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

1.1 Product identifier

Trade name : Roche CARDIAC Control proBNP

Product code : 04890493190

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

Recommended restrictions on use : For professional users only.

1.3 Details of the supplier of the safety data sheet

Company : Roche Diagnostics Deutschland GmbH
-
Sandhoferstrasse 116
68305 Mannheim
Deutschland

Telephone : +496217590
Telefax : +496217592890
Responsible Department : +49(0)621-759-4223
E-mail address : info.dia-sds@roche.com

1.4 Emergency telephone number

In case of emergencies:	:	Central Works Security Roche Diagnostics GmbH	+49(0)621-759-2203
Centre for detoxification:	:	Mainz Munich	+49(0)6131-19240 +49(0)89-19240

SECTION 2: Hazards identification

2.1 Classification of the substance or mixture

The product is a kit consisting of individual ingredients. The classification of the ingredients can be obtained from section 3. Section Label elements contains the resulting labelling for the kit.

2.2 Label elements

Labelling (REGULATION (EC) No 1272/2008)

Hazard pictograms :

Signal word : Warning

Hazard statements	:	H317 May cause an allergic skin reaction. H412 Harmful to aquatic life with long lasting effects.
Precautionary statements	:	**Prevention:** P261 Avoid breathing dust. P273 Avoid release to the environment. P280 Wear protective gloves. **Response:** P333 + P313 If skin irritation or rash occurs: Get medical advice/ attention. P362 + P364 Take off contaminated clothing and wash it before reuse. **Disposal:** P501 Dispose of contents/ container to an approved waste disposal plant.

2.3 Other hazards

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

Ctr 1

Classification (REGULATION (EC) No 1272/2008)

Skin sensitisation, Category 1	H317: May cause an allergic skin reaction.
Long-term (chronic) aquatic hazard, Category 3	H412: Harmful to aquatic life with long lasting effects.

Components

Chemical name	CAS-No. EC-No. Index-No. Registration number	Classification	Concentration (% w/w)
2-methyl-2H-isothiazol-3-one hydrochloride	26172-54-3 247-499-3 01-2120764168-47	Acute Tox. 3; H301 Acute Tox. 2; H330 Acute Tox. 3; H311 Skin Corr. 1A; H314 Eye Dam. 1; H318 Skin Sens. 1A; H317 Aquatic Acute 1; H400	>= 0,25 - < 1,0

		Aquatic Chronic 1; H410 EUH071 M-Factor (Acute aquatic toxicity): 1 M-Factor (Chronic aquatic toxicity): 1 specific concentration limit Skin Sens. 1A; H317 >= 0,0015 % Acute toxicity estimate Acute oral toxicity: 175 mg/kg Acute inhalation toxicity (dust/mist): 0,11 mg/l Acute dermal toxicity: 246 mg/kg	

For explanation of abbreviations see section 16.

Ctr 2

Classification (REGULATION (EC) No 1272/2008)

Skin sensitisation, Category 1	H317: May cause an allergic skin reaction.
Long-term (chronic) aquatic hazard, Category 3	H412: Harmful to aquatic life with long lasting effects.

Components

Chemical name	CAS-No. EC-No. Index-No. Registration number	Classification	Concentration (% w/w)
2-methyl-2H-isothiazol-3-one hydrochloride	26172-54-3 247-499-3 01-2120764168-47	Acute Tox. 3; H301 Acute Tox. 2; H330 Acute Tox. 3; H311 Skin Corr. 1A; H314 Eye Dam. 1; H318 Skin Sens. 1A; H317 Aquatic Acute 1; H400 Aquatic Chronic 1; H410	>= 0,25 - < 1,0

		EUH071 M-Factor (Acute aquatic toxicity): 1 M-Factor (Chronic aquatic toxicity): 1 specific concentration limit Skin Sens. 1A; H317 >= 0,0015 % Acute toxicity esti-mate Acute oral toxicity: 175 mg/kg Acute inhalation tox-icity (dust/mist): 0,11 mg/l Acute dermal toxicity: 246 mg/kg	

For explanation of abbreviations see section 16.

SECTION 4: First aid measures

4.1 Description of first aid measures

General advice : Move out of dangerous area.
Show this safety data sheet to the doctor in attendance.
Do not leave the victim unattended.

If inhaled : Move to fresh air.
If unconscious, place in recovery position and seek medical advice.
If symptoms persist, call a physician.

