

Oxytetracycline / Diclofenac Formulation

Version Revision Date: SDS Number: Date of last issue: 2024/04/06 12.0 2024/09/28 4156032-00017 Date of first issue: 2019/04/17

1. PRODUCT AND COMPANY IDENTIFICATION

Chemical product name : Oxytetracycline / Diclofenac Formulation

Supplier's company name, address and phone number

Company name of supplier : MSD

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

Menuma factory

Telephone : 048-588-8411

E-mail address : EHSDATASTEWARD@msd.com

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

Recommended use of the chemical and restrictions on use

Recommended use : Veterinary product Restrictions on use : Not applicable

2. HAZARDS IDENTIFICATION

GHS classification of chemical product

Serious eye damage/eye irri-

tation

: Category 2B

Skin sensitisation : Category 1

Reproductive toxicity : Category 1A

Specific target organ toxicity - :

repeated exposure

Category 2 (Gastrointestinal tract, Blood, lymphatic system,

Liver, Prostate)

Short-term (acute) aquatic

hazard

: Category 1

Long-term (chronic) aquatic

hazard

Category 1

GHS label elements

Hazard pictograms



Signal word : Danger



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Hazard statements : H317 May cause an allergic skin reaction.

H320 Causes eye irritation.

H360FD May damage fertility. May damage the unborn child. H373 May cause damage to organs (Gastrointestinal tract, Blood, lymphatic system, Liver, Prostate) through prolonged or repeated exposure.

H410 Very toxic to aquatic life with long lasting effects.

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 mist or vapours. P264 Wash skin thoroughly after handling.

P272 Contaminated work clothing should not be allowed out of

the workplace.

P273 Avoid release to the environment.

P280 Wear protective gloves/ protective clothing/ eye protec-

tion/ face protection.

Response:

P302 + P352 IF ON SKIN: Wash with plenty of water.

P305 + P351 + P338 IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.

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

P333 + P313 If skin irritation or rash occurs: Get medical advice/ attention.

P337 + P313 If eye irritation persists: Get medical advice/ attention

P362 + P364 Take off contaminated clothing and wash it before reuse.

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

None known.

3. COMPOSITION/INFORMATION ON INGREDIENTS

Substance / Mixture : Mixture

Components

Chemical name CAS-No. Concentration (% w/w) ENCS No.
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2-Pyrrolidone	616-45-5	>= 50 - < 60	5-112
oxytetracycline	79-57-2	21.6	9-271
Propylene glycol	57-55-6	>= 1 - < 10	2-234
Magnesium oxide	1309-48-4	>= 1 - < 10	1-465
Sodium [2-[(2,6- dichloro- phenyl)amino]phenyl]acetate	15307-79-6	>= 1 - < 2.5	3-3082
Sodium hydroxymethanesulphinate	6035-47-8	>= 0.1 - < 1	2-1633
Disodium EDTA, dihydrate	6381-92-6	>= 0.1 - < 1	2-1265, 2-1265

4. FIRST AID MEASURES

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

vice immediately.

When symptoms persist or in all cases of doubt seek medical

advice.

If inhaled If inhaled, remove to fresh air.

Get medical attention.

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

Remove contaminated clothing and shoes.

Get medical attention. Wash clothing before reuse.

Thoroughly clean shoes before reuse.

In case of eye contact In case of contact, immediately flush eyes with plenty of water

for at least 15 minutes.

If easy to do, remove contact lens, if worn.

Get medical attention.

If swallowed, DO NOT induce vomiting. If swallowed

Get medical attention.

Rinse mouth thoroughly with water. May cause an allergic skin reaction.

Most important symptoms and effects, both acute and

delayed

Causes eye 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).

Treat symptomatically and supportively. Notes to physician

5. FIREFIGHTING MEASURES

Suitable extinguishing media Water spray

> Alcohol-resistant foam Carbon dioxide (CO2)



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Dry chemical

Unsuitable extinguishing

media

None known.

Specific hazards during fire-

fighting

Exposure to combustion products may be a hazard to health.

Hazardous combustion prod: :

ucts

Carbon oxides

Chlorine compounds Nitrogen oxides (NOx)

Sodium oxides

Specific extinguishing meth-

ods

Use extinguishing measures that are appropriate to local cir-

cumstances and the surrounding environment. Use water spray to cool unopened containers.

Remove undamaged containers from fire area if it is safe to do

SO.

Evacuate area.

Special protective equipment :

for firefighters

In the event of fire, wear self-contained breathing apparatus.

Use personal protective equipment.

6. ACCIDENTAL RELEASE MEASURES

Personal precautions, protective equipment and emer-

gency procedures

Use personal protective equipment.

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

tective equipment recommendations (see section 8).

