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

1.1 Product identifier

Trade name : Spiramycin Formulation

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

Use of the Sub- : Veterinary product

stance/Mixture

Recommended restrictions : Not applicable

on use

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)

Eye irritation, Category 2 H319: Causes serious eye irritation.

Reproductive toxicity, Category 1B H360FD: May damage fertility. May damage the

unborn child.

2.2 Label elements

Labelling (REGULATION (EC) No 1272/2008)

Hazard pictograms :

(!)

Signal word : Danger

Hazard statements : H319 Causes serious eye irritation.

H360FD May damage fertility. May damage the unborn

child.

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Precautionary statements : Prevention:

P201 Obtain special instructions before use. P264 Wash skin thoroughly after handling.

P280 Wear protective gloves/ protective clothing/ eye protec-

tion/ face protection.

Response:

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

attention.

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

attention.

Storage:

P405 Store locked up.

Hazardous components which must be listed on the label:

2-Pyrrolidone

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)
2-Pyrrolidone	616-45-5 210-483-1	Eye Irrit. 2; H319 Repr. 1B; H360FD —— specific concentration limit Repr. 1B; H360FD > 3 %	>= 30 - < 50
Benzyl alcohol	100-51-6 202-859-9	Acute Tox. 4; H302 Acute Tox. 4; H332	>= 1 - < 10

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	603-057-00-5	Eye Irrit. 2; H319	
		Acute toxicity esti- mate	
		Acute oral toxicity: 1.620 mg/kg	
Spiramycin	8025-81-8 232-429-6		< 0,1

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 ad-

vice 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 : 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.

Get medical attention.

Rinse mouth thoroughly with water.

4.2 Most important symptoms and effects, both acute and delayed

Risks : Causes serious eye irritation.

May damage fertility. May damage the unborn child.

4.3 Indication of any immediate medical attention and special treatment needed

Treatment : Treat symptomatically and supportively.

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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 prod: :

ucts

Nitrogen oxides (NOx)

Carbon 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 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.

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 pro-

tective 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.

6.3 Methods and material for containment and cleaning up

Methods for cleaning up : Soak up with inert absorbent material.

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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 deter-

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

ventilation.

Advice on safe handling : Do not get on skin or clothing.

Do not breathe vapours or spray mist.

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.

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

environment.

Hygiene measures : If exposure to chemical is likely during typical use, provide eye

flushing systems and safety showers close to the working place. When using do not eat, drink or smoke. Wash contami-

nated 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 locked up. Keep tightly closed. Store in accordance with the particular national

regulations.

Advice on common storage : Do not store with the following product types:

Strong oxidizing agents

Self-reactive substances and mixtures

Organic peroxides

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Explosives Gases

7.3 Specific end use(s)

Specific use(s) : No data available

SECTION 8: Exposure controls/personal protection

8.1 Control parameters

Occupational Exposure Limits

Components	CAS-No.	Value type (Form of exposure)	Control parameters	Basis
Spiramycin	8025-81-8	TWA	1000 ug/m3 (OEB 1)	Internal

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

Substance name	End Use	Exposure routes	Potential health ef- Value fects	
2-Pyrrolidone	Workers	Inhalation	Long-term systemic effects	57,8 mg/m3
	Workers	Skin contact	Long-term systemic effects	10 mg/kg bw/day
	Workers	Skin contact	Acute systemic effects	277 mg/kg bw/day
	Consumers	Inhalation	Long-term systemic effects	17,1 mg/m3
	Consumers	Skin contact	Long-term systemic effects	6 mg/kg bw/day
	Consumers	Skin contact	Acute systemic effects	167 mg/kg bw/day
	Consumers	Ingestion	Long-term systemic effects	5,2 mg/kg bw/day
	Consumers	Ingestion	Acute systemic effects	33,3 mg/kg bw/day
Benzyl alcohol	Workers	Inhalation	Long-term systemic effects	22 mg/m3
	Workers	Inhalation	Acute systemic effects	110 mg/m3
	Workers	Skin contact	Long-term systemic effects	8 mg/kg bw/day
	Workers	Skin contact	Acute systemic effects	40 mg/kg bw/day
	Consumers	Inhalation	Long-term systemic effects	5,4 mg/m3
	Consumers	Inhalation	Acute systemic effects	27 mg/m3
	Consumers	Skin contact	Long-term systemic effects	4 mg/kg bw/day
	Consumers	Skin contact	Acute systemic ef-	20 mg/kg

