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

1.1 Product identifier

Trade name : Levamisole / Oxfendazole Selenised Formulation

Other means of identification : Scanda Selenised (A007368)

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

Use of the Sub- : Veterinary product

stance/Mixture

Recommended restrictions

on use

Not applicable

1.3 Details of the supplier of the safety data sheet

Company : MSD

Kilsheelan

Clonmel Tipperary, IE

Telephone : 353-51-601000

E-mail address of person

responsible for the SDS

: EHSDATASTEWARD@msd.com

1.4 Emergency telephone number

+1-908-423-6000

SECTION 2: Hazards identification

2.1 Classification of the substance or mixture

Classification (REGULATION (EC) No 1272/2008)

Acute toxicity, Category 4 H302: Harmful if swallowed.

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

unborn child.

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

aorv 1

Long-term (chronic) aquatic hazard, Cat-H411: Toxic to aquatic life with long lasting effects.

egory 2

2.2 Label elements

Labelling (REGULATION (EC) No 1272/2008)

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Hazard pictograms :







Signal word : Danger

Hazard statements : H302 Harmful if swallowed.

H360FD May damage fertility. May damage the unborn

child.

H410 Very toxic to aquatic life with long lasting effects.

Precautionary statements : Prevention:

P201 Obtain special instructions before use.

P270 Do not eat, drink or smoke when using this product.

P273 Avoid release to the environment.

P280 Wear protective gloves/ protective clothing/ eye protec-

tion/ face protection.

Response:

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

attention.

P391 Collect spillage.

Hazardous components which must be listed on the label:

levamisole hydrochloride

oxfendazole

Sodium selenate

EUH208 Contains Cobalt disodium ethylenediaminetetraacetate. May produce an allergic

reaction.

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

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



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Chemical name	CAS-No.	Classification	Concentration
- Crieffical Harris	EC-No.	Oldooniodion	(% w/w)
	Index-No.		,
	Registration number		
levamisole hydrochloride	16595-80-5	Acute Tox. 3; H301	>= 3 - < 10
	240-654-6	Repr. 2; H361d	
		STOT RE 2; H373	
		(Blood, Testis)	
		Aquatic Chronic 3; H412	
oxfendazole	53716-50-0	Repr. 1B; H360FD	>= 2,5 - < 10
	258-714-5	STOT RE 2; H373	_, _, _,
		(Liver, Testis)	
		Aquatic Acute 1;	
		H400	
		Aquatic Chronic 1;	
		H410	
		M-Factor (Acute	
		aquatic toxicity): 10	
		M-Factor (Chronic	
		aquatic toxicity): 1	
Citric acid	77-92-9	Eye Irrit. 2; H319	>= 1 - < 10
	201-069-1	STOT SE 3; H335	
	607-750-00-3		
Cobalt disodium ethylenediaminetet-	15137-09-4	Resp. Sens. 1B;	>= 0,25 - < 1
raacetate	239-198-0	H334	,
		Muta. 2; H341	
		Carc. 2; H351	
		Repr. 2; H361f	
		STOT RE 1; H372	
		(Respiratory Tract,	
		Thyroid, Heart,	
		Blood) Aquatic Chronic 1;	
		H410	
		M Footor (Character	
		M-Factor (Chronic	
Sodium selenate	13410-01-0	aquatic toxicity): 1 Acute Tox. 2; H300	>= 0,1 - < 0,25
Socialii Selellale	236-501-8	Acute Tox. 2, H300 Acute Tox. 2; H330	/= U, I - < U,25
	034-002-00-8	Skin Irrit. 2; H315	
	33. 332 33 0	STOT RE 1; H372	
		Aquatic Acute 1;	
		H400	
		Aquatic Chronic 1;	
		H410	
		M-Factor (Acute	
		IN-Factor (Acute	

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			aquatic toxicity): 1 M-Factor (Chronic aquatic toxicity): 1 Acute toxicity estimate	
			Acute oral toxicity: 5 mg/kg	

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 : Flush eyes with water as a precaution.

Get medical attention if irritation develops and persists.

If swallowed, DO NOT induce vomiting.

Get medical attention.

Rinse mouth thoroughly with water.

