pTau CC 5 Elecsys

Version	Revision Date:	Date of last issue: 08-29-2024
1.1	08-29-2024	Date of first issue: 03-18-2022

SECTION 1. IDENTIFICATION

Product name : pTau CC 5 Elecsys

Product code : 07546424190

Manufacturer or supplier's details

Company name of supplier : Roche Diagnostics
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Address : 9115 Hague Road
Indianapolis, IN 46250
USA

Telephone : 1-800-428-5074

Emergency telephone
In case of emergencies : CHEMTREC 1-800-424-9300 (U.S. or Canada)
1-703-527-3887 (International)

Recommended use of the chemical and restrictions on use

Restrictions on use : For professional users only.

SECTION 2. HAZARDS IDENTIFICATION

GHS classification in accordance with the OSHA Hazard Communication Standard (29 CFR 1910.1200)

Combustible dust

Serious eye damage : Category 1

Skin sensitization : Category 1

Specific target organ toxicity - repeated exposure : Category 2

GHS label elements

Hazard pictograms :



Signal Word : Danger

Hazard Statements : May form combustible dust concentrations in air.
H317 May cause an allergic skin reaction.
H318 Causes serious eye damage.
H373 May cause damage to organs through prolonged or repeated exposure.

Precautionary Statements :

Prevention:

P260 Do not breathe dust.
P272 Contaminated work clothing must not be allowed out of the workplace.
P280 Wear protective gloves/ eye protection/ face protection.

Response:

P302 + P352 IF ON SKIN: Wash with plenty of soap and water.
P305 + P351 + P338 + P310 IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. Immediately call a POISON CENTER/ doctor.
P314 Get medical advice/ attention if you feel unwell.
P333 + P313 If skin irritation or rash occurs: Get medical advice/ attention.
P363 Wash contaminated clothing before reuse.

Disposal:

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

Other hazards

None known.

SECTION 3. COMPOSITION/INFORMATION ON INGREDIENTS

Substance / Mixture : Mixture

Components

Chemical name	CAS-No.	Concentration (% w/w)
Albumins, blood serum	9048-46-8	>= 50 - < 70
1,3-Propanediol, 2-amino-2-(hydroxymethyl)-, hydrochloride (1:1)	1185-53-1	>= 20 - < 30
Poly(oxy-1,2-ethanediyl), .alpha.-dodecyl-.omega.-hydroxy-	9002-92-0	>= 1 - < 5
hydroxyl-2-pyridone	822-89-9	>= 1 - < 5
Caseins	9000-71-9	>= 1 - < 5
3(2H)-Isothiazolone, 2-methyl-, hydrochloride (1:1)	26172-54-3	>= 0.1 - < 1

Actual concentration is withheld as a trade secret

SECTION 4. FIRST AID MEASURES

General advice : Move out of dangerous area.
Consult a physician.
Show this material 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	:	Small amounts splashed into eyes can cause irreversible tissue damage and blindness. In the case of contact with eyes, rinse immediately with plenty of water and seek medical advice. Continue rinsing eyes during transport to hospital. Remove contact lenses. Protect unharmed eye. Keep eye wide open while rinsing. If eye irritation persists, consult a specialist.
If swallowed	:	Clean mouth with water and drink afterwards plenty of water. Keep respiratory tract clear. Do NOT induce vomiting. Do not give milk or alcoholic beverages. Never give anything by mouth to an unconscious person. If symptoms persist, call a physician. Take victim immediately to hospital. Rinse mouth with water.
Most important symptoms and effects, both acute and delayed	:	May cause an allergic skin reaction. Causes serious eye damage. May cause damage to organs through prolonged or repeated exposure.
Notes to physician	:	The first aid procedure should be established in consultation with the doctor responsible for industrial medicine.

SECTION 5. FIRE-FIGHTING MEASURES

Suitable extinguishing media	:	Use extinguishing measures that are appropriate to local circumstances and the surrounding environment.
Unsuitable extinguishing media	:	High volume water jet
Specific hazards during fire fighting	:	Do not allow run-off from fire fighting to enter drains or water courses.
Hazardous combustion products	:	Carbon oxides Nitrogen oxides (NOx) Gaseous hydrogen chloride (HCl). Carbon monoxide Carbon dioxide (CO2)
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.