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		fects	bw/day
Consumers	Ingestion	Long-term systemic effects	4 mg/kg bw/day
Consumers	Ingestion	Acute systemic ef- fects	20 mg/kg bw/day

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

Substance name	Environmental Compartment	Value
2-Pyrrolidone	Fresh water	0,5 mg/l
	Freshwater - intermittent	0,5 mg/l
	Marine water	0,05 mg/l
	Sewage treatment plant	10 mg/l
	Fresh water sediment	0,4205 mg/kg dry
		weight (d.w.)
	Soil	0,0612 mg/kg dry
		weight (d.w.)
Benzyl alcohol	Fresh water	1 mg/l
	Marine water	0,1 mg/l
	Intermittent use/release	2,3 mg/l
	Sewage treatment plant	39 mg/l
	Fresh water sediment	5,27 mg/kg
	Marine sediment	0,527 mg/kg
	Soil	0,456 mg/kg

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. Laboratory operations do not require special containment.

Personal protective equipment

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

If the work environment or activity involves dusty conditions,

mists or aerosols, wear the appropriate goggles.

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

aerosols.

Hand protection

Material : Chemical-resistant gloves

Skin and body protection : Work uniform or laboratory coat.

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

sure assessment demonstrates exposures outside the rec-

ommended guidelines, use respiratory protection.

Equipment should conform to NS EN 14387

Filter type : Organic vapour type (A)

SECTION 9: Physical and chemical properties

9.1 Information on basic physical and chemical properties

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Physical state : Aqueous solution

Colour : light yellow

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

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 : 8,0 - 10,0

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 : 0,950 - 1,150 g/cm³

Relative vapour density : No data available

Particle characteristics

Particle size : Not applicable

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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

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 : 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

Acute inhalation toxicity : Acute toxicity estimate: > 5 mg/l

Exposure time: 4 h

Test atmosphere: dust/mist

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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

Benzyl alcohol:

Acute oral toxicity : LD50 (Rat): 1.620 mg/kg

Acute inhalation toxicity : LC50 (Rat): > 4,178 mg/l

Exposure time: 4 h

Test atmosphere: dust/mist

Method: OECD Test Guideline 403

Spiramycin:

Acute oral toxicity : LD50 (Mouse, adult): 2.900 mg/kg

LD50 (Rat, adult): 3.550 mg/kg

LD50 (Dog, adult): 5.200 mg/kg

LD50 (Rabbit, adult): 4.300 mg/kg

Acute inhalation toxicity : Remarks: No data available

Acute toxicity (other routes of :

administration)

LD50 (Mouse): 130 mg/kg

Application Route: Intravenous

LD50 (Rat): 170 mg/kg

Application Route: Intravenous

LD50 (Rabbit): 182 mg/kg Application Route: Intravenous

Skin corrosion/irritation

Not classified based on available information.

Components:

2-Pyrrolidone:

Species : Rabbit

Method : OECD Test Guideline 404

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Result : No skin irritation

Benzyl alcohol:

Species : Rabbit

Method : OECD Test Guideline 404

Result : No skin irritation

Serious eye damage/eye irritation

Causes serious eye irritation.

Components:

2-Pyrrolidone:

Species : Rabbit

Result : Irritation to eyes, reversing within 7 days

Benzyl alcohol:

Species : Rabbit

Method : OECD Test Guideline 405

Result : Irritation to eyes, reversing within 21 days

Respiratory or skin sensitisation

Skin sensitisation

Not classified based on available information.

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

Benzyl alcohol:

Test Type : Maximisation Test
Exposure routes : Skin contact
Species : Guinea pig

Method : OECD Test Guideline 406

Result : negative

Spiramycin:

Test Type : Magnusson-Kligman-Test

Exposure routes : Skin contact Species : Guinea pig

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Result : Not a skin sensitizer.

