SAFETY DATA SHEET

Cortisol CalSet

Version	Revision Date:	Date of last issue: 10-08-2021
3.0	03-15-2022	Date of first issue: 11-08-2015

SECTION 1. IDENTIFICATION

Product name : Cortisol CalSet

Product code : 11875124122

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)

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

GHS label elements

Hazard pictograms :



Signal Word : Warning

Hazard Statements : H317 May cause an allergic skin reaction.

Precautionary Statements :

Prevention:

P261 Avoid breathing dust.
P272 Contaminated work clothing must not be allowed out of the workplace.
P280 Wear protective gloves.

Response:

P302 + P352 IF ON SKIN: Wash with plenty of soap and water.
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

Cal 1

GHS Classification

Skin sensitization : Category 1

Chemical nature : Handle as potentially infectious.

Components

Chemical name	CAS-No.	Concentration (% w/w)
3(2H)-Isothiazolone, 2-methyl-, hydrochloride (1:1)	26172-54-3	>= 0.1 - < 1
Pregn-4-ene-3,20-dione, 11,17,21-trihydroxy-, (11.beta.)-	50-23-7	< 0.1

Actual concentration is withheld as a trade secret

Cal 2

GHS Classification

Skin sensitization : Category 1

Chemical nature : Handle as potentially infectious.

Components

Chemical name	CAS-No.	Concentration (% w/w)
3(2H)-Isothiazolone, 2-methyl-, hydrochloride (1:1)	26172-54-3	>= 0.1 - < 1
Pregn-4-ene-3,20-dione, 11,17,21-trihydroxy-, (11.beta.)-	50-23-7	< 0.1

Actual concentration is withheld as a trade secret

SECTION 4. FIRST AID MEASURES

General advice : Move out of dangerous area.
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 : 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.

Most important symptoms and effects, both acute and delayed : No information available.

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.

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.

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

Cal 1

Ingredients with workplace control parameters

Components	CAS-No.	Value type (Form of exposure)	Control parameters / Permissible concentration	Basis
Pregn-4-ene-3,20-dione, 11,17,21-trihydroxy-, (11.beta.)-	50-23-7	IOEL	0.1 mg/m3	Roche Industrial Hygiene Committee (RIHC)

Cal 2

Ingredients with workplace control parameters

Components	CAS-No.	Value type (Form of exposure)	Control parameters / Permissible concentration	Basis

Pregn-4-ene-3,20-dione, 11,17,21-trihydroxy-, (11.beta.)-	50-23-7	IOEL	0.1 mg/m3	Roche Industrial Hygiene Committee (RIHC)

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
Skin and body protection	:	Choose body protection according to the amount and concentration of the dangerous substance at the work place.
Hygiene measures	:	Wash hands before breaks and at the end of workday.

SECTION 9. PHYSICAL AND CHEMICAL PROPERTIES

Cal 1

Appearance	:	solid
Color	:	white light yellow
Odor	:	very faint
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
Oxidizing properties	:	The substance or mixture is not classified as oxidizing.

Cal 2

Appearance	:	solid
Color	:	white light yellow
Odor	:	very faint

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
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	:	Direct sources of heat.
Incompatible materials	:	No data available
Hazardous decomposition products	:	No hazardous decomposition products are known.

SECTION 11. TOXICOLOGICAL INFORMATION

Cal 1

Acute toxicity

Not classified based on available information.

Components:

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

Pregn-4-ene-3,20-dione, 11,17,21-trihydroxy-, (11.beta.)-:

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

Skin corrosion/irritation

Not classified based on available information.

Components:

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

Not classified based on available information.

Components:

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.

Components:

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.

