

SAFETY DATA SHEET



Complete, 20 tablets

Version
2.1

Revision Date:
05-08-2023

Date of last issue: 03-21-2022
Date of first issue: 08-11-2015

SECTION 1. IDENTIFICATION

Product name : Complete, 20 tablets

Product code : 11697498001

Manufacturer or supplier's details

Company name of supplier : Roche Diagnostics Deutschland GmbH

Address : 116 Sandhoferstrasse
Mannheim, 68305
Germany

Telephone : +496217590

Telefax : +496217592890

E-mail address : info.dia-sds@roche.com

Emergency telephone

In case of emergencies: : CHEMTREC +1 703-741-5970 /
1-800-424-9300


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)

GHS label elements

Hazard pictograms : 

Signal Word : Danger

Hazard Statements : H314 Causes severe skin burns and eye damage.

Precautionary Statements : **Prevention:**
P260 Do not breathe dust.
P264 Wash skin thoroughly after handling.
P280 Wear protective gloves/ protective clothing/ eye protection/ face protection.
Response:
P301 + P330 + P331 IF SWALLOWED: Rinse mouth. Do NOT induce vomiting.
P303 + P361 + P353 IF ON SKIN (or hair): Take off immediately all contaminated clothing. Rinse skin with water/ shower.
P304 + P340 + P310 IF INHALED: Remove person to fresh air and keep comfortable for breathing. Immediately call a POISON

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CENTER/ doctor.
 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.
 P363 Wash contaminated clothing before reuse.

Storage:

P405 Store locked up.

Disposal:

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

Other hazards

None known.

SECTION 3. COMPOSITION/INFORMATION ON INGREDIENTS
Complete Protease Inhibitor Cocktail**GHS Classification**

Skin corrosion : Category 1B

Serious eye damage : Category 1

Components

Chemical name	CAS-No.	Concentration (% w/w)
D-Mannitol	69-65-8	>= 50 - < 70
Glycine, N,N'-1,2-ethanediybis[N-(carboxymethyl)-, sodium salt (1:2)	139-33-3	>= 20 - < 30
4-(2-Aminoethyl)benzenesulfonyl Fluoride Hydrochloride	30827-99-7	>= 5 - < 10
2-Pyrrolidinone, 1-ethenyl-, homopolymer	9003-39-8	>= 1 - < 5
Poly(oxy-1,2-ethanediyl), .alpha.-hydro-.omega.-hydroxy-	25322-68-3	>= 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.
 Consult a physician after significant exposure.
 If unconscious, place in recovery position and seek medical advice.



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- In case of skin contact : Immediate medical treatment is necessary as untreated wounds from corrosion of the skin heal slowly and with difficulty.
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 : 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 : 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.



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Ensure adequate ventilation.

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 contact with skin and eyes.
 For personal protection see section 8.
 Smoking, eating and drinking should be prohibited in the application area.
 Provide sufficient air exchange and/or exhaust in work rooms.
 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.
 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

Complete Protease Inhibitor Cocktail

Ingredients with workplace control parameters

Components	CAS-No.	Value type (Form of exposure)	Control parameters / Permissible concentration	Basis
Poly(oxy-1,2-ethanediyl), .alpha.-hydro-.omega.-hydroxy-	25322-68-3	TWA (aerosol)	10 mg/m3	US WEEL

Engineering measures : No data available

Personal protective equipment

Respiratory protection : In the case of dust or aerosol formation use respirator with an approved filter.
 Effective dust mask



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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

Complete Protease Inhibitor Cocktail

Appearance : solid

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

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Flammability (liquids) : Sustains combustion

Self-ignition : No data available

Upper explosion limit / Upper flammability limit : No data available

Lower explosion limit / Lower flammability limit : No data available

Vapor pressure : No data available

Relative vapor density : Not applicable

Relative density : No data available

Solubility(ies)

 Water solubility : soluble

 Solubility in other solvents : No data available

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

Autoignition temperature : No data available

Decomposition temperature : No data available

Viscosity

 Viscosity, dynamic : Not applicable

 Viscosity, kinematic : Not applicable

Explosive properties : Not explosive

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

SECTION 10. STABILITY AND REACTIVITY

Reactivity : No dangerous reaction known under conditions of normal use.

Chemical stability : Stable under normal conditions.

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

Conditions to avoid : Exposure to moisture.