Never give anything by mouth to an unconscious person.

4.2 Most important symptoms and effects, both acute and delayed

Risks : Harmful if swallowed.

May damage fertility. May damage the unborn child.

May produce an allergic reaction.

4.3 Indication of any immediate medical attention and special treatment needed

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



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Treatment Treat symptomatically and supportively.

SECTION 5: Firefighting measures

5.1 Extinguishing media

Suitable extinguishing media : Water spray

> Alcohol-resistant foam Carbon dioxide (CO2)

Dry chemical

Unsuitable extinguishing

media

None known.

5.2 Special hazards arising from the substance or mixture

fighting

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

Hazardous combustion prod- : Carbon oxides

ucts

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

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

Retain and dispose of contaminated wash water.

Local authorities should be advised if significant spillages

cannot be contained.

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6.3 Methods and material for containment and cleaning up

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

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

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 mist or vapours.

Do not swallow.

Avoid contact with eyes.

Wash skin thoroughly after handling.

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

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.

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

Strong oxidizing agents

Self-reactive substances and mixtures

Organic peroxides

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
levamisole hydro- chloride	16595-80-5	TWA	20 μg/m3 (OEB 3)	Internal
	Further information: Skin			
		Wipe limit	200 μg/100 cm ²	Internal
oxfendazole	53716-50-0	TWA	40 μg/m3 (OEB 3)	Internal
		Wipe limit	400 μg/100 cm ²	Internal
Silicon, amorphous	112945-52-	TWA (respirable	1,5 mg/m3	FOR-2011-
	5	dust)	(Silica)	12-06-1358
Sodium selenate	13410-01-0	TWA	0,05 mg/m3	FOR-2011-
			(selenium)	12-06-1358
	Further information: Substances considered to evoke allergies when coming			
	into touch with the eyes or airways or evoking allergies after coming into con-			
	tact with the skin			
		TWA	20 μg/m3 (OEB 3)	Internal
		Wipe limit	200 μg/100 cm ²	Internal

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

Substance name	End Use	Exposure routes	Potential health effects	Value
Sodium selenate	Workers	Inhalation	Long-term systemic effects	0,12 mg/m3
	Workers	Skin contact	Long-term systemic effects	16,73 mg/kg bw/day
	Consumers	Inhalation	Long-term systemic effects	0,036 mg/m3
	Consumers	Skin contact	Long-term systemic effects	10,28 mg/kg bw/day
	Consumers	Ingestion	Long-term systemic effects	0,01028 mg/kg bw/day

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Cobalt disodium eth- ylenediaminetetraace- tate	Workers	Inhalation	Long-term systemic effects	0,349 mg/m3
	Workers	Skin contact	Long-term systemic effects	1 mg/kg bw/day
	Consumers	Inhalation	Long-term systemic effects	0,087 mg/m3
	Consumers	Skin contact	Long-term systemic effects	0,5 mg/kg bw/day
	Consumers	Ingestion	Long-term systemic effects	0,025 mg/kg bw/day

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

Substance name	Environmental Compartment	Value
Citric acid	Fresh water	0,44 mg/l
	Marine water	0,044 mg/l
	Sewage treatment plant	1000 mg/l
	Fresh water sediment	34,6 mg/kg dry
		weight (d.w.)
	Marine sediment	3,46 mg/kg dry
		weight (d.w.)
	Soil	33,1 mg/kg dry
		weight (d.w.)
Sodium selenate	Fresh water	6,38 µg/l
	Freshwater - intermittent	6,38 µg/l
	Marine water	4,09 µg/l
	Sewage treatment plant	10 mg/l
	Fresh water sediment	19,7 mg/kg dry
		weight (d.w.)
	Marine sediment	12,6 mg/kg dry
		weight (d.w.)
	Soil	0,47 mg/kg dry
		weight (d.w.)
	Oral (Secondary Poisoning)	2,39 mg/kg food
Cobalt disodium ethylenedia- minetetraacetate	Fresh water	0,1 mg/l
	Marine water	0,01 mg/l
	Fresh water sediment	0,758 mg/kg dry
		weight (d.w.)
	Marine sediment	0,0758 mg/kg dry
		weight (d.w.)
	Soil	0,5636 mg/kg dry
		weight (d.w.)

