

KIT CAP/CTM HCV v2.0 72T US-IVD

Version 1.4

Revision Date 09-19-2014

Print Date 12-06-2014

SECTION 1. IDENTIFICATION

Product name : KIT CAP/CTM HCV v2.0 72T US-IVD

Mat.-No./ Genisys-No. : 05480442190

Chemical nature : Handle as potentially infectious.

Manufacturer or supplier's details

Company name of supplier : Roche Diagnostics

Address : 9115 Hague Road
46250 Indianapolis IN

Telephone : 1-800-428-5074

Emergency telephone number:

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**

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

GHS Label elementHazard pictograms : 

Signal word : Danger

Hazard statements : H302 Harmful if swallowed.
H315 Causes skin irritation.
H318 Causes serious eye damage.
H334 May cause allergy or asthma symptoms or breathing difficulties if inhaled.Precautionary statements : **Prevention:**
P261 Avoid breathing dust/ fume/ gas/ mist/ vapours/ spray.
P264 Wash skin thoroughly after handling.
P270 Do not eat, drink or smoke when using this product.
P280 Wear protective gloves/ eye protection/ face protection.
P285 In case of inadequate ventilation wear respiratory protection.
Response:
P301 + P312 IF SWALLOWED: Call a POISON CENTER or doctor/ physician if you feel unwell.

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P302 + P352 IF ON SKIN: Wash with plenty of soap and water.
 P304 + P341 IF INHALED: If breathing is difficult, remove victim to fresh air and keep at rest in a position comfortable for breathing.

P305 + P351 + P338 IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.

P310 Immediately call a POISON CENTER or doctor/ physician.
 P330 Rinse mouth.

P332 + P313 If skin irritation occurs: Get medical advice/ attention.

P362 Take off contaminated clothing and wash before reuse.

Disposal:

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

Other hazards

None known.

SECTION 3. COMPOSITION/INFORMATION ON INGREDIENTS**CS1 - [MGP] / MGP 2****GHS Classification**

Not a hazardous substance or mixture.

Hazardous components

No hazardous ingredients

CS2 - [Lys]**GHS Classification**

Acute toxicity (Oral), Category 4 H302: Harmful if swallowed.

Serious eye damage, Category 1 H318: Causes serious eye damage.

Hazardous components

Chemical Name	CAS-No.	Concentration (%)
guanidinium thiocyanate	593-84-0	>= 30 - < 50
Polidocanol	9002-92-0	>= 5 - < 10
(R*,R*)-1,4-dimercaptobutane-2,3-diol	3483-12-3	>= 1 - < 5

HBV/CS3 [Pase] / P2**GHS Classification**

Skin irritation, Category 2 H315: Causes skin irritation.

Serious eye damage, Category 1 H318: Causes serious eye damage.

Respiratory sensitisation, Category 1 H334: May cause allergy or asthma symptoms or breathing difficulties if inhaled.

Hazardous components

Chemical Name	CAS-No.	Concentration (%)
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glycerol	56-81-5	>= 50 - < 70
Subtilisin	9014-01-1	>= 10 - < 20

CS3 - [EB]**GHS Classification**

Not a hazardous substance or mixture.

Hazardous components

No hazardous ingredients

CS4 [QS/IC]**GHS Classification**

Not a hazardous substance or mixture.

Hazardous components

No hazardous ingredients

CS4 - [CTM Mn2+]**GHS Classification**

Not a hazardous substance or mixture.

Hazardous components

Chemical Name	CAS-No.	Concentration (%)
Mangan(II)-acetate Tetrahydrate	6156-78-1	>= 1 - < 5

CS4 - [MMX]**GHS Classification**

Not a hazardous substance or mixture.

Hazardous components

Chemical Name	CAS-No.	Concentration (%)
dimethyl sulfoxide	67-68-5	>= 10 - < 20
glycerol	56-81-5	>= 10 - < 20

CTM (-)C (Human Plasma)**GHS Classification**

Not a hazardous substance or mixture.

Chemical nature : Handle as potentially infectious.

Hazardous components

No hazardous ingredients

[HCV L(+)]C, v2.0] (Human Plasma)**GHS Classification**

Not a hazardous substance or mixture.

Chemical nature : Handle as potentially infectious.

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Hazardous components

No hazardous ingredients

[HCV H(+)C, v2.0] (Human Plasma)**GHS Classification**

Not a hazardous substance or mixture.

Chemical nature : Handle as potentially infectious.

Hazardous components

No hazardous ingredients

SECTION 4. FIRST AID MEASURES

General advice : Move out of dangerous area.
 Consult a physician.
 Show this safety data sheet to the doctor in attendance.
 Do not leave the victim unattended.

If inhaled : Call a physician or poison control centre immediately.
 Move to fresh air.
 If unconscious place in recovery position and seek medical advice.

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 : No information available.

Notes to physician : The first aid procedure should be established in consultation with the doctor responsible for industrial medicine.

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SECTION 5. FIREFIGHTING 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 firefighting : 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 firefighters : 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.
Ensure adequate ventilation.
Refer to protective measures listed in sections 7 and 8.

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 : Soak up with inert absorbent material (e.g. sand, silica gel, acid binder, universal binder, sawdust).
Keep in suitable, closed containers for disposal.

SECTION 7. HANDLING AND STORAGE

Advice on safe handling : Avoid formation of aerosol.
Do not breathe vapours/dust.
Avoid exposure - obtain special instructions before use.
Avoid contact with skin and eyes.
For personal protection see section 8.
Smoking, eating and drinking should be prohibited in the application area.
Provide sufficient air exchange and/or exhaust in work rooms.
Dispose of rinse water in accordance with local and national regulations.
Persons susceptible to skin sensitisation problems or asthma, allergies, chronic or recurrent respiratory disease should not be employed in any process in which this mixture is being used.
To prevent leaks or spillages from spreading, provide a suitable liquid retention system.

