

SAFETY DATA SHEET



Oxfendazole Formulation

Version
12.0

Revision Date:
2025/06/17

SDS Number:
253202-00026

Date of last issue: 2025/04/14
Date of first issue: 2015/08/28

1. PRODUCT AND COMPANY IDENTIFICATION

Chemical product name : Oxfendazole Formulation

Supplier's company name, address and phone number

Company name of supplier : MSD

Address : 1-13-12, Kudan-kita, Chiyoda-ku, Tokyo, Japan

Telephone : 03-6272-1099

E-mail address : EHSDATASTEWARD@msd.com

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

Recommended use of the chemical and restrictions on use

Recommended use : Veterinary product

Restrictions on use : Not applicable

2. HAZARDS IDENTIFICATION

GHS classification of chemical product

Reproductive toxicity : Category 1B

Specific target organ toxicity - repeated exposure : Category 2 (Liver, Testis)

Short-term (acute) aquatic hazard : Category 1

Long-term (chronic) aquatic hazard : Category 1

GHS label elements

Hazard pictograms :



Signal word : Danger

Hazard statements : H360FD May damage fertility. May damage the unborn child. H373 May cause damage to organs (Liver, Testis) through prolonged or repeated exposure. H410 Very toxic to aquatic life with long lasting effects.

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Precautionary statements

Prevention:

P201 Obtain special instructions before use.
P202 Do not handle until all safety precautions have been read and understood.
P260 Do not breathe dust.
P273 Avoid release to the environment.
P280 Wear protective gloves/ protective clothing/ eye protection/ face protection.

Response:

P308 + P313 IF exposed or concerned: Get medical advice/ attention.
P391 Collect spillage.

Storage:

P405 Store locked up.

Disposal:

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

Other hazards which do not result in classification

Important symptoms and outlines of the emergency assumed : 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.

3. COMPOSITION/INFORMATION ON INGREDIENTS

Substance / Mixture : Mixture

Components

| Chemical name | CAS-No. | Concentration (% w/w) | ENCS No. |
|--------------------|------------|-----------------------|----------|
| oxfendazole | 53716-50-0 | >= 80 - < 90 | - |
| Cellulose | 9004-34-6 | >= 20 - < 30 | |
| Magnesium stearate | 557-04-0 | >= 1 - < 10 | 2-611 |

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.

In case of skin contact : In case of contact, immediately flush skin with soap and plenty of water.

Remove contaminated clothing and shoes.

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| | |
|---|---|
| In case of eye contact | Get medical attention. Wash clothing before reuse. Thoroughly clean shoes before reuse. : 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. 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. May damage fertility. May damage the unborn child. May cause damage to organs through prolonged or repeated exposure. |
| 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). |
| Notes to physician | : Treat symptomatically and supportively. |

5. FIREFIGHTING MEASURES

| | |
|---|---|
| Suitable extinguishing media | : Water spray Alcohol-resistant foam Carbon dioxide (CO ₂) Dry chemical |
| Unsuitable extinguishing media | : High volume water jet |
| 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. Do not use a solid water stream as it may scatter and spread fire. Exposure to combustion products may be a hazard to health. |
| Hazardous combustion products | : Carbon oxides Metal oxides Nitrogen oxides (NO _x) Sulphur oxides |
| 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 firefighters | : In the event of fire, wear self-contained breathing apparatus. Use personal protective equipment. |

6. ACCIDENTAL RELEASE MEASURES

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

Environmental precautions : Avoid release to the environment. Prevent further leakage or spillage if safe to do so. Retain and dispose of contaminated wash water. Local authorities should be advised if significant spillages cannot be contained.

Methods and materials for containment and cleaning up : Sweep up or vacuum up spillage and collect in suitable container for disposal. Avoid dispersal of dust in the air (i.e., clearing dust surfaces with compressed air). Dust deposits should not be allowed to accumulate on surfaces, as these may form an explosive mixture if they are released into the atmosphere in sufficient concentration. Local or national regulations may apply to releases and disposal of this material, as well as those materials and items employed in the cleanup of releases. You will need to determine which regulations are applicable. Sections 13 and 15 of this SDS provide information regarding certain local or national requirements.

