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

1.1 Product identifier

Trade name : Multine B12 Selenised Formulation

Other means of identification : Multine B12 Selenised (A011766)

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)

Long-term (chronic) aquatic hazard, Category 3

H412: Harmful to aquatic life with long lasting ef-

fects.

2.2 Label elements

Labelling (REGULATION (EC) No 1272/2008)

Hazard statements : H412 Harmful to aquatic life with long lasting effects.

Precautionary statements : Prevention:

P273 Avoid release to the environment.

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



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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 Antigen	CAS-No. EC-No. Index-No. Registration number Not Assigned	Classification	Concentration (% w/w) >= 20 - < 30
Sodium selenate	13410-01-0 236-501-8 034-002-00-8	Acute Tox. 2; H300 Acute Tox. 2; H330 Skin Irrit. 2; H315 STOT RE 1; H372 Aquatic Acute 1; H400 Aquatic Chronic 1; H410 M-Factor (Acute aquatic toxicity): 1 M-Factor (Chronic aquatic toxicity): 1 Acute toxicity estimate Acute oral toxicity: 5 mg/kg	>= 0.1 - < 0.25
Acetatocobalamin	22465-48-1 245-019-7	STOT RE 2; H373 (Kidney, Liver)	>= 0.1 - < 1
Thiomersal	54-64-8 200-210-4 080-004-00-7	Acute Tox. 2; H300 Acute Tox. 2; H330 Acute Tox. 1; H310 Repr. 1B; H360	>= 0.0025 - < 0.025

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			STOT RE 1; H372 (Central nervous system, Cardiovascular system, Gastrointestinal tract, Kidney) Aquatic Acute 1; H400 Aquatic Chronic 1; H410
			M-Factor (Acute aquatic toxicity): 10 M-Factor (Chronic aquatic toxicity): 10
			specific concentration limit STOT RE 2; H373 >= 0.1 %
			Acute toxicity estimate
			Acute oral toxicity: 10 mg/kg Acute inhalation toxicity (dust/mist): 0.1 mg/l Acute dermal toxicity:
Eor o	volanation of abbrevia	ations see section 16	10 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 if symptoms occur.

In case of skin contact : Wash with water and soap as a precaution.

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Get medical attention if symptoms occur.

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 if symptoms occur. Rinse mouth thoroughly with water.

4.2 Most important symptoms and effects, both acute and delayed

None known.

4.3 Indication of any immediate medical attention and special treatment needed

Treatment : Treat symptomatically and supportively.

SECTION 5: Firefighting measures

5.1 Extinguishing media

Suitable extinguishing media : Water spray

Alcohol-resistant foam Carbon dioxide (CO2)

Dry chemical

Unsuitable extinguishing

media

None known.

5.2 Special hazards arising from the substance or mixture

Specific hazards during fire-

fighting

Exposure to combustion products may be a hazard to health.

Hazardous combustion prod: :

ucts

Carbon oxides Metal oxides Sulphur oxides

5.3 Advice for firefighters

Special protective equipment:

for firefighters

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

Use personal protective equipment.

Specific extinguishing 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.

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



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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.

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-

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 Use only with adequate ventilation. Advice on safe handling Avoid inhalation of vapour or mist.

Do not swallow.

Avoid contact with eyes.

Avoid prolonged or repeated contact with skin.

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

sessment

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,

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



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appropriate degowning and decontamination procedures, industrial hygiene monitoring, medical surveillance and the

use of administrative controls.

7.2 Conditions for safe storage, including any incompatibilities

Requirements for storage areas and containers

: Keep in properly labelled containers. Store in accordance with

the particular national regulations.