Conditions for safe storage : Keep container tightly closed in a dry and well-ventilated place.

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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.

SECTION 8. EXPOSURE CONTROLS/PERSONAL PROTECTION**CS1 - [MGP] / MGP 2****Components with workplace control parameters**

Contains no substances with occupational exposure limit values.

CS2 - [Lys]**Components with workplace control parameters**

Contains no substances with occupational exposure limit values.

HBV/CS3 [Pase] / P2**Components with workplace control parameters**

Components	CAS-No.	Value type (Form of exposure)	Control parameters / Permissible concentration	Basis
glycerol	56-81-5	TWA (mist, respirable fraction)	5 mg/m3	OSHA Z-1
		TWA (mist, total dust)	15 mg/m3	OSHA Z-1
		TWA (Mist - total dust)	10 mg/m3	OSHA P0
		TWA (Mist - respirable fraction)	5 mg/m3	OSHA P0
Subtilisin	9014-01-1	C	0.00006 mg/m3	OSHA P0
		C	0.00006 mg/m3 (as crystalline active enzyme)	ACGIH
		ST	0.00006 mg/m3	NIOSH REL

CS3 - [EB]**Components with workplace control parameters**

Contains no substances with occupational exposure limit values.

CS4 [QS/IC]**Components with workplace control parameters**

Contains no substances with occupational exposure limit values.

CS4 - [CTM Mn2+]**Components with workplace control parameters**

Components	CAS-No.	Value type (Form of exposure)	Control parameters / Permissible concentration	Basis
Mangan(II)-acetate	6156-78-1	C	5 mg/m3	OSHA Z-1

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Tetrahydrate			(Manganese)	
		C	5 mg/m3 (Manganese)	OSHA P0
		TWA	1 mg/m3 (Manganese)	NIOSH REL
		ST	3 mg/m3 (Manganese)	NIOSH REL

CS4 - [MMX]**Components with workplace control parameters**

Components	CAS-No.	Value type (Form of exposure)	Control parameters / Permissible concentration	Basis
dimethyl sulfoxide	67-68-5	TWA	250 ppm	US WEEL
glycerol	56-81-5	TWA (mist, respirable fraction)	5 mg/m3	OSHA Z-1
		TWA (mist, total dust)	15 mg/m3	OSHA Z-1
		TWA (Mist - total dust)	10 mg/m3	OSHA P0
		TWA (Mist - respirable fraction)	5 mg/m3	OSHA P0

CTM (-)C (Human Plasma)**Components with workplace control parameters**

Contains no substances with occupational exposure limit values.

[HCV L(+)C, v2.0] (Human Plasma)**Components with workplace control parameters**

Contains no substances with occupational exposure limit values.

[HCV H(+)C, v2.0] (Human Plasma)**Components with workplace control parameters**

Contains no substances with occupational exposure limit values.

Personal protective equipment

Respiratory protection : In the case of vapour formation use a respirator with an approved filter.

Hand protection

Material : Protective gloves
 Remarks : The selected protective gloves have to satisfy the specifications of EU Directive 89/686/EEC and the standard EN 374 derived from it. This recommendation is only valid for the product mentioned in the safety data sheet and provided by us and for the application specified by us. Please observe the instructions regarding permeability and breakthrough time which are provided by the supplier of the gloves. Also take into consideration the specific local conditions under which the product is used, such as the danger of cuts, abrasion, and the contact time. The suitability for a specific workplace should be discussed with the producers of the protective gloves.

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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	: impervious clothing 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
CS1 - [MGP] / MGP 2

Appearance	: liquid
Colour	: colourless black
Odour	: none
pH	: 5 - 9
Melting point/range	: No data available
Boiling point/boiling range	: No data available
Flash point	: does not flash
Flammability (solid, gas)	: The product is not flammable.
Upper explosion limit	: No data available
Lower explosion limit	: No data available
Density	: No data available
Solubility(ies)	
Water solubility	: partly soluble
Auto-ignition temperature	: No data available
Thermal decomposition	: No data available
Oxidizing properties	: The substance or mixture is not classified as oxidizing.

CS2 - [Lys]

Appearance	: liquid
pH	: 5
Melting point/range	: No data available

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Boiling point/boiling range	: No data available
Flash point	: does not flash
Flammability (solid, gas)	: The product is not flammable.
Upper explosion limit	: No data available
Lower explosion limit	: No data available
Solubility(ies)	
Water solubility	: soluble
Auto-ignition temperature	: No data available
Thermal decomposition	: No data available
Oxidizing properties	: The substance or mixture is not classified as oxidizing.

HBV/CS3 [Pase] / P2

Appearance	: liquid
Colour	: transparent, light brown
Odour	: odourless
pH	: ca. 5
Boiling point/boiling range	: No data available
Flash point	: does not flash
Upper explosion limit	: No data available
Lower explosion limit	: No data available
Solubility(ies)	
Water solubility	: completely miscible
Auto-ignition temperature	: No data available
Thermal decomposition	: No data available

CS3 - [EB]

Appearance	: liquid
pH	: 9.1
Melting point/range	: No data available
Boiling point/boiling range	: No data available
Flash point	: does not flash
Flammability (solid, gas)	: The product is not flammable.

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Upper explosion limit	: No data available
Lower explosion limit	: No data available
Density	: 1.0 g/cm3
Solubility(ies)	
Water solubility	: soluble
Auto-ignition temperature	: No data available
Thermal decomposition	: No data available
Oxidizing properties	: The substance or mixture is not classified as oxidizing.