7. HANDLING AND STORAGE

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 : If sufficient ventilation is unavailable, use with local exhaust ventilation.

Advice on safe handling : Do not get on skin or clothing. Do not breathe dust. Do not swallow. Avoid contact with eyes. Handle in accordance with good industrial hygiene and safety practice, based on the results of the workplace exposure assessment. Keep container tightly closed. 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

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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.

Storage

Conditions for safe storage : Keep in properly labelled containers.
Store locked up.
Keep tightly closed.
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 parame- ters / Concentra- tion standard / Permissible con- centration | Basis |
|--------------------|------------|--|---|----------|
| oxfendazole | 53716-50-0 | TWA | 40 µg/m ³ (OEB 3) | Internal |
| | | Wipe limit | 400 µg/100 cm ² | Internal |
| Cellulose | 9004-34-6 | TWA | 10 mg/m ³ | ACGIH |
| Magnesium stearate | 557-04-0 | TWA (Inhal- able particu- late matter) | 10 mg/m ³ | ACGIH |
| | | TWA (Res- pirable par- ticulate mat- ter) | 3 mg/m ³ | ACGIH |

Engineering measures

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

Respiratory protection : If adequate local exhaust ventilation is not available or exposure assessment demonstrates exposures outside the rec-

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|--------------------------|--|
| Filter type | ommended guidelines, use respiratory protection. |
| Hand protection | : Particulates type |
| Material | : Chemical-resistant gloves |
| Remarks | : Consider double gloving. |
| 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. 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. |

9. PHYSICAL AND CHEMICAL PROPERTIES

| | |
|--|--|
| Physical state | : powder |
| Colour | : No data available |
| Odour | : No data available |
| Odour Threshold | : No data available |
| Melting point/freezing point | : No data available |
| Boiling point, initial boiling point and boiling range | : No data available |
| Flammability (solid, gas) | : May form explosive dust-air mixture. |
| Flammability (liquids) | : No data available |
| Lower explosion limit and upper explosion limit / flammability limit | |
| Upper explosion limit / Up- per flammability limit | : No data available |
| Lower explosion limit / Lower flammability limit | : No data available |
| Flash point | : Not applicable |
| Decomposition temperature | : No data available |
| pH | : No data available |
| Evaporation rate | : Not applicable |

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| | | |
|--|---|--|
| Auto-ignition temperature | : | No data available |
| Viscosity | | |
| Viscosity, kinematic | : | Not applicable |
| Solubility(ies) | | |
| Water solubility | : | No data available |
| Partition coefficient: n-octanol/water | : | Not applicable |
| Vapour pressure | : | Not applicable |
| Density and / or relative density | | |
| Relative density | : | No data available |
| Density | : | No data available |
| Relative vapour density | : | Not applicable |
| Explosive properties | : | Not explosive |
| Oxidizing properties | : | The substance or mixture is not classified as oxidizing. |
| Molecular weight | : | No data available |
| 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 reactions | : | May form explosive dust-air mixture. Can react with strong oxidizing agents. |
| Conditions to avoid | : | Heat, flames and sparks. Avoid dust formation. |
| Incompatible materials | : | Oxidizing agents |
| Hazardous decomposition products | : | No hazardous decomposition products are known. |

11. TOXICOLOGICAL INFORMATION

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

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Acute toxicity

Not classified based on available information.

Components:

oxfendazole:

| | | |
|---------------------|---|---------------------------|
| Acute oral toxicity | : | LD50 (Rat): > 6,000 mg/kg |
| | | LD50 (Dog): 1,600 mg/kg |
| | | LD50 (sheep): 250 mg/kg |

Cellulose:

| | | |
|---------------------------|---|--|
| Acute oral toxicity | : | LD50 (Rat): > 5,000 mg/kg |
| Acute inhalation toxicity | : | LC50 (Rat): > 5.8 mg/l Exposure time: 4 h Test atmosphere: dust/mist |
| Acute dermal toxicity | : | LD50 (Rabbit): > 2,000 mg/kg |

Magnesium stearate:

| | | |
|-----------------------|---|--|
| Acute oral toxicity | : | LD50 (Rat): > 2,000 mg/kg Method: OECD Test Guideline 423 Assessment: The substance or mixture has no acute oral toxicity Remarks: Based on data from similar materials |
| Acute dermal toxicity | : | LD50 (Rabbit): > 2,000 mg/kg Remarks: Based on data from similar materials |

Skin corrosion/irritation

Not classified based on available information.