Incompatible materials : Strong oxidizing agents

Hazardous decomposition products : No decomposition if stored and applied as directed.

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SECTION 11. TOXICOLOGICAL INFORMATION
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Acute toxicity

Not classified based on available information.

Components:
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

Glycine, N,N'-1,2-ethanediylbis[N-(carboxymethyl)-, sodium salt (1:2):

Acute oral toxicity : LD50 Oral (Rat): > 2,000 - 5,000 mg/kg

Acute inhalation toxicity : LC50 (Rat): > 1 - < 5 mg/l
Exposure time: 6 h
Test atmosphere: dust/mist
Method: OECD Test Guideline 403
Assessment: The component/mixture is moderately toxic after short term inhalation.

4-(2-Aminoethyl)benzenesulfonyl Fluoride Hydrochloride:

Acute oral toxicity : LD50 Oral (Mouse): 2,800 mg/kg

2-Pyrrolidinone, 1-ethenyl-, homopolymer:

Acute oral toxicity : LD50 Oral (Rat): 100,000 mg/kg
Assessment: The substance or mixture has no acute oral toxicity

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

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

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

Acute oral toxicity : LD50 Oral (Rat): 28,000 mg/kg

Acute dermal toxicity : LD50 Dermal (Rabbit): 20,000 mg/kg

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Skin corrosion/irritation

Causes severe burns.

Components:
Glycine, N,N'-1,2-ethanediylbis[N-(carboxymethyl)-, sodium salt (1:2):

Result : No skin irritation

4-(2-Aminoethyl)benzenesulfonyl Fluoride Hydrochloride:

Result : Causes burns.

Remarks : Extremely corrosive and destructive to tissue.

Serious eye damage/eye irritation

Causes serious eye damage.

Components:
Glycine, N,N'-1,2-ethanediylbis[N-(carboxymethyl)-, sodium salt (1:2):

Result : No eye irritation

4-(2-Aminoethyl)benzenesulfonyl Fluoride Hydrochloride:

Remarks : May cause irreversible eye damage.

Respiratory or skin sensitization
Skin sensitization

Not classified based on available information.

Respiratory sensitization

Not classified based on available information.

Components:
Glycine, N,N'-1,2-ethanediylbis[N-(carboxymethyl)-, sodium salt (1:2):

Test Type : Maximization Test

Species : Guinea pig

Assessment : Does not cause skin sensitization.

Method : OECD Test Guideline 406

Germ cell mutagenicity

Not classified based on available information.

Carcinogenicity

Not classified based on available information.

Components:
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.

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.



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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.

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.

2-Pyrrolidinone, 1-ethenyl-, homopolymer:

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:

D-Mannitol:

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

Glycine, N,N'-1,2-ethanediybis[N-(carboxymethyl)-, sodium salt (1:2):

Routes of exposure : inhalation (dust/mist/fume)

Target Organs : Respiratory Tract

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

2-Pyrrolidinone, 1-ethenyl-, homopolymer:

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

Aspiration toxicity

Not classified based on available information.

Components:

D-Mannitol:

No data available

2-Pyrrolidinone, 1-ethenyl-, homopolymer:

No data available

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Further information

Components:

D-Mannitol:

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

4-(2-Aminoethyl)benzenesulfonyl Fluoride Hydrochloride:

Remarks : Other dangerous properties can not be excluded.

2-Pyrrolidinone, 1-ethenyl-, homopolymer:

Remarks : No toxicology information is available.

SECTION 12. ECOLOGICAL INFORMATION

Complete Protease Inhibitor Cocktail

Ecotoxicity

Components:

D-Mannitol:

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

Glycine, N,N'-1,2-ethanediylbis[N-(carboxymethyl)-, sodium salt (1:2):

Toxicity to fish : LC50 (Lepomis macrochirus (Bluegill sunfish)): > 100 mg/l
Exposure time: 96 h
Test Type: static test
Remarks: nominal concentration
Based on data from similar materials

Toxicity to daphnia and other aquatic invertebrates : EC50 (Daphnia magna (Water flea)): > 100 mg/l
Exposure time: 48 h
Test Type: static test
Method: DIN 38412

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Remarks: nominal concentration