8.2 Exposure controls

Engineering measures

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

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

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

Minimize open handling.

Personal protective equipment

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

If the work environment or activity involves dusty conditions,

mists or aerosols, wear the appropriate goggles.

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

aerosols.

Hand protection

Material : Chemical-resistant gloves

Remarks : Consider double gloving.

Skin and body protection : Work uniform or laboratory coat.

Additional body garments should be used based upon the task being performed (e.g., sleevelets, apron, gauntlets, disposable

suits) to avoid exposed skin surfaces.

Use appropriate degowning techniques to remove potentially

contaminated clothing.

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

sure assessment demonstrates exposures outside the rec-

ommended guidelines, use respiratory protection.

Equipment should conform to NS EN 143

Filter type : Particulates type (P)

SECTION 9: Physical and chemical properties

9.1 Information on basic physical and chemical properties

Physical state : suspension

Colour : No data available

Odour : No data available

Odour Threshold : No data available

Melting point/freezing point : No data available

Initial boiling point and boiling

range

No data available

Flammability (solid, gas) : Not applicable

Flammability (liquids) : No data available

Upper explosion limit / Upper

flammability limit

No data available

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Lower explosion limit / Lower

flammability limit

No data available

Flash point : No data available

Auto-ignition temperature : No data available

Decomposition temperature : No data available

pH : No data available

Viscosity

Viscosity, kinematic : No data available

Solubility(ies)

Water solubility : No data available

Partition coefficient: n-

octanol/water

Not applicable

Vapour pressure : No data available

Relative density : No data available

Density : No data available

Relative vapour density : No data available

Particle characteristics

Particle size : Not applicable

9.2 Other information

Explosives : Not explosive

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

Evaporation rate : No data available

Molecular weight : No data available

SECTION 10: Stability and reactivity

10.1 Reactivity

Not classified as a reactivity hazard.

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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

Harmful if swallowed.

Product:

Acute oral toxicity : Acute toxicity estimate: 1.082 mg/kg

Method: Calculation method

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

Exposure time: 4 h

Test atmosphere: dust/mist Method: Calculation method

Components:

levamisole hydrochloride:

Acute oral toxicity : LD50 (Rat): 180 mg/kg

LD50 (Mouse): 223 mg/kg

LD50 (Rabbit): 458 mg/kg

Acute inhalation toxicity : Remarks: No data available

Acute dermal toxicity : Remarks: No data available

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oxfendazole:

Acute oral toxicity : LD50 (Rat): > 6.000 mg/kg

LD50 (Dog): 1.600 mg/kg

LD50 (sheep): 250 mg/kg

Citric acid:

Acute oral toxicity : LD50 (Mouse): 5.400 mg/kg

Acute dermal toxicity : LD50 (Rat): > 2.000 mg/kg

Method: OECD Test Guideline 402

Assessment: The substance or mixture has no acute dermal

toxicity

Cobalt disodium ethylenediaminetetraacetate:

Acute oral toxicity : LD50 (Rat): > 2.000 mg/kg

Remarks: Based on data from similar materials

Sodium selenate:

Acute oral toxicity : LD50 (Rat): > 5 - 50 mg/kg

Remarks: Based on data from similar materials

Acute inhalation toxicity : LC50 (Rat): > 0,052 - 0,51 mg/l

Exposure time: 4 h

Test atmosphere: dust/mist

Method: OECD Test Guideline 403

Skin corrosion/irritation

Not classified based on available information.

Components:

levamisole hydrochloride:

Remarks : No data available

oxfendazole:

Species : Rabbit

Result : No skin irritation

Citric acid:

Species : Rabbit

Method : OECD Test Guideline 404

Result : No skin irritation

Cobalt disodium ethylenediaminetetraacetate:

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Species : Rabbit

Method : OECD Test Guideline 404

Result : No skin irritation

Remarks : Based on data from similar materials

Sodium selenate:

Species : reconstructed human epidermis (RhE)

Method : OECD Test Guideline 431

Species : reconstructed human epidermis (RhE)

Method : OECD Test Guideline 439

Result : Skin irritation

Serious eye damage/eye irritation

Not classified based on available information.