In case of skin contact : If on skin, rinse well with water.

In case of eye contact : Immediately flush eye(s) with plenty of water.
Remove contact lenses.
Protect unharmed eye.
Keep eye wide open while rinsing.
If eye irritation persists, consult a specialist.

If swallowed : Keep respiratory tract clear.
Do not give milk or alcoholic beverages.
Never give anything by mouth to an unconscious person.
If symptoms persist, call a physician.
Rinse mouth 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 : The first aid procedure should be established in consultation with the doctor responsible for industrial medicine.

SECTION 5: Firefighting measures

5.1 Extinguishing media

Suitable extinguishing media : Use extinguishing measures that are appropriate to local circumstances and the surrounding environment.

Unsuitable extinguishing media : High volume water jet

5.2 Special hazards arising from the substance or mixture

Specific hazards during fire-fighting : Do not allow run-off from fire fighting to enter drains or water courses.

5.3 Advice for firefighters

Special protective equipment for firefighters : Wear self-contained breathing apparatus for firefighting if necessary.

Further information : Collect contaminated fire extinguishing water separately. This must not be discharged into drains.
Fire residues and contaminated fire extinguishing water must be disposed of in accordance with local regulations.

SECTION 6: Accidental release measures

6.1 Personal precautions, protective equipment and emergency procedures

Personal precautions : Use personal protective equipment.
Avoid dust formation.
Avoid breathing dust.

6.2 Environmental precautions

Environmental precautions : Prevent product from entering drains.
Prevent further leakage or spillage if safe to do so.

6.3 Methods and material for containment and cleaning up

Methods for cleaning up : Keep in suitable, closed containers for disposal.

6.4 Reference to other sections

Treat recovered material as described in the section "Disposal considerations".

SECTION 7: Handling and storage

7.1 Precautions for safe handling

Advice on safe handling	:	Avoid formation of respirable particles. Do not breathe vapours/dust. Avoid exposure - obtain special instructions before use. Avoid contact with skin and eyes. For personal protection see section 8. Smoking, eating and drinking should be prohibited in the application area. Dispose of rinse water in accordance with local and national regulations. Persons susceptible to skin sensitisation problems or asthma, allergies, chronic or recurrent respiratory disease should not be employed in any process in which this mixture is being used.
Advice on protection against fire and explosion	:	Avoid dust formation. Provide appropriate exhaust ventilation at places where dust is formed.
Hygiene measures	:	Wash hands before breaks and at the end of workday.

7.2 Conditions for safe storage, including any incompatibilities

Requirements for storage areas and containers	:	Keep container tightly closed in a dry and well-ventilated place. Containers which are opened must be carefully resealed and kept upright to prevent leakage. Electrical installations / working materials must comply with the technological safety standards.
Further information on storage conditions	:	See label, package insert or internal guidelines
Storage class (TRGS 510)	:	11, Combustible Solids
Further information on storage stability	:	No decomposition if stored and applied as directed.

7.3 Specific end use(s)

Specific use(s)	:	Laboratory chemicals

SECTION 8: Exposure controls/personal protection

8.1 Control parameters

Ctr 1

Contains no substances with occupational exposure limit values.

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

Substance name	End Use	Exposure routes	Potential health effects	Value
Dipotassium hydrogen phosphate 3 hydrate	Workers	Inhalation	Long-term systemic effects	4,07 mg/m3
	Consumers	Inhalation	Long-term systemic effects	3,04 mg/m3

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

Substance name	Environmental Compartment	Value
Dipotassium hydrogen phosphate 3 hydrate	Fresh water	0,05 mg/l
	Marine water	0,005 mg/l
	Intermittent use/release	0,5 mg/l
	Sewage treatment plant	100 mg/l

Ctr 2

Contains no substances with occupational exposure limit values.

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

Substance name	End Use	Exposure routes	Potential health effects	Value
Dipotassium hydrogen phosphate 3 hydrate	Workers	Inhalation	Long-term systemic effects	4,07 mg/m3
	Consumers	Inhalation	Long-term systemic effects	3,04 mg/m3

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

Substance name	Environmental Compartment	Value
Dipotassium hydrogen phosphate 3 hydrate	Fresh water	0,05 mg/l
	Marine water	0,005 mg/l
	Intermittent use/release	0,5 mg/l
	Sewage treatment plant	100 mg/l

8.2 Exposure controls

Engineering measures

No data available

Personal protective equipment

Eye protection : Eye wash bottle with pure water
Tightly fitting safety goggles

Use eye protection according to EN 166.

