1. Identification of the substances/ mixture and of the company/ undertaking

1.1 Product Identifiers
Product Code       RM565G
Product Name       Lactose monohydrate, Sterile
                   (γ-Irradiated sterile powder)

1.2 Relevant identified uses of the substance or mixture and uses advised against
Identified uses    Laboratory chemicals, Manufacture of substances

1.3 Details of the supplier of the safety data sheet
Produced by       HiMedia Laboratories Pvt. Ltd.
Address           23, Vadhani Indl.Estate, LBS Marg, Mumbai 400 086, India.
Tel. No.           +91-22-2500 0970, +91-22-2500 1607
Fax No.            +91-22-2500 2468

1.4 Emergency Tel. No.
Emergency Tel.No.  Please contact the regional HiMedia representation in your country

2. Hazards Identification

2.1 Classification of the substance or mixture
Not a hazardous substance or mixture according to Regulation (EC) No.1272/2008 This substance is not classified as dangerous according to directive 67/548/EEC.

2.2 Label elements
The Product does not need to be labelled in accordance with EC directives or respective national laws.

2.3 Other hazards - None

3. Composition/Information on Ingredients

3.1 Substances
Synonym : 4-O-β-D-Galactopyranosyl-D-glucose; Milk sugar

   Molecular Formula     \( \text{C}_{12}\text{H}_{22}\text{O}_{11}.\text{H}_{2}\text{O} \)
   Molecular Weight.     360.31

<table>
<thead>
<tr>
<th>Component</th>
<th>Concentration</th>
</tr>
</thead>
<tbody>
<tr>
<td>Lactose monohydrate, Sterile</td>
<td></td>
</tr>
<tr>
<td>CAS-No.</td>
<td>64044-51-5</td>
</tr>
<tr>
<td>EC-No.</td>
<td>200-559-2</td>
</tr>
</tbody>
</table>

4. First Aid Measures

4.1 Description of first aid measures
General advice
Consult a physician. Show this safety data sheet to the doctor in attendance.

If inhaled
If breathed in, move person into fresh air. If not breathing, give artificial respiration. Consult a physician.

In case of skin contact
Wash off with soap and plenty of water. Consult a physician.

In case of eye contact
Rinse thoroughly with plenty of water for at least 15 minutes and consult a physician.

If swallowed
Never give anything by mouth to an unconscious person. Rinse mouth with water. Consult a physician.

4.2 Most important symptoms and effects, both acute and delayed
No data available

4.3 Indication of immediate medical attention and special treatment needed
No data available

5. Fire Fighting Measures
5.1 Extinguishing media
Suitable extinguishing media
Use water spray, alcohol-resistant foam, dry chemical or carbon dioxide.

5.2 Special hazards arising from the substance or mixture
Carbon oxides

5.3 Precautions for fire-fighters
Wear self contained breathing apparatus for fire fighting if necessary.

5.4 Further information
No data available

6 Accidental Release Measures
6.1 Personal precautions, protective equipment and emergency procedures
Wear respiratory protection. Avoid breathing vapors, mist or gas. Ensure adequate ventilation. Evacuate personnel to safe areas.

6.2 Environmental precautions
Prevent further leakage or spillage if safe to do so. Do not let product enter drains.

6.3 Methods and materials for containment and cleaning up
Soak up with inert absorbent material and dispose of as hazardous waste. Keep in suitable, closed containers for disposal.

6.4 Reference to other sections
For disposal see Section 13.

7 Handling and Storage
7.1 Precautions for safe handling
Avoid contact with skin and eyes. Avoid inhalation of vapour or mist. Normal measures for preventive fire protection.

7.3 Conditions for safe storage, including any incompatibilities
Store in cool place. Keep container tightly closed in a dry and well-ventilated place. Containers which are opened must be carefully resealed and kept upright to prevent leakage.

Recommended Storage Temperature: Store below 30°C

7.3 Specific end uses
No data available

8 Exposure Controls/Personal Protection
8.1 Control parameters
Components with workplace control parameters

8.2 Exposure controls
Appropriate engineering controls
Avoid contact with skin, eyes and clothing. Wash hands before breaks and immediately after handling the product.
Personal protective equipment

Hygiene measure
Immediately change contaminated clothing. Apply preventive skin protection. Wash hands face after working with the substance.

Eye/face protection
Tightly fitting safety goggles. Faceshield (8-inch minimum). Use equipment for eye protection tested and approved under appropriate government standards such as NIOSH (US) or EN 166(EU).

Skin protection
Handle with gloves. Gloves must be inspected prior to use. Use proper glove removal technique (Without touching glove's outer surface) to avoid skin contact with this product. Dispose of contaminated gloves after use in accordance with applicable laws and good laboratory practices. Wash and dry hands. The selected protective gloves have to satisfy the specifications of EU Directive 89/686/EEC and the standard EN 374 derived from it.

