

SAFETY DATA SHEET



M-M-R Formulation

Version 4.2 Revision Date: 25.02.2025 SDS Number: 85468-00024 Date of last issue: 30.09.2023
Date of first issue: 26.03.2015

SECTION 1. IDENTIFICATION

Product name : M-M-R Formulation

Manufacturer or supplier's details

Company : MSD

Address : 855 Leandro N. Alem St., 8 Floor
Buenos Aires, Argentina C1001AFB

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

Restrictions on use : Not applicable

SECTION 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

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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.

SECTION 3. COMPOSITION/INFORMATION ON INGREDIENTS

Substance / Mixture : Mixture

Components

| Chemical name | CAS-No. | Concentration (% w/w) |
|--------------------------|-----------|-----------------------|
| Sodium chloride | 7647-14-5 | >= 5 -< 10 |
| Sucrose | 57-50-1 | >= 1 -< 5 |
| Neomycin, sulfate (salt) | 1405-10-3 | >= 0,025 -< 0,1 |

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

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

Unsuitable extinguishing media : None known.

Specific hazards during fire fighting : 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 prod- : Carbon oxides

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| ucts | 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 Advice on safe handling | : Use only with adequate ventilation. : Do not breathe dust. Handle in accordance with good industrial hygiene and safety |

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| 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

| Components | CAS-No. | Value type (Form of exposure) | Control parame- ters / Permissible concentration | Basis | |
|--------------------------|-----------|--|--|----------------------------|--|
| Sucrose | 57-50-1 | CMP | 10 mg/m ³ | AR OEL | |
| | | Further information: A4 - Not classifiable as a human carcinogen | | | |
| Neomycin, sulfate (salt) | 1405-10-3 | TWA | 10 mg/m ³ | ACGIH | |
| | | TWA | 1.5 mg/m ³ (OEB 1) | Internal | |
| | | Further information: DSEN, OTO | | | |
| | | | Wipe limit | 0.1 mg/100 cm ² | |
| | | | | Internal | |

| | |
|----------------------|--|
| Engineering measures | : Use feasible engineering controls to minimize exposure to compound. All engineering controls should be implemented by facility design and operated in accordance with GMP principles to protect products, workers, and the environment. |
|----------------------|--|

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 |
| 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. |
| 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. |

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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 | : | 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 |
| Viscosity | | |
| Viscosity, kinematic | : | No data available |

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Explosive properties : Not explosive

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

Molecular weight : Not applicable

Particle characteristics
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

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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.

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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.

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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.

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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

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| 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 |
|------------------|---|--|

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| 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 fish (Chronic toxicity) | : | NOEC (Pimephales promelas (fathead minnow)): 252 mg/l Exposure time: 33 d |
| Toxicity to daphnia and other aquatic invertebrates (Chronic toxicity) | : | NOEC (Daphnia pulex (Water flea)): 314 mg/l Exposure time: 21 d |
| Toxicity to microorganisms | : | EC10: > 1.000 mg/l |

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 Method: US-EPA OPPTS 850.1035 |
| 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 |
| 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 Test Type: Respiration inhibition Method: OECD Test Guideline 209 |

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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 : Do not dispose of waste into sewer.
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
Environmentally hazardous : yes

IATA-DGR

UN/ID No. : UN 3077
Proper shipping name : Environmentally hazardous substance, solid, n.o.s.

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| | (Neomycin, sulfate (salt)) |
| 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.

SECTION 15. REGULATORY INFORMATION

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

Argentina. Carcinogenic Substances and Agents : Not applicable
Registry.

Control of precursors and essential chemicals for the : Sodium hydrogencarbonate
preparation of drugs.

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

AICS : not determined
DSL : not determined
IECSC : not determined

SECTION 16. OTHER INFORMATION

Revision Date : 25.02.2025
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Further information

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Sources of key data used to compile the Material Safety Data Sheet : Internal technical data, data from raw material SDSs, OECD eChem Portal search results and European Chemicals Agency, <http://echa.europa.eu/>

Full text of other abbreviations

| | |
|--------------|---|
| ACGIH | : USA. ACGIH Threshold Limit Values (TLV) |
| AR OEL | : Argentina. Occupational Exposure Limits |
| ACGIH / TWA | : 8-hour, time-weighted average |
| AR OEL / CMP | : TLV (Threshold Limit Value) |

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; 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.

AR / Z8