Environmental precautions : Avoid release to the environment.

Prevent further leakage or spillage if safe to do so.

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.

Methods and materials for containment and 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 absor-

bent.

Local or national regulations may apply to releases and disposal of this material, as well as those materials and items employed in the cleanup of releases. You will need to deter-

mine which regulations are applicable.

Sections 13 and 15 of this SDS provide information regarding

certain local or national requirements.



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7. HANDLING AND STORAGE

Handling

Technical measures : See Engineering measures under EXPOSURE

CONTROLS/PERSONAL PROTECTION section.

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 mist or vapours.

Do not swallow. Do not get in eyes.

Wash skin thoroughly after handling.

Handle in accordance with good industrial hygiene and safety practice, based on the results of the workplace exposure as-

sessment

Keep container tightly closed.

Do not eat, drink or smoke when using this product.

Take care to prevent spills, waste and minimize release to the

environment.
Oxidizing agents

Avoidance of contact

Hygiene measures : If exposure to c

: 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.

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	Control parame-	Basis
		(Form of	ters / Concentra-	
		exposure)	tion standard /	
		,	Permissible con-	



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			centration	
oxytetracycline	79-57-2	TWA	500 μg/m3 (OEB 2)	Internal
	Further informa	ation: DSEN		
		Wipe limit	100 μg/100 cm ²	Internal
Magnesium oxide	1309-48-4	TWA (Inhal- able particu- late matter)	10 mg/m3	ACGIH
Sodium [2-[(2,6- dichloro- phenyl)amino]phenyl]acetate	15307-79-6	TWA	100 μg/m3 (OEB 2)	Internal
	Further information: Skin			

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.

Laboratory operations do not require special containment.

Personal protective equipment

Respiratory protection : If adequate local exhaust ventilation is not available or expo-

sure assessment demonstrates exposures outside the rec-

ommended guidelines, use respiratory protection. Combined particulates and organic vapour type

Filter type
Hand protection

Material : Chemical-resistant gloves

Remarks : Impermeable protective gloves

Eye protection : Wear safety glasses with side shields or goggles.

If the work environment or activity involves dusty conditions,

mists or aerosols, wear the appropriate goggles.

Wear a faceshield or other full face protection if there is a potential for direct contact to the face with dusts, mists, or

aerosols.

Skin and body protection : Work uniform or laboratory coat.

9. PHYSICAL AND CHEMICAL PROPERTIES

Physical state : liquid

Colour : brown, Greenish yellow

Odour : characteristic

Odour Threshold : No data available

Melting point/freezing point : -33 °C

Boiling point, initial boiling : 100.5 °C



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point and boiling range

Flammability (solid, gas) Not applicable

Flammability (liquids) No data available

Lower explosion limit and upper explosion limit / flammability limit

Upper explosion limit / Up- : No data available

per flammability limit

Lower explosion limit /

Lower flammability limit

No data available

Flash point No data available

Decomposition temperature No data available

No data available рΗ

Evaporation rate No data available

Auto-ignition temperature No data available

Viscosity

50.3 - 50.7 mPa.s (25 °C) Viscosity, dynamic

Viscosity, kinematic No data available

Solubility(ies)

Water solubility soluble

Partition coefficient: n-

octanol/water

Not applicable

Vapour pressure No data available

Density and / or relative density

Relative density 1.15 - 1.19 (25 °C)

Density No data available

Relative vapour density No data available

Explosive properties Not explosive

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

Molecular weight No data available

Particle characteristics

Particle size Not applicable



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10. STABILITY AND REACTIVITY

Reactivity : Not classified as a reactivity hazard.
Chemical stability : Stable under normal conditions.
Possibility of hazardous reac- : Can react with strong oxidizing agents.

tions

Conditions to avoid : None known. Incompatible materials : Oxidizing agents

Hazardous decomposition : No hazardous decomposition products are known.

products

11. TOXICOLOGICAL INFORMATION

Information on likely routes of : Inhalation

exposure 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:

2-Pyrrolidone:

Acute oral toxicity : LD50 (Rat): > 2,000 mg/kg

Method: OECD Test Guideline 401

Assessment: The substance or mixture has no acute oral tox-

icity

Acute dermal toxicity : LD50 (Rabbit): > 2,000 mg/kg

Method: OECD Test Guideline 402

Assessment: The substance or mixture has no acute dermal

toxicity

oxytetracycline:

Acute oral toxicity : LD50 (Rat): 4,800 mg/kg

LD50 (Mouse): 2,240 mg/kg

Remarks: Evidence of phototoxicity was observed

Acute inhalation toxicity : Remarks: No data available

Acute dermal toxicity : Remarks: No data available



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Acute toxicity (other routes of : LD50 (Rat): 4,840 mg/kg

administration)