Hand protection

In case of contact through splashing:

Material : Nitrile rubber
Break through time : > 30 min
Glove thickness : > 0,11 mm

		In case of full contact:
Material	:	butyl-rubber
Break through time	:	> 480 min
Glove thickness	:	> 0,4 mm
Remarks	:	The selected protective gloves have to satisfy the specifications of Regulation (EU) 2016/425 and the standard EN 374 derived from it. This recommendation is only valid for the product mentioned in the safety data sheet and provided by us and for the application specified by us. Please observe the instructions regarding permeability and breakthrough time which are provided by the supplier of the gloves. Also take into consideration the specific local conditions under which the product is used, such as the danger of cuts, abrasion, and the contact time. The suitability for a specific workplace should be discussed with the producers of the protective gloves.
Skin and body protection	:	Choose body protection according to the amount and concentration of the dangerous substance at the work place.

SECTION 9: Physical and chemical properties

9.1 Information on basic physical and chemical properties

Ctr 1

Physical state	:	(lyophilised)
Colour	:	white light yellow
Odour	:	none
Odour Threshold	:	Not applicable
Melting point/range	:	No data available
Boiling point/boiling range	:	No data available
Flammability	:	Sustains combustion
Upper explosion limit / Upper flammability limit	:	No data available
Lower explosion limit / Lower flammability limit	:	No data available
Flash point	:	does not flash
Auto-ignition temperature	:	No data available
Decomposition temperature	:	No data available

pH	:	6,9 - 7,1 (25 °C) (as aqueous solution)
Viscosity		
Viscosity, dynamic	:	Not applicable
Viscosity, kinematic	:	Not applicable
Solubility(ies)		
Water solubility	:	completely soluble
Solubility in other solvents	:	No data available
Partition coefficient: n-octanol/water	:	No data available
Vapour pressure	:	No data available
Relative density	:	No data available
Relative vapour density	:	Not applicable

Ctr 2

Physical state	:	(lyophilised)
Colour	:	white light yellow
Odour	:	none
Odour Threshold	:	Not applicable
Melting point/range	:	No data available
Boiling point/boiling range	:	No data available
Flammability	:	Sustains combustion
Upper explosion limit / Upper flammability limit	:	No data available
Lower explosion limit / Lower flammability limit	:	No data available
Flash point		does not flash
Auto-ignition temperature	:	No data available
Decomposition temperature	:	No data available
pH	:	6,9 - 7,1 (25 °C)

(as aqueous solution)

Viscosity
Viscosity, dynamic : Not applicable

Viscosity, kinematic : Not applicable

Solubility(ies)
Water solubility : completely soluble

Solubility in other solvents : No data available

Partition coefficient: n-octanol/water : No data available

Vapour pressure : No data available

Relative density : No data available

Relative vapour density : Not applicable

9.2 Other information

Ctr 1

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

Flammability (liquids) : Sustains combustion

Self-ignition : No data available

Evaporation rate : No data available

Ctr 2

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

Flammability (liquids) : Sustains combustion

Self-ignition : No data available

Evaporation rate : No data available

SECTION 10: Stability and reactivity

10.1 Reactivity

No dangerous reaction known under conditions of normal use.

10.2 Chemical stability

Stable under normal conditions.

10.3 Possibility of hazardous reactions

Hazardous reactions : No dangerous reaction known under conditions of normal use.

No decomposition if stored and applied as directed.

10.4 Conditions to avoid

Conditions to avoid : Exposure to moisture

10.5 Incompatible materials

Materials to avoid : Strong oxidizing agents

10.6 Hazardous decomposition products

No decomposition if stored and applied as directed.

SECTION 11: Toxicological information

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

Ctr 1

Acute toxicity

Not classified based on available information.

Components:

2-methyl-2H-isothiazol-3-one hydrochloride:

Acute oral toxicity : LD50 Oral (Rat, female): 175 mg/kg
Method: OECD Test Guideline 425

Acute toxicity estimate: 175 mg/kg
Method: Calculation method

Acute inhalation toxicity : LC50 (Rat, male and female): 0,11 mg/l
Exposure time: 4 h
Test atmosphere: dust/mist
Method: OECD Test Guideline 403
Assessment: Corrosive to the respiratory tract.
Remarks: Based on data from similar materials

Acute toxicity estimate: 0,11 mg/l
Test atmosphere: dust/mist
Method: Calculation method

Acute dermal toxicity	:	LD50 Dermal (Rat, male): 246 mg/kg Method: OECD Test Guideline 402 Remarks: Based on data from similar materials Acute toxicity estimate: 246 mg/kg Method: Calculation method

Skin corrosion/irritation

Not classified based on available information.