CS4 [QS/IC]

Appearance	: liquid
pH	: 8.0
Melting point/range	: No data available
Boiling point/boiling range	: No data available
Flash point	: does not flash
Flammability (solid, gas)	: The product is not flammable.
Upper explosion limit	: No data available
Lower explosion limit	: No data available
Density	: 1.006 g/cm3
Solubility(ies)	
Water solubility	: completely miscible
Auto-ignition temperature	: No data available
Thermal decomposition	: No data available
Oxidizing properties	: The substance or mixture is not classified as oxidizing.

CS4 - [CTM Mn2+]

Appearance	: liquid
pH	: 6.25
Melting point/range	: No data available
Boiling point/boiling range	: No data available
Flash point	: does not flash
Flammability (solid, gas)	: The product is not flammable.
Upper explosion limit	: No data available

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Lower explosion limit : No data available
 Density : 1.00 g/cm3
 Solubility(ies)
 Water solubility : completely miscible
 Auto-ignition temperature : No data available
 Thermal decomposition : No data available

CS4 - [MMX]

Appearance : liquid
 pH : 7.8
 Melting point/range : No data available
 Boiling point/boiling range : No data available
 Flash point : does not flash
 Flammability (solid, gas) : The product is not flammable.
 Upper explosion limit : No data available
 Lower explosion limit : No data available
 Density : 1.0708 g/cm3
 Solubility(ies)
 Water solubility : completely miscible
 Auto-ignition temperature : No data available
 Thermal decomposition : No data available
 Oxidizing properties : The substance or mixture is not classified as oxidizing.

CTM (-)C (Human Plasma)

Appearance : liquid
 Melting point/range : No data available
 Boiling point/boiling range : No data available
 Flash point : does not flash
 Flammability (solid, gas) : The product is not flammable.
 Upper explosion limit : No data available
 Lower explosion limit : No data available
 Density : 1.026 g/cm3

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Solubility(ies)
 Water solubility : completely miscible

Auto-ignition temperature : No data available

Thermal decomposition : No data available

[HCV L(+)C, v2.0] (Human Plasma)

Appearance : liquid

Melting point/range : No data available

Boiling point/boiling range : No data available

Flash point : does not flash

Flammability (solid, gas) : The product is not flammable.

Upper explosion limit : No data available

Lower explosion limit : No data available

Density : 1.026 g/cm³

Solubility(ies)
 Water solubility : completely miscible

Auto-ignition temperature : No data available

Thermal decomposition : No data available

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

[HCV H(+)C, v2.0] (Human Plasma)

Appearance : liquid

Melting point/range : No data available

Boiling point/boiling range : No data available

Flash point : does not flash

Flammability (solid, gas) : The product is not flammable.

Upper explosion limit : No data available

Lower explosion limit : No data available

Density : 1.026 g/cm³

Solubility(ies)
 Water solubility : completely miscible

Auto-ignition temperature : No data available

Thermal decomposition : No data available

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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.

Conditions to avoid : No data available

Incompatible materials : No data available

Hazardous decomposition products : No data available

SECTION 11. TOXICOLOGICAL INFORMATION**CS1 - [MGP] / MGP 2****Information on likely routes of exposure****Acute toxicity**

Not classified based on available information.

Product:

Acute oral toxicity : Acute toxicity estimate : > 5,000 mg/kg
Method: Calculation method

Skin corrosion/irritation

Not classified based on available information.

Serious eye damage/eye irritation

Not classified based on available information.

Respiratory or skin sensitisation

Skin sensitisation: Not classified based on available information.

Respiratory sensitisation: Not classified based on available information.

Germ cell mutagenicity

Not classified based on available information.

Carcinogenicity

Not classified based on available information.

IARC

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

ACGIH

No component of this product present at levels greater than or equal to 0.1% is identified as a carcinogen or potential carcinogen by ACGIH.

OSHA

No component of this product present at levels greater than or

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equal to 0.1% is identified as a carcinogen or potential carcinogen by OSHA.

NTP

No component 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.

Product:

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

STOT - repeated exposure

Not classified based on available information.

Product:

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

Aspiration toxicity

Not classified based on available information.

CS2 - [Lys]**Information on likely routes of exposure****Acute toxicity**

Harmful if swallowed.

Product:

Acute oral toxicity : Acute toxicity estimate : 1,174 mg/kg
Method: Calculation method

Acute inhalation toxicity : Acute toxicity estimate : 23.28 mg/l
Exposure time: 4 h
Test atmosphere: vapour
Method: Calculation method

Acute dermal toxicity : Acute toxicity estimate : 2,328 mg/kg
Method: Calculation method

Components:**guanidinium thiocyanate:**

Acute oral toxicity : LD50 Oral (Rat): 593 mg/kg

Acute inhalation toxicity : Acute toxicity estimate : 1.5 mg/l
Test atmosphere: dust/mist
Method: Expert judgement

Acute dermal toxicity : Acute toxicity estimate : 1,100 mg/kg
Method: Expert judgement

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Polidocanol:

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

(R*,R*)-1,4-dimercaptobutane-2,3-diol:

Acute oral toxicity : LD50 Oral (Rat): 400 mg/kg

Acute toxicity (other routes of administration)

: Symptoms: May cause cardiac arrhythmia., Convulsions, Vomiting

Skin corrosion/irritation

Not classified based on available information.

Product:

Remarks: May cause skin irritation and/or dermatitis.

Components:**Polidocanol:**

Result: Irritating to skin.

(R*,R*)-1,4-dimercaptobutane-2,3-diol:

Result: Irritating to skin.

Serious eye damage/eye irritation

Causes serious eye damage.

Product:

Remarks: May cause irreversible eye damage.

Components:**Polidocanol:**

Result: Risk of serious damage to eyes.

(R*,R*)-1,4-dimercaptobutane-2,3-diol:

Result: Irritating to eyes.

Respiratory or skin sensitisation

Skin sensitisation: Not classified based on available information.

