

**Renogen Formulation**

|         |                |                |                                 |
|---------|----------------|----------------|---------------------------------|
| Version | Revision Date: | SDS Number:    | Date of last issue: 05.03.2025  |
| 2.0     | 14.04.2025     | 11516580-00002 | Date of first issue: 05.03.2025 |

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**SECTION 1. IDENTIFICATION**

Product name : Renogen Formulation

Product code : Renogen

**Manufacturer or supplier's details**

Company : MSD

Address : Talcahuano 750, 6th floor, Ciudad Autonoma  
Buenos Aires, Argentina C1013AAP

Telephone : 908-740-4000

Emergency telephone : 1-908-423-6000

E-mail address : EHSDATASTEWARD@msd.com

**Recommended use of the chemical and restrictions on use**

Recommended use : Veterinary product

Restrictions on use : Not applicable

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**SECTION 2. HAZARDS IDENTIFICATION****GHS Classification**

Short-term (acute) aquatic hazard : Category 3

**GHS label elements**

Signal Word : None

Hazard Statements : H402 Harmful to aquatic life.

Precautionary Statements : **Prevention:**  
P273 Avoid release to the environment.**Disposal:**  
P501 Dispose of contents/ container to an approved waste disposal plant.**Other hazards which do not result in classification**Dust contact with the eyes can lead to mechanical irritation.  
Contact with dust can cause mechanical irritation or drying of the skin.  
May form explosive dust-air mixture during processing, handling or other means.

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**SECTION 3. COMPOSITION/INFORMATION ON INGREDIENTS**

Substance / Mixture : Mixture

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**Components**

| Chemical name                                                      | CAS-No.      | Concentration (% w/w)  |
|--------------------------------------------------------------------|--------------|------------------------|
| $\alpha$ -D-Glucopyranoside, $\alpha$ -D-glucopyranosyl, dihydrate | 6138-23-4    | $\geq 90$ - $\leq 100$ |
| Antigen                                                            | Not Assigned | $\geq 5$ - $< 10$      |

**SECTION 4. FIRST AID MEASURES**

- If inhaled : If inhaled, remove to fresh air.  
Get medical attention if symptoms occur.
- In case of skin contact : Wash with water and soap.  
Get medical attention if symptoms occur.
- In case of eye contact : If in eyes, rinse well with water.  
Get medical attention if irritation develops and persists.
- If swallowed : If swallowed, DO NOT induce vomiting.  
Get medical attention if symptoms occur.  
Rinse mouth thoroughly with water.
- Most important symptoms and effects, both acute and delayed : Contact with dust can cause mechanical irritation or drying of the skin.  
Dust contact with the eyes can lead to mechanical irritation.
- Protection of first-aiders : No special precautions are necessary for first aid responders.
- Notes to physician : Treat symptomatically and supportively.

**SECTION 5. FIRE-FIGHTING MEASURES**

- Suitable extinguishing media : Water spray  
Alcohol-resistant foam  
Carbon dioxide (CO<sub>2</sub>)  
Dry chemical
- Unsuitable extinguishing media : None known.
- Specific hazards during fire fighting : Exposure to combustion products may be a hazard to health.
- Hazardous combustion products : Carbon oxides
- Specific extinguishing methods : Use extinguishing measures that are appropriate to local circumstances and the surrounding environment.  
Use water spray to cool unopened containers.  
Remove undamaged containers from fire area if it is safe to do so.  
Evacuate area.
- Special protective equipment for fire-fighters : Wear self-contained breathing apparatus for firefighting if necessary.  
Use personal protective equipment.

**SECTION 6. ACCIDENTAL RELEASE MEASURES**

- Personal precautions, protection : Follow safe handling advice (see section 7) and personal

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|-------------------------------------------------------|---|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| tive equipment and emergency procedures               | : | protective equipment recommendations (see section 8).                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                        |
| Environmental precautions                             | : | Avoid release to the environment.<br>Prevent further leakage or spillage if safe to do so.<br>Retain and dispose of contaminated wash water.<br>Local authorities should be advised if significant spillages cannot be contained.                                                                                                                                                                                                                                                                                                                                                                                                                                                            |
| Methods and materials for containment and cleaning up | : | Sweep up or vacuum up spillage and collect in suitable container for disposal.<br>Avoid dispersal of dust in the air (i.e., clearing dust surfaces with compressed air).<br>Dust deposits should not be allowed to accumulate on surfaces, as these may form an explosive mixture if they are released into the atmosphere in sufficient concentration.<br>Local or national regulations may apply to releases and disposal of this material, as well as those materials and items employed in the cleanup of releases. You will need to determine which regulations are applicable.<br>Sections 13 and 15 of this SDS provide information regarding certain local or national requirements. |