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

SECTION 6. ACCIDENTAL RELEASE MEASURES

Personal precautions, protective equipment and emergency procedures	:	Use personal protective equipment. Avoid dust formation. Avoid breathing dust.
Environmental precautions	:	Prevent product from entering drains. Prevent further leakage or spillage if safe to do so. If the product contaminates rivers and lakes or drains inform respective authorities.
Methods and materials for containment and cleaning up	:	Keep in suitable, closed containers for disposal.

SECTION 7. HANDLING AND STORAGE

Advice on protection against fire and explosion	:	Avoid dust formation. Provide appropriate exhaust ventilation at places where dust is formed.
Advice on safe handling	:	Avoid formation of respirable particles. Do not breathe vapors/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 sensitization problems or asthma, allergies, chronic or recurrent respiratory disease should not be employed in any process in which this mixture is being used.
Conditions for safe storage	:	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
Further information on storage stability	:	No decomposition if stored and applied as directed.

SECTION 8. EXPOSURE CONTROLS/PERSONAL PROTECTION

Ingredients with workplace control parameters

Contains no substances with occupational exposure limit values.

Engineering measures : No data available

Personal protective equipment

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	:	Wear appropriate protective gloves to prevent skin contact. Replace torn or punctured gloves promptly.
Eye protection	:	Eye wash bottle with pure water Tightly fitting safety goggles Wear face-shield and protective suit for abnormal processing problems.
Skin and body protection	:	Dust impervious protective suit Choose body protection according to the amount and concentration of the dangerous substance at the work place.
Hygiene measures	:	When using do not eat or drink. When using do not smoke. Wash hands before breaks and at the end of workday.

SECTION 9. PHYSICAL AND CHEMICAL PROPERTIES

Appearance	:	solid, (lyophilized)
Color	:	white
Odor	:	odorless
Odor Threshold	:	Not applicable
pH	:	Not applicable
Melting point/range	:	No data available
Boiling point/boiling range	:	No data available

Flash point	:	does not flash
Evaporation rate	:	No data available
Flammability (solid, gas)	:	Sustains combustion
Flammability (liquids)	:	Sustains combustion
Self-ignition	:	No data available
Upper explosion limit / Upper flammability limit	:	No data available
Lower explosion limit / Lower flammability limit	:	No data available
Vapor pressure	:	No data available
Relative vapor density	:	Not applicable
Relative density	:	No data available
Solubility(ies)		
Water solubility	:	soluble
Solubility in other solvents	:	No data available
Partition coefficient: n-octanol/water	:	No data available
Autoignition temperature	:	No data available
Decomposition temperature	:	No data available
Viscosity		
Viscosity, dynamic	:	Not applicable
Viscosity, kinematic	:	Not applicable
Explosive properties	:	Not explosive
Oxidizing properties	:	The substance or mixture is not classified as oxidizing.

SECTION 10. STABILITY AND REACTIVITY

Reactivity	:	No dangerous reaction known under conditions of normal use.
Chemical stability	:	Stable under normal conditions.
Possibility of hazardous reactions	:	No dangerous reaction known under conditions of normal use. No decomposition if stored and applied as directed.

Conditions to avoid	:	No data available
Incompatible materials	:	Strong oxidizing agents
Hazardous decomposition products	:	No decomposition if stored and applied as directed.

SECTION 11. TOXICOLOGICAL INFORMATION

Acute toxicity

Not classified based on available information.

