.

Storage - away from : Strong bases. Strong acids. Sources of ignition. Direct sunlight.

7.3. Specific end use(s)

Specific end use(s) : None.

8. Exposure controls and personal protection

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8.1. Exposure controls

Personal protection : Avoid all unnecessary exposure.

☒ Respiratory protection : Wear approved mask.

☒ Hand protection : Wear protective gloves.

☒ Eye protection : Chemical goggles or safety glasses.

☒ Others : When using, do not eat, drink or smoke.

8.2. Control parameters

Occupational Exposure Limits : No data available.

9. Physical and chemical properties

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9.1. Information on basic physical and chemical properties

Physical state at 20 °C : Solid.

Odour threshold : No data available.

pH value : Not applicable.

Melting point [°C] : 214°C

Decomposition point [°C] : N/A

Critical temperature [°C] : N/A

Auto-ignition temperature [°C] : N/A

Flammability (solid, gas) : N/A

Flash point [°C] : N/A

Boiling point [°C] : N/A

Initial boiling point [°C] : N/A

Final boiling point [°C] : N/A

Evaporation rate : N/A

Vapour pressure [20°C] : N/A

Vapour pressure mm/Hg : N/A

Vapour density : N/A

Density [g/cm³] : 1,525

Relative density, gas (air=1) : N/A

Relative density, liquid (water=1) : N/A

Solubility in water [% weight] : Partially soluble in

Solubility in water : N/A

Log Pow octanol / water at 20°C : No data available.

Solubility : N/A

Viscosity at 40°C [mm²/s] : N/A

9.2. Other information

Explosive properties : N/A

Explosion limits - upper [%] : N/A

Explosion limits - lower [%] : N/A

Oxidising properties : No data available

10. Stability and reactivity

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10.1. Reactivity

Reactivity : Not established.

10.2. Chemical stability

Chemical stability : Stable under recommended storage conditions.

10.3. Possibility of hazardous reactions

Hazardous reactions : Not established.

10.4. Conditions to avoid

Conditions to avoid : Direct sunlight. Extremely high or low temperatures.

10.5. Incompatible materials

Materials to avoid : Strong acids. Strong bases.

10.6. Hazardous decomposition products

Hazardous decomposition products : Fumes. Carbon monoxide. Carbon dioxide.

11.1. Information on toxicological effects

Acute toxicity

☒ Inhalation : Based on available data, the classification criteria are not met

☒ Dermal : Based on available data, the classification criteria are not met.

☒ Ingestion : Based on available data, the classification criteria are not met.

Corrosion : Based on available data, the classification criteria are not met.

Irritation : Based on available data, the classification criteria are not met.

Sensitization : Based on available data, the classification criteria are not met.

Mutagenicity : Based on available data, the classification criteria are not met.

Carcinogenicity : Based on available data, the classification criteria are not met.

Toxic for reproduction : Based on available data, the classification criteria are not met.

STOT-single exposure : Based on available data, the classification criteria are not met.

STOT-repeated exposure : Based on available data, the classification criteria are not met.

Aspiration hazard : Based on available data, the classification criteria are not met.

12. Ecological information

12.1. Toxicity

Toxicity information : Not established.

12.2. Persistence - degradability

Persistence - degradability : Biodegradable.

12.3. Bioaccumulative potential

Bioaccumulative potential : Not established.

12.4. Mobility in soil

Mobility in soil : Not established.

12.5. Results of PBT and vPvB assessment

Results of PBT and vPvB assessment : The substance does not fulfil the criteria to be identified as PBT substance or vPvB substance according to Annex XIII of Regulation REACH.

12.6. Other adverse effects

Environmental precautions : Avoid release to the environment.

13. Disposal considerations

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13.1. Waste treatment methods

General : Avoid release to the environment. Dispose in a safe manner in accordance with local/national regulations.

14. Transport information

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14.1. Land transport (ADR-RID)

General information : Not regulated.

14.2. Sea transport (IMDG) [English only]

General information : Not regulated.

14.3. Air transport (ICAO-IATA) [English only]

General information : Not regulated.

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

Safety, health and environmental : Ensure all national/local regulations are observed. regulations/legislation specific for the substance or mixture

REACH Restrictions - Annex XVII : The components of this product are not subject to restrictions.

REACH Authorisation - Annex XIV : The components of this product are not subject to authorization.

15.2. Chemical Safety Assessment

Chemical Safety Assessment : It has not been carried out.

Abbreviations and acronyms : PBT: persistent, bioaccumulative and toxic.

vPvB: very persistent and very bioaccumulative Sources

of key data used : 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

Further information : None.

In accordance with REACH Regulation (CE) N° 1907/2006 and with CLP Regulation (CE) N° 1272/2008

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