Components:

oxfendazole:

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

Magnesium stearate:

| | | |
|---------|---|--------------------------------------|
| Species | : | Rabbit |
| Result | : | No skin irritation |
| Remarks | : | Based on data from similar materials |

Serious eye damage/eye irritation

Not classified based on available information.

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

Magnesium stearate:

| | | |
|---------|---|--------------------------------------|
| Species | : | Rabbit |
| Result | : | No eye irritation |
| Remarks | : | Based on data from similar materials |

Respiratory or skin sensitisation**Skin sensitisation**

Not classified based on available information.

Respiratory sensitisation

Not classified based on available information.

Components:**Magnesium stearate:**

| | | |
|-----------------|---|--------------------------------------|
| Test Type | : | Maximisation Test |
| Exposure routes | : | Skin contact |
| Species | : | Guinea pig |
| Method | : | OECD Test Guideline 406 |
| Result | : | negative |
| Remarks | : | Based on data from similar materials |

Germ cell mutagenicity

Not classified based on available information.

Components:**oxfendazole:**

| | | |
|-----------------------|---|---|
| Genotoxicity in vitro | : | Test Type: Bacterial reverse mutation assay (AMES) Result: negative |
| Genotoxicity in vivo | : | Test Type: Mutagenicity (in vivo mammalian bone-marrow cytogenetic test, chromosomal analysis) Species: Mouse Application Route: Oral Result: positive |

Cellulose:

| | | |
|-----------------------|---|---|
| Genotoxicity in vitro | : | Test Type: Bacterial reverse mutation assay (AMES) Result: negative |
| | : | Test Type: In vitro mammalian cell gene mutation test Result: negative |

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Genotoxicity in vivo : Test Type: Mammalian erythrocyte micronucleus test (in vivo cytogenetic assay)
Species: Mouse
Application Route: Ingestion
Result: negative

Magnesium stearate:

Genotoxicity in vitro : Test Type: In vitro mammalian cell gene mutation test
Result: negative
Remarks: Based on data from similar materials

Test Type: Chromosome aberration test in vitro
Method: OECD Test Guideline 473
Result: negative
Remarks: Based on data from similar materials

Test Type: Bacterial reverse mutation assay (AMES)
Result: negative
Remarks: Based on data from similar materials

Carcinogenicity

Not classified based on available information.

Components:

oxfendazole:

Species : Rat
Application Route : Oral
Exposure time : 1 Years
Symptoms : No adverse effects
Target Organs : Liver

Species : Rat
Application Route : Oral
Exposure time : 2 Years
Symptoms : No adverse effects
Target Organs : Liver

Cellulose:

Species : Rat
Application Route : Ingestion
Exposure time : 72 weeks
Result : negative

Reproductive toxicity

May damage fertility. May damage the unborn child.

Components:

oxfendazole:

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| | |
|---|---|
| Effects on fertility | : Test Type: Fertility/early embryonic development Species: Rat, male Application Route: Oral Fertility: NOAEL: 17 mg/kg body weight Target Organs: Testes Result: Effects on fertility |
| | Test Type: Two-generation reproduction toxicity study Species: Rat Application Route: Oral Fertility: NOAEL: 0.9 mg/kg body weight Target Organs: Liver Result: No effects on fertility |
| | Test Type: Fertility Species: Mouse Application Route: Oral Duration of Single Treatment: 1 Months Fertility: NOAEL: 750 mg/kg body weight Target Organs: Testes Result: Effects on fertility |
| Effects on foetal development | : Test Type: Embryo-foetal development Species: Rat Application Route: Oral Developmental Toxicity: NOAEL: 10 mg/kg body weight Result: positive, Fetal effects |
| | Test Type: Embryo-foetal development Species: Rat Developmental Toxicity: NOAEL: 10 mg/kg body weight Result: positive, Embryo-foetal toxicity |
| | Test Type: Embryo-foetal development Species: Mouse Application Route: Oral Developmental Toxicity: NOAEL: 108 mg/kg body weight Result: positive, Embryo-foetal toxicity, foetal abnormalities |
| | Test Type: Embryo-foetal development Species: Rabbit Application Route: Oral Developmental Toxicity: NOAEL: 0.625 mg/kg body weight |
| Reproductive toxicity - Assessment | : Clear evidence of adverse effects on sexual function and fertility, based on animal experiments., Clear evidence of adverse effects on development, based on animal experiments. |
| Cellulose: Effects on fertility | : Test Type: One-generation reproduction toxicity study Species: Rat Application Route: Ingestion |