Product:

Acute oral toxicity	:	Acute toxicity estimate: > 5,000 mg/kg Method: Calculation method
Acute inhalation toxicity	:	Acute toxicity estimate: 28.68 mg/l Exposure time: 4 h Test atmosphere: dust/mist Method: Calculation method
Acute dermal toxicity	:	Acute toxicity estimate: > 5,000 mg/kg Method: Calculation method

Components:

1,3-Propanediol, 2-amino-2-(hydroxymethyl)-, hydrochloride (1:1):

Acute oral toxicity	:	LD50 (Rat, female): > 5,000 mg/kg Method: OECD Test Guideline 425 GLP: yes

Poly(oxy-1,2-ethanediyl), .alpha.-dodecyl-.omega.-hydroxy-:

Acute oral toxicity	:	LD50 Oral (Rat): 1,000 mg/kg Method: OECD Test Guideline 423 GLP: yes
Acute dermal toxicity	:	LD50 Dermal (Rat, male and female): > 2,000 mg/kg Method: OECD Test Guideline 402 GLP: yes

hydroxyl-2-pyridone:

Acute oral toxicity	:	LD50 Oral (Rat, male and female): 1,723 mg/kg Method: OECD Test Guideline 401 GLP: yes
Acute dermal toxicity	:	LD50 Dermal (Rat, male and female): > 2,000 mg/kg Method: OECD Test Guideline 402 GLP: yes Assessment: The substance or mixture has no acute dermal toxicity Remarks: No mortality observed at this dose.

3(2H)-Isothiazolone, 2-methyl-, hydrochloride (1:1):

Acute oral toxicity	:	LD50 Oral (Rat, female): 175 mg/kg Method: OECD Test Guideline 425
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-methyl-2H-isothiazol-3-one
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-methyl-2H-isothiazol-3-one

Skin corrosion/irritation

Not classified based on available information.

Product:

Remarks	:	May cause skin irritation and/or dermatitis.

Components:

1,3-Propanediol, 2-amino-2-(hydroxymethyl)-, hydrochloride (1:1):

Species	:	human keratinocytes
Exposure time	:	42 min
Method	:	OECD Test Guideline 439
Result	:	No skin irritation
GLP	:	yes

Poly(oxy-1,2-ethanediyl), .alpha.-dodecyl-.omega.-hydroxy-:

Species	:	Rabbit
Exposure time	:	4 h
Method	:	OECD Test Guideline 404
Result	:	No skin irritation
GLP	:	yes

hydroxyl-2-pyridone:

Species	:	Rabbit
Exposure time	:	4 h
Method	:	OECD Test Guideline 404
Result	:	No skin irritation
GLP	:	yes

3(2H)-Isothiazolone, 2-methyl-, hydrochloride (1:1):

Species	:	reconstructed human epidermis (RhE)
Method	:	OECD Test Guideline 431

Result : Causes severe burns.

Serious eye damage/eye irritation

Causes serious eye damage.

Product:

Remarks : May cause irreversible eye damage.

Components:

1,3-Propanediol, 2-amino-2-(hydroxymethyl)-, hydrochloride (1:1):

Species : Bovine cornea
Result : No eye irritation
Exposure time : 240 min
Method : OECD Test Guideline 437
GLP : yes

Poly(oxy-1,2-ethanediyl), .alpha.-dodecyl-.omega.-hydroxy-:

Species : Rabbit
Result : Risk of serious damage to eyes.
Method : OECD Test Guideline 405
GLP : yes

hydroxyl-2-pyridone:

Species : Rabbit
Result : Risk of serious damage to eyes.
Method : OECD Test Guideline 405
GLP : yes

3(2H)-Isothiazolone, 2-methyl-, hydrochloride (1:1):

Result : Risk of serious damage to eyes.

Respiratory or skin sensitization

Skin sensitization

May cause an allergic skin reaction.

Respiratory sensitization

Not classified based on available information.

Product:

Remarks : Causes sensitization.

Components:

1,3-Propanediol, 2-amino-2-(hydroxymethyl)-, hydrochloride (1:1):

Test Type : Maximization Test
Species : Guinea pig
Assessment : Does not cause skin sensitization.
Method : OECD Test Guideline 406
GLP : yes

Poly(oxy-1,2-ethanediyl), .alpha.-dodecyl-.omega.-hydroxy-:

Test Type	:	Draize Test
Species	:	Guinea pig
Result	:	Does not cause skin sensitization.
GLP	:	no

hydroxyl-2-pyridone:

Test Type	:	Maximization Test
Species	:	Guinea pig
Assessment	:	Does not cause skin sensitization.
Method	:	OECD Test Guideline 406
GLP	:	yes

3(2H)-Isothiazolone, 2-methyl-, hydrochloride (1:1):

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

The value is given in analogy to the following substances: 2-methyl-2H-isothiazol-3-one

Test Type	:	Maximization 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-methyl-2H-isothiazol-3-one

Germ cell mutagenicity

Not classified based on available information.