Test Type : Maximization 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:

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

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

Pregn-4-ene-3,20-dione, 11,17,21-trihydroxy-, (11.beta.)-:

Genotoxicity in vitro : Test Type: Ames test
Metabolic activation: with and without metabolic activation
Method: OECD Test Guideline 471
Result: positive
GLP: yes

Test Type: In vitro mammalian cell gene mutation test
Metabolic activation: with and without metabolic activation
Method: OECD Test Guideline 476
Result: negative
GLP: yes

Test Type: Chromosome aberration test in vitro
Metabolic activation: with and without metabolic activation
Method: OECD Test Guideline 473
Result: positive
GLP: yes

Method: OECD Test Guideline 482
Result: negative
GLP: yes

Genotoxicity in vivo : Test Type: In vivo micronucleus test
Species: Mouse (male and female)
Method: OECD Test Guideline 474
Result: negative
GLP: yes

Germ cell mutagenicity - Assessment : In vivo tests did not show mutagenic effects

Carcinogenicity

Not classified based on available information.

Components:

Pregn-4-ene-3,20-dione, 11,17,21-trihydroxy-, (11.beta.)-:

Remarks : 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.

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:

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.

Pregn-4-ene-3,20-dione, 11,17,21-trihydroxy-, (11.beta.)-:

Reproductive toxicity - Assessment : May damage the unborn child. Suspected of damaging fertility., Known human reproductive toxicant

STOT-single exposure

Not classified based on available information.

Components:

Pregn-4-ene-3,20-dione, 11,17,21-trihydroxy-, (11.beta.)-:

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

STOT-repeated exposure

Not classified based on available information.

Components:

Pregn-4-ene-3,20-dione, 11,17,21-trihydroxy-, (11.beta.)-:

Target Organs : Blood, Liver
Assessment : May cause damage to organs through prolonged or repeated exposure.

Repeated dose toxicity

Components:

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.

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.

Components:

Pregn-4-ene-3,20-dione, 11,17,21-trihydroxy-, (11.beta.)-:
No data available

Cal 2

Acute toxicity
Not classified based on available information.

Components:

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

Pregn-4-ene-3,20-dione, 11,17,21-trihydroxy-, (11.beta.)-:

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

Skin corrosion/irritation
Not classified based on available information.

Components:

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
Not classified based on available information.

Components:

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.

Components:

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.

Test Type	:	Maximization 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:

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

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

Pregn-4-ene-3,20-dione, 11,17,21-trihydroxy-, (11.beta.)-:

Genotoxicity in vitro : Test Type: Ames test
Metabolic activation: with and without metabolic activation
Method: OECD Test Guideline 471
Result: positive
GLP: yes

Test Type: In vitro mammalian cell gene mutation test
Metabolic activation: with and without metabolic activation
Method: OECD Test Guideline 476

Result: negative
GLP: yes

Test Type: Chromosome aberration test in vitro
Metabolic activation: with and without metabolic activation
Method: OECD Test Guideline 473
Result: positive
GLP: yes

Method: OECD Test Guideline 482
Result: negative
GLP: yes

Genotoxicity in vivo : Test Type: In vivo micronucleus test
Species: Mouse (male and female)
Method: OECD Test Guideline 474
Result: negative
GLP: yes

Germ cell mutagenicity - Assessment : In vivo tests did not show mutagenic effects

Carcinogenicity

Not classified based on available information.

Components:

Pregn-4-ene-3,20-dione, 11,17,21-trihydroxy-, (11.beta.)-:

Remarks : 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.

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:

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.

Pregn-4-ene-3,20-dione, 11,17,21-trihydroxy-, (11.beta.)-:

Reproductive toxicity - Assessment : May damage the unborn child. Suspected of damaging fertility., Known human reproductive toxicant

STOT-single exposure

Not classified based on available information.

Components:

Pregn-4-ene-3,20-dione, 11,17,21-trihydroxy-, (11.beta.)-:

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

STOT-repeated exposure

Not classified based on available information.

Components:

Pregn-4-ene-3,20-dione, 11,17,21-trihydroxy-, (11.beta.)-:

Target Organs : Blood, Liver
Assessment : May cause damage to organs through prolonged or repeated exposure.

Repeated dose toxicity

Components:

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.

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.

