

SAFETY DATA SHEET

according to Regulation (EC) No. 1907/2006



CARDIAC POC Troponin T Control

Version
4.0

Revision Date:
17.02.2022

Date of last issue: 21.08.2021
Date of first issue: 09.10.2013

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

1.1 Product identifier

Trade name : CARDIAC POC Troponin T Control
Product code : 07912218190

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 +49(0)621-759-2203
Roche Diagnostics GmbH
Centre for detoxification: : Mainz +49(0)6131-19240

SECTION 2: Hazards identification

2.1 Classification of the substance or mixture

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.

2.2 Label elements

Labelling (REGULATION (EC) No 1272/2008)

Hazard pictograms :



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| | | |
|--------------------------|---|---|
| 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

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

Chemical nature : Handle as potentially infectious.

Components

| Chemical name | CAS-No. EC-No. Index-No. Registration number | Classification | Concentration (% w/w) |
|-------------------------|---|--------------------|--------------------------|
| Citric acid monohydrate | 5949-29-1 201-069-1 01-2119457026-42 | Eye Irrit. 2; H319 | >= 1,0 - < 10,0 |

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| | | | |
|--|---|--|-----------------|
| 2-methyl-2H-isothiazol-3-one hydrochloride | 26172-54-3 247-499-3 01-2120764168-47 | <p>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 EUH071</p> <hr/> <p>M-Factor (Acute aquatic toxicity): 1 M-Factor (Chronic aquatic toxicity): 1</p> <hr/> <p>specific concentration limit Skin Sens. 1A; H317 >= 0,0015 %</p> <hr/> <p>Acute toxicity estimate</p> <p>Acute oral toxicity: 175 mg/kg Acute inhalation toxicity (dust/mist): 0,11 mg/l Acute dermal toxicity: 246 mg/kg</p> | >= 0,25 - < 1,0 |
|--|---|--|-----------------|

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.

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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

Risks : May cause an allergic skin reaction.

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.

Hazardous combustion products : Gaseous hydrogen chloride (HCl).
Sodium oxides
Carbon oxides

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.

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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) : 13, Non 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

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SECTION 8: Exposure controls/personal protection

8.1 Control parameters

Occupational Exposure Limits

| Components | CAS-No. | Value type (Form of exposure) | Control parameters | Basis |
|--|-----------|-------------------------------|---------------------|-------------|
| Citric acid monohydrate | 5949-29-1 | AGW (Inhalable fraction) | 2 mg/m ³ | DE TRGS 900 |
| Peak-limit: excursion factor (category): 2;(l) | | | | |
| Further information: When there is compliance with the OEL and biological tolerance values, there is no risk of harming the unborn child | | | | |

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

| Substance name | Environmental Compartment | Value |
|-------------------------|---------------------------|-------------|
| Citric acid monohydrate | Fresh water | 0,44 mg/l |
| | Marine water | 0,044 mg/l |
| | Fresh water sediment | 7,52 mg/kg |
| | Marine sediment | 0,752 mg/kg |
| | Soil | 29,2 mg/kg |

8.2 Exposure controls

Engineering measures

No data available

Personal protective equipment

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

Hand protection
Material : Protective gloves

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

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| | | |
|--|---|--------------------------------|
| Physical state | : | solid |
| Colour | : | white, beige |
| Odour | : | none |
| Odour Threshold | : | No data available |
| Melting point/range | : | No data available |
| Boiling point/boiling range | : | No data available |
| 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 | : | 6,0 |
| Viscosity | | |
| Viscosity, dynamic | : | No data available |
| Viscosity, kinematic | : | No data available |
| Solubility(ies) | | |
| Water solubility | : | 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 |
| Density | : | 1,56 g/cm ³ (20 °C) |
| Relative vapour density | : | No data available |

9.2 Other information

| | | |
|----------------------|---|--|
| Explosives | : | No data available |
| Oxidizing properties | : | The substance or mixture is not classified as oxidizing. |
| Self-ignition | : | No data available |

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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 decomposition if stored and applied as directed.

10.4 Conditions to avoid

Conditions to avoid : No data available

10.5 Incompatible materials

Materials to avoid : No data available

10.6 Hazardous decomposition products

No data available

SECTION 11: Toxicological information

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

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

Acute dermal toxicity : Acute toxicity estimate: > 2.000 mg/kg
Method: Calculation method

Components:

Citric acid monohydrate:

Acute oral toxicity : LD50 Oral (Mouse): 5.400 mg/kg
Method: OECD Test Guideline 401

LD50 Oral (Rat): 3.000 mg/kg

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Remarks: anhydrous substance

Acute dermal toxicity : LD50 Dermal (Rat): > 2.000 mg/kg
Method: OECD Test Guideline 402

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
The value is given in analogy to the following substances: 2-methylisothiazol-3(2H)-one

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
The value is given in analogy to the following substances: 2-methylisothiazol-3(2H)-one

Acute toxicity estimate: 246 mg/kg
Method: Calculation method

Skin corrosion/irritation

Not classified based on available information.