Components:

1,3-Propanediol, 2-amino-2-(hydroxymethyl)-, hydrochloride (1:1):

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
GLP: yes

Test Type: Microbial mutagenesis assay (Ames test)
Test system: Escherichia coli
Metabolic activation: with and without metabolic activation
Method: OECD Test Guideline 471
Result: negative
GLP: yes

Test Type: In vitro mammalian cell gene mutation test
Test system: Chinese hamster ovary cells
Metabolic activation: with and without metabolic activation
Method: OECD Test Guideline 476
Result: negative

GLP: yes

Test Type: Chromosome aberration test in vitro
Test system: Chinese hamster lung cells
Metabolic activation: with and without metabolic activation
Method: OECD Test Guideline 473
Result: negative
GLP: yes

Poly(oxy-1,2-ethanediyl), .alpha.-dodecyl-.omega.-hydroxy-:

Genotoxicity in vitro : Test Type: Ames test
Test system: Salmonella typhimurium
Metabolic activation: with and without metabolic activation
Result: negative

Test Type: Chromosome aberration test in vitro
Test system: Chinese hamster cells
Metabolic activation: with and without metabolic activation
Result: negative

Test Type: In vitro mammalian cell gene mutation test
Test system: mouse lymphoma cells
Result: negative

Genotoxicity in vivo : Test Type: in vivo assay
Species: Mouse (male)
Strain: B6C3F1
Cell type: Bone marrow
Application Route: Intraperitoneal injection
Exposure time: 72 h
Dose: 125 mg/kg
Result: negative

hydroxyl-2-pyridone:

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
GLP: yes

3(2H)-Isothiazolone, 2-methyl-, hydrochloride (1:1):

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-methyl-2H-isothiazol-3-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-methyl-2H-isothiazol-3-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-methyl-2H-isothiazol-3-one

Carcinogenicity

Not classified based on available information.

IARC No ingredient of this product present at levels greater than or equal to 0.1% is identified as probable, possible or confirmed human carcinogen by IARC.

OSHA No component of this product present at levels greater than or equal to 0.1% is on OSHA's list of regulated carcinogens.

NTP No ingredient of this product present at levels greater than or equal to 0.1% is identified as a known or anticipated carcinogen by NTP.

Reproductive toxicity

Not classified based on available information.

Components:

1,3-Propanediol, 2-amino-2-(hydroxymethyl)-, hydrochloride (1:1):

Effects on fertility : Species: Rat, male and female
Application Route: Oral
Dose: 100, 300, 1000 mg/kg bw/day
Duration of Single Treatment: 54 d
General Toxicity F1: NOAEL: > 1,000 mg/kg body weight
Method: OECD Test Guideline 421
Result: No effects on fertility.
GLP: yes

Poly(oxy-1,2-ethanediyl), .alpha.-dodecyl-.omega.-hydroxy-:

Effects on fetal development : Test Type: Two-generation study
Species: Rat, female
Application Route: Oral
Developmental Toxicity: NOAEL: 50 mg/kg bw/day

3(2H)-Isothiazolone, 2-methyl-, hydrochloride (1:1):

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

STOT-single exposure

Not classified based on available information.

Components:

Albumins, blood serum:

Assessment : The substance or mixture is not classified as specific target organ toxicant, single exposure.

Caseins:

Assessment : The substance or mixture is not classified as specific target organ toxicant, single exposure.

STOT-repeated exposure

May cause damage to organs through prolonged or repeated exposure.

Components:

Albumins, blood serum:

Assessment : The substance or mixture is not classified as specific target organ toxicant, repeated exposure.

hydroxyl-2-pyridone:

Assessment : May cause damage to organs through prolonged or repeated exposure.

