

SAFETY DATA SHEET

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



Albendazole Sulfoxide (1.9%) Formulation

Version
7.0

Revision Date:
14.04.2025

SDS Number:
3921331-00022

Date of last issue: 28.09.2024
Date of first issue: 10.12.2018

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

1.1 Product identifier

Trade name : Albendazole Sulfoxide (1.9%) Formulation

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

Use of the Sub-
stance/Mixture : Veterinary product

Recommended restrictions
on use : Not applicable

1.3 Details of the supplier of the safety data sheet

Company : MSD
Kilsheelan
Clonmel Tipperary, IE

Telephone : 353-51-601000

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)

Skin sensitisation, Category 1 : H317: May cause an allergic skin reaction.
Long-term (chronic) aquatic hazard, Cat-
egory 2 : H411: Toxic to aquatic life with long lasting effects.

2.2 Label elements

Labelling (REGULATION (EC) No 1272/2008)

Hazard pictograms :



Signal word : Warning

Hazard statements : H317 May cause an allergic skin reaction.
H411 Toxic to aquatic life with long lasting effects.

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Precautionary statements

: Prevention:

P272 Contaminated work clothing should not be allowed out of the workplace.
P273 Avoid release to the environment.
P280 Wear protective gloves.

: Response:

P333 + P313 If skin irritation or rash occurs: Get medical advice/ attention.
P362 + P364 Take off contaminated clothing and wash it before reuse.
P391 Collect spillage.

Hazardous components which must be listed on the label:

Albendazole Sulfoxide

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.

SECTION 3: Composition/information on ingredients

3.2 Mixtures

Components

| Chemical name | CAS-No. EC-No. Index-No. Registration number | Classification | Concentration (% w/w) |
|-----------------------|---|---|--------------------------|
| Albendazole Sulfoxide | 54029-12-8 | Acute Tox. 4; H302 Skin Sens. 1B; H317 Repr. 2; H361d STOT SE 2; H371 (Gastrointestinal tract, Central nerv- ous system) STOT RE 2; H373 (Gastrointestinal | >= 1 - < 2,5 |

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| | | | |
|--|--|--|--|
| | | tract, Central nervous system, Immune system, Liver) Aquatic Acute 1; H400 Aquatic Chronic 1; H410 M-Factor (Acute aquatic toxicity): 10 M-Factor (Chronic aquatic toxicity): 10 | |
|--|--|--|--|

For explanation of abbreviations see section 16.

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 : First Aid responders should pay attention to self-protection, and use the recommended personal protective equipment when the potential for exposure exists (see section 8).

If inhaled : If inhaled, remove to fresh air.
Get medical attention.

In case of skin contact : In case of contact, immediately flush skin with soap and plenty of water.
Remove contaminated clothing and shoes.
Get medical attention.
Wash clothing before reuse.
Thoroughly clean shoes before reuse.

In case of eye contact : Flush eyes with water as a precaution.
Get medical attention if irritation develops and persists.

If swallowed : If swallowed, DO NOT induce vomiting.
Get medical attention.
Rinse mouth thoroughly with water.
Never give anything by mouth to an unconscious person.

4.2 Most important symptoms and effects, both acute and delayed

Risks : May cause an allergic skin reaction.

4.3 Indication of any immediate medical attention and special treatment needed

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Treatment : Treat symptomatically and supportively.

SECTION 5: Firefighting measures

5.1 Extinguishing media

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

Unsuitable extinguishing media : None known.

5.2 Special hazards arising from the substance or mixture

Specific hazards during fire-fighting : Exposure to combustion products may be a hazard to health.

Hazardous combustion products : Carbon oxides
Nitrogen oxides (NO_x)
Sulphur oxides

5.3 Advice for firefighters

Special protective equipment for firefighters : In the event of fire, wear self-contained breathing apparatus.
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 : Use personal protective equipment.
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.
Prevent spreading over a wide area (e.g. by containment or oil barriers).
Retain and dispose of contaminated wash water.
Local authorities should be advised if significant spillages cannot be contained.