**SECTION 7. HANDLING AND STORAGE**

- |                             |   |                                                                                                                                                                                                                                                                                                                                                                                                                                           |
|-----------------------------|---|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Technical measures          | : | Static electricity may accumulate and ignite suspended dust causing an explosion.<br>Provide adequate precautions, such as electrical grounding and bonding, or inert atmospheres.                                                                                                                                                                                                                                                        |
| Local/Total ventilation     | : | Use only with adequate ventilation.                                                                                                                                                                                                                                                                                                                                                                                                       |
| Advice on safe handling     | : | Do not breathe dust.<br>Handle in accordance with good industrial hygiene and safety practice, based on the results of the workplace exposure assessment<br>Minimize dust generation and accumulation.<br>Keep container closed when not in use.<br>Keep away from heat and sources of ignition.<br>Take precautionary measures against static discharges.<br>Take care to prevent spills, waste and minimize release to the environment. |
| Conditions for safe storage | : | Keep in properly labeled containers.<br>Store in accordance with the particular national regulations.                                                                                                                                                                                                                                                                                                                                     |
| Materials to avoid          | : | Do not store with the following product types:<br>Strong oxidizing agents                                                                                                                                                                                                                                                                                                                                                                 |

**SECTION 8. EXPOSURE CONTROLS/PERSONAL PROTECTION****Ingredients with workplace control parameters**

Contains no substances with occupational exposure limit values.

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|-----------------------------|---|------------------------------------------------------------|
| <b>Engineering measures</b> | : | All engineering controls should be implemented by facility |
|-----------------------------|---|------------------------------------------------------------|

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design and operated in accordance with GMP principles to protect products, workers, and the environment. Containment technologies suitable for controlling compounds are required to control at source and to prevent migration of the compound to uncontrolled areas (e.g., open-face containment devices). Minimize open handling.

**Personal protective equipment**

|                          |   |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                 |
|--------------------------|---|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Respiratory protection   | : | If adequate local exhaust ventilation is not available or exposure assessment demonstrates exposures outside the recommended guidelines, use respiratory protection.                                                                                                                                                                                                                                                                                                                            |
| Filter type              | : | Particulates type                                                                                                                                                                                                                                                                                                                                                                                                                                                                               |
| Hand protection          | : |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                 |
| Material                 | : | Chemical-resistant gloves                                                                                                                                                                                                                                                                                                                                                                                                                                                                       |
| Remarks                  | : | Consider double gloving.                                                                                                                                                                                                                                                                                                                                                                                                                                                                        |
| Eye protection           | : | Wear safety glasses with side shields or goggles. If the work environment or activity involves dusty conditions, mists or aerosols, wear the appropriate goggles. Wear a faceshield or other full face protection if there is a potential for direct contact to the face with dusts, mists, or aerosols.                                                                                                                                                                                        |
| Skin and body protection | : | Work uniform or laboratory coat. Additional body garments should be used based upon the task being performed (e.g., sleevelets, apron, gauntlets, disposable suits) to avoid exposed skin surfaces. Use appropriate degowning techniques to remove potentially contaminated clothing.                                                                                                                                                                                                           |
| Hygiene measures         | : | If exposure to chemical is likely during typical use, provide eye flushing systems and safety showers close to the working place. When using do not eat, drink or smoke. Wash contaminated clothing before re-use. The effective operation of a facility should include review of engineering controls, proper personal protective equipment, appropriate degowning and decontamination procedures, industrial hygiene monitoring, medical surveillance and the use of administrative controls. |

**SECTION 9. PHYSICAL AND CHEMICAL PROPERTIES**

|                              |   |                   |
|------------------------------|---|-------------------|
| Appearance                   | : | solid             |
| Color                        | : | No data available |
| Odor                         | : | No data available |
| Odor Threshold               | : | No data available |
| pH                           | : | No data available |
| Melting point/freezing point | : | No data available |