Components:

Pregn-4-ene-3,20-dione, 11,17,21-trihydroxy-, (11.beta.)-:

No data available

SECTION 12. ECOLOGICAL INFORMATION

Cal 1

Ecotoxicity

Components:

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
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

Pregn-4-ene-3,20-dione, 11,17,21-trihydroxy-, (11.beta.)-:

Toxicity to daphnia and other aquatic invertebrates	:	EC50 (Daphnia magna (Water flea)): > 100 mg/l Exposure time: 48 h Test Type: static test Analytical monitoring: yes Method: OECD Test Guideline 202 GLP: yes NOEC (Daphnia magna (Water flea)): 25 mg/l Exposure time: 48 h Test Type: static test Analytical monitoring: yes Method: OECD Test Guideline 202 GLP: yes
Toxicity to microorganisms	:	(activated sludge): Exposure time: 22 d Test Type: aerobic GLP: yes Remarks: no adverse influence on substrate biodegradation

Ecotoxicology Assessment

Toxicity Data on Soil	:	Not expected to adsorb on soil.

Persistence and degradability

Components:

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

Pregn-4-ene-3,20-dione, 11,17,21-trihydroxy-, (11.beta.)-:

Biodegradability : aerobic
Inoculum: activated sludge, non-adapted
Concentration: 20 mg/l
Result: Readily biodegradable.
Biodegradation: >= 96 %
Exposure time: 22 d
Method: OECD Test Guideline 301E
GLP: yes

Bioaccumulative potential

Components:

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

Pregn-4-ene-3,20-dione, 11,17,21-trihydroxy-, (11.beta.)-:

Partition coefficient: n-octanol/water : Remarks: Not applicable

Mobility in soil

No data available

Other adverse effects

Cal 2

Ecotoxicity

Components:

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

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 : ErC50 (Pseudokirchneriella subcapitata (green algae)): 0.289

plants
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

Pregn-4-ene-3,20-dione, 11,17,21-trihydroxy-, (11.beta.)-:

Toxicity to daphnia and other aquatic invertebrates : EC50 (Daphnia magna (Water flea)): > 100 mg/l
Exposure time: 48 h
Test Type: static test
Analytical monitoring: yes
Method: OECD Test Guideline 202
GLP: yes

NOEC (Daphnia magna (Water flea)): 25 mg/l
Exposure time: 48 h
Test Type: static test
Analytical monitoring: yes
Method: OECD Test Guideline 202
GLP: yes

Toxicity to microorganisms : (activated sludge): Exposure time: 22 d
Test Type: aerobic
GLP: yes
Remarks: no adverse influence on substrate biodegradation

Ecotoxicology Assessment

Toxicity Data on Soil : Not expected to adsorb on soil.

Persistence and degradability

Components:

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

Pregn-4-ene-3,20-dione, 11,17,21-trihydroxy-, (11.beta.)-:

Biodegradability : aerobic
Inoculum: activated sludge, non-adapted
Concentration: 20 mg/l
Result: Readily biodegradable.
Biodegradation: >= 96 %
Exposure time: 22 d
Method: OECD Test Guideline 301E
GLP: yes

Bioaccumulative potential

Components:

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

Pregn-4-ene-3,20-dione, 11,17,21-trihydroxy-, (11.beta.)-:

Partition coefficient: n-octanol/water : Remarks: Not applicable

Mobility in soil

No data available

Other adverse effects

SECTION 13. DISPOSAL CONSIDERATIONS

Disposal methods

Waste from residues : 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

International Regulations

UNRTDG
Not regulated as a dangerous good

IATA-DGR
Not regulated as a dangerous good

IMDG-Code
Not regulated as a dangerous good

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

Not applicable

Domestic regulation

49 CFR

Not regulated as a dangerous good

Special precautions for user

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

SECTION 15. REGULATORY INFORMATION

Cal 1

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 : Respiratory or skin sensitization

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

Human serum /-plasma / -hemolysate, lyophilized	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. Human serum /-plasma / -hemolysate, 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

TSCA list

No substances are subject to a Significant New Use Rule.