Product:

Remarks : May cause skin irritation and/or dermatitis.

Components:

Citric acid monohydrate:

Species : Rabbit
Method : OECD Test Guideline 404
Result : No skin irritation

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

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

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Serious eye damage/eye irritation

Not classified based on available information.

Product:

Remarks : Product dust may be irritating to eyes, skin and respiratory system.

Components:

Citric acid monohydrate:

Method : OECD Test Guideline 405
Result : Irritating to eyes.

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.

Product:

Remarks : Causes sensitisation.

Components:

Citric acid monohydrate:

Assessment : Did not cause sensitisation on laboratory animals.

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.
The value is given in analogy to the following substances: 2-methylisothiazol-3(2H)-one

Test Type : Maximisation Test
Species : Guinea pig
Method : OECD Test Guideline 406
Result : positive
Remarks : Based on data from similar materials
The value is given in analogy to the following substances: 2-methylisothiazol-3(2H)-one

Germ cell mutagenicity

Not classified based on available information.

Components:

Citric acid monohydrate:

Genotoxicity in vitro : Test Type: reverse mutation assay

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

Test Type: Microbial mutagenesis assay (Ames test)
Test system: Salmonella typhimurium
Result: negative
Remarks: Based on data from similar materials

Genotoxicity in vivo : Test Type: Chromosome aberration test in vitro
Species: Rat
Cell type: Bone marrow
Method: OECD Test Guideline 475
Result: negative

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
The value is given in analogy to the following substances: 2-methylisothiazol-3(2H)-one

Genotoxicity in vivo : Test Type: Micronucleus test
Species: Mouse (male and female)
Application Route: Oral
Method: OECD Test Guideline 474
Result: negative
The value is given in analogy to the following substances: 2-methylisothiazol-3(2H)-one

Test Type: unscheduled DNA synthesis assay
Species: Rat (male and female)
Application Route: Oral
Method: OECD Test Guideline 486
Result: negative
The value is given in analogy to the following substances: 2-methylisothiazol-3(2H)-one

Carcinogenicity

Not classified based on available information.

Reproductive toxicity

Not classified based on available information.

Components:

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

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Effects on foetal development : Species: Rat
Application Route: Oral
Dose: 40 mg/kg bw/day
Result: No effects on foetal development
The value is given in analogy to the following substances: 2-methylisothiazol-3(2H)-one

STOT - single exposure

Not classified based on available information.

STOT - repeated exposure

Not classified based on available information.

Repeated dose toxicity

Components:

Citric acid monohydrate:

Species : Rat
NOAEL : 1.200 mg/kg
Application Route : Oral

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.

The value is given in analogy to the following substances: 2-methylisothiazol-3(2H)-one

Species : Dog
NOAEL : 40,9 mg/kg bw/day
Application Route : Oral
Exposure time : 90 d
Method : OECD Test Guideline 409
The value is given in analogy to the following substances: 2-methylisothiazol-3(2H)-one

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.

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SECTION 12: Ecological information

12.1 Toxicity

Components:

Citric acid monohydrate:

- Toxicity to fish : LC50 (*Leuciscus idus* (Golden orfe)): 440 mg/l
Exposure time: 48 h
Test Type: static test
Method: OECD Test Guideline 203
- Toxicity to daphnia and other aquatic invertebrates : EC50 (*Daphnia magna* (Water flea)): 120 mg/l
Exposure time: 72 h
Remarks: anhydrous substance
- LC50 (*Daphnia magna* (Water flea)): 1.535 mg/l
Exposure time: 24 h
Test Type: static test
- Toxicity to algae/aquatic plants : IC50 (*Microcystis aeruginosa* (blue-green algae)): > 80 mg/l
Exposure time: 8 d
Remarks: No toxicity at the limit of solubility
- Toxicity to microorganisms : EC50 (*Pseudomonas putida*): > 10.000 mg/l
Exposure time: 16 h

Ecotoxicology Assessment

- Acute aquatic toxicity : This product has no known ecotoxicological effects.
- Chronic aquatic toxicity : This product has no known ecotoxicological effects.
- Toxicity Data on Soil : Not expected to adsorb on soil.
- Other organisms relevant to the environment : No data available

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
The value is given in analogy to the following substances: 2-methylisothiazol-3(2H)-one
- 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

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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
The value is given in analogy to the following substances: 2-methylisothiazol-3(2H)-one

M-Factor (Chronic aquatic toxicity) : 1

12.2 Persistence and degradability

Components:

Citric acid monohydrate:

Biodegradability : Result: Readily biodegradable.
Biodegradation: 97 %
Exposure time: 28 d
Method: OECD Test Guideline 301B
Remarks: Expected to be ultimately biodegradable

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

Components:

Citric acid monohydrate:

Bioaccumulation : Remarks: Due to the distribution coefficient n-octanol/water, accumulation in organisms is not expected.