Components:

levamisole hydrochloride:

Remarks : No data available

oxfendazole:

Species : Rabbit

Result : No eye irritation

Citric acid:

Species : Rabbit

Method : OECD Test Guideline 405

Result : Irritation to eyes, reversing within 21 days

Cobalt disodium ethylenediaminetetraacetate:

Species : Rabbit

Result : No eye irritation

Remarks : Based on data from similar materials

Sodium selenate:

Species : Bovine cornea

Method : OECD Test Guideline 437

Result : No eye irritation

Respiratory or skin sensitisation

Skin sensitisation

Not classified based on available information.

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Respiratory sensitisation

Not classified based on available information.

Components:

levamisole hydrochloride:

Remarks : No data available

Cobalt disodium ethylenediaminetetraacetate:

Exposure routes : inhalation (dust/mist/fume)

Species : Humans Result : positive

Remarks : Based on data from similar materials

Assessment : Probability or evidence of low to moderate respiratory sensiti-

sation rate in humans

Germ cell mutagenicity

Not classified based on available information.

Components:

levamisole hydrochloride:

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

Result: negative

Test Type: Chromosome aberration test in vitro

Result: negative

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

Citric acid:

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

Result: negative

Test Type: in vitro micronucleus test

Result: positive

Test Type: Bacterial reverse mutation assay (AMES)

Result: negative

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Genotoxicity in vivo : Test Type: Mutagenicity (in vivo mammalian bone-marrow

cytogenetic test, chromosomal analysis)

Species: Rat

Application Route: Ingestion

Result: negative

Cobalt disodium ethylenediaminetetraacetate:

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

Method: OECD Test Guideline 471

Result: negative

Remarks: Based on data from similar materials

Test Type: In vitro mammalian cell gene mutation test

Method: OECD Test Guideline 476

Result: positive

Remarks: Based on data from similar materials

Test Type: Chromosome aberration test in vitro

Method: OECD Test Guideline 473

Result: positive

Remarks: Based on data from similar materials

Genotoxicity in vivo : Test Type: Micronucleus test

Species: Mouse

Application Route: Intraperitoneal injection

Result: positive

Remarks: Based on data from similar materials

Test Type: Mutagenicity (in vivo mammalian bone-marrow

cytogenetic test, chromosomal analysis)

Species: Mouse

Application Route: Ingestion

Result: positive

Remarks: Based on data from similar materials

Test Type: Rodent dominant lethal test (germ cell) (in vivo)

Species: Mouse

Application Route: Ingestion

Result: positive

Remarks: Based on data from similar materials

Germ cell mutagenicity- As-

sessment

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

genicity tests.

Remarks: Based on data from similar materials

Sodium selenate:

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

Carcinogenicity

Not classified based on available information.

Components:

levamisole hydrochloride:

Species : Mouse
Application Route : Oral
Exposure time : 2 Years

NOAEL : 80 mg/kg body weight

Remarks : No significant adverse effects were reported

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

NOAEL : 40 mg/kg body weight

Remarks : No significant adverse effects were reported

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

Cobalt disodium ethylenediaminetetraacetate:

Species : Rat

Application Route : inhalation (dust/mist/fume)

Exposure time : 105 weeks Result : positive

Remarks : Based on data from similar materials

Species : Mouse

Application Route : inhalation (dust/mist/fume)

Exposure time : 105 weeks
Result : positive

Remarks : Based on data from similar materials

Carcinogenicity - Assess- : Limited evidence of carcinogenicity in animal studies

ment Remarks: Based on data from similar materials

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



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Reproductive toxicity

May damage fertility. May damage the unborn child.

Components:

levamisole hydrochloride:

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

Species: Rat

Application Route: Oral

Result: No significant adverse effects were reported

Effects on foetal develop-

ment

Test Type: Embryo-foetal development

Species: Rat

Application Route: Oral

Developmental Toxicity: NOAEL: 20 mg/kg body weight

Result: Fetotoxicity

Test Type: Embryo-foetal development

Species: Rabbit Application Route: Oral

Developmental Toxicity: LOAEL: 40 mg/kg body weight

Result: Fetotoxicity

Reproductive toxicity - As-

sessment

Some evidence of adverse effects on development, based on

animal experiments.

oxfendazole:

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 develop-

ment

Test Type: Embryo-foetal development

Species: Rat

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



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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 - 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.

