

SAFETY DATA SHEET

according to Regulation (EC) No. 1907/2006, as amended by
Commission Regulation (EU) 2020/878



M-M-R Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 25.02.2025
4.3	14.04.2025	85479-00028	Date of first issue: 26.03.2015

SECTION 1: Identification of the substance/mixture and of the company/undertaking

1.1 Product identifier

Trade name : M-M-R Formulation

1.2 Relevant identified uses of the substance or mixture and uses advised against

Use of the Sub-
stance/Mixture : Pharmaceutical

Recommended restrictions
on use : Not applicable

1.3 Details of the supplier of the safety data sheet

Company : MSD
Innishannon
County Cork - Ireland

Telephone : 353 214329300

E-mail address of person
responsible for the SDS : EHSDATASTEWARD@msd.com

1.4 Emergency telephone number

+1-908-423-6000

SECTION 2: Hazards identification

2.1 Classification of the substance or mixture

Classification (REGULATION (EC) No 1272/2008)

Short-term (acute) aquatic hazard, Category 1 H400: Very toxic to aquatic life.

Long-term (chronic) aquatic hazard, Category 3 H412: Harmful to aquatic life with long lasting effects.

2.2 Label elements

Labelling (REGULATION (EC) No 1272/2008)

Hazard pictograms :



Signal word : Warning

Hazard statements : H410 Very toxic to aquatic life with long lasting effects.

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Precautionary statements : **Prevention:**
P273 Avoid release to the environment.
Response:
P391 Collect spillage.

2.3 Other hazards

This substance/mixture contains no components considered to be either persistent, bioaccumulative and toxic (PBT), or very persistent and very bioaccumulative (vPvB) at levels of 0.1% or higher.

Ecological information: The substance/mixture does not contain components considered to have endocrine disrupting properties according to REACH Article 57(f) or Commission Delegated regulation (EU) 2017/2100 or Commission Regulation (EU) 2018/605 at levels of 0.1% or higher.

Toxicological information: The substance/mixture does not contain components considered to have endocrine disrupting properties according to REACH Article 57(f) or Commission Delegated regulation (EU) 2017/2100 or Commission Regulation (EU) 2018/605 at levels of 0.1% or higher.

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

3.2 Mixtures

Components

Chemical name	CAS-No. EC-No. Index-No. Registration number	Classification	Concentration (% w/w)
Neomycin, sulfate (salt)	1405-10-3 215-773-1	Skin Sens. 1B; H317 Repr. 2; H361d STOT RE 2; H373 (Kidney, inner ear) Aquatic Acute 1; H400 Aquatic Chronic 1; H410 M-Factor (Acute aquatic toxicity): 1,000 M-Factor (Chronic aquatic toxicity): 10	≥ 0.025 - < 0.1

For explanation of abbreviations see section 16.

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SECTION 4: First aid measures

4.1 Description of 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. |
| Protection of first-aiders | : | No special precautions are necessary for first aid responders. |
| 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. |

4.2 Most important symptoms and effects, both acute and delayed

- | | | |
|-------|---|---|
| Risks | : | Contact with dust can cause mechanical irritation or drying of the skin.
Dust contact with the eyes can lead to mechanical irritation. |
|-------|---|---|

4.3 Indication of any immediate medical attention and special treatment needed

- | | | |
|-----------|---|---|
| Treatment | : | Treat symptomatically and supportively. |
|-----------|---|---|

SECTION 5: Firefighting measures

5.1 Extinguishing media

- | | | |
|--------------------------------|---|--|
| Suitable extinguishing media | : | Water spray
Alcohol-resistant foam
Carbon dioxide (CO ₂)
Dry chemical |
| Unsuitable extinguishing media | : | None known. |

5.2 Special hazards arising from the substance or mixture

- | | | |
|---------------------------------------|---|---|
| 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. |
|---------------------------------------|---|---|

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

5.3 Advice for firefighters

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

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.

SECTION 6: Accidental release measures

6.1 Personal precautions, protective equipment and emergency procedures

Personal precautions : Follow safe handling advice (see section 7) and personal protective equipment recommendations (see section 8).

6.2 Environmental precautions

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.

6.3 Methods and material for containment and cleaning up

Methods for 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.

6.4 Reference to other sections

See sections: 7, 8, 11, 12 and 13.

