1. PRODUCT AND COMPANY IDENTIFICATION

Product name : M-M-R Formulation

Manufacturer or supplier’s details
Company : Merck & Co., Inc
Address : 2000 Galloping Hill Road
Kenilworth - New Jersey - U.S.A. 07033
Telephone : 908-740-4000
Emergency telephone number : 1-908-423-6000
E-mail address : EHSDATASTEWARD@msd.com

Recommended use of the chemical and restrictions on use
Recommended use : Pharmaceutical

2. HAZARDS IDENTIFICATION

GHS Classification
Short-term (acute) aquatic hazard : Category 1
Long-term (chronic) aquatic hazard : Category 3

GHS label elements
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.

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.

3. COMPOSITION/INFORMATION ON INGREDIENTS

<table>
<thead>
<tr>
<th>Substance / Mixture</th>
<th>Components</th>
</tr>
</thead>
<tbody>
<tr>
<td>Mixture</td>
<td></td>
</tr>
</tbody>
</table>

**Components**

<table>
<thead>
<tr>
<th>Chemical name</th>
<th>CAS-No.</th>
<th>Concentration (% w/w)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sucrose</td>
<td>57-50-1</td>
<td>&lt; 10</td>
</tr>
<tr>
<td>Neomycin, sulfate (salt)</td>
<td>1405-10-3</td>
<td>&gt;= 0.025 -&lt; 0.25</td>
</tr>
</tbody>
</table>

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.

5. FIREFIGHTING MEASURES

**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 firefighters:
- Wear self-contained breathing apparatus for firefighting if necessary.
- Use personal protective equipment.

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.

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

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

8. EXPOSURE CONTROLS/PERSONAL PROTECTION

Components with workplace control parameters

<table>
<thead>
<tr>
<th>Components</th>
<th>CAS-No.</th>
<th>Value type</th>
<th>Control parameters / Permissible concentration</th>
<th>Basis</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sucrose</td>
<td>57-50-1</td>
<td>NAB</td>
<td>10 mg/m³</td>
<td>ID OEL</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>
</tbody>
</table>

Further information:
Not classified as carcinogenic to humans. Not enough data to classify these materials as carcinogenic to humans or animals.

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.
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.

9. PHYSICAL AND CHEMICAL PROPERTIES

Appearance: lyophilised cake
<table>
<thead>
<tr>
<th>Property</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Colour</td>
<td>Light yellow</td>
</tr>
<tr>
<td>Odour</td>
<td>No data available</td>
</tr>
<tr>
<td>Odour Threshold</td>
<td>No data available</td>
</tr>
<tr>
<td>pH</td>
<td>No data available</td>
</tr>
<tr>
<td>Melting point/freezing point</td>
<td>Not applicable</td>
</tr>
<tr>
<td>Initial boiling point and boiling range</td>
<td>Not applicable</td>
</tr>
<tr>
<td>Flash point</td>
<td>Not applicable</td>
</tr>
<tr>
<td>Evaporation rate</td>
<td>No data available</td>
</tr>
<tr>
<td>Flammability (solid, gas)</td>
<td>May form explosive dust-air mixture during processing, handling or other means.</td>
</tr>
<tr>
<td>Flammability (liquids)</td>
<td>No data available</td>
</tr>
<tr>
<td>Upper explosion limit / Upper flammability limit</td>
<td>No data available</td>
</tr>
<tr>
<td>Lower explosion limit / Lower flammability limit</td>
<td>No data available</td>
</tr>
<tr>
<td>Vapour pressure</td>
<td>No data available</td>
</tr>
<tr>
<td>Relative vapour density</td>
<td>No data available</td>
</tr>
<tr>
<td>Density</td>
<td>No data available</td>
</tr>
<tr>
<td>Solubility(ies)</td>
<td></td>
</tr>
<tr>
<td>Water solubility</td>
<td>Soluble</td>
</tr>
<tr>
<td>Partition coefficient: n-octanol/water</td>
<td>No data available</td>
</tr>
<tr>
<td>Auto-ignition temperature</td>
<td>No data available</td>
</tr>
<tr>
<td>Decomposition temperature</td>
<td>No data available</td>
</tr>
<tr>
<td>Viscosity</td>
<td></td>
</tr>
<tr>
<td>Viscosity, kinematic</td>
<td>No data available</td>
</tr>
<tr>
<td>Explosive properties</td>
<td>Not explosive</td>
</tr>
<tr>
<td>Oxidizing properties</td>
<td>The substance or mixture is not classified as oxidizing.</td>
</tr>
<tr>
<td>Molecular weight</td>
<td>Not applicable</td>
</tr>
<tr>
<td>Particle size</td>
<td>No data available</td>
</tr>
</tbody>
</table>
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.

11. TOXICOLOGICAL INFORMATION

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

Acute toxicity
Not classified based on available information.