Respiratory sensitisation: Not classified based on available information.

Germ cell mutagenicity

Not classified based on available information.

Carcinogenicity

Not classified based on available information.

Components:**guanidinium thiocyanate:**

Remarks: No component 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 component 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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ACGIH	No component of this product present at levels greater than or equal to 0.1% is identified as a carcinogen or potential carcinogen by ACGIH.
OSHA	No component of this product present at levels greater than or equal to 0.1% is identified as a carcinogen or potential carcinogen by OSHA.
NTP	No component 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.

STOT - repeated exposure

Not classified based on available information.

Aspiration toxicity

Not classified based on available information.

HBV/CS3 [Pase] / P2**Information on likely routes of exposure****Acute toxicity**

Not classified based on available information.

Product:

Acute oral toxicity	: Acute toxicity estimate : > 5,000 mg/kg Method: Calculation method
Acute dermal toxicity	: Acute toxicity estimate : > 5,000 mg/kg Method: Calculation method

Components:**glycerol:**

Acute oral toxicity : LD50 Oral (Rat): 12,600 mg/kg

LD50 Oral (Mouse): 4,090 mg/kg

Acute inhalation toxicity : Acute toxicity estimate : > 30 mg/l
Method: Expert judgement

Acute dermal toxicity : LD50 Dermal (Rabbit): 10,000 mg/kg

Skin corrosion/irritation

Causes skin irritation.

Product:

Remarks: May cause skin irritation in susceptible persons.

Components:

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Subtilisin:

Result: Skin irritation

Remarks: Extremely corrosive and destructive to tissue.

Serious eye damage/eye irritation

Causes serious eye damage.

Product:

Remarks: May cause irreversible eye damage.

Components:**Subtilisin:**

Result: Risk of serious damage to eyes.

Remarks: May cause irreversible eye damage.

Respiratory or skin sensitisation

Skin sensitisation: Not classified based on available information.

Respiratory sensitisation: May cause allergy or asthma symptoms or breathing difficulties if inhaled.

Components:**Subtilisin:**

Assessment: May cause sensitisation by inhalation.

Result: The product is a respiratory sensitisier, sub-category 1A.

Germ cell mutagenicity

Not classified based on available information.

Carcinogenicity

Not classified based on available information.

IARC

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

ACGIH

No component of this product present at levels greater than or equal to 0.1% is identified as a carcinogen or potential carcinogen by ACGIH.

OSHA

No component of this product present at levels greater than or equal to 0.1% is identified as a carcinogen or potential carcinogen by OSHA.

NTP

No component 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:**Subtilisin:**

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Target Organs: Respiratory system
Assessment: May cause respiratory irritation.

STOT - repeated exposure

Not classified based on available information.

Components:**glycerol:**

Repeated dose toxicity - : Mild eye irritant, Mild respiratory irritant, No skin irritation
Assessment

Aspiration toxicity

Not classified based on available information.

CS3 - [EB]**Information on likely routes of exposure****Acute toxicity**

Not classified based on available information.

Skin corrosion/irritation

Not classified based on available information.

Serious eye damage/eye irritation

Not classified based on available information.

Respiratory or skin sensitisation

Skin sensitisation: Not classified based on available information.

Respiratory sensitisation: Not classified based on available information.

Germ cell mutagenicity

Not classified based on available information.

Carcinogenicity

Not classified based on available information.

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

ACGIH No component of this product present at levels greater than or equal to 0.1% is identified as a carcinogen or potential carcinogen by ACGIH.

OSHA No component of this product present at levels greater than or equal to 0.1% is identified as a carcinogen or potential carcinogen by OSHA.

NTP No component 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.

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STOT - repeated exposure

Not classified based on available information.

Aspiration toxicity

Not classified based on available information.

CS4 [QS/IC]**Information on likely routes of exposure****Acute toxicity**

Not classified based on available information.

Product:

Acute oral toxicity : Acute toxicity estimate : > 5,000 mg/kg
Method: Calculation method

Skin corrosion/irritation

Not classified based on available information.

Serious eye damage/eye irritation

Not classified based on available information.

Respiratory or skin sensitisation

Skin sensitisation: Not classified based on available information.

Respiratory sensitisation: Not classified based on available information.

Germ cell mutagenicity

Not classified based on available information.

Carcinogenicity

Not classified based on available information.

IARC

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

ACGIH

No component of this product present at levels greater than or equal to 0.1% is identified as a carcinogen or potential carcinogen by ACGIH.

OSHA

No component of this product present at levels greater than or equal to 0.1% is identified as a carcinogen or potential carcinogen by OSHA.

NTP

No component 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.

STOT - repeated exposure

Not classified based on available information.

Aspiration toxicity

Not classified based on available information.

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CS4 - [CTM Mn2+]**Information on likely routes of exposure****Acute toxicity**

Not classified based on available information.

Product:

Acute oral toxicity : Acute toxicity estimate : > 5,000 mg/kg
Method: Calculation method

Components:**Mangan(II)-acetate Tetrahydrate:**

Acute oral toxicity : LD50 Oral (Rat): 3,730 mg/kg

Skin corrosion/irritation

Not classified based on available information.

Product:

Remarks: May cause skin irritation and/or dermatitis.

Components:**Mangan(II)-acetate Tetrahydrate:**

Result: Irritating to skin.

Remarks: May cause skin irritation in susceptible persons.

Serious eye damage/eye irritation

Not classified based on available information.

Product:

Remarks: Vapours may cause irritation to the eyes, respiratory system and the skin.

Components:**Mangan(II)-acetate Tetrahydrate:**

Result: Irritating to eyes.

Remarks: May cause irreversible eye damage.

Respiratory or skin sensitisation

Skin sensitisation: Not classified based on available information.

Respiratory sensitisation: Not classified based on available information.