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SECTION 7: Handling and storage

7.1 Precautions for safe 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 assessment
Minimize dust generation and accumulation.
Keep container closed when not in use.
Keep away from heat and sources of ignition.
Take precautionary measures against static discharges.
Take care to prevent spills, waste and minimize release to the environment. |
| Hygiene measures | : | If exposure to chemical is likely during typical use, provide eye flushing systems and safety showers close to the working place. When using do not eat, drink or smoke. Wash contaminated clothing before re-use.
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. |

7.2 Conditions for safe storage, including any incompatibilities

- | | | |
|---|---|---|
| Requirements for storage areas and containers | : | Keep in properly labelled containers. Store in accordance with the particular national regulations. |
| Advice on common storage | : | Do not store with the following product types:
Strong oxidizing agents |

7.3 Specific end use(s)

- | | | |
|-----------------|---|-------------------|
| Specific use(s) | : | No data available |
|-----------------|---|-------------------|

SECTION 8: Exposure controls/personal protection

8.1 Control parameters

Occupational Exposure Limits

- | | |
|--------------------|---|
| dusts non-specific | 4 mg/m ³
Value type (Form of exposure): OELV - 8 hrs (TWA) (Respirable dust)
Basis: IE OEL |
| | 10 mg/m ³
Value type (Form of exposure): OELV - 8 hrs (TWA) (inhalable) |

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dust)
Basis: IE OEL

Components	CAS-No.	Value type (Form of exposure)	Control parameters	Basis
Sucrose	57-50-1	OELV - 8 hrs (TWA)	10 mg/m ³	IE OEL
		OELV - 15 min (STEL)	20 mg/m ³	IE OEL
Neomycin, sulfate (salt)	1405-10-3	TWA	1.5 mg/m ³ (OEB 1)	Internal
Further information: DSEN, OTO				
		Wipe limit	0.1 mg/100 cm ²	Internal

Derived No Effect Level (DNEL) according to Regulation (EC) No. 1907/2006

Substance name	End Use	Exposure routes	Potential health effects	Value
Sodium chloride	Workers	Inhalation	Long-term systemic effects	2068.62 mg/m ³
	Workers	Inhalation	Acute systemic effects	2068.62 mg/m ³
	Workers	Skin contact	Long-term systemic effects	295.52 mg/kg bw/day
	Workers	Skin contact	Acute systemic effects	295.52 mg/kg bw/day
	Consumers	Inhalation	Long-term systemic effects	443.28 mg/m ³
	Consumers	Inhalation	Acute systemic effects	443.28 mg/m ³
	Consumers	Skin contact	Long-term systemic effects	126.65 mg/kg bw/day
	Consumers	Skin contact	Acute systemic effects	126.65 mg/kg bw/day
	Consumers	Ingestion	Long-term systemic effects	126.65 mg/kg bw/day
	Consumers	Ingestion	Acute systemic effects	126.65 mg/kg bw/day
Sodium dihydrogenorthophosphate	Workers	Inhalation	Long-term systemic effects	4.07 mg/m ³
	Consumers	Inhalation	Long-term systemic effects	3.04 mg/m ³
Disodium hydrogenorthophosphate	Workers	Inhalation	Long-term systemic effects	4.07 mg/m ³
	Consumers	Inhalation	Long-term systemic effects	3.04 mg/m ³

Predicted No Effect Concentration (PNEC) according to Regulation (EC) No. 1907/2006

Substance name	Environmental Compartment	Value
Sodium chloride	Fresh water	5 mg/l

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	Sewage treatment plant	500 mg/l
	Soil	4.86 mg/kg dry weight (d.w.)
Sodium dihydrogenorthophosphate	Fresh water	0.05 mg/l
	Intermittent use/release	0.5 mg/l
	Marine water	0.005 mg/l
	Sewage treatment plant	50 mg/l
Disodium hydrogenorthophosphate	Fresh water	0.05 mg/l
	Marine water	0.005 mg/l
	Intermittent use/release	0.5 mg/l
	Sewage treatment plant	50 mg/l
Neomycin, sulfate (salt)	Water	0.00004 mg/l

8.2 Exposure controls

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

Eye/face 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.
Hand protection	:	
Material	:	Chemical-resistant gloves
Skin and body protection	:	Work uniform or laboratory coat.
Respiratory protection	:	If adequate local exhaust ventilation is not available or exposure assessment demonstrates exposures outside the recommended guidelines, use respiratory protection. Equipment should conform to I.S. EN 143
Filter type	:	Particulates type (P)

SECTION 9: Physical and chemical properties

9.1 Information on basic 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
Initial boiling point and boiling	:	Not applicable

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range

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

Flash point : Not applicable

Auto-ignition temperature : No data available

Decomposition temperature : No data available

pH : 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 : No data available

Relative vapour density : No data available

Particle characteristics
Particle size : No data available

9.2 Other information

Explosives : Not explosive

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

Evaporation rate : No data available

Molecular weight : Not applicable

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SECTION 10: Stability and reactivity

10.1 Reactivity

Not classified as a reactivity hazard.