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Result: negative

Effects on foetal development

: Test Type: Fertility/early embryonic development
Species: Rat
Application Route: Ingestion
Result: negative

Magnesium stearate:

Effects on fertility

: Test Type: Combined repeated dose toxicity study with the reproduction/developmental toxicity screening test
Species: Rat
Application Route: Ingestion
Method: OECD Test Guideline 422
Result: negative
Remarks: Based on data from similar materials

Effects on foetal development

: Test Type: Embryo-foetal development
Species: Rat
Application Route: Ingestion
Result: negative
Remarks: Based on data from similar materials

STOT - single exposure

Not classified based on available information.

STOT - repeated exposure

May cause damage to organs (Liver, Testis) through prolonged or repeated exposure.

Components:

oxfendazole:

Exposure routes
Target Organs
Assessment

: Oral
: Liver, Testis
: May cause damage to organs through prolonged or repeated exposure.

Repeated dose toxicity

Components:

oxfendazole:

Species
NOAEL
Application Route
Exposure time
Target Organs

: Rat
: 11 mg/kg
: Oral
: 2 Weeks
: Blood, Liver, Testis

Species
NOAEL
Application Route
Exposure time

: Rat
: 3.8 mg/kg
: Oral
: 3 Months

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| | | |
|-------------------|---|--|
| Target Organs | : | Liver, Testis |
| Species | : | Mouse |
| NOAEL | : | 750 mg/kg |
| Application Route | : | Oral |
| Exposure time | : | 1 Months |
| Target Organs | : | Liver |
| Species | : | Mouse |
| NOAEL | : | 37.5 mg/kg |
| Application Route | : | Oral |
| Exposure time | : | 3 Months |
| Target Organs | : | Liver |
| Species | : | Dog |
| NOAEL | : | 6 mg/kg |
| Application Route | : | Oral |
| Exposure time | : | 1 Months |
| Remarks | : | No significant adverse effects were reported |
| Species | : | Dog |
| NOAEL | : | 11 mg/kg |
| Application Route | : | Oral |
| Exposure time | : | 2 Weeks |
| Target Organs | : | Lymph nodes, thymus gland |
| Species | : | Dog |
| NOAEL | : | 13.5 mg/kg |
| Application Route | : | Oral |
| Exposure time | : | 12 Months |
| Target Organs | : | Liver |

Cellulose:

| | | |
|-------------------|---|----------------|
| Species | : | Rat |
| NOAEL | : | >= 9,000 mg/kg |
| Application Route | : | Ingestion |
| Exposure time | : | 90 Days |

Magnesium stearate:

| | | |
|-------------------|---|--------------------------------------|
| Species | : | Rat |
| NOAEL | : | > 100 mg/kg |
| Application Route | : | Ingestion |
| Exposure time | : | 90 Days |
| Remarks | : | Based on data from similar materials |

Aspiration toxicity

Not classified based on available information.

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12. ECOLOGICAL INFORMATION

Ecotoxicity

Components:

oxfendazole:

| | | |
|--|---|--|
| Toxicity to fish | : | LC50 (Lepomis macrochirus (Bluegill sunfish)): > 2.7 mg/l Exposure time: 96 h |
| | | LC50 (Oncorhynchus mykiss (rainbow trout)): > 2.5 mg/l Exposure time: 96 h |
| Toxicity to daphnia and other aquatic invertebrates | : | EC50 (Daphnia magna (Water flea)): 0.059 mg/l Exposure time: 48 h Method: OECD Test Guideline 202 |
| Toxicity to algae/aquatic plants | : | EC50 (Pseudokirchneriella subcapitata (green algae)): > 4 mg/l Exposure time: 72 h Method: OECD Test Guideline 201 |
| | | NOEC (Pseudokirchneriella subcapitata (green algae)): > 4 mg/l Exposure time: 72 h Method: OECD Test Guideline 201 |
| M-Factor (Acute aquatic toxicity) | : | 10 |
| Toxicity to daphnia and other aquatic invertebrates (Chronic toxicity) | : | NOEC (Daphnia magna (Water flea)): 0.023 mg/l Exposure time: 21 d Method: OECD Test Guideline 211 |
| M-Factor (Chronic aquatic toxicity) | : | 1 |