Components:

2-methyl-2H-isothiazol-3-one hydrochloride:

Species	:	reconstructed human epidermis (RhE)
Method	:	OECD Test Guideline 431
Result	:	Causes severe burns.

Serious eye damage/eye irritation

Not classified based on available information.

Components:

2-methyl-2H-isothiazol-3-one hydrochloride:

Result	:	Risk of serious damage to eyes.

Respiratory or skin sensitisation

Skin sensitisation

May cause an allergic skin reaction.

Respiratory sensitisation

Not classified based on available information.

Components:

2-methyl-2H-isothiazol-3-one hydrochloride:

Test Type	:	Local lymph node assay (LLNA)
Method	:	OECD Test Guideline 429
Result	:	The product is a skin sensitiser, sub-category 1A.
Test Type	:	Maximisation Test
Species	:	Guinea pig
Method	:	OECD Test Guideline 406
Result	:	positive
Remarks	:	Based on data from similar materials

Germ cell mutagenicity

Not classified based on available information.

Components:

2-methyl-2H-isothiazol-3-one hydrochloride:

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

Metabolic activation: with and without metabolic activation
Method: OECD Test Guideline 471
Result: negative

Test Type: In vitro mammalian cell gene mutation test
Test system: Chinese hamster ovary cells
Method: OECD Test Guideline 476
Result: negative

Genotoxicity in vivo : Test Type: Micronucleus test
Species: Mouse (male and female)
Application Route: Oral
Method: OECD Test Guideline 474
Result: negative

Test Type: unscheduled DNA synthesis assay
Species: Rat (male and female)
Application Route: Oral
Method: OECD Test Guideline 486
Result: negative

Carcinogenicity

Not classified based on available information.

Reproductive toxicity

Not classified based on available information.

Components:

2-methyl-2H-isothiazol-3-one hydrochloride:

Effects on foetal development : Species: Rat
Application Route: Oral
Dose: 40 mg/kg bw/day
Result: No effects on foetal development

STOT - single exposure

Not classified based on available information.

STOT - repeated exposure

Not classified based on available information.

Repeated dose toxicity

Components:

2-methyl-2H-isothiazol-3-one hydrochloride:

Species : Rat
NOEL : 94 mg/kg bw/day
Application Route : Oral
Exposure time : 90 d
Method : OECD Test Guideline 408
Remarks : No significant adverse effects were reported
No human information is available.

Species : Dog

NOAEL	:	40,9 mg/kg bw/day
Application Route	:	Oral
Exposure time	:	90 d
Method	:	OECD Test Guideline 409

Aspiration toxicity

Not classified based on available information.

Ctr 2

Acute toxicity

Not classified based on available information.

Components:

2-methyl-2H-isothiazol-3-one hydrochloride:

Acute oral toxicity	:	LD50 Oral (Rat, female): 175 mg/kg Method: OECD Test Guideline 425 Acute toxicity estimate: 175 mg/kg Method: Calculation method
Acute inhalation toxicity	:	LC50 (Rat, male and female): 0,11 mg/l Exposure time: 4 h Test atmosphere: dust/mist Method: OECD Test Guideline 403 Assessment: Corrosive to the respiratory tract. Remarks: Based on data from similar materials Acute toxicity estimate: 0,11 mg/l Test atmosphere: dust/mist Method: Calculation method
Acute dermal toxicity	:	LD50 Dermal (Rat, male): 246 mg/kg Method: OECD Test Guideline 402 Remarks: Based on data from similar materials Acute toxicity estimate: 246 mg/kg Method: Calculation method

Skin corrosion/irritation

Not classified based on available information.

Components:

2-methyl-2H-isothiazol-3-one hydrochloride:

Species	:	reconstructed human epidermis (RhE)
Method	:	OECD Test Guideline 431
Result	:	Causes severe burns.

Serious eye damage/eye irritation

Not classified based on available information.

Components:

2-methyl-2H-isothiazol-3-one hydrochloride:

Result : Risk of serious damage to eyes.