10.2 Chemical stability

Stable under normal conditions.

10.3 Possibility of hazardous reactions

Hazardous reactions : May form explosive dust-air mixture during processing, handling or other means.
Can react with strong oxidizing agents.

10.4 Conditions to avoid

Conditions to avoid : Heat, flames and sparks.
Avoid dust formation.

10.5 Incompatible materials

Materials to avoid : Oxidizing agents

10.6 Hazardous decomposition products

No hazardous decomposition products are known.

SECTION 11: Toxicological information

11.1 Information on hazard classes as defined in Regulation (EC) No 1272/2008

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

Acute toxicity

Not classified based on available information.

Components:

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

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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

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:

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

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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.

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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

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Application Route	:	Subcutaneous
Exposure time	:	90 d
Target Organs	:	Kidney

Aspiration toxicity

Not classified based on available information.

11.2 Information on other hazards

Endocrine disrupting properties

Not classified based on available information.

Product:

Assessment	:	The substance/mixture does not contain components considered to have endocrine disrupting properties according to REACH Article 57(f) or Commission Delegated regulation (EU) 2017/2100 or Commission Regulation (EU) 2018/605 at levels of 0.1% or higher.
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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

SECTION 12: Ecological information

12.1 Toxicity

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 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

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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

12.2 Persistence and degradability

Components:

Neomycin, sulfate (salt):

Biodegradability : Result: rapidly degradable
Biodegradation: 50 %
Exposure time: 1.2 d
Method: OECD Test Guideline 314

12.3 Bioaccumulative potential

Components:

Neomycin, sulfate (salt):

Partition coefficient: n-octanol/water : log Pow: < -2

12.4 Mobility in soil

No data available

12.5 Results of PBT and vPvB assessment

Product:

Assessment : This substance/mixture contains no components considered to be either persistent, bioaccumulative and toxic (PBT), or very persistent and very bioaccumulative (vPvB) at levels of

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0.1% or higher.

12.6 Endocrine disrupting properties

Product:

Assessment : The substance/mixture does not contain components considered to have endocrine disrupting properties according to REACH Article 57(f) or Commission Delegated regulation (EU) 2017/2100 or Commission Regulation (EU) 2018/605 at levels of 0.1% or higher.

12.7 Other adverse effects

No data available

SECTION 13: Disposal considerations

13.1 Waste treatment methods

Product	: Dispose of in accordance with local regulations. According to the European Waste Catalogue, Waste Codes are not product specific, but application specific. Waste codes should be assigned by the user, preferably in discussion with the waste disposal authorities. Do not dispose of waste into sewer.
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

14.1 UN number or ID number

ADN	: UN 3077
ADR	: UN 3077
RID	: UN 3077
IMDG	: UN 3077
IATA	: UN 3077

14.2 UN proper shipping name

ADN	: ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID, N.O.S. (Neomycin, sulfate (salt))
ADR	: ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID, N.O.S. (Neomycin, sulfate (salt))
RID	: ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID, N.O.S. (Neomycin, sulfate (salt))

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IMDG	:	ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID, N.O.S. (Neomycin, sulfate (salt))
IATA	:	Environmentally hazardous substance, solid, n.o.s. (Neomycin, sulfate (salt))

14.3 Transport hazard class(es)

	Class	Subsidiary risks
ADN	: 9	
ADR	: 9	
RID	: 9	
IMDG	: 9	
IATA	: 9	

14.4 Packing group

ADN	
Packing group	: III
Classification Code	: M7
Hazard Identification Number	: 90
Labels	: 9
ADR	
Packing group	: III
Classification Code	: M7
Hazard Identification Number	: 90
Labels	: 9
Tunnel restriction code	: (-)
RID	
Packing group	: III
Classification Code	: M7
Hazard Identification Number	: 90
Labels	: 9
IMDG	
Packing group	: III
Labels	: 9
EmS Code	: F-A, S-F
IATA (Cargo)	
Packing instruction (cargo aircraft)	: 956
Packing instruction (LQ)	: Y956
Packing group	: III
Labels	: Miscellaneous
IATA (Passenger)	
Packing instruction (passenger aircraft)	: 956
Packing instruction (LQ)	: Y956

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Packing group : III
Labels : Miscellaneous

14.5 Environmental hazards

ADN

Environmentally hazardous : yes

ADR

Environmentally hazardous : yes

RID

Environmentally hazardous : yes

IMDG

Marine pollutant : yes

IATA (Passenger)

Environmentally hazardous : yes

IATA (Cargo)

Environmentally hazardous : yes

14.6 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.