Components:

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:

Neomycin, sulfate (salt):
Species: Rabbit
Result: Mild skin irritation
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M-M-R Formulation

Version 2.13  Revision Date: 2021/08/27  SDS Number: 81076-00019  Date of last issue: 2021/04/09
Date of first issue: 2015/03/26

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

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

Respiratory or skin sensitisation
Skin sensitisation
Not classified based on available information.
Respiratory sensitisation
Not classified based on available information.

Components:
Neomycin, sulfate (salt):
Exposure routes: Dermal
Species: Humans
Result: positive

Germ cell mutagenicity
Not classified based on available information.

Components:
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:
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 foetal development : Test Type: Embryo-foetal development
Species: Rat
Application Route: Oral
Embryo-foetal 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:**

**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: Sensitisation
  - Remarks: May irritate skin.

- **Eye contact:**
  - Remarks: May cause eye irritation.

- **Ingestion:**
  - Symptoms: Nausea, Vomiting, Diarrhoea, tinnitus, hearing loss, Loss of balance

12. ECOLOGICAL INFORMATION

**Ecotoxicity**

**Components:**

**Neomycin, sulfate (salt):**

- **Toxicity to daphnia and other aquatic invertebrates:**
  - EC50 (Daphnia magna (Water flea)): > 72 mg/l
  - Exposure time: 48 h
  - Method: OECD Test Guideline 202

  - LC50 (Americamysis): 39 mg/l
  - Exposure time: 96 h

- **Toxicity to algae/aquatic plants:**
  - EC50 (Anabaena flos-aquae (cyanobacterium)): 0.00075 mg/l
  - Exposure time: 72 h
  - Method: OECD Test Guideline 201

  - NOEC (Anabaena flos-aquae (cyanobacterium)): 0.0003 mg/l
  - Exposure time: 72 h
  - Method: OECD Test Guideline 201

  - EC50 (Pseudokirchneriella subcapitata (green algae)): 0.0099 mg/l
  - Exposure time: 72 h
  - Method: OECD Test Guideline 201

  - NOEC (Pseudokirchneriella subcapitata (green algae)): 0.0022 mg/l
  - Exposure time: 72 h
  - Method: OECD Test Guideline 201

- **M-Factor (Acute aquatic toxicity):**
  - 1,000

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

- **Toxicity to microorganisms:**
  - EC50 (Natural microorganism): 107.6 mg/l
  - Exposure time: 3 h
  - Test Type: Respiration inhibition
  - Method: OECD Test Guideline 209

  - EC10 (Natural microorganism): 2.8 mg/l
  - Exposure time: 3 h
Persistance 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

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.

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.
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Class : 9
Packing group : III
Labels : Miscellaneous
Packing instruction (cargo aircraft) : 956
Packing instruction (passenger aircraft) : 956
Environmentally hazardous : yes

IMDG-Code
UN number : UN 3077
Proper shipping name : ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID, N.O.S. (Neomycin, sulfate (salt))

Class : 9
Packing group : III
Labels : 9
EmS Code : F-A, S-F
Marine pollutant : yes

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
The transport classification(s) provided herein are for informational purposes only, and solely based upon the properties of the unpackaged material as it is described within this Safety Data Sheet. Transportation classifications may vary by mode of transportation, package sizes, and variations in regional or country regulations.

15. REGULATORY INFORMATION

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

Minister of Industry Regulation No. 23/M-IND/PER/4/2013 concerning the Revision of Minister of Industry Regulation No. 87/M-IND/PER/9/2009 concerning Globally Harmonized System of Classification and Labelling of Chemicals.

Regulation of the Minister of Health No. 472 of 1996 on the Safeguarding of Substances Hazardous to Health
Hazardous substances that must be registered : Not applicable

Government Regulation No. 74 of 2001 on the Management of Hazardous and Toxic Substances
Hazardous substances approved for use : Not applicable
Prohibited substances : Not applicable
Restricted substances : Not applicable

Regulation of the Minister of Trade No. 44 of 2009 on Procurement, Distribution and Supervision of Hazardous Materials
Type of Hazardous Materials Restricted to Import, : Not applicable
Distribution and Supervision

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

- **AICS**: not determined
- **DSL**: not determined
- **IECSC**: not determined

### 16. OTHER INFORMATION

**Further information**

Sources of key data used to compile the Safety Data Sheet:

Date format:
- yyyy/mm/dd

**Full text of other abbreviations**

- **ACGIH** (USA): ACGIH Threshold Limit Values (TLV)
- **ID OEL** (Indonesia): Occupational Exposure Limits
- **ACGIH / TWA** (8-hour, time-weighted average)
- **ID OEL / NAB** (Long term exposure limit)

Additional abbreviations:
- **AICL**: 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)
- **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)
- **ISOS**: Not Otherwise Specified
- **KECI**: Korea Existing Chemicals Inventory
- **LC50**: Lethal Concentration to 50% of a test population
- **LD50**: Lethal Dose to 50% of a test population
- **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
- **SADT**: Self-Accelerating Decomposition Temperature
- **SDS**: Safety Data Sheet
- **TECI**: Thailand Existing Chemicals Inventory
- **TSCA**: Toxic Substances Control Act

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13 / 14
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.

ID / EN