Citric acid:

Effects on foetal develop-

ment

Test Type: One-generation reproduction toxicity study

Species: Rat

Application Route: Ingestion

Result: negative

Cobalt disodium ethylenediaminetetraacetate:

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

Species: Rat

Application Route: Ingestion

Result: positive

Remarks: Based on data from similar materials

Test Type: Fertility/early embryonic development

Species: Mouse

Application Route: Ingestion

Result: positive

Remarks: Based on data from similar materials

Test Type: Fertility/early embryonic development

Species: Mouse

Application Route: inhalation (dust/mist/fume)

Result: positive

Remarks: Based on data from similar materials

Test Type: Fertility/early embryonic development

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



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Species: Rat

Application Route: inhalation (dust/mist/fume)

Result: positive

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: negative

Remarks: Based on data from similar materials

Reproductive toxicity - As-

sessment

Some evidence of adverse effects on sexual function and

fertility, based on animal experiments.

Remarks: Based on data from similar materials

Sodium selenate:

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

Species: Rat

Application Route: Ingestion

Result: negative

Remarks: Based on data from similar materials

Effects on foetal develop-

ment

Test Type: Embryo-foetal development

Species: Mouse

Application Route: Ingestion

Result: negative

Remarks: Based on data from similar materials

STOT - single exposure

Not classified based on available information.

Components:

Citric acid:

Assessment : May cause respiratory irritation.

STOT - repeated exposure

Not classified based on available information.

Components:

levamisole hydrochloride:

Target Organs : Blood, Testis

Assessment : May cause damage to organs through prolonged or repeated

exposure.

oxfendazole:

Exposure routes : Oral

Target Organs : Liver, Testis

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



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Assessment : May cause damage to organs through prolonged or repeated

exposure.

Cobalt disodium ethylenediaminetetraacetate:

Exposure routes : inhalation (dust/mist/fume)

Target Organs : Respiratory Tract

Assessment : Shown to produce significant health effects in animals at con-

centrations of 0.02 mg/l/6h/d or less.

Remarks : Based on data from similar materials

Exposure routes : Ingestion

Target Organs : Thyroid, Heart, Blood

Assessment : Shown to produce significant health effects in animals at con-

centrations of >10 to 100 mg/kg bw.

Remarks : Based on data from similar materials

Sodium selenate:

Exposure routes : Ingestion

Assessment : Shown to produce significant health effects in animals at con-

centrations of 10 mg/kg bw or less.

Repeated dose toxicity

Components:

levamisole hydrochloride:

Species : Rat
NOAEL : 2,5 mg/kg
Application Route : Oral
Exposure time : 18 Months
Target Organs : Testis

Species : Dog LOAEL : 20 mg/kg Application Route : Oral Exposure time : 18 Months Target Organs : Blood

Species : Dog LOAEL : 40 mg/kg Application Route : Oral Exposure time : 3 Months

oxfendazole:

Species : Rat
NOAEL : 11 mg/kg
Application Route : Oral
Exposure time : 2 Weeks

Target Organs : Blood, Liver, Testis

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



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Species : Rat
NOAEL : 3,8 mg/kg
Application Route : Oral
Exposure time : 3 Months
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

Citric acid:

Species : Rat

NOAEL : 4.000 mg/kg
LOAEL : 8.000 mg/kg
Application Route : Ingestion
Exposure time : 10 Days

Cobalt disodium ethylenediaminetetraacetate:

Species : Rat

LOAEL : > 10 mg/kg
Application Route : Ingestion
Exposure time : 90 Days

Remarks : Based on data from similar materials

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



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Species : Rat

LOAEL : < 0.01 mg/l

Application Route : inhalation (dust/mist/fume)

Exposure time : 13 Weeks

Method : OECD Test Guideline 413

Remarks : Based on data from similar materials

Species : Mouse LOAEL : < 0,01 mg/l

Application Route : inhalation (dust/mist/fume)