Respiratory or skin sensitisation

Skin sensitisation

May cause an allergic skin reaction.

Respiratory sensitisation

Not classified based on available information.

Components:

2-methyl-2H-isothiazol-3-one hydrochloride:

Test Type : Local lymph node assay (LLNA)
Method : OECD Test Guideline 429
Result : The product is a skin sensitiser, sub-category 1A.

Test Type : Maximisation Test
Species : Guinea pig
Method : OECD Test Guideline 406
Result : positive
Remarks : Based on data from similar materials

Germ cell mutagenicity

Not classified based on available information.

Components:

2-methyl-2H-isothiazol-3-one hydrochloride:

Genotoxicity in vitro : Test Type: Microbial mutagenesis assay (Ames test)
Test system: Salmonella typhimurium
Metabolic activation: with and without metabolic activation
Method: OECD Test Guideline 471
Result: negative

Test Type: In vitro mammalian cell gene mutation test
Test system: Chinese hamster ovary cells
Method: OECD Test Guideline 476
Result: negative

Genotoxicity in vivo : Test Type: Micronucleus test
Species: Mouse (male and female)
Application Route: Oral
Method: OECD Test Guideline 474
Result: negative

Test Type: unscheduled DNA synthesis assay
Species: Rat (male and female)
Application Route: Oral
Method: OECD Test Guideline 486
Result: negative

Carcinogenicity

Not classified based on available information.

Reproductive toxicity

Not classified based on available information.

Components:

2-methyl-2H-isothiazol-3-one hydrochloride:

Effects on foetal development	:	Species: Rat Application Route: Oral Dose: 40 mg/kg bw/day Result: No effects on foetal development

STOT - single exposure

Not classified based on available information.

STOT - repeated exposure

Not classified based on available information.

Repeated dose toxicity

Components:

2-methyl-2H-isothiazol-3-one hydrochloride:

Species	:	Rat
NOEL	:	94 mg/kg bw/day
Application Route	:	Oral
Exposure time	:	90 d
Method	:	OECD Test Guideline 408
Remarks	:	No significant adverse effects were reported No human information is available.
Species	:	Dog
NOAEL	:	40,9 mg/kg bw/day
Application Route	:	Oral
Exposure time	:	90 d
Method	:	OECD Test Guideline 409

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 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.

Ctr 1

Endocrine disrupting properties

Product:

Assessment : 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.

Ctr 2

Endocrine disrupting properties

Product:

Assessment : 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 12: Ecological information

12.1 Toxicity

Ctr 1

Components:

2-methyl-2H-isothiazol-3-one hydrochloride:

Toxicity to fish : LC50 (Oncorhynchus mykiss (rainbow trout)): 4,77 mg/l
Exposure time: 96 h
Test Type: flow-through test
Method: OECD Test Guideline 203

Toxicity to daphnia and other aquatic invertebrates : EC50 (Daphnia magna (Water flea)): 2,33 mg/l
Exposure time: 48 h
Test Type: static test
Method: OECD Test Guideline 202

Toxicity to algae/aquatic plants : ErC50 (Pseudokirchneriella subcapitata (green algae)): 0,289 mg/l
Exposure time: 72 h
Test Type: static test
Method: OECD Test Guideline 201

M-Factor (Acute aquatic toxicity) : 1

Toxicity to daphnia and other aquatic invertebrates (Chronic toxicity) : NOEC: 0,0442 mg/l
Exposure time: 21 d
Species: Daphnia magna (Water flea)
Method: OECD Test Guideline 211

M-Factor (Chronic aquatic toxicity) : 1

Ctr 2

Components:

2-methyl-2H-isothiazol-3-one hydrochloride:

Toxicity to fish : LC50 (Oncorhynchus mykiss (rainbow trout)): 4,77 mg/l
Exposure time: 96 h
Test Type: flow-through test
Method: OECD Test Guideline 203

Toxicity to daphnia and other aquatic invertebrates : EC50 (Daphnia magna (Water flea)): 2,33 mg/l
Exposure time: 48 h
Test Type: static test
Method: OECD Test Guideline 202

Toxicity to algae/aquatic plants : ErC50 (Pseudokirchneriella subcapitata (green algae)): 0,289 mg/l
Exposure time: 72 h
Test Type: static test
Method: OECD Test Guideline 201