Germ cell mutagenicity

Not classified based on available information.

Carcinogenicity

Not classified based on available information.

IARC

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

ACGIH

No component of this product present at levels greater than or equal to 0.1% is identified as a carcinogen or potential carcinogen by ACGIH.

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OSHA

No component of this product present at levels greater than or equal to 0.1% is identified as a carcinogen or potential carcinogen by OSHA.

NTP

No component 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:**Mangan(II)-acetate Tetrahydrate:**

Assessment: May cause respiratory irritation.

STOT - repeated exposure

Not classified based on available information.

Components:**Mangan(II)-acetate Tetrahydrate:**

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

Aspiration toxicity

Not classified based on available information.

Components:**Mangan(II)-acetate Tetrahydrate:**

No data available

CS4 - [MMX]**Information on likely routes of exposure****Acute toxicity**

Not classified based on available information.

Product:

Acute oral toxicity : Acute toxicity estimate : > 5,000 mg/kg
Method: Calculation method

Components:**dimethyl sulfoxide:**

Acute oral toxicity : LD50 Oral (Rat): 14,500 mg/kg
LD50 Oral (Mouse): 7,920 mg/kg

Acute inhalation toxicity : Acute toxicity estimate : > 30 mg/l
Test atmosphere: vapour
Method: Expert judgement

Acute dermal toxicity : LD50 Dermal (Rat): 40,000 mg/kg

glycerol:

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Acute oral toxicity	: LD50 Oral (Rat): 12,600 mg/kg LD50 Oral (Mouse): 4,090 mg/kg
Acute inhalation toxicity	: Acute toxicity estimate : > 30 mg/l Method: Expert judgement
Acute dermal toxicity	: LD50 Dermal (Rabbit): 10,000 mg/kg

Skin corrosion/irritation

Not classified based on available information.

Components:**dimethyl sulfoxide:**

Remarks: This information is not available.

Serious eye damage/eye irritation

Not classified based on available information.

Components:**dimethyl sulfoxide:**

Remarks: This information is not available.

Respiratory or skin sensitisation

Skin sensitisation: Not classified based on available information.

Respiratory sensitisation: Not classified based on available information.

Components:**dimethyl sulfoxide:**

Species: Guinea pig

Result: Does not cause skin sensitisation.

Germ cell mutagenicity

Not classified based on available information.

Carcinogenicity

Not classified based on available information.

IARC

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

ACGIH

No component of this product present at levels greater than or equal to 0.1% is identified as a carcinogen or potential carcinogen by ACGIH.

OSHA

No component of this product present at levels greater than or equal to 0.1% is identified as a carcinogen or potential carcinogen by OSHA.

NTP

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

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Reproductive toxicity

Not classified based on available information.

STOT - single exposure

Not classified based on available information.

Components:**dimethyl sulfoxide:**

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:**dimethyl sulfoxide:**

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

Components:**dimethyl sulfoxide:**

Repeated dose toxicity - : Mild eye irritation, Mild skin irritation
Assessment

glycerol:

Repeated dose toxicity - : Mild eye irritant, Mild respiratory irritant, No skin irritation
Assessment

Aspiration toxicity

Not classified based on available information.

Components:**dimethyl sulfoxide:**

No data available

CTM (-)C (Human Plasma)**Information on likely routes of exposure****Acute toxicity**

Not classified based on available information.

Skin corrosion/irritation

Not classified based on available information.

Product:

Remarks: May cause skin irritation and/or dermatitis.

Serious eye damage/eye irritation

Not classified based on available information.

Product:

Remarks: Vapours may cause irritation to the eyes, respiratory system and the skin.

Respiratory or skin sensitisation

Skin sensitisation: Not classified based on available information.

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Respiratory sensitisation: Not classified based on available information.

Product:

Remarks: Causes sensitisation.

Germ cell mutagenicity

Not classified based on available information.

Carcinogenicity

Not classified based on available information.

IARC

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

ACGIH

No component of this product present at levels greater than or equal to 0.1% is identified as a carcinogen or potential carcinogen by ACGIH.

OSHA

No component of this product present at levels greater than or equal to 0.1% is identified as a carcinogen or potential carcinogen by OSHA.

NTP

No component 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.

STOT - repeated exposure

Not classified based on available information.

Aspiration toxicity

Not classified based on available information.

[HCV L(+)]C, v2.0] (Human Plasma)**Information on likely routes of exposure****Acute toxicity**

Not classified based on available information.

Skin corrosion/irritation

Not classified based on available information.

Product:

Remarks: May cause skin irritation and/or dermatitis.

Serious eye damage/eye irritation

Not classified based on available information.

Product:

Remarks: Vapours may cause irritation to the eyes, respiratory system and the skin.

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Respiratory or skin sensitisation

Skin sensitisation: Not classified based on available information.

Respiratory sensitisation: Not classified based on available information.

Product:

Remarks: Causes sensitisation.

Germ cell mutagenicity

Not classified based on available information.

Carcinogenicity

Not classified based on available information.

IARC

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

ACGIH

No component of this product present at levels greater than or equal to 0.1% is identified as a carcinogen or potential carcinogen by ACGIH.

OSHA

No component of this product present at levels greater than or equal to 0.1% is identified as a carcinogen or potential carcinogen by OSHA.

NTP

No component 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.

STOT - repeated exposure

Not classified based on available information.

Aspiration toxicity

Not classified based on available information.

[HCV H(+)C, v2.0] (Human Plasma)**Information on likely routes of exposure****Acute toxicity**

Not classified based on available information.

Skin corrosion/irritation

Not classified based on available information.

Product:

Remarks: May cause skin irritation and/or dermatitis.

Serious eye damage/eye irritation

Not classified based on available information.

Product:

Remarks: Vapours may cause irritation to the eyes, respiratory system and the skin.

