

CalSet IGFBP-3Version
2.0Revision Date:
03-27-2022Date of last issue: 10-11-2021
Date of first issue: 03-22-2018**SECTION 1. IDENTIFICATION**

Product name : CalSet IGFBP-3

Product code : 07574762190

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 : Danger

Hazard Statements : H318 Causes serious eye damage.
H373 May cause damage to organs through prolonged or repeated exposure.

Precautionary Statements :

Prevention:

P260 Do not breathe dust.

P280 Wear eye protection/ face protection.

Response:

P305 + P351 + P338 + P310 IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present

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and easy to do. Continue rinsing. Immediately call a POISON CENTER/ doctor.

P314 Get medical advice/ attention if you feel unwell.

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

Combustible dust

Serious eye damage : Category 1

Specific target organ toxicity : Category 2
- repeated exposure

Chemical nature : Handle as potentially infectious.

Components

Chemical name	CAS-No.	Concentration (% w/w)
1-Piperazineethanesulfonic acid, 4-(2-hydroxyethyl)-	7365-45-9	$\geq 20 - < 30$
D-Mannitol	69-65-8	$\geq 20 - < 30$
Edetic acid disodium salt dihydrate (EDTA-2Na-2H ₂ O)	6381-92-6	$\geq 10 - < 20$
hydroxyl-2-pyridone	822-89-9	$\geq 1 - < 5$
1-Tetradecanaminium, N,N,N-trimethyl-, bromide (1:1)	1119-97-7	$\geq 1 - < 5$

Actual concentration is withheld as a trade secret

Cal 2

GHS Classification

Combustible dust

Serious eye damage : Category 1

Specific target organ toxicity : Category 2
- repeated exposure

Chemical nature : Handle as potentially infectious.

Components

Chemical name	CAS-No.	Concentration (% w/w)
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1-Piperazineethanesulfonic acid, 4-(2-hydroxyethyl)-	7365-45-9	$\geq 20 - < 30$
D-Mannitol	69-65-8	$\geq 20 - < 30$
Edetic acid disodium salt dihydrate (EDTA-2Na-2H ₂ O)	6381-92-6	$\geq 10 - < 20$
hydroxyl-2-pyridone	822-89-9	$\geq 1 - < 5$
1-Tetradecanaminium, N,N,N-trimethyl-, bromide (1:1)	1119-97-7	$\geq 1 - < 5$

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 skin irritation persists, call a physician.
If on skin, rinse well with water.
If on clothes, remove clothes.
- 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 : None known.
- Notes to physician : The first aid procedure should be established in consultation with the doctor responsible for industrial medicine.

SECTION 5. FIRE-FIGHTING MEASURES

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- 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.
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 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.
- 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 : See label, package insert or internal guidelines

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age conditions

Further information on stor- : No decomposition if stored and applied as directed.
age stability

SECTION 8. EXPOSURE CONTROLS/PERSONAL PROTECTION**Cal 1****Ingredients with workplace control parameters**

Contains no substances with occupational exposure limit values.

Cal 2**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	: 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**Cal 1**

Appearance : (lyophilized)

Color : white

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Odor	:	none
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	:	No data available
Oxidizing properties	:	The substance or mixture is not classified as oxidizing.

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Appearance	:	(lyophilized)
Color	:	white
Odor	:	none
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

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Viscosity
Viscosity, dynamic : Not applicable
Viscosity, kinematic : Not applicable
Explosive properties : No data available
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 decomposition if stored and applied as directed.
Incompatible materials : Strong oxidizing agents
Hazardous decomposition products : No decomposition if stored and applied as directed.

SECTION 11. TOXICOLOGICAL INFORMATION**Cal 1****Acute toxicity**

Not classified based on available information.

Components:**1-Piperazineethanesulfonic acid, 4-(2-hydroxyethyl)-:**

Acute oral toxicity : LD50 Oral (Rat, male and female): > 2,000 mg/kg
Method: OECD Test Guideline 423
GLP: yes
Assessment: The substance or mixture has no acute oral toxicity
Remarks: No mortality observed at this dose.

