SECTION 1. PRODUCT AND COMPANY IDENTIFICATION

Product name : M-M-R Formulation

Manufacturer or supplier's details
Company : MSD
Address : Avenida Tanner de Melo, Quadra 10 Lote 4A, Galpão A Parque Industrial Vice Presidente José Alencar Aparecida de Goias – GO, Brazil
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 : Pharmaceutical

SECTION 2. HAZARDS IDENTIFICATION

GHS Classification in accordance with ABNT NBR 14725 Standard
Short-term (acute) aquatic hazard : Category 1
Long-term (chronic) aquatic hazard : Category 3

GHS label elements in accordance with ABNT NBR 14725 Standard
Hazard pictograms :

Signal Word : Warning
Hazard Statements : H400 Very toxic to aquatic life.
H412 Harmful to aquatic life with long lasting effects.
Precautionary Statements : Prevention:
P273 Avoid release to the environment.
Response:
P391 Collect spillage.

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.
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May form explosive dust-air mixture during processing, handling or other means.

SECTION 3. COMPOSITION/INFORMATION ON INGREDIENTS

Substance / Mixture : Mixture

Components

<table>
<thead>
<tr>
<th>Chemical name</th>
<th>CAS-No.</th>
<th>Classification</th>
<th>Concentration (% w/w)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sodium chloride</td>
<td>7647-14-5</td>
<td>Acute toxicity (Oral), Category 5</td>
<td>&gt;= 5 -&lt; 10</td>
</tr>
<tr>
<td>Sucrose</td>
<td>57-50-1</td>
<td>Acute toxicity (Oral)</td>
<td>&gt;= 1 -&lt; 5</td>
</tr>
<tr>
<td>Neomycin, sulfate (salt)</td>
<td>1405-10-3</td>
<td>Acute toxicity (Oral), Category 5, Skin sensitization, Sub-category 1B, Reproductive toxicity, Category 2, Specific target organ toxicity - repeated exposure (Kidney, inner ear), Category 2, Short-term (acute) aquatic hazard, Category 1, Long-term (chronic) aquatic hazard, Category 1</td>
<td>&gt;= 0,025 -&lt; 0,1</td>
</tr>
</tbody>
</table>

SECTION 4. FIRST AID MEASURES

General advice : In the case of accident or if you feel unwell, seek medical advice immediately. When symptoms persist or in all cases of doubt seek medical advice.

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
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Suitable extinguishing media: Water spray
Alcohol-resistant foam
Carbon dioxide (CO2)
Dry chemical

Unsuitable extinguishing media: None known.

Specific hazards during firefighting: Avoid generating dust; fine dust dispersed in air in sufficient concentrations, and in the presence of an ignition source is a potential dust explosion hazard. Exposure to combustion products may be a hazard to health.

Hazardous combustion products: Carbon oxides
Metal oxides
Chlorine compounds
Oxides of phosphorus
Phosphorus compounds
Nitrogen oxides (NOx)

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, protective equipment and emergency procedures: Follow safe handling advice (see section 7) and personal protective equipment recommendations (see section 8).

Environmental precautions: Avoid release to the environment.
Prevent further leakage or spillage if safe to do so.
Retain and dispose of contaminated wash water.
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.
Avoid dispersal of dust in the air (i.e., clearing dust surfaces with compressed air).
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.
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.
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. 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. Handle in accordance with good industrial hygiene and safety practice, based on the results of the workplace exposure assessment. Minimize dust generation and accumulation. Keep container closed when not in use. Keep away from heat and sources of ignition. Take precautionary measures against static discharges. Take care to prevent spills, waste and minimize release to the environment.

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.

Conditions for safe storage: Keep in properly labeled containers. Store in accordance with the particular national regulations.

Materials to avoid: Do not store with the following product types: Strong oxidizing agents

SECTION 8. EXPOSURE CONTROLS/PERSONAL PROTECTION

Ingredients with workplace control parameters

<table>
<thead>
<tr>
<th>Components</th>
<th>CAS-No.</th>
<th>Value type (Form of exposure)</th>
<th>Control parameters / Permissible concentration</th>
<th>Basis</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sucrose</td>
<td>57-50-1</td>
<td>TWA</td>
<td>10 mg/m³</td>
<td>ACGIH</td>
</tr>
<tr>
<td>Neomycin, sulfate (salt)</td>
<td>1405-10-3</td>
<td>TWA</td>
<td>1 mg/m³ (OEB 1)</td>
<td>Internal</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Wipe limit</td>
<td>0.1 mg/100 cm²</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Further information: DSEN, OTO</td>
<td></td>
</tr>
</tbody>
</table>

Engineering measures: Ensure adequate ventilation, especially in confined areas. Minimize workplace exposure concentrations. Apply measures to prevent dust explosions. Ensure that dust-handling systems (such as exhaust ducts, dust collectors, vessels, and processing equipment) are designed in a manner to prevent the escape of dust into the work area (i.e., there is no leakage from the equipment).