Application Route: Intramuscular

LD50 (Mouse): 3,500 mg/kg Application Route: Subcutaneous

Propylene glycol:

Acute oral toxicity : LD50 (Rat): 22,000 mg/kg

: LC50 (Rat): > 44.9 mg/l Acute inhalation toxicity

Exposure time: 4 h

Test atmosphere: dust/mist

: LD50 (Rabbit): > 2,000 mg/kg Acute dermal toxicity

Assessment: The substance or mixture has no acute dermal

toxicity

Magnesium oxide:

Acute oral toxicity LD50 (Rat): > 2,000 mg/kg

Method: OECD Test Guideline 423

Assessment: The substance or mixture has no acute oral tox-

Remarks: Based on data from similar materials

Acute inhalation toxicity LC50 (Rat): > 2.1 mg/l

Exposure time: 4 h

Test atmosphere: dust/mist

Method: OECD Test Guideline 403

Remarks: Based on data from similar materials

Sodium [2-[(2,6-dichlorophenyl)amino]phenyl]acetate:

Acute oral toxicity : LD50 (Rat): 55 - 240 mg/kg

LD50 (Mouse): 170 - 389 mg/kg

Acute toxicity (other routes of:

administration)

LD50 (Rat): 97 - 161 mg/kg

Application Route: Intravenous

LD50 (Mouse): 92 - 147 mg/kg Application Route: Intravenous

Sodium hydroxymethanesulphinate:

Acute oral toxicity LD50 (Rat): > 5,000 mg/kg

Method: OECD Test Guideline 423

Remarks: Based on data from similar materials

: LD50 (Rat): > 2,000 mg/kg Acute dermal toxicity

Method: OECD Test Guideline 402

Remarks: Based on data from similar materials



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П

Disodium EDTA, dihydrate:

Acute oral toxicity : LD50 (Rat): 2,800 mg/kg

Acute inhalation toxicity : LC50 (Rat, male): > 1 mg/l

Exposure time: 6 h

Test atmosphere: dust/mist Method: OECD Test Guideline 412

Skin corrosion/irritation

Not classified based on available information.

Components:

2-Pyrrolidone:

Species : Rabbit

Method : OECD Test Guideline 404

Result : No skin irritation

oxytetracycline:

Remarks : No data available

Propylene glycol:

Species : Rabbit

Method : OECD Test Guideline 404

Result : No skin irritation

Sodium [2-[(2,6-dichlorophenyl)amino]phenyl]acetate:

Result : irritating

Sodium hydroxymethanesulphinate:

Species : Rat

Result : No skin irritation

Remarks : Based on data from similar materials

Serious eye damage/eye irritation

Causes eye irritation.

Components:

2-Pyrrolidone:

Species : Rabbit

Result : Irritation to eyes, reversing within 7 days

oxytetracycline:

Remarks : No data available



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Propylene glycol:

Species : Rabbit

Result : No eye irritation

Method : OECD Test Guideline 405

Magnesium oxide:

Species : Rabbit

Result : No eye irritation

Method : OECD Test Guideline 405

Remarks : Based on data from similar materials

Sodium [2-[(2,6-dichlorophenyl)amino]phenyl]acetate:

Result : Mild eye irritation

Sodium hydroxymethanesulphinate:

Species : Rabbit

Result : No eye irritation

Method : OECD Test Guideline 405

Remarks : Based on data from similar materials

Disodium EDTA, dihydrate:

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:

2-Pyrrolidone:

Test Type : Local lymph node assay (LLNA)

Exposure routes : Skin contact Species : Mouse

Method : OECD Test Guideline 429

Result : negative

Remarks : Based on data from similar materials

oxytetracycline:

Test Type : Human repeat insult patch test (HRIPT)

Result : Sensitiser

Propylene glycol:

Test Type : Maximisation Test



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Exposure routes : Skin contact
Species : Guinea pig
Result : negative

Magnesium oxide:

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

Sodium hydroxymethanesulphinate:

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

Disodium EDTA, dihydrate:

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:

2-Pyrrolidone:

Genotoxicity in vitro : Test Type: Bacterial reverse mutation assay (AMES)

Result: negative

Test Type: In vitro mammalian cell gene mutation test

Method: OECD Test Guideline 476

Result: negative

Remarks: Based on data from similar materials

Test Type: Chromosome aberration test in vitro

Method: OECD Test Guideline 473

Result: negative

Genotoxicity in vivo : Test Type: Mammalian erythrocyte micronucleus test (in vivo

cytogenetic assay) Species: Mouse

Application Route: Intraperitoneal injection



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Method: OECD Test Guideline 474

Result: negative

oxytetracycline:

Genotoxicity in vitro : Test Type: Microbial mutagenesis assay (Ames test)

Result: negative

Test Type: Mouse Lymphoma

Metabolic activation: Metabolic activation

Result: positive

Test Type: sister chromatid exchange assay Test system: Chinese hamster ovary cells

Result: equivocal

Test Type: Chromosomal aberration

Result: negative

Genotoxicity in vivo : Test Type: Micronucleus test

Species: Mouse

Cell type: Bone marrow Application Route: Oral Result: equivocal

Test Type: in vivo assay

Species: Mouse

Application Route: Intraperitoneal injection

Result: negative

Germ cell mutagenicity -

Assessment

Weight of evidence does not support classification as a germ

cell mutagen.