Body protection
Complete suit protecting against chemicals, The type of protective equipment must be selected according to the concentration and amount of the dangerous substance at the specific work place.

Respiratory protection
Where risk assessment shows air-purifying respirators are appropriate use a fullface respirator with multi-purpose combination (US) or type ABEK(EN 14387) respirator cartridges as a backup to the engineering controls. If the respirator is the sole means of protection, use a full-face supplied air respirator. Use respirators and components tested and approved under appropriate government standards such as NIOSH (US) or CEN (EU).

Environment exposure controls
Do not empty into drains

9 Physical and chemical properties

9.1 Information on basic physical and chemical properties

<table>
<thead>
<tr>
<th>Property</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Appearance</td>
<td>Pale yellow fine powder.</td>
</tr>
<tr>
<td>Odour</td>
<td>No data available</td>
</tr>
<tr>
<td>Odour Threshold</td>
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<tr>
<td>Odour Threshold</td>
<td>No data available</td>
</tr>
<tr>
<td>pH</td>
<td>No data available</td>
</tr>
<tr>
<td>Melting/freezing point</td>
<td>No data available</td>
</tr>
<tr>
<td>Initial boiling point and boiling range</td>
<td>No data available</td>
</tr>
<tr>
<td>Flash point</td>
<td>No data available</td>
</tr>
<tr>
<td>Upper/lower flammability or explosive limits</td>
<td>No data available</td>
</tr>
<tr>
<td>Vapour pressure</td>
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</tr>
<tr>
<td>Vapour density</td>
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</tr>
<tr>
<td>Relative density</td>
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</tr>
<tr>
<td>Water Solubility</td>
<td>No data available</td>
</tr>
<tr>
<td>Partition coefficient: n-octanol/Water</td>
<td>No data available</td>
</tr>
<tr>
<td>Autoignition Temperature</td>
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</tr>
<tr>
<td>Decomposition Temperature</td>
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</tr>
<tr>
<td>Viscosity</td>
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</tr>
<tr>
<td>Explosive properties</td>
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</tr>
<tr>
<td>Oxidizing properties</td>
<td>No data available</td>
</tr>
</tbody>
</table>

9.2 Other safety information

No data available

10 Stability and Reactivity

10.1 Reactivity
No data available

10.2 Chemical stability
No data available

10.3 Possibility of hazardous reactions
No data available

10.4 Conditions to avoid
10.5 Incompatible materials
Strong oxidizing agents

10.6 Hazardous decomposition products
Other decomposition products - No data available

11 Toxicological Information

11.1 Information on toxicological effects

Acute toxicity
No data available

Skin corrosion/irritation
No data available

Serious eye damage/eye irritation
No data available

Respiratory or skin sensitisation
No data available

Germ cell mutagenicity
No data available

Carcinogenicity
IARC: No component of this product present at levels greater than or equal to 0.1% is identified as probable, possible or confirmed human carcinogen by IARC.

Reproductive toxicity
No data available

Specific target organ toxicity—single exposure
No data available

Aspiration hazard
No data available

Potential Health Effects
Inhalation.
Refer Section 2

Skin
Refer Section 2

Eyes
Refer Section 2

Ingestion
Refer Section 2

Additional Information
RTECS : Not Available

12 Ecological Information

12.1 Toxicity
No data available

12.2 Persistence and degradability
No data available

12.3 Bioaccumulative potential
No data available

12.4 Mobility in soil
No data available

12.5 PBT and vPvB assessment
No data available

12.6 Other adverse effects
No data available

13 Disposal Considerations

13.1 Waste treatments methods
Product
Offer surplus and non-recyclable solutions to a licenced disposal company. Contact a licenced professional waste disposal service to dispose of this material.

13.2 Contaminated packaging
Dispose of as unused product.

14 Transport Information
14.1 UN-No.
ADR/RID: - IMDG: - IATA: -

14.2 UN proper shipping name
ADR/RID: no dangerous goods
IMDG: no dangerous goods
IATA: no dangerous goods

14.3 Transport hazard class(es)
ADR/RID: - IMDG: - IATA: -

14.4 Packaging group
ADR/RID: - IMDG: - IATA: -

14.5 Environmental hazards
ADR/RID: No IMDG: Marine Pollutant: No IATA: No

14.6 Special precautions for use
No data available

15 Regulatory Information
This safety datasheet complies with the requirements of Regulation(EC) No.1907/2006

15.1 Safety health and environment regulations/legislation specific for the substance or mixture
No data available

15.2 Chemical Safety Assessment
No data available

16 Other Information
Further information
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