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Respiratory or skin sensitisation

Skin sensitisation: Not classified based on available information.

Respiratory sensitisation: Not classified based on available information.

Product:

Remarks: Causes sensitisation.

Germ cell mutagenicity

Not classified based on available information.

Carcinogenicity

Not classified based on available information.

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

ACGIH No component of this product present at levels greater than or equal to 0.1% is identified as a carcinogen or potential carcinogen by ACGIH.

OSHA No component of this product present at levels greater than or equal to 0.1% is identified as a carcinogen or potential carcinogen by OSHA.

NTP No component 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.

STOT - repeated exposure

Not classified based on available information.

Aspiration toxicity

Not classified based on available information.

SECTION 12. ECOLOGICAL INFORMATION**CS1 - [MGP] / MGP 2****Ecotoxicity****Product:**

Ecotoxicology Assessment

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

Other organisms relevant to the environment : No data available

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aquatic invertebrates Exposure time: 48 h

Ecotoxicology Assessment
Toxicity Data on Soil : Not expected to adsorb on soil.Other organisms relevant to
the environment : No data available**Persistence and degradability****Components:****Polidocanol:**Biodegradability : Biodegradation: > 99 %
Exposure time: 672 h
Method: OECD Test Guideline 302**Bioaccumulative potential****Components:****guanidinium thiocyanate:**Partition coefficient: n-
octanol/water : log Pow: -1.38**(R*,R*)-1,4-dimercaptobutane-2,3-diol:**Partition coefficient: n-
octanol/water : log Pow: ca. -0.48**Mobility in soil**

No data available

Other adverse effects

No data available

Product:Regulation 40 CFR Protection of Environment; Part 82 Protection of
Stratospheric Ozone - CAA Section 602 Class I SubstancesRemarks This product neither contains, nor was manufactured with a
Class I or Class II ODS as defined by the U.S. Clean Air Act
Section 602 (40 CFR 82, Subpt. A, App.A + B).Additional ecological
information : An environmental hazard cannot be excluded in the event of
unprofessional handling or disposal.
Harmful to aquatic life with long lasting effects.**Components:****Polidocanol:**Additional ecological
information : Very toxic to aquatic life.
An environmental hazard cannot be excluded in the event of
unprofessional handling or disposal.***HBV/CS3 [Pase] / P2*****Ecotoxicity****Product:**

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

Other organisms relevant to
the environment : No data available

Components:**glycerol:**

Toxicity to fish : LC50: > 100 mg/l
Exposure time: 96 h

Toxicity to algae : EC0 (Scenedesmus quadricauda (Green algae)): > 10,000 mg/l
Exposure time: 7 d

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

Toxicity to bacteria : EC0 (Pseudomonas putida): > 10,000 mg/l
Exposure time: 16 h

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

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

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

Other organisms relevant to
the environment : No data available

Subtilisin:

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:****glycerol:**

Biodegradability : Remarks: The product is miscible in water and readily
biodegradable in both water and soil. Accumulation is not
expected.

Bioaccumulative potential**Components:****glycerol:**

Partition coefficient: n-
octanol/water : log Pow: -2.66

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Persistence and degradability

No data available

Bioaccumulative potential

No data available

Mobility in soil

No data available

Other adverse effects

No data available

Product:

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

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

CS4 - [CTM Mn2+]**Ecotoxicity****Product:**

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

Components:**Mangan(II)-acetate Tetrahydrate:**

Ecotoxicology Assessment

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

Other organisms relevant to the environment : No data available

Persistence and degradability

No data available

Bioaccumulative potential

No data available

Mobility in soil

No data available

Other adverse effects

No data available

Product:

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

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

Components:**Mangan(II)-acetate Tetrahydrate:**

Additional ecological information : No data available

CS4 - [MMX]**Ecotoxicity****Product:**

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

Other organisms relevant to the environment : No data available

Components:**dimethyl sulfoxide:**

Toxicity to fish : LC50 (Fish): 32,500 mg/l
Exposure time: 96 h

Toxicity to daphnia and other aquatic invertebrates : EC50 (Daphnia magna (Water flea)): 24,600 mg/l
Exposure time: 48 h
Method: OECD Test Guideline 202

Toxicity to bacteria : EC50 (Photobacterium phosphoreum): ca. 70,000 mg/l
Exposure time: 0.25 h

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

Other organisms relevant to the environment : No data available

glycerol:

Toxicity to fish : LC50: > 100 mg/l
Exposure time: 96 h

Toxicity to algae : EC0 (Scenedesmus quadricauda (Green algae)): > 10,000 mg/l
Exposure time: 7 d

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

Toxicity to bacteria : EC0 (Pseudomonas putida): > 10,000 mg/l
Exposure time: 16 h

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

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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:****dimethyl sulfoxide:**

Biodegradability : Biodegradation: 4 %
Exposure time: 1 d

Biodegradation: 6 %
Exposure time: 8 d

Biodegradation: 29 %
Exposure time: 15 d

Biodegradation: 90 %
Exposure time: 28 d
Method: OECD Test Guideline 302

glycerol:

Biodegradability : Remarks: The product is miscible in water and readily biodegradable in both water and soil. Accumulation is not expected.