# SAFETY DATA SHEET



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|                                                  |   |                                                                                 |
|--------------------------------------------------|---|---------------------------------------------------------------------------------|
| Initial boiling point and boiling range          | : | No data available                                                               |
| Flash point                                      | : | Not applicable                                                                  |
| Evaporation rate                                 | : | Not applicable                                                                  |
| Flammability (solid, gas)                        | : | May form explosive dust-air mixture during processing, handling or other means. |
| Flammability (liquids)                           | : | Not applicable                                                                  |
| Upper explosion limit / Upper flammability limit | : | No data available                                                               |
| Lower explosion limit / Lower flammability limit | : | No data available                                                               |
| Vapor pressure                                   | : | Not applicable                                                                  |
| Relative vapor density                           | : | Not applicable                                                                  |
| Relative density                                 | : | No data available                                                               |
| Density                                          | : | No data available                                                               |
| Solubility(ies)<br>Water solubility              | : | No data available                                                               |
| Partition coefficient: n-octanol/water           | : | Not applicable                                                                  |
| Autoignition temperature                         | : | No data available                                                               |
| Decomposition temperature                        | : | No data available                                                               |
| Viscosity<br>Viscosity, kinematic                | : | Not applicable                                                                  |
| Explosive properties                             | : | Not explosive                                                                   |
| Oxidizing properties                             | : | The substance or mixture is not classified as oxidizing.                        |
| Molecular weight                                 | : | No data available                                                               |
| Particle characteristics<br>Particle size        | : | No data available                                                               |

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### SECTION 10. STABILITY AND REACTIVITY

|                                |   |                                                        |
|--------------------------------|---|--------------------------------------------------------|
| Reactivity                     | : | Not classified as a reactivity hazard.                 |
| Chemical stability             | : | Stable under normal conditions.                        |
| Possibility of hazardous reac- | : | May form explosive dust-air mixture during processing, |

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|                                  |                                                                     |
|----------------------------------|---------------------------------------------------------------------|
| tions                            | handling or other means.<br>Can react with strong oxidizing agents. |
| Conditions to avoid              | : Heat, flames and sparks.<br>Avoid dust formation.                 |
| Incompatible materials           | : Oxidizing agents                                                  |
| Hazardous decomposition products | : No hazardous decomposition products are known.                    |

## SECTION 11. TOXICOLOGICAL INFORMATION

Information on likely routes of exposure : Inhalation  
Skin contact  
Ingestion  
Eye contact

**Acute toxicity**

Not classified based on available information.

**Components:****α-D-Glucopyranoside, α-D-glucopyranosyl, dihydrate:**

|                     |                                                                 |
|---------------------|-----------------------------------------------------------------|
| Acute oral toxicity | : LD50 (Rat): > 16.000 mg/kg<br>Method: OECD Test Guideline 401 |
|---------------------|-----------------------------------------------------------------|

**Skin corrosion/irritation**

Not classified based on available information.

**Components:****α-D-Glucopyranoside, α-D-glucopyranosyl, dihydrate:**

|         |                           |
|---------|---------------------------|
| Species | : Rabbit                  |
| Method  | : OECD Test Guideline 404 |
| Result  | : No skin irritation      |

**Serious eye damage/eye irritation**

Not classified based on available information.

**Components:****α-D-Glucopyranoside, α-D-glucopyranosyl, dihydrate:**

|         |                           |
|---------|---------------------------|
| Species | : Rabbit                  |
| Result  | : No eye irritation       |
| Method  | : OECD Test Guideline 405 |

**Respiratory or skin sensitization****Skin sensitization**

Not classified based on available information.

**Respiratory sensitization**

Not classified based on available information.

**Germ cell mutagenicity**

Not classified based on available information.

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**Components:** **$\alpha$ -D-Glucopyranoside,  $\alpha$ -D-glucopyranosyl, dihydrate:**

|                       |   |                                                                                                |
|-----------------------|---|------------------------------------------------------------------------------------------------|
| Genotoxicity in vitro | : | Test Type: Bacterial reverse mutation assay (AMES)                                             |
|                       |   | Method: OECD Test Guideline 471                                                                |
|                       |   | Result: negative                                                                               |
|                       |   | Test Type: In vitro mammalian cell gene mutation test                                          |
|                       |   | Method: OECD Test Guideline 476                                                                |
|                       |   | Result: negative                                                                               |
|                       |   | Test Type: Chromosome aberration test in vitro                                                 |
|                       |   | Result: negative                                                                               |
| Genotoxicity in vivo  | : | Test Type: Mutagenicity (in vivo mammalian bone-marrow cytogenetic test, chromosomal analysis) |
|                       |   | Species: Mouse                                                                                 |
|                       |   | Application Route: Intraperitoneal injection                                                   |
|                       |   | Result: negative                                                                               |

**Carcinogenicity**

Not classified based on available information.