Exposure time : 13 Weeks

Method : OECD Test Guideline 413

Remarks : Based on data from similar materials

Sodium selenate:

Species : Rat
NOAEL : 0,4 mg/kg
Application Route : Ingestion
Exposure time : 13 Weeks

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:

levamisole hydrochloride:

Ingestion : Symptoms: Nausea, Vomiting, Headache, Dizziness, hypo-

tension

Cobalt disodium ethylenediaminetetraacetate:

Inhalation : Target Organs: Respiratory system

Remarks: Based on data from similar materials

Ingestion : Target Organs: Blood

Remarks: Based on data from similar materials

Target Organs: Heart Target Organs: Thyroid

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



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SECTION 12: Ecological information

12.1 Toxicity

Components:

levamisole hydrochloride:

Toxicity to fish : LC50 (Oryzias latipes (Japanese medaka)): 37,3 mg/l

Exposure time: 96 h

Method: OECD Test Guideline 203

Toxicity to daphnia and other :

aquatic invertebrates

EC50 (Daphnia magna (Water flea)): 64 mg/l

Exposure time: 48 h

Method: OECD Test Guideline 202

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

mq/l

Exposure time: 72 h

Method: OECD Test Guideline 201

M-Factor (Acute aquatic tox- :

icity)

10

Toxicity to daphnia and other :

aquatic invertebrates (Chron-

ic toxicity)

NOEC: 0,023 mg/l Exposure time: 21 d

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

M-Factor (Chronic aquatic

toxicity)

: 1

Citric acid:

Toxicity to fish : LC50 (Pimephales promelas (fathead minnow)): > 100 mg/l

Exposure time: 96 h

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



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Toxicity to daphnia and other :

aquatic invertebrates

EC50 (Daphnia magna (Water flea)): 1.535 mg/l

Exposure time: 24 h

Cobalt disodium ethylenediaminetetraacetate:

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/aguatic

plants

ErC50 (Raphidocelis subcapitata (freshwater green alga)): >

100 ma/l

Exposure time: 72 h

Method: OECD Test Guideline 201

Remarks: Based on data from similar materials

Toxicity to fish (Chronic tox-

icity)

EC10: > 1 mg/l

Exposure time: 34 d Species: Danio rerio (zebra fish)

Remarks: Based on data from similar materials

Toxicity to daphnia and other :

aquatic invertebrates (Chron-

ic toxicity)

EC10: > 0.01 - 0.1 mg/lExposure time: 28 d

Species: Hyalella azteca (Amphipod) Method: OECD Test Guideline 211

Remarks: Based on data from similar materials

M-Factor (Chronic aquatic

toxicity)

: 1

Sodium selenate:

LC50 (Pimephales promelas (fathead minnow)): > 1 - 10 mg/l Toxicity to fish

Exposure time: 96 h

Remarks: Based on data from similar materials

Toxicity to daphnia and other :

aquatic invertebrates

EC50 (Daphnia magna (Water flea)): > 1 - 10 mg/l

Exposure time: 48 h

Remarks: Based on data from similar materials

Toxicity to algae/aquatic

plants

ErC50 (Chlamydomonas reinhardtii (green algae)): 245 µg/l

Exposure time: 96 h

NOEC (Chlamydomonas reinhardtii (green algae)): 197 µg/l

Exposure time: 96 h

M-Factor (Acute aquatic tox- : 1

icity)

Toxicity to microorganisms EC10 (activated sludge): 590 mg/l

Exposure time: 3 h

Method: OECD Test Guideline 209

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



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Toxicity to fish (Chronic tox-

icity)

NOEC: > 0.01 - 0.1 mg/l

Exposure time: 258 d

Species: Lepomis macrochirus (Bluegill sunfish) Remarks: Based on data from similar materials

Toxicity to daphnia and other :

aquatic invertebrates (Chron-

ic toxicity)

NOEC: > 0,1 - 1 mg/lExposure time: 28 d

Remarks: Based on data from similar materials

M-Factor (Chronic aquatic

toxicity)

12.2 Persistence and degradability

Components:

oxfendazole:

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

Citric acid:

Biodegradability Result: Readily biodegradable.