Bioaccumulative potential**Components:****dimethyl sulfoxide:**

Partition coefficient: n-octanol/water : log Pow: -1.35

glycerol:

Partition coefficient: n-octanol/water : log Pow: -2.66

Mobility in soil

No data available

Other adverse effects

No data available

Product:

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

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

CTM (-)C (Human Plasma)

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Ecotoxicity**Product:**

Ecotoxicology Assessment

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

Other organisms relevant to the environment : No data available

Persistence and degradability

No data available

Bioaccumulative potential

No data available

Mobility in soil

No data available

Other adverse effects

No data available

Product:

Regulation

40 CFR Protection of Environment; Part 82 Protection of Stratospheric Ozone - CAA Section 602 Class I Substances

Remarks

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

[HCV L(+)]C, v2.0] (Human Plasma)**Ecotoxicity****Product:**

Ecotoxicology Assessment

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

Other organisms relevant to the environment : No data available

Persistence and degradability

No data available

Bioaccumulative potential

No data available

Mobility in soil

No data available

Other adverse effects

No data available

Product:

Regulation

40 CFR Protection of Environment; Part 82 Protection of Stratospheric Ozone - CAA Section 602 Class I Substances

Remarks

This product neither contains, nor was manufactured with a Class I or Class II ODS as defined by the U.S. Clean Air Act

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Section 602 (40 CFR 82, Subpt. A, App.A + B).

[HCV H(+)C, v2.0] (Human Plasma)**Ecotoxicity****Product:**

Ecotoxicology Assessment

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

Other organisms relevant to the environment : No data available

Persistence and degradability

No data available

Bioaccumulative potential

No data available

Mobility in soil

No data available

Other adverse effects

No data available

Product:

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

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

SECTION 13. DISPOSAL CONSIDERATIONS**Disposal methods**

Waste from residues : Special treatment as infectious material is mandatory in compliance with local regulations (disinfection and incineration).
 The product should not be allowed to enter drains, water courses or the soil.
 Do not contaminate ponds, waterways or ditches with chemical or used container.
 Send to a licensed waste management company.

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 Regulation**

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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 for product as supplied.

National Regulations**49 CFR**

Not regulated as a dangerous good

SECTION 15. REGULATORY INFORMATION**CS1 - [MGP] / MGP 2****EPCRA - Emergency Planning and Community Right-to-Know Act****CERCLA Reportable Quantity**

Components	CAS-No.	Component RQ (lbs)	Calculated product RQ (lbs)
Sodium azide	26628-22-8	1000	*

*: Calculated RQ exceeds reasonably attainable upper limit.

SARA 304 Extremely Hazardous Substances Reportable Quantity

Components	CAS-No.	Component RQ (lbs)	Calculated product RQ (lbs)
Sodium azide	26628-22-8	1000	*

*: Calculated RQ exceeds reasonably attainable upper limit.

SARA 302 : No chemicals in this material are subject to the reporting requirements of SARA Title III, Section 302.

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 does not contain any hazardous air pollutants (HAP), as defined by the U.S. Clean Air Act Section 12 (40 CFR 61).

This product does not contain any chemicals listed under the U.S. Clean Air Act Section 112(r) for Accidental Release Prevention (40 CFR 68.130, Subpart F).

This product does not contain any chemicals listed under the U.S. Clean Air Act Section 111 SOCMI Intermediate or Final VOC's (40 CFR 60.489).

Clean Water Act

This product does not contain any Hazardous Substances listed under the U.S. CleanWater Act, Section 311, Table 116.4A.

This product does not contain any Hazardous Chemicals listed under the U.S. CleanWater Act, Section 311, Table 117.3.

This product does not contain any toxic pollutants listed under the U.S. Clean Water Act Section 307

Massachusetts Right To Know

sodium azide

26628-22-8

0 - 0.1 %

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Pennsylvania Right To Know

water	7732-18-5	90 - 100 %
Magnetische Glaspartikel (MGP)	Not Assigned	5 - 10 %
sodium azide	26628-22-8	0 - 0.1 %

New Jersey Right To Know

water	7732-18-5	90 - 100 %
Magnetische Glaspartikel (MGP)	Not Assigned	5 - 10 %

California Prop 65 : This product does not contain any chemicals known to State of California to cause cancer, birth defects, or any other reproductive harm.

CS2 - [Lys]**EPCRA - Emergency Planning and Community Right-to-Know Act****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 : No chemicals in this material are subject to the reporting requirements of SARA Title III, Section 302.

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 does not contain any hazardous air pollutants (HAP), as defined by the U.S. Clean Air Act Section 12 (40 CFR 61).

This product does not contain any chemicals listed under the U.S. Clean Air Act Section 112(r) for Accidental Release Prevention (40 CFR 68.130, Subpart F).

This product does not contain any chemicals listed under the U.S. Clean Air Act Section 111 SOCMI Intermediate or Final VOC's (40 CFR 60.489).

Clean Water Act

This product does not contain any Hazardous Substances listed under the U.S. CleanWater Act, Section 311, Table 116.4A.

This product does not contain any Hazardous Chemicals listed under the U.S. CleanWater Act, Section 311, Table 117.3.

This product does not contain any toxic pollutants listed under the U.S. Clean Water Act Section 307

Massachusetts Right To Know

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

Pennsylvania Right To Know

guanidinium thiocyanate	593-84-0	30 - 50 %
water	7732-18-5	30 - 50 %
Polidocanol	9002-92-0	5 - 10 %

New Jersey Right To Know

guanidinium thiocyanate	593-84-0	30 - 50 %
water	7732-18-5	30 - 50 %

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Polidocanol (R*,R*)-1,4-dimercaptobutane-2,3-diol	9002-92-0 3483-12-3	5 - 10 % 1 - 5 %
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California Prop 65 : This product does not contain any chemicals known to State of California to cause cancer, birth defects, or any other reproductive harm.

HBV/CS3 [Pase] / P2
EPCRA - Emergency Planning and Community Right-to-Know Act
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 : No chemicals in this material are subject to the reporting requirements of SARA Title III, Section 302.