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.

D-Mannitol:

Acute oral toxicity : LD50 Oral (Rat): 13,500 mg/kg
LD50 Oral (Mouse): 22,000 mg/kg
Acute inhalation toxicity : Acute toxicity estimate: > 30 mg/l

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Test atmosphere: dust/mist
Method: Expert judgment

Acute dermal toxicity : Acute toxicity estimate: > 5,000 mg/kg
Method: Expert judgment

Edetic acid disodium salt dihydrate (EDTA-2Na-2H₂O):

Acute oral toxicity : LD50 Oral (Rat, male and female): 2,800 mg/kg
Method: OECD Test Guideline 401

Acute inhalation toxicity : Acute toxicity estimate: 1.6 mg/l
Test atmosphere: dust/mist
Method: Expert judgment

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.

1-Tetradecanaminium, N,N,N-trimethyl-, bromide (1:1):

Acute oral toxicity : LD50 (Rat): 390 mg/kg

Acute inhalation toxicity : LC50 (Mouse): 1,8 mg/m³
Test atmosphere: dust/mist
Assessment: The substance or mixture has no acute inhalation toxicity

Acute dermal toxicity : LD50 Dermal (Rabbit): ca. 2,150 mg/kg

Skin corrosion/irritation

Not classified based on available information.

Components:**1-Piperazineethanesulfonic acid, 4-(2-hydroxyethyl)-:**

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

Edetic acid disodium salt dihydrate (EDTA-2Na-2H₂O):

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

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

1-Tetradecanaminium, N,N,N-trimethyl-, bromide (1:1):

Result : Irritating to skin.

Serious eye damage/eye irritation

Causes serious eye damage.

Components:**1-Piperazineethanesulfonic acid, 4-(2-hydroxyethyl)-:**

Species : Rabbit
Result : No eye irritation
Exposure time : 30 s
Method : OECD Test Guideline 405
GLP : yes

Edetic acid disodium salt dihydrate (EDTA-2Na-2H₂O):

Species : Rabbit
Result : No eye irritation
Test substance : anhydrous substance
Remarks : Based on data from similar materials

hydroxyl-2-pyridone:

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

1-Tetradecanaminium, N,N,N-trimethyl-, bromide (1:1):

Result : Risk of serious damage to eyes.

Respiratory or skin sensitization**Skin sensitization**

Not classified based on available information.

Respiratory sensitization

Not classified based on available information.

Components:**1-Piperazineethanesulfonic acid, 4-(2-hydroxyethyl)-:**

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

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Result : Does not cause skin sensitization.
GLP : yes

Edetic acid disodium salt dihydrate (EDTA-2Na-2H₂O):

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

hydroxyl-2-pyridone:

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

Germ cell mutagenicity

Not classified based on available information.

Components:**1-Piperazineethanesulfonic acid, 4-(2-hydroxyethyl)-:**

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: Chromosome aberration test in vitro
Test system: Human lymphocytes
Metabolic activation: with and without metabolic activation
Method: OECD Test Guideline 473
Result: negative
GLP: yes

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

Carcinogenicity

Not classified based on available information.

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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.

D-Mannitol:

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.

1-Tetradecanaminium, N,N,N-trimethyl-, bromide (1:1):

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:**1-Piperazineethanesulfonic acid, 4-(2-hydroxyethyl)-:**

Effects on fetal development : Species: Rat, female
Application Route: Oral
Dose: 100, 300, 1000 mg/kg bw/day
Duration of Single Treatment: 14 d
General Toxicity Maternal: NOEL: 1,000 mg/kg body weight
Embryo-fetal toxicity.: NOEL: 1,000 mg/kg body weight
Method: OECD Test Guideline 414
GLP: yes

STOT-single exposure

Not classified based on available information.