Caseins:

Assessment : The substance or mixture is not classified as specific target organ toxicant, repeated exposure.

Repeated dose toxicity

Components:

1,3-Propanediol, 2-amino-2-(hydroxymethyl)-, hydrochloride (1:1):

Species	:	Rat, male and female
NOAEL	:	> 1000 mg/kg
Application Route	:	Oral
Exposure time	:	54 d
Dose	:	100, 300, 1000 mg/kg bw/day
Method	:	OECD Test Guideline 421
GLP	:	yes

Poly(oxy-1,2-ethanediyl), .alpha.-dodecyl-.omega.-hydroxy-:

Species	:	Rat, male
NOAEL	:	mg/kg bw/day, 390
Application Route	:	Oral
Exposure time	:	22 d

hydroxyl-2-pyridone:

Species	:	Rat, male and female
NOAEL	:	5 mg/kg
Application Route	:	Oral
Exposure time	:	28 d
Dose	:	25, 150, 1000 mg/kg bw/day
Method	:	OECD Test Guideline 407
GLP	:	yes

3(2H)-Isothiazolone, 2-methyl-, hydrochloride (1:1):

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-methyl-2H-isothiazol-3-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-methyl-2H-isothiazol-3-one

Aspiration toxicity

Not classified based on available information.

Further information

Components:

Albumins, blood serum:

Remarks	:	Health injuries are not known or expected under normal use.

SECTION 12. ECOLOGICAL INFORMATION

Ecotoxicity

Components:

Albumins, blood serum:

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

1,3-Propanediol, 2-amino-2-(hydroxymethyl)-, hydrochloride (1:1):

Toxicity to fish	:	LC50 (Leuciscus idus (Golden orfe)): 460 mg/l End point: mortality Exposure time: 96 h Test Type: static test Analytical monitoring: no Method: OECD Test Guideline 203 GLP: No information available.
Toxicity to daphnia and other aquatic invertebrates	:	EC50 (Daphnia magna (Water flea)): > 117 mg/l End point: Immobilization Exposure time: 48 h Test Type: static test Analytical monitoring: yes Method: OECD Test Guideline 202 GLP: yes
Toxicity to algae/aquatic plants	:	EC50 (Pseudokirchneriella subcapitata (green algae)): 397 mg/l Exposure time: 72 h Test Type: static test Analytical monitoring: no Method: OECD Test Guideline 201 GLP: No information available.
Toxicity to microorganisms	:	EC50 (activated sludge): > 1,000 mg/l Exposure time: 3 h Test Type: static test Analytical monitoring: no Method: OECD Test Guideline 209 GLP: yes

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

Poly(oxy-1,2-ethanediyl), .alpha.-dodecyl-.omega.-hydroxy-:

Toxicity to fish	:	LC50 (Salmo salar (Atlantic salmon)): 1.5 mg/l End point: mortality

Exposure time: 96 h

Toxicity to daphnia and other aquatic invertebrates : EC50 (Daphnia magna (Water flea)): 6.46 mg/l
Exposure time: 48 h

Toxicity to algae/aquatic plants : ErC50 (Desmodesmus subspicatus (green algae)): 0.237 mg/l
Exposure time: 72 h
Method: OECD Test Guideline 201

EbC50 (Desmodesmus subspicatus (green algae)): 1,502 mg/l
Exposure time: 72 h
Method: OECD Test Guideline 201

Toxicity to daphnia and other aquatic invertebrates (Chronic toxicity) : NOEC (Daphnia magna (Water flea)): 0.144 mg/l
Exposure time: 21 d
Method: QSAR

Toxicity to microorganisms : (Photobacterium phosphoreum): 2.5 mg/l
Test Type: EC50

Ecotoxicology Assessment

Acute aquatic toxicity : Toxic to aquatic life.
Remarks: Expert judgment

Chronic aquatic toxicity : Harmful to aquatic life with long lasting effects.
Remarks: Expert judgment

hydroxyl-2-pyridone:

Toxicity to fish : LC50 (Lepomis macrochirus (Bluegill sunfish)): > 97.8 mg/l
End point: mortality
Exposure time: 96 h
Test Type: static test
Analytical monitoring: yes
Method: OECD Test Guideline 203
GLP: yes

Toxicity to daphnia and other aquatic invertebrates : EC50 (Daphnia magna (Water flea)): 78.6 mg/l
End point: Immobilization
Exposure time: 48 h
Test Type: static test
Analytical monitoring: yes
Method: OECD Test Guideline 202
GLP: yes

Toxicity to algae/aquatic plants : EC50 (Pseudokirchneriella subcapitata (green algae)): 6.60 mg/l
End point: Growth rate
Exposure time: 72 h
Test Type: static test
Analytical monitoring: yes
Method: OECD Test Guideline 201
GLP: yes

Toxicity to microorganisms	:	EC50 (activated sludge): 320.8 mg/l End point: Respiration inhibition Exposure time: 3 h Test Type: static test Analytical monitoring: no Method: OECD Test Guideline 209 GLP: yes

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

Caseins:

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

3(2H)-Isothiazolone, 2-methyl-, hydrochloride (1:1):

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-methyl-2H-isothiazol-3-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 Test Type: static test Method: OECD Test Guideline 201
Toxicity to daphnia and other aquatic invertebrates (Chronic toxicity)	:	NOEC (Daphnia magna (Water flea)): 0.0442 mg/l Exposure time: 21 d Method: OECD Test Guideline 211

The value is given in analogy to the following substances: 2-methyl-2H-isothiazol-3-one

Persistence and degradability

Components:

1,3-Propanediol, 2-amino-2-(hydroxymethyl)-, hydrochloride (1:1):

Biodegradability : aerobic
Inoculum: activated sludge, non-adapted
Concentration: 30 mg/l
Result: Readily biodegradable.
Biodegradation: 97.1 %
Exposure time: 28 d
Method: OECD Test Guideline 301F
GLP: yes

Poly(oxy-1,2-ethanediyl), .alpha.-dodecyl-.omega.-hydroxy-:

Biodegradability : aerobic
Inoculum: activated sludge
Concentration: 30 mg/l
Result: Readily biodegradable.
Biodegradation: 74 %
Exposure time: 28 d
Method: OECD Test Guideline 301C

hydroxyl-2-pyridone:

Biodegradability : aerobic
Inoculum: activated sludge
Concentration: 22.2 mg/l
Result: Readily biodegradable.
Biodegradation: 94 %
Exposure time: 29 d
Method: OECD Test Guideline 301B
GLP: yes
Remarks: According to the results of tests of biodegradability this product is considered as being readily biodegradable.

Impact on Sewage Treatment : Do not discharge product into the aquatic environment without pretreatment (biological treatment plant).

3(2H)-Isothiazolone, 2-methyl-, hydrochloride (1:1):

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

Bioaccumulative potential

Components:

Albumins, blood serum:

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

1,3-Propanediol, 2-amino-2-(hydroxymethyl)-, hydrochloride (1:1):

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

Partition coefficient: n-octanol/water : log Pow: -3.6 (68 °F / 20 °C)
pH: 5 - 7
Method: OECD Test Guideline 107
GLP: no

Poly(oxy-1,2-ethanediyl), .alpha.-dodecyl-.omega.-hydroxy-:

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

hydroxyl-2-pyridone:

Partition coefficient: n-octanol/water : log Pow: -0.489 (77 °F / 25 °C)
pH: 4.99
Method: OECD Test Guideline 107
GLP: yes

log Pow: -2.73 (77 °F / 25 °C)
pH: 9
Method: OECD Test Guideline 107
GLP: yes

log Pow: -1.59 (77 °F / 25 °C)
pH: 7
Method: OECD Test Guideline 107
GLP: yes

Caseins:

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

3(2H)-Isothiazolone, 2-methyl-, hydrochloride (1:1):

Bioaccumulation : Remarks: No bioaccumulation is to be expected (log Pow <= 4).