- Toxicity to algae/aquatic plants : ErC50 (Pseudokirchneriella subcapitata (green algae)): > 100 mg/l
 Exposure time: 72 h
 Test Type: static test
 Remarks: Based on data from similar materials
- Toxicity to fish (Chronic toxicity) : NOEC (Danio rerio (zebra fish)): >= 36.9 mg/l
 Exposure time: 35 d
 Test Type: flow-through test
 Method: OECD Test Guideline 210
 Remarks: Based on data from similar materials
- Toxicity to microorganisms : EC20 (activated sludge): > 500 mg/l
 Exposure time: 30 min
 Method: OECD Test Guideline 209

4-(2-Aminoethyl)benzenesulfonyl Fluoride Hydrochloride:
Ecotoxicology Assessment

- Toxicity Data on Soil : Not expected to adsorb on soil.
- Other organisms relevant to the environment : No data available

2-Pyrrolidinone, 1-ethenyl-, homopolymer:
Ecotoxicology Assessment

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

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

- Toxicity to fish : LC50 (Cyprinus carpio (Carp)): > 100 mg/l
 Exposure time: 4 d
 Method: OECD Test Guideline 203
- Toxicity to daphnia and other aquatic invertebrates : EC50 (Daphnia magna (Water flea)): > 100 mg/l
 Exposure time: 48 h
 Method: OECD Test Guideline 202
- Toxicity to algae/aquatic plants : EC50 (Desmodesmus subspicatus (green algae)): > 100 mg/l
 Exposure time: 72 h
- Toxicity to fish (Chronic toxicity) : > 1 mg/l

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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

Persistence and degradability
Components:
D-Mannitol:

Biodegradability : Biodegradation: 68 %
Exposure time: 28 d

Glycine, N,N'-1,2-ethanediylbis[N-(carboxymethyl)-, sodium salt (1:2):

Biodegradability : aerobic
Result: Not readily biodegradable.
Method: OECD Test Guideline 301D
Remarks: Based on data from similar materials

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

Biodegradability : Biodegradation: > 90 %
Exposure time: 28 d
Method: OECD Test Guideline 301

Bioaccumulative potential
Components:
D-Mannitol:

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

Glycine, N,N'-1,2-ethanediylbis[N-(carboxymethyl)-, sodium salt (1:2):

Bioaccumulation : Species: Lepomis macrochirus (Bluegill sunfish)
Bioconcentration factor (BCF): 1.8
Exposure time: 28 d
Remarks: Bioaccumulation is unlikely.

Partition coefficient: n-octanol/water : log Pow: -4.3 (77 °F / 25 °C)
pH: 4.5

4-(2-Aminoethyl)benzenesulfonyl Fluoride Hydrochloride:

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

2-Pyrrolidinone, 1-ethenyl-, homopolymer:



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

Poly(oxy-1,2-ethanediyl), .alpha.-hydro.-omega.-hydroxy-:
Partition coefficient: n-octanol/water : Remarks: No data available

Mobility in soil
No data available

Other adverse effects

Components:

Poly(oxy-1,2-ethanediyl), .alpha.-hydro.-omega.-hydroxy-:
Adsorbed organic bound halogens (AOX) : Remarks: Not applicable

SECTION 13. DISPOSAL CONSIDERATIONS

Disposal methods

- Waste from residues : Do not contaminate ponds, waterways or ditches with chemical or used container.
Send to a licensed waste management company.

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

SECTION 14. TRANSPORT INFORMATION

International Regulations

UNRTDG
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



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

SECTION 15. REGULATORY INFORMATION

Complete Protease Inhibitor Cocktail

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 : Skin corrosion or irritation
 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).

The following chemical(s) are listed under the U.S. Clean Air Act Section 111 SOCM I Intermediate or Final VOC's (40 CFR 60.489):

Poly(oxy-1,2-ethanediy), .alpha.-hydro-.omega.-hydroxy-	25322-68-3	>= 1 - < 5 %
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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

D-Mannitol	69-65-8
Glycine, N,N'-1,2-ethanediybis[N-(carboxymethyl)-, sodium salt (1:2)	139-33-3
4-(2-Aminoethyl)benzenesulfonyl Fluoride Hydrochloride	30827-99-7



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2-Pyrrolidinone, 1-ethenyl-, homopolymer 9003-39-8

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

California List of Hazardous Substances

2-Pyrrolidinone, 1-ethenyl-, homopolymer 9003-39-8

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.
 - 4-(2-Aminoethyl)benzenesulfonyl Fluoride Hydrochloride
 - Leupeptin hemisulfate
 - AprotininTrypsin inhibitor, pancreas type (BPTI) from bovine lung
- NZIoC : On the inventory, or 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 : On the inventory, or in compliance with the inventory
- TCSI : On the inventory, or 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.