Components:**D-Mannitol:**

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

1-Tetradecanaminium, N,N,N-trimethyl-, bromide (1:1):

Routes of exposure : Inhalation
Target Organs : Respiratory system

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Assessment : May cause respiratory irritation.

STOT-repeated exposure

May cause damage to organs through prolonged or repeated exposure.

Components:**D-Mannitol:**

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.

Repeated dose toxicity**Components:****1-Piperazineethanesulfonic acid, 4-(2-hydroxyethyl)-:**

Species : Rat, male and female
NOEL : 1000 mg/kg
Application Route : Oral
Exposure time : 28 d
Dose : 100, 300, 1000 mg/kg bw/day
Method : OECD Test Guideline 407
GLP : yes

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

1-Tetradecanaminium, N,N,N-trimethyl-, bromide (1:1):

Species : Rat
 : 75 mg/kg
Application Route : Oral
Test atmosphere : dust/mist
Exposure time : 21 d
Assessment : The substance or mixture is classified as specific target organ toxicant, repeated exposure, category 2.

Aspiration toxicity

Not classified based on available information.

Components:**D-Mannitol:**

No data available

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

1-Tetradecanaminium, N,N,N-trimethyl-, bromide (1:1):

Remarks : Other dangerous properties can not be excluded.

Cal 2**Acute toxicity**

Not classified based on available information.

Components:**1-Piperazineethanesulfonic acid, 4-(2-hydroxyethyl)-:**

Acute oral toxicity : LD50 Oral (Rat, male and female): > 2,000 mg/kg
Method: OECD Test Guideline 423
GLP: yes
Assessment: The substance or mixture has no acute oral toxicity
Remarks: No mortality observed at this dose.

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.

D-Mannitol:

Acute oral toxicity : LD50 Oral (Rat): 13,500 mg/kg
LD50 Oral (Mouse): 22,000 mg/kg

Acute inhalation toxicity : Acute toxicity estimate: > 30 mg/l
Test atmosphere: dust/mist
Method: Expert judgment

Acute dermal toxicity : Acute toxicity estimate: > 5,000 mg/kg
Method: Expert judgment

Edetic acid disodium salt dihydrate (EDTA-2Na-2H₂O):

Acute oral toxicity : LD50 Oral (Rat, male and female): 2,800 mg/kg
Method: OECD Test Guideline 401

Acute inhalation toxicity : Acute toxicity estimate: 1.6 mg/l
Test atmosphere: dust/mist
Method: Expert judgment

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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.

1-Tetradecanaminium, N,N,N-trimethyl-, bromide (1:1):

- Acute oral toxicity : LD50 (Rat): 390 mg/kg
- Acute inhalation toxicity : LC50 (Mouse): 1,8 mg/m³
Test atmosphere: dust/mist
Assessment: The substance or mixture has no acute inhalation toxicity
- Acute dermal toxicity : LD50 Dermal (Rabbit): ca. 2,150 mg/kg

Skin corrosion/irritation

Not classified based on available information.

Components:**1-Piperazineethanesulfonic acid, 4-(2-hydroxyethyl)-:**

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

Edetic acid disodium salt dihydrate (EDTA-2Na-2H₂O):

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

hydroxyl-2-pyridone:

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

1-Tetradecanaminium, N,N,N-trimethyl-, bromide (1:1):

- Result : Irritating to skin.

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Causes serious eye damage.

Components:**1-Piperazineethanesulfonic acid, 4-(2-hydroxyethyl)-:**

Species	: Rabbit
Result	: No eye irritation
Exposure time	: 30 s
Method	: OECD Test Guideline 405
GLP	: yes

Edetic acid disodium salt dihydrate (EDTA-2Na-2H₂O):

Species	: Rabbit
Result	: No eye irritation
Test substance	: anhydrous substance
Remarks	: Based on data from similar materials

hydroxyl-2-pyridone:

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

1-Tetradecanaminium, N,N,N-trimethyl-, bromide (1:1):

Result	: Risk of serious damage to eyes.
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Respiratory or skin sensitization**Skin sensitization**

Not classified based on available information.