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

Cal 2

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 : Respiratory or skin sensitization

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

Human serum /-plasma / -hemolysate, lyophilized 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.

Human serum /-plasma / -hemolysate, 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

TSCA list

No substances are subject to a Significant New Use Rule.

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

Cal 1

GHS label elements

Hazard pictograms :



Signal Word : Warning

Hazard Statements : H317 May cause an allergic skin reaction.

Precautionary Statements :

Prevention:

P261 Avoid breathing dust.
P272 Contaminated work clothing must not be allowed out of the workplace.
P280 Wear protective gloves.

Response:

P302 + P352 IF ON SKIN: Wash with plenty of soap and water.
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.

Cal 2

GHS label elements

Hazard pictograms :



Signal Word : Warning

Hazard Statements : H317 May cause an allergic skin reaction.

Precautionary Statements :

Prevention:

P261 Avoid breathing dust.
P272 Contaminated work clothing must not be allowed out of the workplace.
P280 Wear protective gloves.

Response:

P302 + P352 IF ON SKIN: Wash with plenty of soap and water.
P333 + P313 If skin irritation or rash occurs: Get medical advice/ attention.
P363 Wash contaminated clothing before reuse.

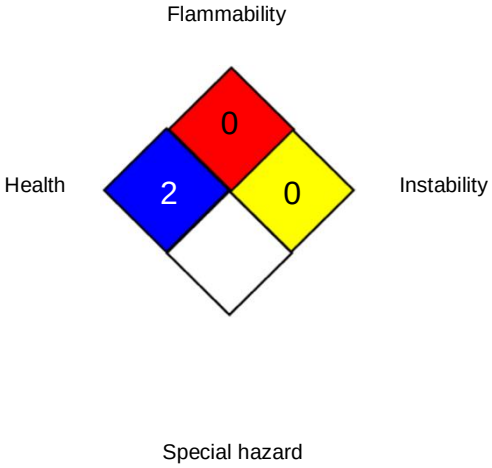
Disposal:

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

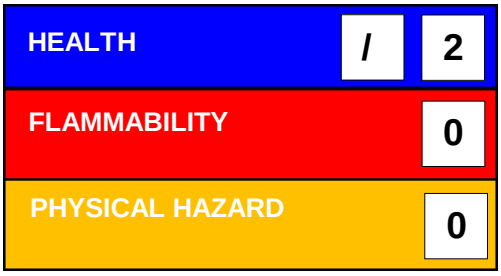
SECTION 16. OTHER INFORMATION

Further information

NFPA 704:

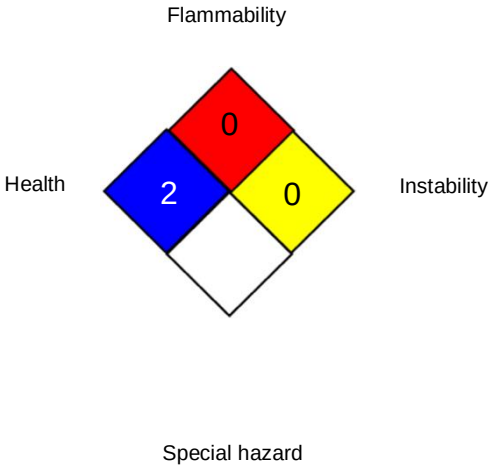


HMIS® IV:

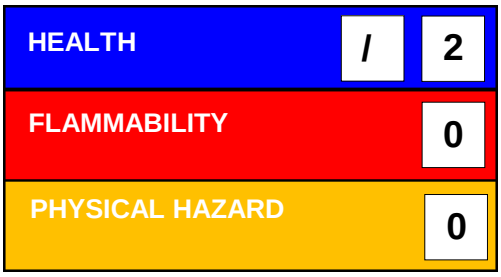


HMIS® ratings are based on a 0-4 rating scale, with 0 representing minimal hazards or risks, and 4 representing significant hazards or risks. The "*" represents a chronic hazard, while the "/" represents the absence of a chronic hazard.

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 : 03-15-2022

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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