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

Method: OECD Test Guideline 474

Result: negative

Benzyl alcohol:

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

Result: negative

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

cytogenetic assay) Species: Mouse

Application Route: Intraperitoneal injection

Result: negative

Spiramycin:

Genotoxicity in vitro : Test Type: In vitro mammalian cell gene mutation test

Test system: Chinese hamster ovary cells

Result: negative

Test Type: Cytogenetic assay

Test system: Chinese hamster ovary cells

Result: negative

Test Type: In vitro mammalian cell gene mutation test

Test system: Mouse Result: negative

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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

Benzyl alcohol:

Species : Mouse
Application Route : Ingestion
Exposure time : 103 weeks

Method : OECD Test Guideline 451

Result : negative

Spiramycin:

Species : Rat, male and female

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

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.

Benzyl alcohol:

Effects on fertility : Test Type: Fertility/early embryonic development

Species: Rat

Application Route: Ingestion

Result: negative

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Remarks: Based on data from similar materials

Effects on foetal develop-

ment

: Test Type: Embryo-foetal development

Species: Mouse

Application Route: Ingestion

Result: negative

Spiramycin:

Effects on fertility : Test Type: Fertility

Species: Rat, male

Target Organs: Reproductive organs

Result: alteration in sperm morphology, Effects on male re-

productive organs

Effects on foetal develop-

ment

Test Type: Embryo-foetal development

Species: Rabbit

Application Route: Oral

General Toxicity Maternal: 100 mg/kg body weight Developmental Toxicity: LOAEL: 200 mg/kg body weight Embryo-foetal toxicity: LOAEL: 200 mg/kg body weight

STOT - single exposure

Not classified based on available information.

STOT - repeated exposure

Not classified based on available information.

Repeated dose toxicity

Components:

2-Pyrrolidone:

Species : Rat
NOAEL : 207 mg/kg
Application Route : Ingestion
Exposure time : 3 Months

Method : OECD Test Guideline 408

Benzyl alcohol:

Species : Rat

NOAEL : 1,072 mg/l

Application Route : inhalation (dust/mist/fume)

Exposure time : 28 Days

Method : OECD Test Guideline 412

Spiramycin:

Species : Rat, male and female

NOAEL : 140 mg/kg
Application Route : Oral
Exposure time : 13 Weeks
Target Organs : Immune system

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Species : Rat, male and female

LOAEL : 5,6 mg/kg Application Route : Intravenous

Exposure time : 32 d

Target Organs : Central nervous system

Species : Dog, male and female

NOAEL : 75 mg/kg Application Route : Oral Exposure time : 2 yr

Target Organs : Kidney, male reproductive organs, optic nerve

Species : Dog, male and female

LOAEL : 169 mg/kg
Application Route : Intravenous
Exposure time : 4 Weeks

Number of exposures : 2 injections per day Target Organs : spleen, Kidney

Species : Dog, male and female

LOAEL : 50 mg/kg
Application Route : Intravenous
Exposure time : 4 Weeks

Target Organs : Central nervous system

Aspiration toxicity

Not classified based on available information.

11.2 Information on other hazards

Endocrine disrupting properties

Product:

Assessment : The substance/mixture does not contain components consid-

ered 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:

Spiramycin:

General Information : May cause

Symptoms: Nausea, Vomiting, Diarrhoea

Further information

Components:

Spiramycin:

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Remarks : No data available

SECTION 12: Ecological information

12.1 Toxicity

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

Benzyl alcohol:

Toxicity to fish : LC50 (Pimephales promelas (fathead minnow)): 460 mg/l

Exposure time: 96 h

Toxicity to daphnia and other:

aquatic invertebrates

EC50 (Daphnia magna (Water flea)): 230 mg/l

Exposure time: 48 h

Method: OECD Test Guideline 202

Toxicity to algae/aquatic

plants

EC50 (Pseudokirchneriella subcapitata (green algae)): 770

mg/l

Exposure time: 72 h

Method: OECD Test Guideline 201

NOEC (Pseudokirchneriella subcapitata (green algae)): 310

mg/l

Exposure time: 72 h

Method: OECD Test Guideline 201

Toxicity to daphnia and other : aquatic invertebrates (Chron-

ic toxicity)

NOEC: 51 mg/l Exposure time: 21 d

Species: Daphnia magna (Water flea) Method: OECD Test Guideline 211

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12.2 Persistence and degradability

Components:

2-Pyrrolidone:

Biodegradability : Result: Readily biodegradable.