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

Strong oxidizing agents

Gases

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
Aluminium potas- sium sulfate do- decahydrate	7784-24-9	OELV - 8 hrs (TWA)	2 mg/m3 (Aluminium)	IE OEL
Sodium selenate	13410-01-0	OELV - 8 hrs (TWA)	0.1 mg/m3 (selenium)	IE OEL
		TWA	20 μg/m3 (OEB 3)	Internal
		Wipe limit	200 μg/100 cm ²	Internal
Acetatocobalamin	22465-48-1	OELV - 8 hrs (TWA)	0.02 mg/m3 (Cobalt)	IE OEL
	Further inform	nation: Chemical age	ents which following exposure	e may cause
	sensitisation of the respiratory tract and lead to asthma, rhinitis or extrinsic allergic alveolitis, Carc 1B - Substances presumed to have carcinogenic potential for humans, Repr 1B - Substances which are presumed human reproductive toxicants			or extrinsic
				cinogenic po-
				human repro-
		TWA	10 μg/m3 (OEB 3)	Internal
		Wipe limit	100 μg/100 cm ²	Internal
Thiomersal	54-64-8	OELV - 8 hrs (TWA)	0.01 mg/m3 (Mercury)	IE OEL
	Further information: Substances which have the capacity to penetrate intact skin when they come in contact with it, and be absorbed into the body			netrate intact
		OELV - 15 min	0.03 mg/m3	IE OEL
		(STEL)	(Mercury)	
	Further information: Substances which have the capacity to penetrate intact skin when they come in contact with it, and be absorbed into the body			

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

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Substance name	End Use	Exposure routes	Potential health effects	Value
Aluminium potassium sulfate dodecahydrate	Workers	Inhalation	Long-term systemic effects	13.05 mg/m3
	Consumers	Ingestion	Long-term systemic effects	15.54 mg/kg bw/day
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

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

Substance name	Environmental Compartment	Value
Aluminium potassium sulfate	Fresh water	0.112 mg/l
dodecahydrate		
	Freshwater - intermittent	1.1 mg/l
	Marine water	0.011 mg/l
	Sewage treatment plant	63 mg/l
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

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.

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

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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, dis-

posable 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 I.S. EN 143

Filter type : Particulates type (P)

SECTION 9: Physical and chemical properties

9.1 Information on basic physical and chemical properties

Physical state : Aqueous solution

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

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

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pH : No data available

Viscosity

Viscosity, kinematic : No data available

Solubility(ies)

Water solubility : No data available

Partition coefficient: n-

octanol/water

Not applicable

Vapour pressure : No data available

Relative density : No data available

Density : No data available

Relative vapour density : No data available

Particle characteristics

Particle size : Not applicable

9.2 Other information

Explosives : Not explosive

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

Evaporation rate : No data available

Molecular weight : No data available

SECTION 10: Stability and reactivity

10.1 Reactivity

Not classified as a reactivity hazard.

10.2 Chemical stability

Stable under normal conditions.

10.3 Possibility of hazardous reactions

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

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10.6 Hazardous decomposition products

No hazardous decomposition products are known.

SECTION 11: Toxicological information

11.1 Information on hazard classes as defined in Regulation (EC) No 1272/2008

Information on likely routes of:

exposure

Inhalation Skin contact

Ingestion Eye contact

Acute toxicity

Not classified based on available information.

Product:

Acute oral toxicity : Acute toxicity estimate: > 2,000 mg/kg

Method: Calculation method

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

Exposure time: 4 h

Test atmosphere: dust/mist Method: Calculation method

Components:

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

Acetatocobalamin:

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

Acute toxicity (other routes of :

administration)

LD50 (Mouse): > 2,000 mg/kg Application Route: Intravenous

LDLo (Mouse): 1.4 mg/kg

Application Route: Intraperitoneal

LDLo (Mouse): 2.7 mg/kg Application Route: Intravenous

Thiomersal:

Acute oral toxicity : LD50 (Rat): 75 mg/kg

Acute toxicity estimate: 10 mg/kg

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Method: Expert judgement

Remarks: Based on national or regional regulation.