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: For prolonged or repeated contact use protective gloves. Wash hands before breaks and at the end of workday.

Eye protection: Wear the following personal protective equipment: Safety goggles

Skin and body protection: Skin should be washed after contact.

SECTION 9. PHYSICAL AND CHEMICAL PROPERTIES

Appearance: lyophilized cake

Color: light yellow

Odor: No data available

Odor Threshold: No data available

pH: No data available

Melting point/freezing point: Not applicable

Initial boiling point and boiling range: Not applicable

Flash point: Not applicable

Evaporation rate: No data available

Flammability (solid, gas): May form explosive dust-air mixture during processing, handling or other means.

Flammability (liquids): No data available

Upper explosion limit / Upper flammability limit: No data available

Lower explosion limit / Lower flammability limit: No data available

Vapor pressure: No data available

Relative vapor density: No data available

Density: No data available

Solubility(ies): Water solubility: soluble

Partition coefficient: n-octanol/water: No data available

Autoignition temperature: No data available

Decomposition temperature: No data available
SAFETY DATA SHEET

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<table>
<thead>
<tr>
<th>Version</th>
<th>Revision Date:</th>
<th>SDS Number:</th>
<th>Date of last issue:</th>
<th>Date of first issue:</th>
</tr>
</thead>
<tbody>
<tr>
<td>3.3</td>
<td>27.08.2021</td>
<td>81069-00018</td>
<td>10.10.2020</td>
<td>26.03.2015</td>
</tr>
</tbody>
</table>

Viscosity
Viscosity, kinematic: No data available

Explosive properties: Not explosive

Oxidizing properties: The substance or mixture is not classified as oxidizing.

Molecular weight: Not applicable

Particle size: No data available

SECTION 10. STABILITY AND REACTIVITY

Reactivity: Not classified as a reactivity hazard.
Chemical stability: Stable under normal conditions.
Possibility of hazardous reactions:
May form explosive dust-air mixture during processing, handling or other means.
Can react with strong oxidizing agents.

Conditions to avoid: Heat, flames and sparks.
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.

Product:
Acute oral toxicity: Acute toxicity estimate: > 5.000 mg/kg
Method: Calculation method

Components:
Sodium chloride:
Acute oral toxicity: LD50 (Rat): 3.550 mg/kg

Acute inhalation toxicity: LC50 (Rat): > 42 mg/l
Exposure time: 1 h
Test atmosphere: dust/mist

Acute dermal toxicity: LD50 (Rabbit): > 5.000 mg/kg

Sucrose:
Acute oral toxicity: LD50 (Rat): 29.700 mg/kg
Neomycin, sulfate (salt):
Acute oral toxicity: LD50 (Mouse): 2.880 mg/kg
LD50 (Rat): 2.750 mg/kg
Acute toxicity (other routes of administration):
LD50 (Rat): 633 mg/kg
Application Route: Subcutaneous
LD50 (Mouse): 116 mg/kg
Application Route: Intraperitoneal
LD50 (Mouse): 27.6 mg/kg
Application Route: Intravenous
LD50 (Mouse): 275 mg/kg
Application Route: Subcutaneous

Skin corrosion/irritation
Not classified based on available information.

Components:
Sodium chloride:
Species: Rabbit
Result: No skin irritation

Neomycin, sulfate (salt):
Species: Rabbit
Result: Mild skin irritation

Serious eye damage/eye irritation
Not classified based on available information.

Components:
Sodium chloride:
Species: Rabbit
Result: No eye irritation

Neomycin, sulfate (salt):
Species: Rabbit
Result: No eye irritation

Respiratory or skin sensitization

Skin sensitization
Not classified based on available information.

Respiratory sensitization
Not classified based on available information.
Components:

Sodium chloride:
Test Type: Local lymph node assay (LLNA)
Routes of exposure: Skin contact
Species: Mouse
Result: negative

Neomycin, sulfate (salt):
Routes of exposure: Dermal
Species: Humans
Result: positive

Germ cell mutagenicity
Not classified based on available information.