Partition coefficient: n-octanol/water : log Pow: ca. -0.44 (68 °F / 20 °C)
Method: OECD Test Guideline 107

Mobility in soil

No data available

Other adverse effects

Product:

Ozone-Depletion Potential : Regulation: 40 CFR Protection of Environment; Part 82 Protection of Stratospheric Ozone - CAA Section 602 Class I

Substances
Remarks: This product neither contains, nor was manufactured with a Class I or Class II ODS as defined by the U.S. Clean Air Act Section 602 (40 CFR 82, Subpt. A, App.A + B).

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.

Components:

hydroxyl-2-pyridone:

Additional ecological information : No data available

SECTION 13. DISPOSAL CONSIDERATIONS

Disposal methods

Waste from residues : 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.

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

International Regulations

UNRTDG

UN number	:	UN 3082
Proper shipping name	:	ENVIRONMENTALLY HAZARDOUS SUBSTANCE, LIQUID, N.O.S. (Polidocanol)
Class	:	9
Packing group	:	III
Labels	:	9

IATA-DGR

UN/ID No.	:	UN 3082
Proper shipping name	:	Environmentally hazardous substance, liquid, n.o.s. (Polidocanol)
Class	:	9
Packing group	:	III
Labels	:	Miscellaneous
Packing instruction (cargo aircraft)	:	964

Packing instruction (passenger aircraft)	:	964
Environmentally hazardous	:	yes

IMDG-Code

UN number	:	UN 3082
Proper shipping name	:	ENVIRONMENTALLY HAZARDOUS SUBSTANCE, LIQUID, N.O.S. (Polidocanol)
Class	:	9
Packing group	:	III
Labels	:	9
EmS Code	:	F-A, S-F
Marine pollutant	:	yes

Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code

Not applicable

Domestic regulation

49 CFR

UN/ID/NA number	:	UN 3082
Proper shipping name	:	Environmentally hazardous substance, liquid, n.o.s. (Polidocanol)
Class	:	9
Packing group	:	III
Labels	:	CLASS 9
ERG Code	:	171
Marine pollutant	:	no

Special precautions for user

Remarks	:	No data available

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

SECTION 15. REGULATORY INFORMATION

CERCLA Reportable Quantity

This material does not contain any components with a CERCLA RQ.

SARA 304 Extremely Hazardous Substances Reportable Quantity

This material does not contain any components with a section 304 EHS RQ.

SARA 302 Extremely Hazardous Substances Threshold Planning Quantity

This material does not contain any components with a section 302 EHS TPQ.

SARA 311/312 Hazards	:	Combustible dust Respiratory or skin sensitization Specific target organ toxicity (single or repeated exposure) Serious eye damage or eye irritation

SARA 313 : This material does not contain any chemical components with known CAS numbers that exceed the threshold (De Minimis) reporting levels established by SARA Title III, Section 313.

Clean Air Act

This product neither contains, nor was manufactured with a Class I or Class II ODS as defined by the U.S. Clean Air Act Section 602 (40 CFR 82, Subpt. A, App.A + B).
This product does not contain any hazardous air pollutants (HAP), as defined by the U.S. Clean Air Act Section 112 (40 CFR 61).
This product does not contain any chemicals listed under the U.S. Clean Air Act Section 112(r) for Accidental Release Prevention (40 CFR 68.130, Subpart F).
This product does not contain any chemicals listed under the U.S. Clean Air Act Section 111 SOCMI Intermediate or Final VOC's (40 CFR 60.489).

Clean Water Act

This product does not contain any Hazardous Substances listed under the U.S. CleanWater Act, Section 311, Table 116.4A.
This product does not contain any Hazardous Chemicals listed under the U.S. CleanWater Act, Section 311, Table 117.3.
This product does not contain any toxic pollutants listed under the U.S. Clean Water Act Section 307
This product does not contain any priority pollutants related to the U.S. Clean Water Act

US State Regulations

Massachusetts Right To Know

No components are subject to the Massachusetts Right to Know Act.