Partition coefficient: n-octanol/water : log Pow: -1,72 (20 °C)
Method: OECD Test Guideline 117
Remarks: anhydrous substance

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

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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 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

Product:

Additional ecological information : An environmental hazard cannot be excluded in the event of unprofessional handling or disposal.
Harmful to aquatic life with long lasting effects.

SECTION 13: Disposal considerations

13.1 Waste treatment methods

Product : Special treatment as infectious material is mandatory in compliance with local regulations (disinfection and incineration).
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

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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

REACH - Restrictions on the manufacture, placing on the market and use of certain dangerous substances, mixtures 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

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
Classification according to AwSV, Annex 1 (5.2)

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- TA Luft List (Germany) : Total dust:
Not applicable
Inorganic substances in powdered form:
Not applicable
Inorganic substances in vapour or gaseous form:
Not applicable
Organic Substances:
portion Class 1: 1,38 %
- Carcinogenic substances:
Not applicable
Mutagenic:
Not applicable
Toxic to reproduction:
Not applicable
- Volatile organic compounds : Directive 2010/75/EU of 24 November 2010 on industrial emissions (integrated pollution prevention and control)
Not applicable

Other regulations:

Take note of Law on the protection of mothers at work, in education and in studies (Maternity Protection Act - MuSchG).

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.

Human serum /-plasma / -hemolysate, lyophilized
hydroxyl-2-pyridone
Troponin T
- 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.

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TECI : Not in compliance with the inventory

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.
H319 : Causes serious eye irritation.
H330 : Fatal if inhaled.
H400 : Very toxic to aquatic life.
H410 : Very toxic to aquatic life with long lasting effects.
EUH071 : Corrosive to the respiratory tract.

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
Eye Irrit. : Eye irritation
Skin Corr. : Skin corrosion
Skin Sens. : Skin sensitisation
DE TRGS 900 : Germany. TRGS 900 - Occupational exposure limit values.
DE TRGS 900 / AGW : Time Weighted Average

ADN - European Agreement concerning the International Carriage of Dangerous Goods by Inland Waterways; ADR - Agreement concerning the International Carriage of Dangerous Goods by Road; AIIC - Australian Inventory of Industrial Chemicals; ASTM - American Society for the Testing of Materials; bw - Body weight; CLP - Classification Labelling Packaging Regulation; Regulation (EC) No 1272/2008; CMR - Carcinogen, Mutagen or Reproductive Toxicant; DIN - Standard of the German Institute for Standardisation; DSL - Domestic Substances List (Canada); ECHA - European Chemicals Agency; EC-Number - European Community number; ECx - Concentration associated with x% response; ELx - Loading rate associated with x% response; EmS - Emergency Schedule; ENCS - Existing and New Chemical Substances (Japan); ErCx - Concentration associated with x% growth rate response; GHS - Globally Harmonized System; GLP - Good Laboratory Practice; IARC - International Agency for Research on Cancer; IATA - International Air Transport Association; IBC - International Code for the Construction and Equipment of Ships carrying Dangerous Chemicals in Bulk; IC50 - Half maximal inhibitory concentration; ICAO - International Civil Aviation Organization; IECSC - Inventory of Existing Chemical Substances in China; IMDG - International Maritime Dangerous Goods; IMO - International Maritime Organization; ISHL - Industrial Safety and Health Law (Japan); ISO - International Organisation for Standardization; KECI - Korea Existing Chemicals Inventory; LC50 - Lethal Concentration to 50 % of a test population; LD50 - Lethal Dose to 50% of a test population (Median Lethal Dose); MARPOL - International Convention for the Prevention of Pollution from Ships; n.o.s. - Not Otherwise Specified; NO(A)EC - No Observed (Adverse) Effect Concentration; NO(A)EL - No Observed (Adverse) Effect Level; NOELR - No Observable Effect Loading Rate; NZIoC - New Zealand Inventory of Chemicals; OECD - Organization for Economic Co-operation and Development; OPPTS - Office of Chemical Safety and Pollution Prevention; PBT - Persistent, Bioaccumulative and Toxic sub-

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stance; 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; TECL - 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

Classification of the mixture:

| | |
|-------------------|------|
| Skin Sens. 1 | H317 |
| Aquatic Chronic 3 | H412 |

Classification procedure:

| |
|--------------------|
| Calculation method |
| 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 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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