Propylene glycol:

Genotoxicity in vitro : Test Type: Bacterial reverse mutation assay (AMES)

Result: negative

Test Type: Chromosome aberration test in vitro

Method: OECD Test Guideline 473

Result: negative

Genotoxicity in vivo : Test Type: Mammalian erythrocyte micronucleus test (in vivo

cytogenetic assay) Species: Mouse

Application Route: Intraperitoneal injection

Result: negative

Magnesium oxide:

Genotoxicity in vitro : Test Type: Bacterial reverse mutation assay (AMES)

Method: OECD Test Guideline 471

Result: negative



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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: In vitro mammalian cell gene mutation test

Method: OECD Test Guideline 476

Result: negative

Remarks: Based on data from similar materials

Sodium [2-[(2,6-dichlorophenyl)amino]phenyl]acetate:

Genotoxicity in vitro : Test Type: Bacterial reverse mutation assay (AMES)

Result: negative

Test Type: Mouse Lymphoma

Result: negative

Genotoxicity in vivo : Test Type: Chromosomal aberration

Species: CHO Result: negative

Sodium hydroxymethanesulphinate:

Genotoxicity in vitro : Test Type: Bacterial reverse mutation assay (AMES)

Method: OECD Test Guideline 471

Result: negative

Remarks: Based on data from similar materials

Genotoxicity in vivo : Test Type: Mammalian erythrocyte micronucleus test (in vivo

cytogenetic assay) Species: Mouse

Application Route: Intraperitoneal injection

Method: OECD Test Guideline 474

Result: positive

Remarks: Based on data from similar materials

Germ cell mutagenicity -

Assessment

Positive result(s) from in vivo mammalian somatic cell muta-

genicity tests.

Disodium EDTA, dihydrate:

Genotoxicity in vitro : Test Type: Bacterial reverse mutation assay (AMES)

Result: negative

Remarks: Based on data from similar materials

Test Type: In vitro mammalian cell gene mutation test

Result: negative

Test Type: Chromosome aberration test in vitro

Result: negative



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Remarks: Based on data from similar materials

Genotoxicity in vivo : Test Type: Mammalian erythrocyte micronucleus test (in vivo

cytogenetic assay) Species: Mouse

Application Route: Ingestion Method: OECD Test Guideline 474

Result: negative

Carcinogenicity

Not classified based on available information.

Components:

2-Pyrrolidone:

Species : Mouse
Application Route : Ingestion
Exposure time : 18 month(s)
Result : negative

Remarks : Based on data from similar materials

oxytetracycline:

Species: MouseApplication Route: OralExposure time: 104 weeksResult: negative

Species : Rat
Application Route : Oral
Exposure time : 103 weeks
Result : equivocal

Target Organs : Adrenal gland, Pituitary gland

Remarks : The mechanism or mode of action may not be relevant in

humans.

Carcinogenicity - Assess-

ment

: Weight of evidence does not support classification as a car-

cinogen

Propylene glycol:

Species : Rat
Application Route : Ingestion
Exposure time : 2 Years
Result : negative

Magnesium oxide:

Species : Mouse
Application Route : Ingestion
Exposure time : 96 weeks
Result : negative

Remarks : Based on data from similar materials



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Sodium [2-[(2,6-dichlorophenyl)amino]phenyl]acetate:

Species : Rat
Application Route : Oral
Exposure time : 2 Years
Result : negative

Species: MouseApplication Route: OralExposure time: 2 YearsResult: negative

Disodium EDTA, dihydrate:

Species : Rat
Application Route : Ingestion
Exposure time : 103 weeks
Result : negative

Remarks : Based on data from similar materials

Reproductive toxicity

May damage fertility. May damage the unborn child.