Acute inhalation toxicity : Acute toxicity estimate: 0.1 mg/l

Exposure time: 4 h

Test atmosphere: dust/mist Method: Expert judgement

Remarks: Based on national or regional regulation.

Acute dermal toxicity : Acute toxicity estimate: 10 mg/kg

Method: Expert judgement

Remarks: Based on national or regional regulation.

Skin corrosion/irritation

Not classified based on available information.

Components:

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

Acetatocobalamin:

Remarks : No data available

Serious eye damage/eye irritation

Not classified based on available information.

Components:

Sodium selenate:

Species : Bovine cornea

Method : OECD Test Guideline 437

Result : No eye irritation

Acetatocobalamin:

Remarks : No data available

Respiratory or skin sensitisation

Skin sensitisation

Not classified based on available information.

Respiratory sensitisation

Not classified based on available information.

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Components:

Acetatocobalamin:

Remarks : No data available

Germ cell mutagenicity

Not classified based on available information.

Components:

Sodium selenate:

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

Method: OECD Test Guideline 471

Result: negative

Remarks: Based on data from similar materials

Acetatocobalamin:

Genotoxicity in vitro : Test Type: Mutagenicity (Escherichia coli - reverse mutation

assay)

Result: negative

Test Type: Ames test

Test system: Salmonella typhimurium

Result: negative

Test Type: Mutagenicity (Salmonella typhimurium - reverse

mutation assay) Result: negative

Thiomersal:

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

Result: negative

Genotoxicity in vivo : Test Type: Mammalian spermatogonial chromosome aberra-

tion test (in vivo) Species: Mouse

Application Route: Ingestion

Result: negative

Carcinogenicity

Not classified based on available information.

Components:

Thiomersal:

Species : Rat
Exposure time : 1 Years
Result : negative

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Reproductive toxicity

Not classified based on available information.

Components:

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

Thiomersal:

Effects on foetal develop-

ment

Species: Rat

Application Route: Ingestion

Result: positive

Remarks: Based on data from similar materials

Reproductive toxicity - As-

sessment

Clear evidence of adverse effects on sexual function and fertil-

ity, and/or on development, based on animal experiments

STOT - single exposure

Not classified based on available information.

STOT - repeated exposure

Not classified based on available information.

Components:

Sodium selenate:

Exposure routes : Ingestion

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

centrations of 10 mg/kg bw or less.

Acetatocobalamin:

Target Organs : Kidney, Liver

Assessment : May cause damage to organs through prolonged or repeated

exposure.

Thiomersal:

Target Organs : Central nervous system, Cardio-vascular system, Gastrointes-

tinal tract, Kidney

Assessment : Causes damage to organs through prolonged or repeated

exposure.

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Repeated dose toxicity

Components:

Sodium selenate:

Species : Rat

NOAEL : 0.4 mg/kg

Application Route : Ingestion

Exposure time : 13 Weeks

Acetatocobalamin:

Species : Dog
LOAEL : 300 mg/kg
Application Route : Oral
Number of exposures : 3 days
Target Organs : Kidney, Liver

Symptoms : kidney effects, liver function change Remarks : May cause damage to organs.

Species: DogLOAEL: 75 mg/kgApplication Route: IntravenousNumber of exposures: 4 weeksTarget Organs: Kidney, Liver

Remarks : May cause damage to organs.

Thiomersal:

Species : Rat

LOAEL : >= 0.5 mg/kg
Application Route : Ingestion

Remarks : Based on data from similar materials

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.