Respiratory sensitization

Not classified based on available information.

Components:**1-Piperazineethanesulfonic acid, 4-(2-hydroxyethyl)-:**

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

Edetic acid disodium salt dihydrate (EDTA-2Na-2H₂O):

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

hydroxyl-2-pyridone:

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

Germ cell mutagenicity

Not classified based on available information.

Components:**1-Piperazineethanesulfonic acid, 4-(2-hydroxyethyl)-:**

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: Chromosome aberration test in vitro
Test system: Human lymphocytes
Metabolic activation: with and without metabolic activation
Method: OECD Test Guideline 473
Result: negative
GLP: yes

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

Carcinogenicity

Not classified based on available information.

Components:**1-Piperazineethanesulfonic acid, 4-(2-hydroxyethyl)-:**

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.

D-Mannitol:

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.

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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:**1-Piperazineethanesulfonic acid, 4-(2-hydroxyethyl)-:**

Effects on fetal development : Species: Rat, female
Application Route: Oral
Dose: 100, 300, 1000 mg/kg bw/day
Duration of Single Treatment: 14 d
General Toxicity Maternal: NOEL: 1,000 mg/kg body weight
Embryo-fetal toxicity.: NOEL: 1,000 mg/kg body weight
Method: OECD Test Guideline 414
GLP: yes

STOT-single exposure

Not classified based on available information.

Components:**D-Mannitol:**

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

1-Tetradecanaminium, N,N,N-trimethyl-, bromide (1:1):

Routes of exposure : Inhalation
Target Organs : Respiratory system
Assessment : May cause respiratory irritation.

STOT-repeated exposure

May cause damage to organs through prolonged or repeated exposure.

Components:**D-Mannitol:**

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

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

Repeated dose toxicity**Components:****1-Piperazineethanesulfonic acid, 4-(2-hydroxyethyl)-:**

Species : Rat, male and female
NOEL : 1000 mg/kg
Application Route : Oral
Exposure time : 28 d
Dose : 100, 300, 1000 mg/kg bw/day
Method : OECD Test Guideline 407
GLP : yes

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

1-Tetradecanaminium, N,N,N-trimethyl-, bromide (1:1):

Species : Rat
: 75 mg/kg
Application Route : Oral
Test atmosphere : dust/mist
Exposure time : 21 d
Assessment : The substance or mixture is classified as specific target organ toxicant, repeated exposure, category 2.

Aspiration toxicity

Not classified based on available information.

Components:**D-Mannitol:**

No data available

Further information**Components:****D-Mannitol:**

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

1-Tetradecanaminium, N,N,N-trimethyl-, bromide (1:1):

Remarks : Other dangerous properties can not be excluded.

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SECTION 12. ECOLOGICAL INFORMATION**Cal 1****Ecotoxicity****Components:****1-Piperazineethanesulfonic acid, 4-(2-hydroxyethyl)-:**

- Toxicity to fish : LC50 (Brachydanio rerio (zebrafish)): > 100 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)): > 100 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 : ErC50 (Pseudokirchneriella subcapitata (green algae)): > 100 mg/l
End point: Growth rate
Exposure time: 72 h
Test Type: static test
Analytical monitoring: yes
Method: OECD Test Guideline 201
GLP: yes
- NOEC (Pseudokirchneriella subcapitata (green algae)): > 100 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): > 1,000 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