Components:

2-Pyrrolidone:

Effects on fertility: Test Type: One-generation reproduction toxicity study

Species: Rat

Application Route: Ingestion

Result: positive

Remarks: Based on data from similar materials

Effects on foetal develop-

ment

Test Type: Embryo-foetal development

Species: Rat

Application Route: Ingestion

Result: positive

Reproductive toxicity - As-

sessment

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.

oxytetracycline:

Effects on fertility : Test Type: Two-generation reproduction toxicity study

Species: Rat

Application Route: Oral

Fertility: NOAEL: 18 mg/kg body weight

Result: No effects on fertility, No effect on reproduction capac-

ity, No significant adverse effects were reported

Effects on foetal develop-

ment

Test Type: Embryo-foetal development

Species: Rat



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Application Route: Oral

Embryo-foetal toxicity: LOAEL: 48 mg/kg body weight Result: Postimplantation loss., Skeletal malformations

Test Type: Embryo-foetal development

Species: Rat

Application Route: Oral

General Toxicity Maternal: LOAEL: 1,200 mg/kg body weight Embryo-foetal toxicity: NOAEL: 1,500 mg/kg body weight

Result: No teratogenic effects Remarks: Maternal toxicity observed.

Test Type: Embryo-foetal development

Species: Mouse Application Route: Oral

General Toxicity Maternal: LOAEL: 1,325 mg/kg body weight Embryo-foetal toxicity: NOAEL: 2,100 mg/kg body weight

Result: No teratogenic effects Remarks: Maternal toxicity observed.

Test Type: Embryo-foetal development

Species: Rabbit

Application Route: Intramuscular

Embryo-foetal toxicity: LOAEL: 41.5 mg/kg body weight Result: Postimplantation loss., No foetal abnormalities

Test Type: Embryo-foetal development

Species: Dog

Application Route: Intramuscular

Embryo-foetal toxicity: LOAEL: 20.75 mg/kg body weight Result: Skeletal and visceral variations, Postimplantation loss.

Reproductive toxicity - As-

sessment

Positive evidence of adverse effects on development from

human epidemiological studies.

Propylene glycol:

Effects on fertility : Test Type: Two-generation reproduction toxicity study

Species: Mouse

Application Route: Ingestion

Result: negative

Effects on foetal develop-

ment

Test Type: Embryo-foetal development

Species: Mouse

Application Route: Ingestion

Result: negative

Magnesium oxide:

Effects on fertility : Test Type: Combined repeated dose toxicity study with the

reproduction/developmental toxicity screening test

Species: Rat

Application Route: Ingestion



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Method: OECD Test Guideline 422

Result: negative

Remarks: Based on data from similar materials

Effects on foetal develop-

ment

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

Sodium [2-[(2,6-dichlorophenyl)amino]phenyl]acetate:

Effects on fertility Test Type: Fertility

Species: Rat, male and female

Application Route: Oral

Fertility: NOAEL: 4 mg/kg body weight

Result: No effects on fertility

Effects on foetal develop-

ment

Test Type: Development

Species: Rat

Application Route: Oral

Developmental Toxicity: LOAEL: 1 mg/kg body weight Result: Embryo-foetal toxicity, No teratogenic effects

Test Type: Development

Species: Rabbit Application Route: Oral

Developmental Toxicity: LOAEL: 5 mg/kg body weight

Result: Embryo-foetal toxicity, No teratogenic effects

Reproductive toxicity - As-

sessment

Suspected of damaging the unborn child.

Sodium hydroxymethanesulphinate:

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 develop-

ment

Test Type: Embryo-foetal development

Species: Rat

Application Route: Ingestion Method: OECD Test Guideline 414

Result: positive

Remarks: Based on data from similar materials

Reproductive toxicity - As-

sessment

Some evidence of adverse effects on development, based on

animal experiments.



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II

Disodium EDTA, dihydrate:

Effects on fertility : Test Type: Four-generation reproduction toxicity study

Species: Rat

Application Route: Ingestion

Result: negative

Remarks: Based on data from similar materials

Effects on foetal develop: Test Type: Embryo-foetal development

ment

Species: Rat

Application Route: Ingestion

Result: negative

STOT - single exposure

Not classified based on available information.

STOT - repeated exposure

May cause damage to organs (Gastrointestinal tract, Blood, lymphatic system, Liver, Prostate) through prolonged or repeated exposure.

Components:

Sodium [2-[(2,6-dichlorophenyl)amino]phenyl]acetate:

Target Organs : Gastrointestinal tract, Blood, lymphatic system, Liver, Prostate

Assessment : Causes damage to organs through prolonged or repeated

exposure.

Disodium EDTA, dihydrate:

Exposure routes : inhalation (dust/mist/fume)

Target Organs : Respiratory Tract

Assessment : May cause damage to organs through prolonged or repeated

exposure.