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Experience with human exposure

Components:

Acetatocobalamin:

General Information Symptoms: asthenia, Dizziness, Headache, Nausea, sinusitis

Remarks: The most common side effects are:

SECTION 12: Ecological information

12.1 Toxicity

Components:

Sodium selenate:

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

Exposure time: 96 h

Remarks: Based on data from similar materials

aquatic invertebrates

Toxicity to daphnia and other : 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- :

icity)

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

Exposure time: 3 h

Method: OECD Test Guideline 209

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)

: 1

Thiomersal:

LC50 (Poecilia reticulata (guppy)): > 0.01 - 0.1 mg/l Toxicity to fish

Exposure time: 96 h

Remarks: Based on data from similar materials

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Toxicity to daphnia and other:

aquatic invertebrates

EC50 (Daphnia magna (Water flea)): > 0.01 - 0.1 mg/l

Exposure time: 48 h

Remarks: Based on data from similar materials

Toxicity to algae/aquatic

plants

: EC50 (Pseudokirchneriella subcapitata (green algae)): > 0.01

- 0.1 mg/l

Exposure time: 96 h

Remarks: Based on data from similar materials

M-Factor (Acute aquatic tox- :

icity)

10

Toxicity to daphnia and other : aquatic invertebrates (Chron-

ic toxicity)

NOEC: > 0.001 - 0.01 mg/l Exposure time: 21 d

Species: Daphnia sp. (water flea)

Remarks: Based on data from similar materials

M-Factor (Chronic aquatic : 10

toxicity)

12.2 Persistence and degradability

No data available

12.3 Bioaccumulative potential

No data available

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.

12.7 Other adverse effects

No data available

SECTION 13: Disposal considerations

13.1 Waste treatment methods

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



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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 : 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

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



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14.5 Environmental hazards

Not regulated as a dangerous good

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)

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Conditions of restriction for the following entries should be considered: Number on list 3

Number on list 18: Thiomersal

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

Substance(s) or mixture(s) are listed here according to their appearance in the regulation, irrespective of their use/purpose or the conditions of the restriction. Please refer to the conditions in corresponding Regulation to determine whether an entry is applicable to the placing on the market or

Not applicable

REACH - Candidate List of Substances of Very High Concern for Authorisation (Article 59).

Regulation (EC) on substances that deplete the ozone

layer

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

tants (recast)

Regulation (EU) No 649/2012 of the European Parliament and the Council concerning the export and import

of dangerous chemicals

REACH - List of substances subject to authorisation

(Annex XIV)

Not applicable

Not applicable

Not applicable

Not applicable

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:

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



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Take note of Directive 92/85/EEC regarding maternity protection or stricter national regulations, where applicable.

The components of this product are reported in the following inventories:

AICS : not determined

DSL : not determined

IECSC : not determined

15.2 Chemical safety assessment

A Chemical Safety Assessment has not been carried out.

SECTION 16: Other information

Other information : Items where changes have been made to the previous version

are highlighted in the body of this document by two vertical

lines.

Full text of H-Statements

H300 : Fatal if swallowed.
H310 : Fatal in contact with skin.
H315 : Causes skin irritation.
H330 : Fatal if inhaled.

H360 : May damage fertility or the unborn child.

H372 : Causes damage to organs through prolonged or repeated

exposure.

H373 : May cause damage to organs through prolonged or repeated

exposure.

H400 : Very toxic to aquatic life.

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

Full text of other abbreviations

Acute Tox. : Acute toxicity

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

Repr. : Reproductive toxicity

Skin Irrit. : Skin irritation

STOT RE : Specific target organ toxicity - repeated exposure

IE OEL : Ireland. List of Chemical Agents and Carcinogens with Occu-

pational Exposure Limit Values - Code of Practice, Schedule 1

and 2

IE OEL / OELV - 8 hrs (TWA) : Occupational exposure limit value (8-hour reference period)
IE OEL / OELV - 15 min : Occupational exposure limit value (15-minute reference peri-

(STEL) od)

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 -

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



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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; TRGS - Technical Rule for Hazardous Substances; TSCA - Toxic Substances Control Act (United States); UN - United Nations; 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:

Aquatic Chronic 3 H412 Calculation method

Items where changes have been made to the previous version are highlighted in the body of this document by two vertical lines.

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

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