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

Other organisms relevant to
the environment : No data available**D-Mannitol:**Toxicity to fish : LC50 (Fish): > 100 mg/l
Exposure time: 96 hToxicity to fish (Chronic tox-
icity) : > 1 mg/l**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**Edetic acid disodium salt dihydrate (EDTA-2Na-2H₂O):**Toxicity to fish : LC50 (Lepomis macrochirus (Bluegill sunfish)): 41 mg/l
Exposure time: 96 hToxicity to daphnia and other : EC50 (Daphnia magna (Water flea)): 140 mg/l
aquatic invertebrates : Exposure time: 48 h
Test Type: static test
Method: DIN 38412Toxicity to microorganisms : EC20 (activated sludge): > 500 mg/l
Exposure time: 0.5 h
Test Type: Respiration inhibition
Method: OECD Test Guideline 209**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**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

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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

1-Tetradecanaminium, N,N,N-trimethyl-, bromide (1:1):

Toxicity to fish : LC50 (*Danio rerio* (zebra fish)): 1.81 mg/l
Exposure time: 96 h

Toxicity to daphnia and other aquatic invertebrates : EC50 (*Daphnia magna* (Water flea)): 0.022 mg/l
Exposure time: 48 h

Toxicity to algae/aquatic plants : EC50 (*Pseudokirchneriella subcapitata* (green algae)): 0.00538 mg/l
Exposure time: 72 h

NOEC (*Pseudokirchneriella subcapitata* (green algae)): 0.0013 mg/l
Exposure time: 72 h

Toxicity to daphnia and other : NOEC (*Daphnia magna* (Water flea)): 0.023 mg/l

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aquatic invertebrates (Chronic toxicity)

Exposure time: 21 d

Toxicity to microorganisms : EC50 (Natural microorganism): 19 mg/l

Persistence and degradability**Components:****1-Piperazineethanesulfonic acid, 4-(2-hydroxyethyl)-:**

Biodegradability : aerobic
Inoculum: activated sludge, non-adapted
Result: Not readily biodegradable.
Biodegradation: 0 %
Exposure time: 28 d
Method: OECD Test Guideline 301D
GLP: yes

D-Mannitol:

Biodegradability : Biodegradation: 68 %
Exposure time: 28 d

Edetic acid disodium salt dihydrate (EDTA-2Na-2H₂O):

Biodegradability : Result: Not readily biodegradable.

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).

1-Tetradecanaminium, N,N,N-trimethyl-, bromide (1:1):

Biodegradability : Result: Readily biodegradable.

Bioaccumulative potential**Components:****1-Piperazineethanesulfonic acid, 4-(2-hydroxyethyl)-:**

Partition coefficient: n-octanol/water : log Pow: < -3.85 (68 °F / 20 °C)
Method: OECD Test Guideline 107
GLP: yes

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octanol/water : log Pow: -3.10**Edetic acid disodium salt dihydrate (EDTA-2Na-2H₂O):**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: yeslog Pow: -2.73 (77 °F / 25 °C)
pH: 9
Method: OECD Test Guideline 107
GLP: yeslog Pow: -1.59 (77 °F / 25 °C)
pH: 7
Method: OECD Test Guideline 107
GLP: yes**1-Tetradecanaminium, N,N,N-trimethyl-, bromide (1:1):**Bioaccumulation : Bioconcentration factor (BCF): 750
Remarks: Does not bioaccumulate.Partition coefficient: n-
octanol/water : log Pow: 2.2 (68 °F / 20 °C)**Mobility in soil**

No data available

Other adverse effects**Components:****1-Piperazineethanesulfonic acid, 4-(2-hydroxyethyl)-:**Additional ecological infor-
mation : No data available**hydroxyl-2-pyridone:**Additional ecological infor-
mation : No data available**Cal 2**

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Ecotoxicity**Components:****1-Piperazineethanesulfonic acid, 4-(2-hydroxyethyl)-:**

Toxicity to fish : LC50 (Brachydanio rerio (zebrafish)): > 100 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)): > 100 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 : ErC50 (Pseudokirchneriella subcapitata (green algae)): > 100 mg/l
End point: Growth rate
Exposure time: 72 h
Test Type: static test
Analytical monitoring: yes
Method: OECD Test Guideline 201
GLP: yes