Components:

Sodium chloride:
Genotoxicity in vitro:
Test Type: In vitro mammalian cell gene mutation test
Result: positive
Test Type: Bacterial reverse mutation assay (AMES)
Result: negative
Test Type: Saccharomyces cerevisiae, gene mutation assay (in vitro)
Result: positive
Test Type: DNA damage and repair, unscheduled DNA synthesis in mammalian cells (in vitro)
Result: positive
Test Type: Chromosome aberration test in vitro
Result: positive
Test Type: Chromosome aberration test in vitro
Result: negative

Genotoxicity in vivo:
Test Type: In vivo micronucleus test
Species: Mouse
Application Route: Intraperitoneal injection
Result: negative
Test Type: Mutagenicity (in vivo mammalian bone-marrow cytogenetic test, chromosomal analysis)
Species: Rat
Application Route: Intraperitoneal injection
Result: positive

Germ cell mutagenicity - Assessment:
Weight of evidence does not support classification as a germ cell mutagen.
Sucrose:
Genotoxicity in vitro: Test Type: In vitro mammalian cell gene mutation test
Result: negative

Neomycin, sulfate (salt):
Genotoxicity in vitro:
- Test Type: Bacterial reverse mutation assay (AMES)
  Result: negative
- Test Type: In vitro mammalian cell gene mutation test
  Test system: Chinese hamster ovary cells
  Result: negative
- Test Type: Chromosomal aberration
  Test system: Human lymphocytes
  Result: positive
- Test Type: in vitro micronucleus test
  Result: negative

Genotoxicity in vivo:
- Test Type: Cytogenetic assay
  Species: Mouse
  Cell type: Bone marrow
  Application Route: Intravenous injection
  Result: negative

Carcinogenicity
Not classified based on available information.

Components:
Sodium chloride:
Species: Rat
Application Route: Ingestion
Exposure time: 2 Years
Result: negative

Neomycin, sulfate (salt):
Species: Rat
Exposure time: 2 Years
Result: negative

Reproductive toxicity
Not classified based on available information.

Components:
Neomycin, sulfate (salt):
Effects on fertility:
- Test Type: Three-generation reproduction toxicity study
  Species: Rat
  Application Route: Oral
  General Toxicity Parent: NOAEL: 25 mg/kg body weight
  Result: No effects on fertility and early embryonic development were detected.
Effects on fetal development:

Test Type: Embryo-fetal development
Species: Rat
Application Route: Oral
Embryo-fetal toxicity: NOAEL: 275 mg/kg body weight
Result: No adverse effects, No teratogenic effects.

Test Type: Development
Species: Rat
Application Route: Subcutaneous
Developmental Toxicity: LOAEL: 6 mg/kg body weight
Result: positive

Reproductive toxicity - Assessment:
Some evidence of adverse effects on development, based on animal experiments.

STOT-single exposure
Not classified based on available information.

STOT-repeated exposure
Not classified based on available information.

Components:

Neomycin, sulfate (salt):
Target Organs: Kidney, inner ear
Assessment: May cause damage to organs through prolonged or repeated exposure.
Remarks: Based on human experience.

Repeated dose toxicity

Components:

Sodium chloride:
Species: Rat
LOAEL: 2.533 mg/kg
Application Route: Ingestion
Exposure time: 2 y

Neomycin, sulfate (salt):
Species: Mouse
LOAEL: 30 mg/kg
Application Route: Subcutaneous
Exposure time: 14 d
Target Organs: Kidney

Species: Guinea pig
NOAEL: 50 mg/kg
LOAEL: 100 mg/kg
Application Route: Intramuscular
Exposure time: 30 - 60 Weeks
Target Organs: ear
Species: Guinea pig
NOAEL: 10 mg/kg
Application Route: Oral
Exposure time: 90 d
Remarks: No significant adverse effects were reported

Species: Guinea pig
LOAEL: 100 mg/kg
Application Route: Subcutaneous
Exposure time: 34 d

Species: Dog
LOAEL: 24 mg/kg
Application Route: Intramuscular
Exposure time: 30 d
Target Organs: Kidney

Species: Rat
LOAEL: 25 mg/kg
Application Route: oral (feed)
Exposure time: 84 Weeks
Target Organs: ear
Symptoms: hearing loss
Remarks: mortality observed

Species: Dog
LOAEL: 20 mg/kg
Application Route: Subcutaneous
Exposure time: 90 d
Target Organs: Kidney

Aspiration toxicity
Not classified based on available information.