M-Factor (Acute aquatic toxicity) : 1

Toxicity to daphnia and other aquatic invertebrates (Chronic toxicity) : NOEC: 0,0442 mg/l
Exposure time: 21 d
Species: Daphnia magna (Water flea)
Method: OECD Test Guideline 211

M-Factor (Chronic aquatic toxicity) : 1

12.2 Persistence and degradability

Ctr 1

Components:

2-methyl-2H-isothiazol-3-one hydrochloride:

Biodegradability : Test Type: aerobic
Result: Not readily biodegradable.
Biodegradation: 0 %
Exposure time: 28 d
Method: OECD Test Guideline 301B

Ctr 2

Components:

2-methyl-2H-isothiazol-3-one hydrochloride:

Biodegradability : Test Type: aerobic

Result: Not readily biodegradable.
Biodegradation: 0 %
Exposure time: 28 d
Method: OECD Test Guideline 301B

12.3 Bioaccumulative potential

Ctr 1

Components:

2-methyl-2H-isothiazol-3-one hydrochloride:

Bioaccumulation	:	Remarks: No bioaccumulation is to be expected (log Pow <= 4).
Partition coefficient: n-octanol/water	:	log Pow: ca. -0,44 (20 °C) Method: OECD Test Guideline 107

Ctr 2

Components:

2-methyl-2H-isothiazol-3-one hydrochloride:

Bioaccumulation	:	Remarks: No bioaccumulation is to be expected (log Pow <= 4).
Partition coefficient: n-octanol/water	:	log Pow: ca. -0,44 (20 °C) Method: OECD Test Guideline 107

12.4 Mobility in soil

Ctr 1

No data available

Ctr 2

No data available

12.5 Results of PBT and vPvB assessment

Ctr 1

Not relevant

Ctr 2

Not relevant

12.6 Endocrine disrupting properties

Product:

Assessment	:	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.

Ctr 1

Product:

Assessment : 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.

Ctr 2

Assessment : 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.

12.7 Other adverse effects

Ctr 1

No data available

Ctr 2

No data available

SECTION 13: Disposal considerations

13.1 Waste treatment methods

Product : The product should not be allowed to enter drains, water courses or the soil.
Do not contaminate ponds, waterways or ditches with chemical or used container.
Send to a licensed waste management company.
Can be disposed as waste water, when in compliance with local regulations.

Contaminated packaging : Empty remaining contents.
Dispose of as unused product.
Empty containers should be taken to an approved waste handling site for recycling or disposal.
Do not re-use empty containers.

SECTION 14: Transport information

14.1 UN number or ID number

Not regulated as a dangerous good

14.2 UN proper shipping name

Not regulated as a dangerous good

14.3 Transport hazard class(es)

Not regulated as a dangerous good

14.4 Packing group

Not regulated as a dangerous good

14.5 Environmental hazards

Not regulated as a dangerous good

14.6 Special precautions for user

Remarks : Not dangerous goods in the meaning of ADR/RID, ADN, IMDG-Code, ICAO/IATA-DGR

14.7 Maritime transport in bulk according to IMO instruments

Remarks : Not applicable

SECTION 15: Regulatory information

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

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

Water hazard class (Germany) : WGK 2 obviously hazardous to water

Ctr 1

REACH - Restrictions on the manufacture, placing on the market and use of certain dangerous substances, preparations and articles (Annex XVII) : Not applicable

REACH - Candidate List of Substances of Very High Concern for Authorisation (Article 59). : Not applicable

Regulation (EC) No 1005/2009 on substances that deplete the ozone layer : Not applicable

Regulation (EU) 2019/1021 on persistent organic pollutants (recast) : Not applicable

Regulation (EC) No 649/2012 of the European Parliament and the Council concerning the export and import of dangerous chemicals : Not applicable

REACH - List of substances subject to authorisation (Annex XIV) : Not applicable

Other regulations:

Take note of Directive 94/33/EC on the protection of young people at work or stricter national regulations, where applicable.