**Reproductive toxicity**

Not classified based on available information.

**Components:** **$\alpha$ -D-Glucopyranoside,  $\alpha$ -D-glucopyranosyl, dihydrate:**

|                              |   |                                                       |
|------------------------------|---|-------------------------------------------------------|
| Effects on fertility         | : | Test Type: Two-generation reproduction toxicity study |
|                              |   | Species: Rat                                          |
|                              |   | Application Route: Ingestion                          |
|                              |   | Method: OECD Test Guideline 416                       |
|                              |   | Result: negative                                      |
| Effects on fetal development | : | Test Type: Embryo-fetal development                   |
|                              |   | Species: Rat                                          |
|                              |   | Application Route: Ingestion                          |
|                              |   | Method: OECD Test Guideline 414                       |
|                              |   | Result: negative                                      |

**STOT-single exposure**

Not classified based on available information.

**STOT-repeated exposure**

Not classified based on available information.

**Repeated dose toxicity****Components:** **$\alpha$ -D-Glucopyranoside,  $\alpha$ -D-glucopyranosyl, dihydrate:**

|                   |   |             |
|-------------------|---|-------------|
| Species           | : | Mouse       |
| NOAEL             | : | 8.289 mg/kg |
| Application Route | : | Ingestion   |

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|               |                           |
|---------------|---------------------------|
| Exposure time | : 90 Days                 |
| Method        | : OECD Test Guideline 408 |

**Aspiration toxicity**

Not classified based on available information.

**SECTION 12. ECOLOGICAL INFORMATION****Ecotoxicity****Components:** **$\alpha$ -D-Glucopyranoside,  $\alpha$ -D-glucopyranosyl, dihydrate:**

|                                                     |                                                                                                                                                                                                                                                |
|-----------------------------------------------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Toxicity to fish                                    | : LC50 (Danio rerio (zebra fish)): > 100 mg/l<br>Exposure time: 96 h                                                                                                                                                                           |
| Toxicity to daphnia and other aquatic invertebrates | : EC50 (Daphnia magna (Water flea)): > 100 mg/l<br>Exposure time: 48 h<br>Method: OECD Test Guideline 202                                                                                                                                      |
| Toxicity to algae/aquatic plants                    | : ErC50 (Desmodesmus subspicatus (green algae)): 33,6 mg/l<br>Exposure time: 72 h<br>Method: OECD Test Guideline 201<br><br>EC10 (Desmodesmus subspicatus (green algae)): 13,82 mg/l<br>Exposure time: 72 h<br>Method: OECD Test Guideline 201 |

**Persistence and degradability****Components:** **$\alpha$ -D-Glucopyranoside,  $\alpha$ -D-glucopyranosyl, dihydrate:**

|                  |                                                                                          |
|------------------|------------------------------------------------------------------------------------------|
| Biodegradability | : Result: Not readily biodegradable.<br>Biodegradation: 68 - 74 %<br>Exposure time: 28 d |
|------------------|------------------------------------------------------------------------------------------|

**Bioaccumulative potential****Components:** **$\alpha$ -D-Glucopyranoside,  $\alpha$ -D-glucopyranosyl, dihydrate:**

|                                        |                                                     |
|----------------------------------------|-----------------------------------------------------|
| Partition coefficient: n-octanol/water | : log Pow: < 0,3<br>Method: OECD Test Guideline 117 |
|----------------------------------------|-----------------------------------------------------|

**Mobility in soil**

No data available

**Other adverse effects**

No data available



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**SECTION 13. DISPOSAL CONSIDERATIONS****Disposal methods**

|                        |   |                                                                                                                                                             |
|------------------------|---|-------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Waste from residues    | : | Do not dispose of waste into sewer.<br>Dispose of in accordance with local regulations.                                                                     |
| Contaminated packaging | : | Empty containers should be taken to an approved waste handling site for recycling or disposal.<br>If not otherwise specified: Dispose of as unused product. |

**SECTION 14. TRANSPORT INFORMATION****International Regulations****UNRTDG**

Not regulated as a dangerous good

**IATA-DGR**

Not regulated as a dangerous good

**IMDG-Code**

Not regulated as a dangerous good

**Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code**

Not applicable for product as supplied.