Experience with human exposure

Components:

Neomycin, sulfate (salt):
Skin contact: Symptoms: Sensitization
Remarks: May irritate skin.
Eye contact: Remarks: May cause eye irritation.
Ingestion: Symptoms: Nausea, Vomiting, Diarrhea, tinnitus, hearing loss, Loss of balance

SECTION 12. ECOLOGICAL INFORMATION

Ecotoxicity

Components:

Sodium chloride:
Toxicity to fish: LC50 (Lepomis macrochirus (Bluegill sunfish)): 5.840 mg/l
Exposure time: 96 h
<table>
<thead>
<tr>
<th>Toxicity to daphnia and other aquatic invertebrates</th>
<th>EC50 (Daphnia magna (Water flea)): 4.136 mg/l Exposure time: 48 h</th>
</tr>
</thead>
<tbody>
<tr>
<td>Toxicity to algae/aquatic plants</td>
<td>EC50: &gt; 2.000 mg/l Exposure time: 96 h</td>
</tr>
<tr>
<td>Toxicity to fish (Chronic toxicity)</td>
<td>NOEC (Pimephales promelas (fathead minnow)): 252 mg/l Exposure time: 33 d</td>
</tr>
<tr>
<td>Toxicity to daphnia and other aquatic invertebrates (Chronic toxicity)</td>
<td>NOEC (Daphnia pulex (Water flea)): 314 mg/l Exposure time: 21 d</td>
</tr>
<tr>
<td>Toxicity to microorganisms</td>
<td>EC10: &gt; 1.000 mg/l</td>
</tr>
</tbody>
</table>

**Neomycin, sulfate (salt):**

<table>
<thead>
<tr>
<th>Toxicity to daphnia and other aquatic invertebrates</th>
<th>EC50 (Daphnia magna (Water flea)): &gt; 72 mg/l Exposure time: 48 h Method: OECD Test Guideline 202</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>LC50 (Americamysis): 39 mg/l Exposure time: 96 h Method: US-EPA OPPTS 850.1035</td>
</tr>
<tr>
<td>Toxicity to algae/aquatic plants</td>
<td>EC50 (Anabaena flos-aquae (cyanobacterium)): 0.00075 mg/l Exposure time: 72 h Method: OECD Test Guideline 201</td>
</tr>
<tr>
<td></td>
<td>NOEC (Anabaena flos-aquae (cyanobacterium)): 0.0003 mg/l Exposure time: 72 h Method: OECD Test Guideline 201</td>
</tr>
<tr>
<td></td>
<td>EC50 (Pseudokirchneriella subcapitata (green algae)): 0.0099 mg/l Exposure time: 72 h Method: OECD Test Guideline 201</td>
</tr>
<tr>
<td></td>
<td>NOEC (Pseudokirchneriella subcapitata (green algae)): 0.0022 mg/l Exposure time: 72 h Method: OECD Test Guideline 201</td>
</tr>
</tbody>
</table>

**M-Factor (Acute aquatic toxicity):** 1.000

**M-Factor (Chronic aquatic toxicity):** 10

**Toxicity to microorganisms:**

<table>
<thead>
<tr>
<th>Test Type: Respiration inhibition</th>
<th>EC10 (Natural microorganism): 2.8 mg/l Exposure time: 3 h Method: OECD Test Guideline 209</th>
</tr>
</thead>
<tbody>
<tr>
<td>Test Type: Respiration inhibition</td>
<td>EC10 (Natural microorganism): 2.8 mg/l Exposure time: 3 h Method: OECD Test Guideline 209</td>
</tr>
</tbody>
</table>
Persistence and degradability

Components:

Neomycin, sulfate (salt):
Biodegradability: Result: rapidly degradable
Biodegradation: 50 %
Exposure time: 1.2 d
Method: OECD Test Guideline 314

Bioaccumulative potential

Components:

Sucrose:
Partition coefficient: n-octanol/water: Pow: < 1

Neomycin, sulfate (salt):
Partition coefficient: n-octanol/water: log Pow: < -2

Mobility in soil
No data available

Other adverse effects
No data available

SECTION 13. DISPOSAL CONSIDERATIONS

Disposal methods
Waste from residues: Dispose of in accordance with local regulations.
Contaminated packaging: Empty containers should be taken to an approved waste handling site for recycling or disposal. If not otherwise specified: Dispose of as unused product.

SECTION 14. TRANSPORT INFORMATION

International Regulations

UNRTDG
UN number: UN 3077
Proper shipping name: ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID, N.O.S. (Neomycin, sulfate (salt))
Class: 9
Packing group: III
Labels: 9

IATA-DGR
UN/ID No.: UN 3077
Proper shipping name: Environmentally hazardous substance, solid, n.o.s. (Neomycin, sulfate (salt))
Class: 9
SECTION 15. REGULATORY INFORMATION

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

National List of Carcinogenic Agents for Humans - (LINACH) : Not applicable

Brazil. List of chemicals controlled by the Federal Police : Not applicable

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

AICS : not determined

DSL : not determined
SECTION 16. OTHER INFORMATION

Further information

Full text of other abbreviations
ACGIH: USA. ACGIH Threshold Limit Values (TLV)
ACGIH / TWA: 8-hour, time-weighted average

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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