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

AIIC	:	Not in compliance with the inventory
DSL	:	This product contains the following components that are not on the Canadian DSL nor NDSL. Animal serum /-plasma /- hemolysate - different species, ly-ophilized hydroxyl-2-pyridone
NZIoC	:	Not in compliance with the inventory
ENCS	:	Not in compliance with the inventory
ISHL	:	Not in compliance with the inventory
KECI	:	Not in compliance with the inventory
PICCS	:	Not in compliance with the inventory
IECSC	:	Not in compliance with the inventory
TCSI	:	Not in compliance with the inventory
TSCA	:	Product contains substance(s) not listed on TSCA inventory.
TECI	:	Not in compliance with the inventory
Volatile organic compounds	:	Directive 2010/75/EU of 24 November 2010 on industrial emissions (integrated pollution prevention and control) Not applicable

Labelling (REGULATION (EC) No 1272/2008)

Hazard pictograms	:	
Signal word	:	Warning
Hazard statements	:	H317 May cause an allergic skin reaction. H412 Harmful to aquatic life with long lasting effects.
Precautionary statements	:	**Prevention:** P261 Avoid breathing dust. P273 Avoid release to the environment.

P280 Wear protective gloves.

Response:

P333 + P313 If skin irritation or rash occurs: Get medical advice/ attention.
P362 + P364 Take off contaminated clothing and wash it before reuse.

Disposal:

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

Hazardous components which must be listed on the label:

26172-54-3 2-methyl-2H-isothiazol-3-one hydrochloride

Ctr 2

REACH - Restrictions on the manufacture, placing on the market and use of certain dangerous substances, preparations and articles (Annex XVII)	:	Not applicable
REACH - Candidate List of Substances of Very High Concern for Authorisation (Article 59).	:	Not applicable
Regulation (EC) No 1005/2009 on substances that deplete the ozone layer	:	Not applicable
Regulation (EU) 2019/1021 on persistent organic pollutants (recast)	:	Not applicable
Regulation (EC) No 649/2012 of the European Parliament and the Council concerning the export and import of dangerous chemicals	:	Not applicable
REACH - List of substances subject to authorisation (Annex XIV)	:	Not applicable

Other regulations:

Take note of Directive 94/33/EC on the protection of young people at work or stricter national regulations, where applicable.

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

AIIC	:	Not in compliance with the inventory
DSL	:	This product contains the following components that are not on the Canadian DSL nor NDSL. Animal serum /-plasma /- hemolysate - different species, lyophilized

hydroxyl-2-pyridone

NZIoC	:	Not in compliance with the inventory
ENCS	:	Not in compliance with the inventory
ISHL	:	Not in compliance with the inventory
KECI	:	Not in compliance with the inventory
PICCS	:	Not in compliance with the inventory
IECSC	:	Not in compliance with the inventory
TCSI	:	Not in compliance with the inventory
TSCA	:	Product contains substance(s) not listed on TSCA inventory.
TECI	:	Not in compliance with the inventory
Volatile organic compounds	:	Directive 2010/75/EU of 24 November 2010 on industrial emissions (integrated pollution prevention and control) Not applicable

Labelling (REGULATION (EC) No 1272/2008)

Hazard pictograms :

Signal word : Warning

Hazard statements :
H317 May cause an allergic skin reaction.
H412 Harmful to aquatic life with long lasting effects.

Precautionary statements :

Prevention:

P261 Avoid breathing dust.
P273 Avoid release to the environment.
P280 Wear protective gloves.

Response:

P333 + P313 If skin irritation or rash occurs: Get medical advice/ attention.
P362 + P364 Take off contaminated clothing and wash it before reuse.

Disposal:

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

Hazardous components which must be listed on the label:

26172-54-3	2-methyl-2H-isothiazol-3-one hydrochloride

15.2 Chemical safety assessment

Chemical Safety Assessments for all substances in this product are either Complete or Not applicable.

SECTION 16: Other information

Full text of H-Statements

H301	:	Toxic if swallowed.
H311	:	Toxic in contact with skin.
H314	:	Causes severe skin burns and eye damage.
H317	:	May cause an allergic skin reaction.
H318	:	Causes serious eye damage.
H330	:	Fatal if inhaled.
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
Eye Dam.	:	Serious eye damage
Skin Corr.	:	Skin corrosion
Skin Sens.	:	Skin sensitisation

ADN - European Agreement concerning the International Carriage of Dangerous Goods by Inland Waterways; ADR - European 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; TRGS - Technical Rule for Hazardous Substances; TSCA - Toxic Substances Control Act (United States); UN - United Nations; vPvB - Very Persistent and Very Bioaccumulative

Further information

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 given is designed only as a guidance for safe handling, use, processing, storage, transportation, disposal and release and is not to be considered a warranty or quality specification. The information relates only to the specific material designated and may not be valid for such material used in combination with any other materials or in any process, unless specified in the text.

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