14.7 Maritime transport in bulk according to IMO instruments

Remarks : Not applicable for product as supplied.

SECTION 15: Regulatory information

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

REACH - Restrictions on the manufacture, placing on the market and use of certain dangerous substances, mixtures and articles (Annex XVII) : Conditions of restriction for the following entries should be considered:
Number on list 75: If you intend to use this product as tattoo ink, please contact your vendor.

Substance(s) or mixture(s) are listed here according to their appearance in the regulation, irrespective of their use/purpose or the conditions of the restriction. Please refer to the conditions in corresponding Regulation to determine whether an entry is applicable to the placing on the market or not.

REACH - Candidate List of Substances of Very High Concern for Authorisation (Article 59) : Not applicable

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Regulation (EU) No 2024/590 on substances that deplete the ozone layer : Not applicable
Regulation (EU) 2019/1021 on persistent organic pollutants (recast) : Not applicable
Regulation (EU) No 649/2012 of the European Parliament and the Council concerning the export and import of dangerous chemicals : Not applicable
REACH - List of substances subject to authorisation (Annex XIV) : Not applicable
Seveso III: Directive 2012/18/EU of the European Parliament and of the Council on the control of major-accident hazards involving dangerous substances.

E1	ENVIRONMENTAL HAZARDS	Quantity 1 100 t	Quantity 2 200 t
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The components of this product are reported in the following inventories:

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

15.2 Chemical safety assessment

A Chemical Safety Assessment has not been carried out.

SECTION 16: Other information

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

Full text of H-Statements

H317 : May cause an allergic skin reaction.
H361d : Suspected of damaging the unborn child.
H373 : May cause damage to organs through prolonged or repeated exposure.
H400 : Very toxic to aquatic life.
H410 : Very toxic to aquatic life with long lasting effects.

Full text of other abbreviations

Aquatic Acute : Short-term (acute) aquatic hazard
Aquatic Chronic : Long-term (chronic) aquatic hazard
Repr. : Reproductive toxicity
Skin Sens. : Skin sensitisation
STOT RE : Specific target organ toxicity - repeated exposure
IE OEL : Ireland. List of Chemical Agents and Carcinogens with Occupational Exposure Limit Values - Code of Practice, Schedule 1 and 2
IE OEL / OELV - 8 hrs (TWA) : Occupational exposure limit value (8-hour reference period)
IE OEL / OELV - 15 min (STEL) : Occupational exposure limit value (15-minute reference period)

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ADN - European Agreement concerning the International Carriage of Dangerous Goods by Inland Waterways; ADR - Agreement concerning the International Carriage of Dangerous Goods by Road; AIIIC - Australian Inventory of Industrial Chemicals; ASTM - American Society for the Testing of Materials; bw - Body weight; CLP - Classification Labelling Packaging Regulation; Regulation (EC) No 1272/2008; CMR - Carcinogen, Mutagen or Reproductive Toxicant; DIN - Standard of the German Institute for Standardisation; DSL - Domestic Substances List (Canada); ECHA - European Chemicals Agency; EC-Number - European Community number; 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; 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; NO(A)EC - No Observed (Adverse) Effect Concentration; NO(A)EL - No Observed (Adverse) Effect Level; NOELR - No Observable Effect Loading Rate; 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; RID - Regulations concerning the International Carriage of Dangerous Goods by Rail; SADT - Self-Accelerating Decomposition Temperature; SDS - Safety Data Sheet; SVHC - Substance of Very High Concern; TCSI - Taiwan Chemical Substance Inventory; TECI - Thailand Existing Chemicals Inventory; TRGS - Technical Rule for Hazardous Substances; TSCA - Toxic Substances Control Act (United States); UN - United Nations; vPvB - Very Persistent and Very Bioaccumulative

Further information

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

Classification of the mixture:

Aquatic Acute 1	H400
Aquatic Chronic 3	H412

Classification procedure:

Calculation method
Calculation method

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

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intended manner of handling, use, processing and storage, including an assessment of the appropriateness of the SDS material in the user's end product, if applicable.

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