Remarks: Based on data from similar materials

Benzyl alcohol:

Biodegradability : Result: Readily biodegradable.

Biodegradation: 92 - 96 %

Exposure time: 14 d

12.3 Bioaccumulative potential

Components:

2-Pyrrolidone:

Partition coefficient: n- : log Pow: -0,71

octanol/water Method: OECD Test Guideline 107

Benzyl alcohol:

Partition coefficient: n-

octanol/water

log Pow: 1,05

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 consid-

ered 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 13: Disposal considerations

13.1 Waste treatment methods

Product : Dispose of in accordance with local regulations.

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



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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 han-

dling 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 : Not regulated as a dangerous good
ADR : Not regulated as a dangerous good
RID : Not regulated as a dangerous good
IMDG : Not regulated as a dangerous good
IATA : Not regulated as a dangerous good

14.2 UN proper shipping name

ADN : Not regulated as a dangerous good
ADR : Not regulated as a dangerous good
RID : Not regulated as a dangerous good
IMDG : Not regulated as a dangerous good
IATA : Not regulated as a dangerous good

14.3 Transport hazard class(es)

ADN : Not regulated as a dangerous good
ADR : Not regulated as a dangerous good
RID : Not regulated as a dangerous good
IMDG : Not regulated as a dangerous good
IATA : Not regulated as a dangerous good

14.4 Packing group

ADN : Not regulated as a dangerous good
ADR : Not regulated as a dangerous good
RID : Not regulated as a dangerous good
IMDG : Not regulated as a dangerous good
IATA (Cargo) : Not regulated as a dangerous good
IATA (Passenger) : Not regulated as a dangerous good

14.5 Environmental hazards

Not regulated as a dangerous good

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



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14.6 Special precautions for user

Not applicable

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

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.

Not applicable

Not applicable

Not applicable

Not applicable

Not applicable

REACH - Candidate List of Substances of Very High

Concern for Authorisation (Article 59).

REACH - List of substances subject to authorisation

(Annex XIV)

Regulation (EC) No 1005/2009 on substances that de-

plete the ozone layer

Regulation (EU) 2019/1021 on persistent organic pollu-

tants (recast)

Regulation (EU) No 649/2012 of the European Parlia-

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.

Not applicable

Other regulations:

Note the Working Environment Act § 4-1 and § 4-2 on requirements for the employer to protect pregnant employees against discomfort and injury as a result of the work situation and the working environment.

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

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



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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.

H319 : Causes serious eye irritation.

H332 : Harmful if inhaled.

H360FD : May damage fertility. May damage the unborn child.

Full text of other abbreviations

Acute Tox. : Acute toxicity Eye Irrit. : Eye irritation

Repr. : Reproductive toxicity

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 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

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



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- United Nations; UNRTDG - United Nations Recommendations on the Transport of Dangerous Goods; vPvB - Very Persistent and Very Bioaccumulative

Further information

Sheet

Sources of key data used to compile the Safety Data

Internal technical data, data from raw material SDSs, OECD eChem Portal search results and European Chemicals Agen-

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

Classification of the mixture: Classification procedure:

Eye Irrit. 2 H319 Calculation method Repr. 1B H360FD Calculation method

The information provided in this Safety Data Sheet is correct to the best of our knowledge, information and belief at the date of its publication. The information is designed only as a guidance for safe handling, use, processing, storage, transportation, disposal and release and shall not be considered a warranty or quality specification of any type. The information provided relates only to the specific material identified at the top of this SDS and may not be valid when the SDS material is used in combination with any other materials or in any process, unless specified in the text. Material users should review the information and recommendations in the specific context of their 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