## M-M-R Formulation



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#### 1. PRODUCT AND COMPANY IDENTIFICATION

Chemical product name : M-M-R Formulation

Supplier's company name, address and phone number

Company name of supplier : MSD

Address : Kumagaya, Saitama Prefecture , Xicheng 810 MSD Co., Ltd.

Menuma factory

Telephone : 048-588-8411

E-mail address : EHSDATASTEWARD@msd.com

Emergency telephone number : +1-908-423-6000

Recommended use of the chemical and restrictions on use

Recommended use : Pharmaceutical Restrictions on use : Not applicable

#### 2. HAZARDS IDENTIFICATION

GHS classification of chemical product

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.





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#### Disposal:

P501 Dispose of contents/ container to an approved waste disposal plant.

#### Other hazards which do not result in classification

Important symptoms and out- : lines of the emergency assumed

Dust contact with the eyes can lead to mechanical irritation. Contact with dust can cause mechanical irritation or drying of

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

#### 3. COMPOSITION/INFORMATION ON INGREDIENTS

Substance / Mixture Mixture

Components

Chemical name	CAS-No.	Concentration (% w/w)	ENCS No.
Sucrose	57-50-1	>= 1 - < 10	-
Neomycin, sulfate (salt)	1405-10-3	>= 0.025 - < 0.1	-

## 4. FIRST AID MEASURES

General advice In the case of accident or if you feel unwell, seek medical ad-

vice 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.

If in eyes, rinse well with water. In case of eye contact

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

Protection of first-aiders Notes to physician

Contact with dust can cause mechanical irritation or drying of

the skin.

Dust contact with the eyes can lead to mechanical irritation. No special precautions are necessary for first aid responders.

Treat symptomatically and supportively.

#### 5. FIREFIGHTING MEASURES

Suitable extinguishing media : Water spray

> Alcohol-resistant foam Carbon dioxide (CO2)

Dry chemical





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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: :

ucts

Carbon oxides

Metal oxides

Chlorine compounds
Oxides of phosphorus
Phosphorus compounds
Nitrogen oxides (NOx)

Specific extinguishing meth-

ods

Use extinguishing measures that are appropriate to local cir-

cumstances 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 nec-

essarv.

Use personal protective equipment.

#### **6. ACCIDENTAL RELEASE MEASURES**

Personal precautions, protective equipment and emer-

gency procedures

Follow safe handling advice (see section 7) and personal pro-

tective 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 con-

tainer 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 deter-

mine which regulations are applicable.

Sections 13 and 15 of this SDS provide information regarding





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certain local or national requirements.

#### 7. HANDLING AND STORAGE

Handling

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-

sessment

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.

Avoidance of contact : Oxidizing agents

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.

**Storage** 

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

Packaging material : Unsuitable material: None known.

#### 8. EXPOSURE CONTROLS/PERSONAL PROTECTION

## Threshold limit value and permissible exposure limits for each component in the work environment

Components	CAS-No.	Value type (Form of exposure)	Control parameters / Concentration standard / Permissible concentration	Basis			
Sucrose	57-50-1	TWA	10 mg/m3	ACGIH			
Neomycin, sulfate (salt)	1405-10-3	TWA	1 mg/m3 (OEB 1)	Internal			
	Further inform	Further information: DSEN, OTO					
		Wipe limit	0.1 mg/100 cm <sup>2</sup>	Internal			





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**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 expo-

sure assessment demonstrates exposures outside the rec-

ommended 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.

9. PHYSICAL AND CHEMICAL PROPERTIES

Physical state lyophilised cake

Colour light yellow

Odour No data available

Odour Threshold No data available

Melting point/freezing point Not applicable

Boiling point, initial boiling

point and boiling range

Not applicable

Flammability (solid, gas) May form explosive dust-air mixture during processing, han-

dling or other means.

Flammability (liquids) No data available

Lower explosion limit and upper explosion limit / flammability limit

Upper explosion limit / Up- : No data available

per flammability limit

Lower explosion limit /

Lower flammability limit

No data available

Flash point Not applicable





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Decomposition temperature : No data available

pH : No data available

Evaporation rate : No data available

Auto-ignition temperature : No data available

Viscosity

Viscosity, kinematic : No data available

Solubility(ies)

Water solubility : soluble

Partition coefficient: n-

octanol/water

No data available

Vapour pressure : No data available

Density and / or relative density

Density : No data available

Relative vapour density : No data available

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

### 10. STABILITY AND REACTIVITY

Reactivity : Not classified as a reactivity hazard. Chemical stability : Stable under normal conditions.

Possibility of hazardous reac-

tions

Stable under normal conditions.

May form explosive dust-air mixture during processing, han-

dling or other means.

Can react with strong oxidizing agents.

Conditions to avoid : Heat, flames and sparks.

Avoid dust formation.

Oxidizing agents

Incompatible materials

Hazardous decomposition : No

products

No hazardous decomposition products are known.

#### 11. TOXICOLOGICAL INFORMATION

Information on likely routes of : Inhalation





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exposure 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

Serious eye damage/eye irritation

Not classified based on available information.