Repeated dose toxicity

Components:

2-Pyrrolidone:

Species : Rat

NOAEL : 207 mg/kg

Application Route : Ingestion

Exposure time : 3 Months

Method : OECD Test Guideline 408

oxytetracycline:

Species : Rat
LOAEL : 198 mg/kg
Application Route : Oral
Exposure time : 13 Weeks
Target Organs : Bone



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Remarks : No significant adverse effects were reported

Species : Mouse
LOAEL : 7,990 mg/kg
Application Route : Oral
Exposure time : 13 Weeks
Target Organs : Bone

Remarks : No significant adverse effects were reported

Species: DogNOAEL: 125 mg/kgLOAEL: 250 mg/kgApplication Route: OralExposure time: 12 MonthsTarget Organs: Testis

Remarks : Significant toxicity observed in testing

Species : Rat

NOAEL : 40 mg/kg

LOAEL : 100 mg/kg

Application Route : Intraperitoneal

Exposure time : 14 Days

Target Organs : Kidney

Propylene glycol:

Species : Rat, male

NOAEL : >= 1,700 mg/kg

Application Route : Ingestion

Exposure time : 2 yr

Magnesium oxide:

Species : Rat

NOAEL : >= 1,000 mg/kg
Application Route : Ingestion
Exposure time : 28 Days

Method : OECD Test Guideline 407

Remarks : Based on data from similar materials

Sodium [2-[(2,6-dichlorophenyl)amino]phenyl]acetate:

Species : Rat LOAEL : 0.25 mg/kg Application Route : Oral

Exposure time : 98 w

Target Organs : Gastrointestinal tract, Blood, lymphatic system, Liver, Prostate

Species : Dog
LOAEL : 1 mg/kg
Application Route : Oral
Exposure time : 12 w
Target Organs : Blood



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Species : Baboon

NOAEL : 0.5 mg/kg

LOAEL : 5 mg/kg

Application Route : Oral

Exposure time : 52 w

Target Organs : Gastrointestinal tract, Blood Symptoms : constipation, Diarrhoea

Sodium hydroxymethanesulphinate:

Species : Rat NOAEL : 600 mg/kg

Application Route : Ingestion
Exposure time : 90 Days

Method : OECD Test Guideline 408

Remarks : Based on data from similar materials

Disodium EDTA, dihydrate:

Species: RatNOAEL: 500 mg/kgApplication Route: IngestionExposure time: 13 Weeks

Species : Rat LOAEL : 0.03 mg/l

Application Route : inhalation (dust/mist/fume)

Exposure time : 4 Weeks

Method : OECD Test Guideline 412

Aspiration toxicity

Not classified based on available information.

Experience with human exposure

Components:

oxytetracycline:

Ingestion : Symptoms: Gastrointestinal disturbance, tooth discoloration

Remarks: May cause birth defects.

Sodium [2-[(2,6-dichlorophenyl)amino]phenyl]acetate:

Ingestion : Symptoms: Abdominal pain, Diarrhoea, constipation, heart-

burn, Ulceration, Dizziness, Headache, Breathing difficulties,

Rash



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12. ECOLOGICAL INFORMATION

Ecotoxicity

Components:

2-Pyrrolidone:

Toxicity to fish : LC50 (Danio rerio (zebra fish)): > 4,600 - 10,000 mg/l

Exposure time: 96 h

Method: OECD Test Guideline 203

Toxicity to daphnia and other :

aquatic invertebrates

EC50 (Daphnia magna (Water flea)): > 500 mg/l

Exposure time: 48 h

Toxicity to algae/aquatic

plants

: ErC50 (Desmodesmus subspicatus (green algae)): > 500 mg/l

Exposure time: 72 h

EC10 (Desmodesmus subspicatus (green algae)): 22.2 mg/l

Exposure time: 72 h

Toxicity to microorganisms : EC50: > 1,000 mg/l

Exposure time: 30 min

Method: OECD Test Guideline 209

oxytetracycline:

Toxicity to fish : LC50 (Oryzias latipes (Japanese medaka)): 110 mg/l

Exposure time: 96 h

Method: OECD Test Guideline 203

Toxicity to daphnia and other:

aquatic invertebrates

EC50 (Daphnia magna (Water flea)): 621 mg/l

Exposure time: 48 h

Method: OECD Test Guideline 202

EC50 (Daphnia magna (Water flea)): 669 mg/l

Exposure time: 48 h

Method: OECD Test Guideline 202

Toxicity to algae/aquatic

plants

EC50 (Anabaena): 0.032 mg/l

Exposure time: 72 h

NOEC (Anabaena): 0.0031 mg/l

Exposure time: 72 h

M-Factor (Acute aquatic tox- :

city)

: 10: 10

M-Factor (Chronic aquatic

toxicity)

icity)

Toxicity to microorganisms : EC50: 17.9 mg/l Exposure time: 3 h

Test Type: Respiration inhibition



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Method: OECD Test Guideline 209