Pennsylvania Right To Know

Albumins, blood serum	9048-46-8
1,3-Propanediol, 2-amino-2-(hydroxymethyl)-, hydrochloride (1:1)	1185-53-1
1,3-Propanediol, 2-amino-2-(hydroxymethyl)-	77-86-1
Poly(oxy-1,2-ethanediyl), .alpha.-dodecyl-.omega.-hydroxy-	9002-92-0
hydroxyl-2-pyridone	822-89-9
PAK<->R-IGG(DET)	Not Assigned

Maine Chemicals of High Concern

Product does not contain any listed chemicals

Vermont Chemicals of High Concern

Product does not contain any listed chemicals

Washington Chemicals of High Concern

Product does not contain any listed chemicals

The ingredients 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.

hydroxyl-2-pyridone

PAK<->R-IGG(DET)

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

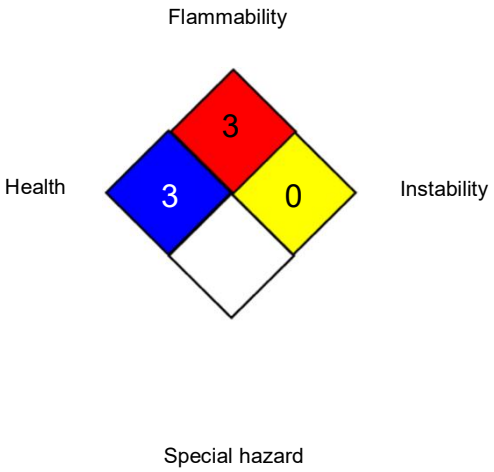
TSCA list

No substances are subject to a Significant New Use Rule.

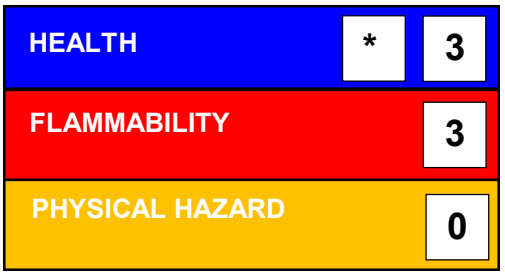
No substances are subject to TSCA 12(b) export notification requirements.

SECTION 16. OTHER INFORMATION

NFPA 704:



HMIS® IV:



HMIS® ratings are based on a 0-4 rating scale, with 0 representing minimal hazards or risks, and 4 representing significant hazards or risks. The "*" represents a chronic hazard, while the "/" represents the absence of a chronic hazard.

Full text of other abbreviations

AIIC - Australian Inventory of Industrial Chemicals; ASTM - American Society for the Testing of Materials; bw - Body weight; CERCLA - Comprehensive Environmental Response, Compensation, and Liability Act; CMR - Carcinogen, Mutagen or Reproductive Toxicant; DIN -

Standard of the German Institute for Standardisation; DOT - Department of Transportation; DSL - Domestic Substances List (Canada); ECx - Concentration associated with x% response; EHS - Extremely Hazardous Substance; 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; ERG - Emergency Response Guide; GHS - Globally Harmonized System; GLP - Good Laboratory Practice; HMIS - Hazardous Materials Identification System; 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; MSHA - Mine Safety and Health Administration; n.o.s. - Not Otherwise Specified; NFPA - National Fire Protection Association; NO(A)EC - No Observed (Adverse) Effect Concentration; NO(A)EL - No Observed (Adverse) Effect Level; NOELR - No Observable Effect Loading Rate; NTP - National Toxicology Program; 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; RCRA - Resource Conservation and Recovery Act; REACH - Regulation (EC) No 1907/2006 of the European Parliament and of the Council concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals; RQ - Reportable Quantity; SADT - Self-Accelerating Decomposition Temperature; SARA - Superfund Amendments and Reauthorization Act; SDS - Safety Data Sheet; TCSI - Taiwan Chemical Substance Inventory; TECI - Thailand Existing Chemicals Inventory; TSCA - Toxic Substances Control Act (United States); UN - United Nations; UNRTDG - United Nations Recommendations on the Transport of Dangerous Goods; vPvB - Very Persistent and Very Bioaccumulative

Revision Date : 08-29-2024

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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