1. PRODUCT AND COMPANY IDENTIFICATION

Product name : M-M-R Formulation

Manufacturer or supplier's details
Company : MSD
Address : Briahnager - Off Pune Nagar Road
Wagholi - Pune - India 412 207
Telephone : +1-908-740-4000
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

Manufacture, Storage and Import of Hazardous Chemicals Rules 1989
Classification
Not classified as hazardous according to criteria laid down in Part I of Schedule-1.

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>

<table>
<thead>
<tr>
<th>Chemical name</th>
<th>CAS-No.</th>
<th>Concentration (% w/w)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sodium chloride</td>
<td>7647-14-5</td>
<td>&gt;= 5 - &lt; 10</td>
</tr>
<tr>
<td>Sucrose</td>
<td>57-50-1</td>
<td>&gt;= 1 - &lt; 5</td>
</tr>
<tr>
<td>Neomycin, sulfate (salt)</td>
<td>1405-10-3</td>
<td>&gt;= 0.025 - &lt; 0.1</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.
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 as-
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/PERSOANL PROTECTION

Components 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>
</tbody>
</table>

Further information: DSEN, OTO

Wipe limit 0.1 mg/100 cm² Internal

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: 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.
Appearance : lyophilised cake

Colour : light yellow

Odour : No data available

Odour 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

Vapour pressure : No data available

Relative vapour density : No data available

Density : No data available

Solubility(ies)
  Water solubility : soluble

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

Auto-ignition temperature : No data available

Decomposition temperature : No data available

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
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.

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

**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

<table>
<thead>
<tr>
<th>Route</th>
<th>LD50 (Mouse)</th>
<th>Route</th>
<th>LD50 (Mouse)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Intraperitoneal</td>
<td>27.6 mg/kg</td>
<td>Intravenous</td>
<td>275 mg/kg</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Subcutaneous</td>
<td></td>
</tr>
</tbody>
</table>

### 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 sensitisation

#### Skin sensitisation

Not classified based on available information.

#### Respiratory sensitisation

Not classified based on available information.

**Components:**

### Sodium chloride:

- **Test Type:** Local lymph node assay (LLNA)
- **Exposure routes:** Skin contact
- **Species:** Mouse
- **Result:** negative

### Neomycin, sulfate (salt):

- **Exposure routes:** Dermal
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 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:

Sodium chloride:
Species: Rat
LOAEL: 2,533 mg/kg
Application Route: Ingestion
Exposure time: 2 yr

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
11. ASPIRATION TOXICITY

Not classified based on available information.

12. 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:

**Sodium chloride:**
- **Toxicity to fish**
  - LC50 (Lepomis macrochirus (Bluegill sunfish)): 5,840 mg/l
  - Exposure time: 96 h
- **Toxicity to daphnia and other aquatic invertebrates**
  - EC50 (Daphnia magna (Water flea)): 4,136 mg/l
  - Exposure time: 48 h
- **Toxicity to algae/aquatic plants**
  - EC50: > 2,000 mg/l
  - Exposure time: 96 h
- **Toxicity to microorganisms**
  - EC10: > 1,000 mg/l
- **Toxicity to fish (Chronic toxicity)**
  - NOEC: 252 mg/l
  - Exposure time: 33 d
  - Species: Pimephales promelas (fathead minnow)
Toxicity to daphnia and other aquatic invertebrates (Chronic toxicity):

- NOEC: 314 mg/l
- Exposure time: 21 d
- Species: Daphnia pulex (Water flea)

**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

**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
  - Test Type: Respiration inhibition
  - Method: OECD Test Guideline 209

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

10

**Persistence and degradability**

**Components:**

**Neomycin, sulfate (salt):**

Biodegradability: Result: rapidly degradable
SAFETY DATA SHEET

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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.
(Neomycin, sulfate (salt))
Class : 9
Packing group : III
Labels : Miscellaneous
Packing instruction (cargo aircraft) : 956
Packing instruction (passen- : 956
SAFETY DATA SHEET

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Date of first issue: 26.03.2015

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Date of first issue: 26.03.2015

ger aircraft)
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 IMO instruments
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

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

Date format : dd.mm.yyyy

Full text of other abbreviations
ACGIH : USA. ACGIH Threshold Limit Values (TLV)

ACGIH / TWA : 8-hour, time-weighted average

AIIIC - 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
SAFETY DATA SHEET

M-M-R Formulation

Version  2.12
Revision Date:  27.08.2021
SDS Number:  85480-00018
Date of last issue:  10.10.2020
Date of first issue:  26.03.2015

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; TECI - 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.

IN / EN