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GHS label elements

Hazard pictograms : 

Signal Word : Danger

Hazard Statements : H314 Causes severe skin burns and eye damage.

Precautionary Statements : **Prevention:**
P260 Do not breathe dust.
P264 Wash skin thoroughly after handling.
P280 Wear protective gloves/ protective clothing/ eye protection/ face protection.
Response:
P301 + P330 + P331 IF SWALLOWED: Rinse mouth. Do NOT induce vomiting.
P303 + P361 + P353 IF ON SKIN (or hair): Take off immediately all contaminated clothing. Rinse skin with water/ shower.
P304 + P340 + P310 IF INHALED: Remove person to fresh air and keep comfortable for breathing. Immediately call a POISON CENTER/ doctor.
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.
P363 Wash contaminated clothing before reuse.
Storage:
P405 Store locked up.
Disposal:
P501 Dispose of contents/ container to an approved waste disposal plant.

SECTION 16. OTHER INFORMATION

Further information
Complete Protease Inhibitor Cocktail

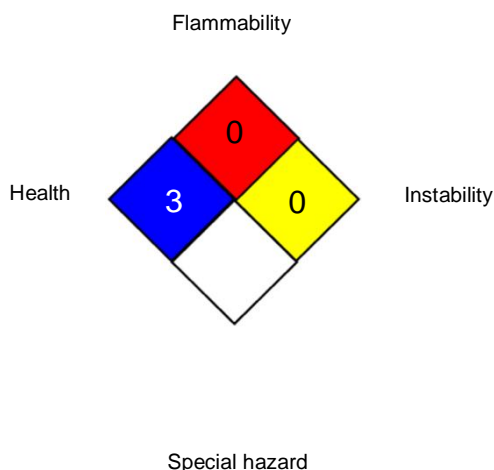
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NFPA 704:



HMIS® IV:

HEALTH	/	3
FLAMMABILITY	0	
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.

Distributor

MilliporeSigma
3050 Spruce Street
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MO 63103 USA

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

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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

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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.

US / Z8 / 2204

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SECTION 1. IDENTIFICATION

Product name : Complete, 3 x 20 tablets

Product code : 11836145001

Manufacturer or supplier's details

Company name of supplier : Roche Diagnostics Deutschland GmbH

Address : 116 Sandhoferstrasse
Mannheim, 68305
Germany

Telephone : +496217590

Telefax : +496217592890

E-mail address : info.dia-sds@roche.com

Emergency telephone

In case of emergencies: : CHEMTREC +1 703-741-5970 /
1-800-424-9300


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)

GHS label elements

Hazard pictograms : 

Signal Word : Danger

Hazard Statements : H314 Causes severe skin burns and eye damage.

Precautionary Statements : **Prevention:**
P260 Do not breathe dust.
P264 Wash skin thoroughly after handling.
P280 Wear protective gloves/ protective clothing/ eye protection/ face protection.
Response:
P301 + P330 + P331 IF SWALLOWED: Rinse mouth. Do NOT induce vomiting.
P303 + P361 + P353 IF ON SKIN (or hair): Take off immediately all contaminated clothing. Rinse skin with water/ shower.
P304 + P340 + P310 IF INHALED: Remove person to fresh air and keep comfortable for breathing. Immediately call a POISON

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CENTER/ doctor.
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.
P363 Wash contaminated clothing before reuse.

Storage:

P405 Store locked up.

Disposal:

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

Other hazards

None known.