NOEC (Pseudokirchneriella subcapitata (green algae)): > 100 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): > 1,000 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

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

Other organisms relevant to the environment : No data available

D-Mannitol:

Toxicity to fish : LC50 (Fish): > 100 mg/l

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Exposure time: 96 h

Toxicity to fish (Chronic toxicity) : > 1 mg/l

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

Edetic acid disodium salt dihydrate (EDTA-2Na-2H₂O):Toxicity to fish : LC50 (Lepomis macrochirus (Bluegill sunfish)): 41 mg/l
Exposure time: 96 hToxicity to daphnia and other aquatic invertebrates : EC50 (Daphnia magna (Water flea)): 140 mg/l
Exposure time: 48 h
Test Type: static test
Method: DIN 38412Toxicity to microorganisms : EC20 (activated sludge): > 500 mg/l
Exposure time: 0.5 h
Test Type: Respiration inhibition
Method: OECD Test Guideline 209**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

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: yesToxicity 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

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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

1-Tetradecanaminium, N,N,N-trimethyl-, bromide (1:1):

Toxicity to fish : LC50 (Danio rerio (zebra fish)): 1.81 mg/l
Exposure time: 96 h

Toxicity to daphnia and other aquatic invertebrates : EC50 (Daphnia magna (Water flea)): 0.022 mg/l
Exposure time: 48 h

Toxicity to algae/aquatic plants : EC50 (Pseudokirchneriella subcapitata (green algae)): 0.00538 mg/l
Exposure time: 72 h

NOEC (Pseudokirchneriella subcapitata (green algae)): 0.0013 mg/l
Exposure time: 72 h

Toxicity to daphnia and other aquatic invertebrates (Chronic toxicity) : NOEC (Daphnia magna (Water flea)): 0.023 mg/l
Exposure time: 21 d

Toxicity to microorganisms : EC50 (Natural microorganism): 19 mg/l

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Biodegradability : aerobic
Inoculum: activated sludge, non-adapted
Result: Not readily biodegradable.
Biodegradation: 0 %
Exposure time: 28 d
Method: OECD Test Guideline 301D
GLP: yes

D-Mannitol:

Biodegradability : Biodegradation: 68 %
Exposure time: 28 d

Edetic acid disodium salt dihydrate (EDTA-2Na-2H₂O):

Biodegradability : Result: Not readily biodegradable.

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).

1-Tetradecanaminium, N,N,N-trimethyl-, bromide (1:1):

Biodegradability : Result: Readily biodegradable.

Bioaccumulative potential**Components:****1-Piperazineethanesulfonic acid, 4-(2-hydroxyethyl)-:**

Partition coefficient: n-octanol/water : log Pow: < -3.85 (68 °F / 20 °C)
Method: OECD Test Guideline 107
GLP: yes

D-Mannitol:

Partition coefficient: n-octanol/water : log Pow: -3.10

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Date of first issue: 03-22-2018**Edetic acid disodium salt dihydrate (EDTA-2Na-2H₂O):**

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: yeslog Pow: -2.73 (77 °F / 25 °C)
pH: 9
Method: OECD Test Guideline 107
GLP: yeslog Pow: -1.59 (77 °F / 25 °C)
pH: 7
Method: OECD Test Guideline 107
GLP: yes**1-Tetradecanaminium, N,N,N-trimethyl-, bromide (1:1):**Bioaccumulation : Bioconcentration factor (BCF): 750
Remarks: Does not bioaccumulate.

Partition coefficient: n-octanol/water : log Pow: 2.2 (68 °F / 20 °C)

Mobility in soil

No data available

Other adverse effects**Components:****1-Piperazineethanesulfonic acid, 4-(2-hydroxyethyl)-:**

Additional ecological information : No data available

hydroxyl-2-pyridone:

Additional ecological information : No data available

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.

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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**

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 : Combustible dust
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.