Biodegradation: 97 % Exposure time: 28 d

Method: OECD Test Guideline 301B

12.3 Bioaccumulative potential

Components:

oxfendazole:

Partition coefficient: n-

log Pow: 1,95

octanol/water

Citric acid:

Partition coefficient: n-

log Pow: -1,72

octanol/water

Cobalt disodium ethylenediaminetetraacetate:

Partition coefficient: n-: log Pow: -3,86 Remarks: Calculation octanol/water

12.4 Mobility in soil

Components:

oxfendazole:

Distribution among environ- : log Koc: 3,2

mental compartments

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



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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.

12.7 Other adverse effects

No data available

SECTION 13: Disposal considerations

13.1 Waste treatment methods

Product : Dispose of in accordance with local regulations.

According to the European Waste Catalogue, Waste Codes

are not product specific, but application specific.

Waste codes should be assigned by the user, preferably in

discussion with the waste disposal authorities.

Do not dispose of waste into sewer.

Contaminated packaging : Empty containers should be taken to an approved waste 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 : UN 3082
ADR : UN 3082
RID : UN 3082
IMDG : UN 3082
IATA : UN 3082

14.2 UN proper shipping name

ADN : ENVIRONMENTALLY HAZARDOUS SUBSTANCE, LIQUID,

N.O.S.

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



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(oxfendazole, Cobalt disodium ethylenediaminetetraacetate)

ADR : ENVIRONMENTALLY HAZARDOUS SUBSTANCE, LIQUID,

N.O.S.

(oxfendazole, Cobalt disodium ethylenediaminetetraacetate)

RID : ENVIRONMENTALLY HAZARDOUS SUBSTANCE, LIQUID,

N.O.S.

(oxfendazole, Cobalt disodium ethylenediaminetetraacetate)

IMDG : ENVIRONMENTALLY HAZARDOUS SUBSTANCE, LIQUID,

N.O.S.

(oxfendazole, Cobalt disodium ethylenediaminetetraacetate)

IATA : Environmentally hazardous substance, liquid, n.o.s.

(oxfendazole, Cobalt disodium ethylenediaminetetraacetate)

14.3 Transport hazard class(es)

Class Subsidiary risks

 ADN
 : 9

 ADR
 : 9

 RID
 : 9

 IMDG
 : 9

 IATA
 : 9

14.4 Packing group

ADN

Packing group : III
Classification Code : M6
Hazard Identification Number : 90
Labels : 9

ADR

Packing group : III
Classification Code : M6
Hazard Identification Number : 90
Labels : 9
Tunnel restriction code : (-)

RID

Packing group : III
Classification Code : M6
Hazard Identification Number : 90
Labels : 9

IMDG

Packing group : III Labels : 9

EmS Code : F-A, S-F

IATA (Cargo)

Packing instruction (cargo : 964

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



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aircraft)

Packing instruction (LQ) : Y964
Packing group : III

Labels : Miscellaneous

IATA (Passenger)

Packing instruction (passen: 964

ger aircraft)

Packing instruction (LQ) : Y964
Packing group : III

Labels : Miscellaneous

14.5 Environmental hazards

ADN

Environmentally hazardous : yes

ADR

Environmentally hazardous : yes

RID

Environmentally hazardous : yes

IMDG

Marine pollutant : yes

IATA (Passenger)

Environmentally hazardous : yes

IATA (Cargo)

Environmentally hazardous : yes

14.6 Special precautions for user

The transport classification(s) provided herein are for informational purposes only, and solely based upon the properties of the unpackaged material as it is described within this Safety Data Sheet. Transportation classifications may vary by mode of transportation, package sizes, and variations in regional or country regulations.

14.7 Maritime transport in bulk according to IMO instruments

Remarks : Not applicable for product as supplied.

SECTION 15: Regulatory information

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

REACH - Restrictions on the manufacture, placing on the market and use of certain dangerous substances, mixtures and articles (Annex XVII) Conditions of restriction for the following entries should be considered: Number on list 3

Number on list 75: If you intend to use this product as tattoo ink, please contact your vendor.