Cellulose:

| | | |
|------------------|---|--|
| Toxicity to fish | : | LC50 (Oryzias latipes (Japanese medaka)): > 100 mg/l Exposure time: 48 h Remarks: Based on data from similar materials |
|------------------|---|--|

Magnesium stearate:

| | | |
|---|---|--|
| Toxicity to fish | : | LC50 (Leuciscus idus (Golden orfe)): > 100 mg/l Exposure time: 48 h Method: DIN 38412 Remarks: Based on data from similar materials |
| Toxicity to daphnia and other aquatic invertebrates | : | EL50 (Daphnia magna (Water flea)): > 1 mg/l Exposure time: 47 h Test substance: Water Accommodated Fraction Method: Directive 67/548/EEC, Annex V, C.2. |

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| | | Remarks: Based on data from similar materials No toxicity at the limit of solubility |
| Toxicity to algae/aquatic plants | : | EL50 (Pseudokirchneriella subcapitata (green algae)): > 1 mg/l Exposure time: 72 h Test substance: Water Accommodated Fraction Method: OECD Test Guideline 201 Remarks: Based on data from similar materials No toxicity at the limit of solubility |
| | | NOELR (Pseudokirchneriella subcapitata (green algae)): > 1 mg/l Exposure time: 72 h Test substance: Water Accommodated Fraction Method: OECD Test Guideline 201 Remarks: Based on data from similar materials |
| Toxicity to microorganisms | : | EC10 (Pseudomonas putida): > 100 mg/l Exposure time: 16 h Test substance: Water Accommodated Fraction Remarks: Based on data from similar materials |

Persistence and degradability

Components:

oxfendazole:

| | | |
|--------------------|---|------------------------|
| Stability in water | : | Hydrolysis: < 5 %(4 d) |
|--------------------|---|------------------------|

Cellulose:

| | | |
|------------------|---|--------------------------------|
| Biodegradability | : | Result: Readily biodegradable. |
|------------------|---|--------------------------------|

Magnesium stearate:

| | | |
|------------------|---|--|
| Biodegradability | : | Result: Not biodegradable Remarks: Based on data from similar materials |
|------------------|---|--|

Bioaccumulative potential

Components:

oxfendazole:

| | | |
|--|---|---------------|
| Partition coefficient: n-octanol/water | : | log Pow: 1.95 |
|--|---|---------------|

Magnesium stearate:

| | | |
|--|---|--------------|
| Partition coefficient: n-octanol/water | : | log Pow: > 4 |
|--|---|--------------|

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Mobility in soil

Components:

oxfendazole:

Distribution among environmental compartments : log Koc: 3.2

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 handling site for recycling or disposal.
If not otherwise specified: Dispose of as unused product.

14. TRANSPORT INFORMATION

International Regulations

UNRTDG

UN number : UN 3077
Proper shipping name : ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID, N.O.S.
(oxfendazole)
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.
(oxfendazole)
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,

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N.O.S.
(oxfendazole)
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.

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

Law Article 57-2 (Ministerial Order Article 34-2 Appended Table 2)

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| Chemical name | Concentration (%) | Remarks |
|--------------------|-------------------|---------|
| Magnesium stearate | >=1 - <10 | - |

Substances Subject to be Indicated Names

Law Article 57 (Ministerial Order Article 30 Appended Table 2)

| Chemical name | Remarks |
|--------------------|---------|
| Magnesium stearate | - |

Skin and Eye Damage Substances (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

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)

Aviation Law

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

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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

In this SDS, if the concentration of substances subject to notification under the Industrial Safety and Health Law is indicated as a range, it includes cases where it is a trade secret.

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/>

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

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

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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.

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