SECTION 3. COMPOSITION/INFORMATION ON INGREDIENTS

Complete Protease Inhibitor Cocktail

GHS Classification

Skin corrosion : Category 1B

Serious eye damage : Category 1

Components

Chemical name	CAS-No.	Concentration (% w/w)
D-Mannitol	69-65-8	$\geq 50 - < 70$
Glycine, N,N'-1,2-ethanediylbis[N-(carboxymethyl)-, sodium salt (1:2)	139-33-3	$\geq 20 - < 30$
4-(2-Aminoethyl)benzenesulfonyl Fluoride Hydrochloride	30827-99-7	$\geq 5 - < 10$
2-Pyrrolidinone, 1-ethenyl-, homopolymer	9003-39-8	$\geq 1 - < 5$
Poly(oxy-1,2-ethanediyl), .alpha.-hydro-.omega.-hydroxy-	25322-68-3	$\geq 1 - < 5$

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.
Consult a physician after significant exposure.
If unconscious, place in recovery position and seek medical advice.



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- In case of skin contact : Immediate medical treatment is necessary as untreated wounds from corrosion of the skin heal slowly and with difficulty.
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 : 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 : 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.



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Ensure adequate ventilation.

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 contact with skin and eyes.
 For personal protection see section 8.
 Smoking, eating and drinking should be prohibited in the application area.
 Provide sufficient air exchange and/or exhaust in work rooms.
 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.
 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

Complete Protease Inhibitor Cocktail

Ingredients with workplace control parameters

Components	CAS-No.	Value type (Form of exposure)	Control parameters / Permissible concentration	Basis
Poly(oxy-1,2-ethanediyl), .alpha.-hydro-.omega.-hydroxy-	25322-68-3	TWA (aerosol)	10 mg/m3	US WEEL

Engineering measures : No data available

Personal protective equipment

Respiratory protection : In the case of dust or aerosol formation use respirator with an approved filter.
 Effective dust mask



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- 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

Complete Protease Inhibitor Cocktail

- Appearance : solid
- 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

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

SECTION 10. STABILITY AND REACTIVITY

Reactivity	:	No dangerous reaction known under conditions of normal use.
Chemical stability	:	Stable under normal conditions.
Possibility of hazardous reactions	:	No dangerous reaction known under conditions of normal use. No decomposition if stored and applied as directed.
Conditions to avoid	:	Exposure to moisture.
Incompatible materials	:	Strong oxidizing agents
Hazardous decomposition products	:	No decomposition if stored and applied as directed.

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SECTION 11. TOXICOLOGICAL INFORMATION
Complete Protease Inhibitor Cocktail
Acute toxicity

Not classified based on available information.

Components:
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

Glycine, N,N'-1,2-ethanediylbis[N-(carboxymethyl)-, sodium salt (1:2):

Acute oral toxicity : LD50 Oral (Rat): > 2,000 - 5,000 mg/kg

Acute inhalation toxicity : LC50 (Rat): > 1 - < 5 mg/l
Exposure time: 6 h
Test atmosphere: dust/mist
Method: OECD Test Guideline 403
Assessment: The component/mixture is moderately toxic after short term inhalation.

4-(2-Aminoethyl)benzenesulfonyl Fluoride Hydrochloride:

Acute oral toxicity : LD50 Oral (Mouse): 2,800 mg/kg

2-Pyrrolidinone, 1-ethenyl-, homopolymer:

Acute oral toxicity : LD50 Oral (Rat): 100,000 mg/kg
Assessment: The substance or mixture has no acute oral toxicity

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

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

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

Acute oral toxicity : LD50 Oral (Rat): 28,000 mg/kg

Acute dermal toxicity : LD50 Dermal (Rabbit): 20,000 mg/kg



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Skin corrosion/irritation

Causes severe burns.

Components:

Glycine, N,N'-1,2-ethanediylbis[N-(carboxymethyl)-, sodium salt (1:2):

Result : No skin irritation

4-(2-Aminoethyl)benzenesulfonyl Fluoride Hydrochloride:

Result : Causes burns.

Remarks : Extremely corrosive and destructive to tissue.

Serious eye damage/eye irritation

Causes serious eye damage.

Components:

Glycine, N,N'-1,2-ethanediylbis[N-(carboxymethyl)-, sodium salt (1:2):

Result : No eye irritation

4-(2-Aminoethyl)benzenesulfonyl Fluoride Hydrochloride:

Remarks : May cause irreversible eye damage.

Respiratory or skin sensitization

Skin sensitization

Not classified based on available information.

Respiratory sensitization

Not classified based on available information.

Components:

Glycine, N,N'-1,2-ethanediylbis[N-(carboxymethyl)-, sodium salt (1:2):

Test Type : Maximization Test

Species : Guinea pig

Assessment : Does not cause skin sensitization.