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



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> 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

REACH - Candidate List of Substances of Very High

Concern for Authorisation (Article 59).

REACH - List of substances subject to authorisation Not applicable

(Annex XIV)

Regulation (EC) on substances that deplete the ozone

laver

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.

Quantity 1 Quantity 2

E1 **ENVIRONMENTAL**

HAZARDS

100 t 200 t

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

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.

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



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Full text of H-Statements

H300 : Fatal if swallowed.
H301 : Toxic if swallowed.
H315 : Causes skin irritation.

H319 : Causes serious eye irritation.

H330 : Fatal if inhaled.

H334 : May cause allergy or asthma symptoms or breathing difficul-

ties if inhaled.

H335 : May cause respiratory irritation.
H341 : Suspected of causing genetic defects.

H351 : Suspected of causing cancer.

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

H361d : Suspected of damaging the unborn child.

H361f : Suspected of damaging fertility.

H372 : Causes damage to organs through prolonged or repeated

exposure.

H373 : May cause damage to organs through prolonged or repeated

exposure.

H373 : May cause damage to organs through prolonged or repeated

exposure if swallowed.

H400 : Very toxic to aquatic life.

H410 : Very toxic to aquatic life with long lasting effects.
H412 : Harmful to aquatic life with long lasting effects.

Full text of other abbreviations

Acute Tox. : Acute toxicity

Aquatic Acute : Short-term (acute) aquatic hazard
Aquatic Chronic : Long-term (chronic) aquatic hazard

Carc. : Carcinogenicity
Eye Irrit. : Eye irritation

Muta. : Germ cell mutagenicity
Repr. : Reproductive toxicity
Resp. Sens. : Respiratory sensitisation

Skin Irrit. : Skin irritation

STOT RE : Specific target organ toxicity - repeated exposure STOT SE : Specific target organ toxicity - single exposure

FOR-2011-12-06-1358 : Norway. Occupational Exposure limits

FOR-2011-12-06-1358 / : Long term exposure limit

TWA

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 car-

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



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rying Dangerous Chemicals in Bulk; IC50 - Half maximal inhibitory concentration; ICAO - International Civil Aviation Organization; IECSC - Inventory of Existing Chemical Substances in China; IMDG - International Maritime Dangerous Goods; IMO - International Maritime Organization; ISHL - Industrial Safety and Health Law (Japan); ISO - International Organisation for Standardization; KECI - Korea Existing Chemicals Inventory; LC50 - Lethal Concentration to 50 % of a test population; LD50 - Lethal Dose to 50% of a test population (Median Lethal Dose); MARPOL - International Convention for the Prevention of Pollution from Ships; n.o.s. - Not Otherwise Specified; NO(A)EC - No Observed (Adverse) Effect Concentration; NO(A)EL - No Observed (Adverse) Effect Level; NOELR - No Observable Effect Loading Rate; NZIoC - New Zealand Inventory of Chemicals; OECD - Organization for Economic Co-operation and Development; OPPTS - Office of Chemical Safety and Pollution Prevention; PBT - Persistent, Bioaccumulative and Toxic substance; PICCS - Philippines Inventory of Chemicals and Chemical Substances; (Q)SAR - (Quantitative) Structure Activity Relationship; REACH - Regulation (EC) No 1907/2006 of the European Parliament and of the Council concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals; RID - Regulations concerning the International Carriage of Dangerous Goods by Rail; SADT - Self-Accelerating Decomposition Temperature; SDS - Safety Data Sheet; SVHC - Substance of very high concern; TCSI - Taiwan Chemical Substance Inventory; TECI -Thailand Existing Chemicals Inventory; TSCA - Toxic Substances Control Act (United States); UN - United Nations; UNRTDG - United Nations Recommendations on the Transport of Dangerous Goods; vPvB - Very Persistent and Very Bioaccumulative

Further information

Sources of key data used to compile the Safety Data Sheet

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

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

Classification of the mixture:

Classification procedure:

Acute Tox. 4 H302 Calculation method Repr. 1B H360FD Calculation method Aquatic Acute 1 H400 Calculation method Aquatic Chronic 2 H411 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