NOEC: 0.2 mg/l Exposure time: 3 h

Test Type: Respiration inhibition Method: OECD Test Guideline 209

Propylene glycol:

Toxicity to fish : LC50 (Oncorhynchus mykiss (rainbow trout)): 40,613 mg/l

Exposure time: 96 h

Toxicity to daphnia and other :

aquatic invertebrates

EC50 (Ceriodaphnia dubia (water flea)): 18,340 mg/l

Exposure time: 48 h

Toxicity to algae/aquatic

plants

ErC50 (Skeletonema costatum (marine diatom)): 19,300 mg/l

Exposure time: 72 h

Method: OECD Test Guideline 201

Toxicity to daphnia and other :

aquatic invertebrates (Chron-

ic toxicity)

NOEC (Ceriodaphnia dubia (water flea)): 13,020 mg/l

Exposure time: 7 d

Toxicity to microorganisms : NOEC (Pseudomonas putida): > 20,000 mg/l

Exposure time: 18 h

Magnesium oxide:

Toxicity to fish : LL50 (Pimephales promelas (fathead minnow)): > 100 mg/l

Exposure time: 96 h

Remarks: Based on data from similar materials

Toxicity to daphnia and other:

aquatic invertebrates

EL50 (Daphnia magna (Water flea)): > 100 mg/l

Exposure time: 48 h

Remarks: Based on data from similar materials

Toxicity to algae/aquatic

plants

EL50 (Pseudokirchneriella subcapitata (green algae)): > 100

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 : EC50: > 100 mg/l

Exposure time: 3 h

Method: OECD Test Guideline 209

Remarks: Based on data from similar materials

Sodium [2-[(2,6-dichlorophenyl)amino]phenyl]acetate:

Toxicity to fish : LC50 (Pimephales promelas (fathead minnow)): 166.6 mg/l

Exposure time: 96 h

Method: OECD Test Guideline 203



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aquatic invertebrates

Toxicity to daphnia and other : EC50 (Daphnia magna (Water flea)): 80.1 mg/l

Exposure time: 48 h

Method: OECD Test Guideline 202

Toxicity to algae/aquatic

plants

EC50 (Pseudokirchneriella subcapitata (green algae)): 71.9

ma/l

Exposure time: 72 h

Method: OECD Test Guideline 201

NOEC (Pseudokirchneriella subcapitata (green algae)): 49.2

mg/l

Exposure time: 72 h

Method: OECD Test Guideline 201

Toxicity to fish (Chronic tox-

icity)

NOEC (Pimephales promelas (fathead minnow)): 0.32 mg/l

Exposure time: 32 d

Method: OECD Test Guideline 210

Toxicity to daphnia and other:

aquatic invertebrates (Chron-

ic toxicity)

NOEC (Daphnia magna (Water flea)): 10 mg/l

Exposure time: 21 d

Method: OECD Test Guideline 211

Sodium hydroxymethanesulphinate:

Toxicity to fish LC50 (Leuciscus idus (Golden orfe)): > 10,000 mg/l

Exposure time: 96 h

Remarks: Based on data from similar materials

Toxicity to daphnia and other :

aquatic invertebrates

EC50 (Daphnia magna (Water flea)): > 100 mg/l

Exposure time: 48 h

Method: OECD Test Guideline 202

Remarks: Based on data from similar materials

Toxicity to algae/aquatic

plants

ErC50 (Desmodesmus subspicatus (green algae)): 370 mg/l

Exposure time: 72 h

Method: OECD Test Guideline 201

Remarks: Based on data from similar materials

Toxicity to fish (Chronic tox-

icity)

NOEC (Danio rerio (zebra fish)): 13.5 mg/l

Exposure time: 35 d

Method: OECD Test Guideline 210

Remarks: Based on data from similar materials

Toxicity to daphnia and other: aquatic invertebrates (Chron-

ic toxicity)

NOEC (Daphnia magna (Water flea)): 5.6 mg/l

Exposure time: 21 d

Method: OECD Test Guideline 211

Remarks: Based on data from similar materials

Toxicity to microorganisms EC50: > 1,000 mg/l

Exposure time: 4 h

Remarks: Based on data from similar materials



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Disodium EDTA, dihydrate:

Toxicity to fish : LC50 (Lepomis macrochirus (Bluegill sunfish)): > 100 mg/l

Exposure time: 96 h

Remarks: Based on data from similar materials

Toxicity to daphnia and other:

aquatic invertebrates

EC50 (Daphnia magna (Water flea)): 140 mg/l

Exposure time: 48 h Method: DIN 38412

Toxicity to algae/aquatic

plants

ErC50 (Pseudokirchneriella subcapitata (green algae)): > 100

mg/

Exposure time: 72 h

Method: OECD Test Guideline 201

Remarks: Based on data from similar materials

EC10 (Pseudokirchneriella subcapitata (green algae)): > 1

mg/l

Exposure time: 72 h

Method: OECD Test Guideline 201

Remarks: Based on data from similar materials

Toxicity to daphnia and other : aquatic invertebrates (Chron-

ic toxicity)

NOEC (Daphnia magna (Water flea)): 25 mg/l

Exposure time: 21 d

Toxicity to microorganisms

EC10 (activated sludge): > 500 mg/l

Exposure time: 30 min

Method: OECD Test Guideline 209

Persistence and degradability

Components:

2-Pyrrolidone:

Biodegradability : Result: Readily biodegradable.