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6.3 Methods and material for containment and cleaning up

Methods for cleaning up : Soak up with inert absorbent material. For large spills, provide dyking or other appropriate containment to keep material from spreading. If dyked material can be pumped, store recovered material in appropriate container. Clean up remaining materials from spill with suitable absorbent. 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.

SECTION 7: Handling and storage

7.1 Precautions for safe handling

Technical measures : See Engineering measures under EXPOSURE CONTROLS/PERSONAL PROTECTION section.

Local/Total ventilation : Use only with adequate ventilation.

Advice on safe handling : Do not get on skin or clothing.
Do not breathe mist or vapours.
Do not swallow.
Avoid contact with eyes.
Wash skin thoroughly after handling.
Handle in accordance with good industrial hygiene and safety practice, based on the results of the workplace exposure assessment
Do not eat, drink or smoke when using this product.
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. Contaminated work clothing should not be allowed out of the workplace.
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
Gases

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7.3 Specific end use(s)

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

SECTION 8: Exposure controls/personal protection

8.1 Control parameters

Occupational Exposure Limits

| Components | CAS-No. | Value type (Form of exposure) | Control parameters | Basis | |
|-----------------------|------------|-------------------------------|------------------------------|----------|--|
| Albendazole Sulfoxide | 54029-12-8 | TWA | 45 µg/m ³ (OEB 3) | Internal | |
| | | Further information: DSEN | | | |
| | | Wipe limit | 100 µg/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 |
|----------------|-----------|-----------------|----------------------------|----------------------|
| Glycerine | Workers | Inhalation | Long-term local effects | 56 mg/m ³ |
| | Consumers | Ingestion | Long-term systemic effects | 229 mg/kg bw/day |
| | Consumers | Inhalation | Long-term local effects | 33 mg/m ³ |

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

| Substance name | Environmental Compartment | Value |
|-----------------------|---------------------------|-------------------------------|
| Albendazole Sulfoxide | Water | 0,00004 mg/l |
| Glycerine | Fresh water | 0,885 mg/l |
| | Marine water | 0,0885 mg/l |
| | Intermittent use/release | 8,85 mg/l |
| | Sewage treatment plant | 1000 mg/l |
| | Fresh water sediment | 3,3 mg/kg dry weight (d.w.) |
| | Marine sediment | 0,33 mg/kg dry weight (d.w.) |
| | Soil | 0,141 mg/kg dry weight (d.w.) |

8.2 Exposure controls

Engineering measures

Use appropriate engineering controls and manufacturing technologies to control airborne concentrations (e.g., drip-less quick connections).

All engineering controls should be implemented by facility design and operated in accordance with GMP principles to protect products, workers, and the environment.

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Containment technologies suitable for controlling compounds are required to control at source and to prevent migration of the compound to uncontrolled areas (e.g., open-face containment devices).

Minimize open handling.

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 |
| Remarks | : Consider double gloving. |
| Skin and body protection | : Work uniform or laboratory coat. Additional body garments should be used based upon the task being performed (e.g., sleevelets, apron, gauntlets, disposable suits) to avoid exposed skin surfaces. Use appropriate degowning techniques to remove potentially contaminated clothing. |
| Respiratory protection | : If adequate local exhaust ventilation is not available or exposure assessment demonstrates exposures outside the recommended guidelines, use respiratory protection. Filter should conform to NS EN 14387 |
| Filter type | : Combined particulates and organic vapour type (A-P) |

SECTION 9: Physical and chemical properties

9.1 Information on basic physical and chemical properties

| | |
|--|---------------------|
| Physical state | : suspension |
| Colour | : white |
| Odour | : No data available |
| Odour Threshold | : No data available |
| Melting point/freezing point | : No data available |
| Initial boiling point and boiling range | : No data available |
| Flammability (solid, gas) | : Not applicable |
| Flammability (liquids) | : No data available |
| Upper explosion limit / Upper flammability limit | : No data available |

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Lower explosion limit / Lower flammability limit : No data available

Flash point : No data available

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 : No data available

Partition coefficient: n-octanol/water : Not applicable

Vapour pressure : No data available

Relative density : No data available

Density : No data available

Relative vapour density : No data available

Particle characteristics
Particle size : Not applicable

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 : No data available

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

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Hazardous reactions : Can react with strong oxidizing agents.