Method : OECD Test Guideline 406

Germ cell mutagenicity

Not classified based on available information.

Carcinogenicity

Not classified based on available information.

Components:

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.

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.



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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.

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.

2-Pyrrolidinone, 1-ethenyl-, homopolymer:

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:

D-Mannitol:

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

Glycine, N,N'-1,2-ethanediybis[N-(carboxymethyl)-, sodium salt (1:2):

Routes of exposure : inhalation (dust/mist/fume)
Target Organs : Respiratory Tract
Assessment : May cause damage to organs through prolonged or repeated exposure.

2-Pyrrolidinone, 1-ethenyl-, homopolymer:

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

Aspiration toxicity

Not classified based on available information.

Components:

D-Mannitol:

No data available

2-Pyrrolidinone, 1-ethenyl-, homopolymer:

No data available

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

4-(2-Aminoethyl)benzenesulfonyl Fluoride Hydrochloride:

Remarks : Other dangerous properties can not be excluded.

2-Pyrrolidinone, 1-ethenyl-, homopolymer:

Remarks : No toxicology information is available.

SECTION 12. ECOLOGICAL INFORMATION
Complete Protease Inhibitor Cocktail**Ecotoxicity****Components:****D-Mannitol:**Toxicity to fish : LC50 (Fish): > 100 mg/l
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

Glycine, N,N'-1,2-ethanediylbis[N-(carboxymethyl)-, sodium salt (1:2):Toxicity to fish : LC50 (Lepomis macrochirus (Bluegill sunfish)): > 100 mg/l
Exposure time: 96 h
Test Type: static test
Remarks: nominal concentration
Based on data from similar materialsToxicity to daphnia and other aquatic invertebrates : EC50 (Daphnia magna (Water flea)): > 100 mg/l
Exposure time: 48 h
Test Type: static test
Method: DIN 38412



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Remarks: nominal concentration

- Toxicity to algae/aquatic plants : ErC50 (Pseudokirchneriella subcapitata (green algae)): > 100 mg/l
Exposure time: 72 h
Test Type: static test
Remarks: Based on data from similar materials

- Toxicity to fish (Chronic toxicity) : NOEC (Danio rerio (zebra fish)): >= 36.9 mg/l
Exposure time: 35 d
Test Type: flow-through test
Method: OECD Test Guideline 210
Remarks: Based on data from similar materials

- Toxicity to microorganisms : EC20 (activated sludge): > 500 mg/l
Exposure time: 30 min
Method: OECD Test Guideline 209

4-(2-Aminoethyl)benzenesulfonyl Fluoride Hydrochloride:

Ecotoxicology Assessment

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

- Other organisms relevant to the environment : No data available

2-Pyrrolidinone, 1-ethenyl-, homopolymer:

Ecotoxicology Assessment

- Acute aquatic toxicity : This product has no known ecotoxicological effects.

- Chronic aquatic toxicity : This product has no known ecotoxicological effects.

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

- Other organisms relevant to the environment : No data available

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

- Toxicity to fish : LC50 (Cyprinus carpio (Carp)): > 100 mg/l
Exposure time: 4 d
Method: OECD Test Guideline 203

- Toxicity to daphnia and other aquatic invertebrates : EC50 (Daphnia magna (Water flea)): > 100 mg/l
Exposure time: 48 h
Method: OECD Test Guideline 202

- Toxicity to algae/aquatic plants : EC50 (Desmodesmus subspicatus (green algae)): > 100 mg/l
Exposure time: 72 h

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

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- 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

Persistence and degradability**Components:****D-Mannitol:**

- Biodegradability : Biodegradation: 68 %
Exposure time: 28 d

Glycine, N,N'-1,2-ethanediylbis[N-(carboxymethyl)-, sodium salt (1:2):

- Biodegradability : aerobic
Result: Not readily biodegradable.
Method: OECD Test Guideline 301D
Remarks: Based on data from similar materials

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

- Biodegradability : Biodegradation: > 90 %
Exposure time: 28 d
Method: OECD Test Guideline 301

Bioaccumulative potential**Components:****D-Mannitol:**

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

Glycine, N,N'-1,2-ethanediylbis[N-(carboxymethyl)-, sodium salt (1:2):

- Bioaccumulation : Species: Lepomis macrochirus (Bluegill sunfish)
Bioconcentration factor (BCF): 1.8
Exposure time: 28 d
Remarks: Bioaccumulation is unlikely.