Remarks: Based on data from similar materials

Propylene glycol:

Biodegradability : Result: Readily biodegradable.

Biodegradation: 98.3 % Exposure time: 28 d

Method: OECD Test Guideline 301F

Sodium hydroxymethanesulphinate:

Biodegradability : Result: Readily biodegradable.

Biodegradation: 77 % Exposure time: 28 d

Method: OECD Test Guideline 301B

Remarks: Based on data from similar materials

Disodium EDTA, dihydrate:



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Biodegradability : Result: Not readily biodegradable.

Biodegradation: 2 % Exposure time: 28 d

Method: OECD Test Guideline 301D

Bioaccumulative potential

Components:

2-Pyrrolidone:

Partition coefficient: n- : log Pow: -0.71

octanol/water Method: OECD Test Guideline 107

Propylene glycol:

Partition coefficient: n- : log Pow: -1.07

octanol/water Method: Regulation (EC) No. 440/2008, Annex, A.8

Sodium [2-[(2,6-dichlorophenyl)amino]phenyl]acetate:

Partition coefficient: n- : log Pow: 4.51

octanol/water

Disodium EDTA, dihydrate:

Bioaccumulation : Species: Lepomis macrochirus (Bluegill sunfish)

Bioconcentration factor (BCF): < 500

Remarks: Based on data from similar materials

Partition coefficient: n- : log Pow: -4.3

octanol/water

Mobility in soilNo data available

Hazardous to the ozone layer

Not applicable

Other adverse effects

No data available

13. DISPOSAL CONSIDERATIONS

Disposal methods

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

Do not dispose of waste into sewer.

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

dling site for recycling or disposal.

If not otherwise specified: Dispose of as unused product.

14. TRANSPORT INFORMATION

International Regulations



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UNRTDG

UN number : UN 3082

Proper shipping name : ENVIRONMENTALLY HAZARDOUS SUBSTANCE, LIQUID,

N.O.S.

(oxytetracycline)

Class : 9
Packing group : III
Labels : 9
Environmentally hazardous : yes

IATA-DGR

UN/ID No. : UN 3082

Proper shipping name : Environmentally hazardous substance, liquid, n.o.s.

(oxytetracycline)

Class : 9 Packing group : III

Labels : Miscellaneous

Packing instruction (cargo : 964

aircraft)

Packing instruction (passen: 964

ger aircraft)

Environmentally hazardous : yes

IMDG-Code

UN number : UN 3082

Proper shipping name : ENVIRONMENTALLY HAZARDOUS SUBSTANCE, LIQUID,

N.O.S.

(oxytetracycline)

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



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Not applicable to dangerous materials / designated flammables.

Chemical Substance Control Law

Priority Assessment Chemical Substance

Chemical name	Number
Propane-1,2-diol	106
Sodium salt of 2,2',2"'-(ethane-1,2-diyldinitrilo)tetraacetic acid	268

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

Article 57-2 (Enforcement Order Table 9)

Chemical name	Concentration (%)	Remarks
Propylene glycol	>=1 - <10	From April 1st, 2025
magnesium oxide	>=1 - <10	From April 1st, 2026

Substances Subject to be Indicated Names

Article 57 (Enforcement Order Article 18)

Author of (Embroombile Gradi Author 10)	
Chemical name	Remarks
Propylene glycol	From April 1st, 2025
magnesium oxide	From April 1st, 2026

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

•	Chemical name
	Oxytetracycline

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



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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

Class I Designated Chemical Substances

	Chemical name	Administration number	Concentration (%)
I	(4S,4aR,5S,5aR,6S,12aS)-4-	648	22
	(Dimethylamino)-3,5,6,10,12,12a-		
	hexahydroxy-6-methyl-1,11-dioxo-		
	1,4,4a,5,5a,6,11,12a-octahydrotetracen-		
	2-carboxamide		

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

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



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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

compile the Safety Data

Sheet

Sources of key data used to : Internal technical data, data from raw material SDSs. OECD eChem Portal search results and European Chemicals Agen-

cy, 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 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



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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.

JP / EN