10.4 Conditions to avoid

Conditions to avoid : None known.

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.

Product:

Acute oral toxicity : Acute toxicity estimate: > 2.000 mg/kg
Method: Calculation method

Components:

Albendazole Sulfoxide:

||| Acute oral toxicity : LD50 (Mouse): 1.500 mg/kg
LD50 (Rat): 2.400 mg/kg

||| Acute toxicity (other routes of administration) : LD50 (Rat): 265 mg/kg
Application Route: Intravenous

Skin corrosion/irritation

||| Not classified based on available information.

Components:

Albendazole Sulfoxide:

||| Species : Rabbit
Result : No skin irritation

Serious eye damage/eye irritation

||| Not classified based on available information.

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Components:

Albendazole Sulfoxide:

| | | |
|---------|---|-------------------|
| Species | : | Rabbit |
| Result | : | No eye irritation |

Respiratory or skin sensitisation

Skin sensitisation

|| May cause an allergic skin reaction.

Respiratory sensitisation

|| Not classified based on available information.

Components:

Albendazole Sulfoxide:

| | | |
|-----------------|---|--|
| Test Type | : | Maximisation Test |
| Exposure routes | : | Dermal |
| Assessment | : | Probability or evidence of low to moderate skin sensitisation rate in humans |
| Result | : | positive |
| Test Type | : | Maximisation Test |
| Exposure routes | : | Dermal |
| Result | : | Sensitiser |

Germ cell mutagenicity

|| Not classified based on available information.

Components:

Albendazole Sulfoxide:

| | | |
|-----------------------|---|---|
| Genotoxicity in vitro | : | Test Type: Bacterial reverse mutation assay (AMES) Result: negative |
| | | Test Type: Chromosomal aberration Test system: Chinese hamster ovary cells Result: negative |
| Genotoxicity in vivo | : | Test Type: Micronucleus test Species: Mouse Cell type: Bone marrow Result: negative |

Carcinogenicity

|| Not classified based on available information.

Components:

Albendazole Sulfoxide:

| | | |
|-------------------|---|-------|
| Species | : | Mouse |
| Application Route | : | Oral |

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| | | |
|------------------------------|---|---|
| Exposure time | : | 2 Years |
| NOAEL | : | 400 mg/kg body weight |
| Result | : | negative |
| Species | : | Rat |
| Application Route | : | Oral |
| Exposure time | : | 2 Years |
| NOAEL | : | 20 mg/kg body weight |
| Result | : | negative |
| Carcinogenicity - Assessment | : | No evidence of carcinogenicity in animal studies. |

Reproductive toxicity

Not classified based on available information.

Components:

Albendazole Sulfoxide:

| | | |
|------------------------------------|---|--|
| Effects on fertility | : | Test Type: Fertility Species: Rat Application Route: Oral Fertility: NOAEL: 30 mg/kg body weight Result: No effects on fertility |
| Effects on foetal development | : | Test Type: Development Species: Rat Application Route: Oral Developmental Toxicity: LOAEL: 10 mg/kg body weight Result: Embryotoxic effects., Skeletal malformations |
| | : | Test Type: Development Species: Rabbit Application Route: Oral Developmental Toxicity: LOAEL: 30 mg/kg body weight Result: Embryotoxic effects., Skeletal malformations, Maternal toxicity observed. |
| | : | Test Type: Development Species: Rat Application Route: Oral Developmental Toxicity: NOAEL: 5,8 mg/kg body weight Result: Effects on postnatal development |
| | : | Test Type: Development Species: Rat Application Route: Oral Developmental Toxicity: LOAEL: 7 mg/kg body weight Result: Embryotoxic effects and adverse effects on the offspring were detected. |
| Reproductive toxicity - Assessment | : | Suspected of damaging the unborn child. |

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STOT - single exposure

||| Not classified based on available information.