**Special precautions for user**

Not applicable

**SECTION 15. REGULATORY INFORMATION****Safety, health and environmental regulations/legislation specific for the substance or mixture**

Argentina. Carcinogenic Substances and Agents Registry. : Not applicable

Control of precursors and essential chemicals for the preparation of drugs. : Not applicable

**The ingredients of this product are reported in the following inventories:**

DSL : not determined

AICS : not determined

IECSC : not determined

**SECTION 16. OTHER INFORMATION**

|               |   |            |
|---------------|---|------------|
| Revision Date | : | 14.04.2025 |
| Date format   | : | dd.mm.yyyy |

**Further information**

Sources of key data used to : Internal technical data, data from raw material SDSs, OECD

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compile the Material Safety  
Data Sheet

eChem Portal search results and European Chemicals Agency, <http://echa.europa.eu/>

Items where changes have been made to the previous version are highlighted in the body of this document by two vertical lines.

**Full text of other abbreviations**

AIIC - Australian Inventory of Industrial Chemicals; ANTT - National Agency for Transport by Land of Brazil; ASTM - American Society for the Testing of Materials; bw - Body weight; CMR - Carcinogen, Mutagen or Reproductive Toxicant; DIN - Standard of the German Institute for Standardisation; DSL - Domestic Substances List (Canada); ECx - Concentration associated with x% response; ELx - Loading rate associated with x% response; EmS - Emergency Schedule; ENCS - Existing and New Chemical Substances (Japan); ErCx - Concentration associated with x% growth rate response; ERG - Emergency Response Guide; GHS - Globally Harmonized System; GLP - Good Laboratory Practice; IARC - International Agency for Research on Cancer; IATA - International Air Transport Association; IBC - International Code for the Construction and Equipment of Ships carrying Dangerous Chemicals in Bulk; IC50 - Half maximal inhibitory concentration; ICAO - International Civil Aviation Organization; IECSC - Inventory of Existing Chemical Substances in China; IMDG - International Maritime Dangerous Goods; IMO - International Maritime Organization; ISHL - Industrial Safety and Health Law (Japan); ISO - International Organisation for Standardization; KECI - Korea Existing Chemicals Inventory; LC50 - Lethal Concentration to 50 % of a test population; LD50 - Lethal Dose to 50% of a test population (Median Lethal Dose); MARPOL - International Convention for the Prevention of Pollution from Ships; n.o.s. - Not Otherwise Specified; Nch - Chilean Norm; NO(A)EC - No Observed (Adverse) Effect Concentration; NO(A)EL - No Observed (Adverse) Effect Level; NOELR - No Observable Effect Loading Rate; NOM - Official Mexican Norm; NTP - National Toxicology Program; NZIoC - New Zealand Inventory of Chemicals; OECD - Organization for Economic Co-operation and Development; OPPTS - Office of Chemical Safety and Pollution Prevention; PBT - Persistent, Bioaccumulative and Toxic substance; PICCS - Philippines Inventory of Chemicals and Chemical Substances; (Q)SAR - (Quantitative) Structure Activity Relationship; REACH - Regulation (EC) No 1907/2006 of the European Parliament and of the Council concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals; SADT - Self-Accelerating Decomposition Temperature; SDS - Safety Data Sheet; TCSI - Taiwan Chemical Substance Inventory; TDG - Transportation of Dangerous Goods; TECL - Thailand Existing Chemicals Inventory; TSCA - Toxic Substances Control Act (United States); UN - United Nations; UNRTDG - United Nations Recommendations on the Transport of Dangerous Goods; vPvB - Very Persistent and Very Bioaccumulative; WHMIS - Workplace Hazardous Materials Information System

The information provided in this Safety Data Sheet is correct to the best of our knowledge, information and belief at the date of its publication. The information is designed only as a guidance for safe handling, use, processing, storage, transportation, disposal and release and shall not be considered a warranty or quality specification of any type. The information provided relates only to the specific material identified at the top of this SDS and may not be valid when the SDS material is used in combination with any other materials or in any process, unless specified in the text. Material users should review the information and recommendations in the specific context of their intended manner of handling, use, processing and storage, including an assessment of the appropriateness of the SDS material in the user's end product, if applicable.

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