- Partition coefficient: n-octanol/water : log Pow: -4.3 (77 °F / 25 °C)
pH: 4.5

4-(2-Aminoethyl)benzenesulfonyl Fluoride Hydrochloride:

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

2-Pyrrolidinone, 1-ethenyl-, homopolymer:



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

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

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

Mobility in soil

No data available

Other adverse effects

Components:

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

Adsorbed organic bound halogens (AOX) : Remarks: Not applicable

SECTION 13. DISPOSAL CONSIDERATIONS

Disposal methods

Waste from residues : Do not contaminate ponds, waterways or ditches with chemical or used container.
Send to a licensed waste management company.

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

SECTION 14. TRANSPORT INFORMATION

International Regulations

UNRTDG

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

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

SECTION 15. REGULATORY INFORMATION

Complete Protease Inhibitor Cocktail

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 : Skin corrosion or irritation
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).

The following chemical(s) are listed under the U.S. Clean Air Act Section 111 SOCM I Intermediate or Final VOC's (40 CFR 60.489):

Poly(oxy-1,2-ethanediy), .alpha.-hydro-.omega.-hydroxy-	25322-68-3	>= 1 - < 5 %
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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

D-Mannitol	69-65-8
Glycine, N,N'-1,2-ethanediybis[N-(carboxymethyl)-, sodium salt (1:2)	139-33-3
4-(2-Aminoethyl)benzenesulfonyl Fluoride Hydrochloride	30827-99-7



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2-Pyrrolidinone, 1-ethenyl-, homopolymer 9003-39-8

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

California List of Hazardous Substances

2-Pyrrolidinone, 1-ethenyl-, homopolymer 9003-39-8

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.
 - 4-(2-Aminoethyl)benzenesulfonyl Fluoride Hydrochloride
 - Leupeptin hemisulfate
 - AprotininTrypsin inhibitor, pancreas type (BPTI) from bovine lung
- NZIoC : On the inventory, or 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 : On the inventory, or in compliance with the inventory
- TCSI : On the inventory, or 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.

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GHS label elements

Hazard pictograms :



Signal Word : Danger

Hazard Statements : H314 Causes severe skin burns and eye damage.

Precautionary Statements : **Prevention:**
P260 Do not breathe dust.
P264 Wash skin thoroughly after handling.
P280 Wear protective gloves/ protective clothing/ eye protection/ face protection.
Response:
P301 + P330 + P331 IF SWALLOWED: Rinse mouth. Do NOT induce vomiting.
P303 + P361 + P353 IF ON SKIN (or hair): Take off immediately all contaminated clothing. Rinse skin with water/ shower.
P304 + P340 + P310 IF INHALED: Remove person to fresh air and keep comfortable for breathing. Immediately call a POISON CENTER/ doctor.
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.
P363 Wash contaminated clothing before reuse.
Storage:
P405 Store locked up.
Disposal:
P501 Dispose of contents/ container to an approved waste disposal plant.

SECTION 16. OTHER INFORMATION

Further information

Complete Protease Inhibitor Cocktail

SAFETY DATA SHEET



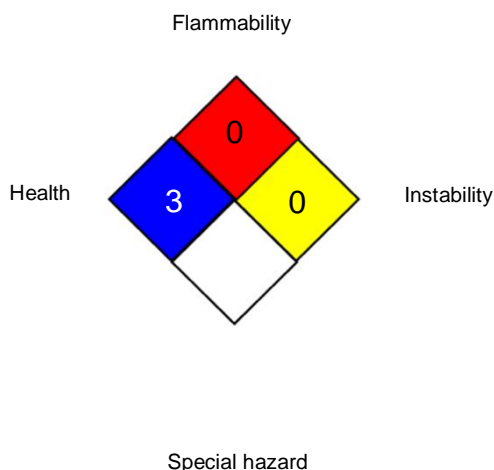
Complete, 3 x 20 tablets

Version
2.1

Revision Date:
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Date of last issue: 03-21-2022
Date of first issue: 08-11-2015

NFPA 704:



HMIS® IV:

HEALTH	/	3
FLAMMABILITY		0
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.

Distributor

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Full text of other abbreviations

AICC - 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

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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 : 05-08-2023

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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