Components:

Albendazole Sulfoxide:

| | |
|-----------------|--|
| Exposure routes | : Oral |
| Target Organs | : Gastrointestinal tract, Central nervous system |
| Assessment | : May cause damage to organs. |

STOT - repeated exposure

||| Not classified based on available information.

Components:

Albendazole Sulfoxide:

| | |
|-----------------|--|
| Exposure routes | : Oral |
| Target Organs | : Gastrointestinal tract, Central nervous system, Immune system, Liver |
| Assessment | : May cause damage to organs through prolonged or repeated exposure. |

Repeated dose toxicity

Components:

Albendazole Sulfoxide:

| | |
|-------------------|----------------------------------|
| Species | : Rat |
| LOAEL | : 168 mg/kg |
| Application Route | : Oral |
| Exposure time | : 4 Weeks |
| Target Organs | : Gastrointestinal tract, Testis |
| Symptoms | : Diarrhoea, Vomiting |

| | |
|-------------------|--------------------------|
| Species | : Dog |
| LOAEL | : 48 mg/kg |
| Application Route | : Oral |
| Exposure time | : 4 Weeks |
| Target Organs | : Gastrointestinal tract |
| Symptoms | : Diarrhoea, Vomiting |

| | |
|-------------------|--------------------------------------|
| Species | : Mouse |
| LOAEL | : 40 mg/kg |
| Application Route | : Oral |
| Exposure time | : 3 Months |
| Target Organs | : Blood, Liver, Nose |
| Symptoms | : Hematologic effects, Liver effects |

| | |
|-------------------|---------------|
| Species | : Rat |
| LOAEL | : >= 30 mg/kg |
| Application Route | : Oral |
| Exposure time | : 6 Months |
| Target Organs | : Blood |

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| | |
|-------------------|--|
| Symptoms | : Hematologic effects |
| Species | : Dog |
| LOAEL | : 40 mg/kg |
| Application Route | : Oral |
| Exposure time | : 6 Months |
| Target Organs | : Blood, Liver |
| Symptoms | : Hematologic effects, Liver effects |
| Species | : Rat |
| NOAEL | : 7 mg/kg |
| Application Route | : Oral |
| Exposure time | : 60 d |
| Target Organs | : Liver, Testis |
| Symptoms | : Liver effects, male reproductive effects |

Aspiration toxicity

II 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.

Experience with human exposure

Components:

Albendazole Sulfoxide:

| | |
|---------------------|--|
| General Information | : Symptoms: Allergic reactions, hair loss, Gastrointestinal disturbance, Headache, Dizziness |
| Skin contact | : Target Organs: Skin Symptoms: Allergic reactions Remarks: May cause sensitisation by skin contact. |
| Ingestion | : Target Organs: Gastrointestinal tract Symptoms: Gastrointestinal disturbance, Diarrhoea, Abdominal pain Target Organs: Central nervous system Symptoms: Headache, Dizziness Target Organs: Liver Symptoms: liver function change Target Organs: Immune system Symptoms: immune system effects |

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SECTION 12: Ecological information

12.1 Toxicity

Components:

Albendazole Sulfoxide:

| | | |
|---|---|---|
| Toxicity to fish | : | EC50 (Brachydanio rerio (zebrafish)): 0,042 mg/l Exposure time: 144 hrs |
| Toxicity to daphnia and other aquatic invertebrates | : | EC50 (Daphnia magna (Water flea)): 0,068 mg/l Exposure time: 48 h Method: OECD Test Guideline 202 |
| Toxicity to algae/aquatic plants | : | EC50 (Raphidocelis subcapitata (freshwater green alga)): 0,024 mg/l Exposure time: 72 h Method: OECD Test Guideline 201 |
| M-Factor (Acute aquatic toxicity) | : | 10 |
| M-Factor (Chronic aquatic toxicity) | : | 10 |