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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 SOCM 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

1-Piperazineethanesulfonic acid, 4-(2-hydroxyethyl)-	7365-45-9
Human serum /-plasma / -hemolysate, lyophilized	Not Assigned
D-Mannitol	69-65-8
Edetic acid disodium salt dihydrate (EDTA-2Na-2H ₂ O)	6381-92-6

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
	4-(2-Aminoethyl)benzenesulfonyl Fluoride Hydrochloride
	Leupeptin hemisulfate
	AprotininTrypsin inhibitor, pancreas type (BPTI) from bovine lung
NZIoC	: Not in compliance with the inventory

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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 : Combustible dust
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 SOCM Intermediate or Final VOC's (40 CFR 60.489).

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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

1-Piperazineethanesulfonic acid, 4-(2-hydroxyethyl)-	7365-45-9
Human serum /-plasma / -hemolysate, lyophilized	Not Assigned
D-Mannitol	69-65-8
Edetic acid disodium salt dihydrate (EDTA-2Na-2H ₂ O)	6381-92-6

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
		4-(2-Aminoethyl)benzenesulfonyl Fluoride Hydrochloride
		Leupeptin hemisulfate
		AprotininTrypsin inhibitor, pancreas type (BPTI) from bovine lung
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

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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 : Danger

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

Precautionary Statements : **Prevention:**
P260 Do not breathe dust.
P280 Wear eye protection/ face protection.

Response:
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.

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

Cal 2
GHS label elements

Hazard pictograms :



Signal Word : Danger

SAFETY DATA SHEET



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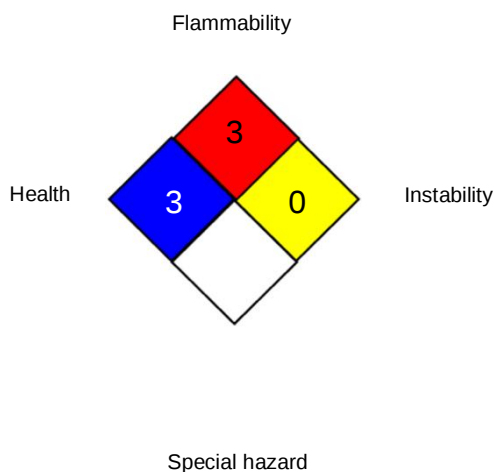
Date of last issue: 10-11-2021
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- Hazard Statements : May form combustible dust concentrations in air.
H318 Causes serious eye damage.
H373 May cause damage to organs through prolonged or repeated exposure.
- Precautionary Statements : **Prevention:**
P260 Do not breathe dust.
P280 Wear eye protection/ face protection.
- Response:**
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.
- Disposal:**
P501 Dispose of contents/ container to an approved waste disposal plant.

SECTION 16. OTHER INFORMATION

Further information

NFPA 704:



HMIS® IV:

HEALTH	*	3
FLAMMABILITY		3
PHYSICAL HAZARD		0

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.

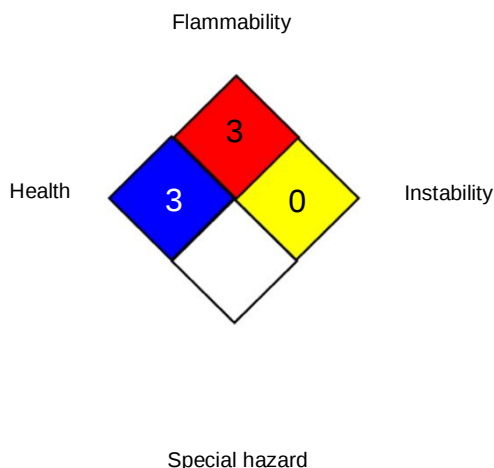
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NFPA 704:



HMIS® IV:

HEALTH	*	3
FLAMMABILITY		3
PHYSICAL HAZARD		0

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; IECS - 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; TECL - 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

SAFETY DATA SHEET



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