**Components:** 

Neomycin, sulfate (salt):

Species : Rabbit

Result : No eye irritation





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### 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





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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 develop-

ment were detected.

Effects on foetal develop-

ment

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 - As-

sessment

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



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Application Route Subcutaneous

Exposure time 14 d Target Organs Kidney

Guinea pig Species NOAEL 50 mg/kg 100 mg/kg LOAEL 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 LÖAEL 100 mg/kg Subcutaneous Application Route

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 LÖAEL 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.





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Eve contact Remarks: May cause eye irritation.

Symptoms: Nausea, Vomiting, Diarrhoea, tinnitus, hearing Ingestion

loss, Loss of balance

#### 12. ECOLOGICAL INFORMATION

## **Ecotoxicity**

#### **Components:**

Neomycin, sulfate (salt):

aquatic invertebrates

Toxicity to daphnia and other : 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

NOEC (Pseudokirchneriella subcapitata (green algae)):

0.0022 mg/l

Exposure time: 72 h

Method: OECD Test Guideline 201

M-Factor (Acute aquatic tox- :

M-Factor (Chronic aquatic

toxicity)

10

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





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Method: OECD Test Guideline 209

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-

: Pow: < 1

octanol/water

Neomycin, sulfate (salt):

Partition coefficient: n-

: log Pow: < -2

octanol/water

Mobility in soil
No data available

Hazardous to the ozone layer

Not applicable

Other adverse effects

No data available

13. DISPOSAL CONSIDERATIONS

**Disposal methods** 

Waste from residues : Dispose of in accordance with local regulations.

Do not dispose of waste into sewer.

Contaminated packaging : Empty containers should be taken to an approved waste han-

dling 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





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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.

(Neomycin, sulfate (salt))

Class : 9 Packing group : III

Labels : Miscellaneous

Packing instruction (cargo : 956

aircraft)

Packing instruction (passen: 956

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 Annex II of MARPOL 73/78 and the IBC Code

Not applicable for product as supplied.

#### **National Regulations**

Refer to section 15 for specific national regulation.

## 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.

ERG Code : 171

## 15. REGULATORY INFORMATION

#### **Related Regulations**

#### **Fire Service Law**

Not applicable to dangerous materials / designated flammables.

#### **Chemical Substance Control Law**

Not applicable for Specified Chemical Substance, Monitoring Chemical Substance and Priority Assessment Chemical Substance.



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#### **Industrial Safety and Health Law**

#### Harmful Substances Prohibited from Manufacture

Not applicable

#### Harmful Substances Required Permission for Manufacture

Not applicable

#### **Substances Prevented From Impairment of Health**

Not applicable

## Circular concerning Information on Chemicals having Mutagenicity - Annex 2: Information on Existing Chemicals having Mutagenicity

Not applicable

## Circular concerning Information on Chemicals having Mutagenicity - Annex 1: Information on Notified Substances having Mutagenicity

Not applicable

## **Substances Subject to be Notified Names**

Not applicable

#### **Substances Subject to be Indicated Names**

Not applicable

## Skin and Eye Damage Substances for PPE Requirements (ISHL MO Art. 594-2)

Not applicable

## Carcinogenic Substances (Article 577-2 of the Occupational Health and Safety Regulations)

Not applicable

### Ordinance on Prevention of Hazards Due to Specified Chemical Substances

Not applicable

## **Ordinance on Prevention of Lead Poisoning**

Not applicable

#### Ordinance on Prevention of Tetraalkyl Lead Poisoning

Not applicable

## **Ordinance on Prevention of Organic Solvent Poisoning**

Not applicable

## Enforcement Order of the Industrial Safety and Health Law - Attached table 1 (Dangerous Substances)

Not applicable

## **Poisonous and Deleterious Substances Control Law**

Not applicable

# Act on Confirmation, etc. of Release Amounts of Specific Chemical Substances in the Environment and Promotion of Improvements to the Management Thereof

Not applicable





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#### **High Pressure Gas Safety Act**

Not applicable

#### **Explosive Control Law**

Not applicable

#### **Vessel Safety Law**

Miscellaneous dangerous substances and articles (Article 2 and 3 of rules on shipping and storage of dangerous goods and its Attached Table 1)

Miscellaneous dangerous substances and articles (Article 194 of The Enforcement Rules of Aviation Law and its Attached Table 1)

#### Marine Pollution and Sea Disaster Prevention etc Law

**Bulk transportation** Not classified as noxious liquid substance

Pack transportation Classified as marine pollutant

#### **Narcotics and Psychotropics Control Act**

Narcotic or Psychotropic Raw Material (Export / Import Permission)

Not applicable

Specific Narcotic or Psychotropic Raw Material (Export / Import permission)

Not applicable

#### Waste Disposal and Public Cleansing Law

Industrial waste

#### 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

eChem Portal search results and European Chemicals Agen-

Sheet

cy, http://echa.europa.eu/

Internal technical data, data from raw material SDSs, OECD

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

Date format yyyy/mm/dd

Full text of other abbreviations

**ACGIH** USA. ACGIH Threshold Limit Values (TLV)

ACGIH / TWA 8-hour, time-weighted average





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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.

JP / EN