12.2 Persistence and degradability

No data available

12.3 Bioaccumulative potential

Components:

Albendazole Sulfoxide:

| | | |
|--|---|------------------------|
| Partition coefficient: n-octanol/water | : | log Pow: 1,27 pH: 7 |
|--|---|------------------------|

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

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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 3082 |
| ADR | : UN 3082 |
| RID | : UN 3082 |
| IMDG | : UN 3082 |
| IATA | : UN 3082 |

14.2 UN proper shipping name

| | |
|------|--|
| ADN | : ENVIRONMENTALLY HAZARDOUS SUBSTANCE, LIQUID, N.O.S. (Albendazole Sulfoxide) |
| ADR | : ENVIRONMENTALLY HAZARDOUS SUBSTANCE, LIQUID, N.O.S. (Albendazole Sulfoxide) |
| RID | : ENVIRONMENTALLY HAZARDOUS SUBSTANCE, LIQUID, N.O.S. (Albendazole Sulfoxide) |
| IMDG | : ENVIRONMENTALLY HAZARDOUS SUBSTANCE, LIQUID, N.O.S. (Albendazole Sulfoxide) |
| IATA | : Environmentally hazardous substance, liquid, n.o.s. (Albendazole Sulfoxide) |

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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 | : M6 |
| Hazard Identification Number | : 90 |
| Labels | : 9 |
| ADR | |
| Packing group | : III |
| Classification Code | : M6 |
| Hazard Identification Number | : 90 |
| Labels | : 9 |
| Tunnel restriction code | : (-) |
| RID | |
| Packing group | : III |
| Classification Code | : M6 |
| Hazard Identification Number | : 90 |
| Labels | : 9 |
| IMDG | |
| Packing group | : III |
| Labels | : 9 |
| EmS Code | : F-A, S-F |
| IATA (Cargo) | |
| Packing instruction (cargo aircraft) | : 964 |
| Packing instruction (LQ) | : Y964 |
| Packing group | : III |
| Labels | : Miscellaneous |
| IATA (Passenger) | |
| Packing instruction (passenger aircraft) | : 964 |
| Packing instruction (LQ) | : Y964 |
| Packing group | : III |
| Labels | : Miscellaneous |

14.5 Environmental hazards

| | |
|---------------------------|-------|
| ADN | |
| Environmentally hazardous | : yes |
| ADR | |

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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 3

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

REACH - List of substances subject to authorisation (Annex XIV)

: Not applicable

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 Parlia-

: Not applicable

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ment and the Council concerning the export and import of dangerous chemicals

Seveso III: Directive 2012/18/EU of the European Parliament and of the Council on the control of major-accident hazards involving dangerous substances.

| Major accident hazards involving dangerous substances | | Quantity 1 | Quantity 2 |
|---|-----------------------|------------|------------|
| E2 | ENVIRONMENTAL HAZARDS | 200 t | 500 t |

Other regulations:

Note the regulation on organization, leadership and participation, chapter 12 on the work of children and young people

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

H302 : Harmful if swallowed.
H317 : May cause an allergic skin reaction.
H361d : Suspected of damaging the unborn child.
H371 : May cause damage to organs if swallowed.
H373 : May cause damage to organs through prolonged or repeated exposure if swallowed.
H400 : Very toxic to aquatic life.
H410 : Very toxic to aquatic life with long lasting effects.

Full text of other abbreviations

| | |
|-----------------|--|
| Acute Tox. | : Acute toxicity |
| 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 |
| STOT SE | : Specific target organ toxicity - single exposure |

ADN - European Agreement concerning the International Carriage of Dangerous Goods by Inland Waterways; ADR - Agreement concerning the International Carriage of Dangerous Goods by Road; AIIC - 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

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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; 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

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:

| | |
|-------------------|------|
| Skin Sens. 1 | H317 |
| Aquatic Chronic 2 | H411 |

Classification procedure:

| |
|--------------------|
| Calculation method |
| Calculation method |

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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.

NO / EN

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