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 does not contain any hazardous air pollutants (HAP), as defined by the U.S. Clean Air Act Section 12 (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 SOCMi

Intermediate or Final VOC's (40 CFR 60.489):

glycerol	56-81-5	50 %
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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

Massachusetts Right To Know

glycerol	56-81-5	50 - 70 %
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Pennsylvania Right To Know

glycerol	56-81-5	50 - 70 %
water	7732-18-5	30 - 50 %
Subtilisin	9014-01-1	10 - 20 %

New Jersey Right To Know

glycerol	56-81-5	50 - 70 %
water	7732-18-5	30 - 50 %
Subtilisin	9014-01-1	10 - 20 %

California Prop 65 : This product does not contain any chemicals known to State of California to cause cancer, birth defects, or any other reproductive harm.

CS3 - [EB]

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EPCRA - Emergency Planning and Community Right-to-Know Act**CERCLA Reportable Quantity**

Components	CAS-No.	Component RQ (lbs)	Calculated product RQ (lbs)
Sodium azide	26628-22-8	1000	*

*: Calculated RQ exceeds reasonably attainable upper limit.

SARA 304 Extremely Hazardous Substances Reportable Quantity

Components	CAS-No.	Component RQ (lbs)	Calculated product RQ (lbs)
Sodium azide	26628-22-8	1000	*

*: Calculated RQ exceeds reasonably attainable upper limit.

SARA 302 : No chemicals in this material are subject to the reporting requirements of SARA Title III, Section 302.

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 does not contain any hazardous air pollutants (HAP), as defined by the U.S. Clean Air Act Section 12 (40 CFR 61).

This product does not contain any chemicals listed under the U.S. Clean Air Act Section 112(r) for Accidental Release Prevention (40 CFR 68.130, Subpart F).

This product does not contain any chemicals listed under the U.S. Clean Air Act Section 111 SOCMI Intermediate or Final VOC's (40 CFR 60.489).

Clean Water Act

This product does not contain any Hazardous Substances listed under the U.S. CleanWater Act, Section 311, Table 116.4A.

This product does not contain any Hazardous Chemicals listed under the U.S. CleanWater Act, Section 311, Table 117.3.

This product does not contain any toxic pollutants listed under the U.S. Clean Water Act Section 307

Massachusetts Right To Know

sodium azide	26628-22-8	0 - 0.1 %
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Pennsylvania Right To Know

water	7732-18-5	90 - 100 %
sodium azide	26628-22-8	0 - 0.1 %

New Jersey Right To Know

water	7732-18-5	90 - 100 %
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California Prop 65 : This product does not contain any chemicals known to State of California to cause cancer, birth defects, or any other reproductive harm.

CS4 [QS/IC]**EPCRA - Emergency Planning and Community Right-to-Know Act****CERCLA Reportable Quantity**

Components	CAS-No.	Component RQ	Calculated product RQ
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		(lbs)	(lbs)
Sodium azide	26628-22-8	1000	*

*: Calculated RQ exceeds reasonably attainable upper limit.

SARA 304 Extremely Hazardous Substances Reportable Quantity

Components	CAS-No.	Component RQ (lbs)	Calculated product RQ (lbs)
Sodium azide	26628-22-8	1000	*

*: Calculated RQ exceeds reasonably attainable upper limit.

SARA 302 : No chemicals in this material are subject to the reporting requirements of SARA Title III, Section 302.

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 does not contain any hazardous air pollutants (HAP), as defined by the U.S. Clean Air Act Section 12 (40 CFR 61).

This product does not contain any chemicals listed under the U.S. Clean Air Act Section 112(r) for Accidental Release Prevention (40 CFR 68.130, Subpart F).

This product does not contain any chemicals listed under the U.S. Clean Air Act Section 111 SOCMI Intermediate or Final VOC's (40 CFR 60.489).

Clean Water Act

This product does not contain any Hazardous Substances listed under the U.S. CleanWater Act, Section 311, Table 116.4A.

This product does not contain any Hazardous Chemicals listed under the U.S. CleanWater Act, Section 311, Table 117.3.

This product does not contain any toxic pollutants listed under the U.S. Clean Water Act Section 307

Massachusetts Right To Know

sodium azide	26628-22-8	0 - 0.1 %
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Pennsylvania Right To Know

water	7732-18-5	90 - 100 %
sodium azide	26628-22-8	0 - 0.1 %

New Jersey Right To Know

water	7732-18-5	90 - 100 %
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California Prop 65 : This product does not contain any chemicals known to State of California to cause cancer, birth defects, or any other reproductive harm.

CS4 - [CTM Mn2+]**EPCRA - Emergency Planning and Community Right-to-Know Act****CERCLA Reportable Quantity**

Components	CAS-No.	Component RQ (lbs)	Calculated product RQ (lbs)
Sodium azide	26628-22-8	1000	*

*: Calculated RQ exceeds reasonably attainable upper limit.

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SARA 304 Extremely Hazardous Substances Reportable Quantity

Components	CAS-No.	Component RQ (lbs)	Calculated product RQ (lbs)
Sodium azide	26628-22-8	1000	*

*: Calculated RQ exceeds reasonably attainable upper limit.

SARA 302 : No chemicals in this material are subject to the reporting requirements of SARA Title III, Section 302.

SARA 313 : The following components are subject to reporting levels established by SARA Title III, Section 313:

Mangan(II)-acetate Tetrahydrate	6156-78-1	1.23 %
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Clean Air Act

The following chemical(s) are listed as HAP under the U.S. Clean Air Act, Section 12 (40 CFR 61):

Mangan(II)-acetate Tetrahydrate	6156-78-1	1.23 %
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This product does not contain any chemicals listed under the U.S. Clean Air Act Section 112(r) for Accidental Release Prevention (40 CFR 68.130, Subpart F).

This product does not contain any chemicals listed under the U.S. Clean Air Act Section 111 SOCMI Intermediate or Final VOC's (40 CFR 60.489).

Clean Water Act

The following Hazardous Substances are listed under the U.S. CleanWater Act, Section 311, Table 116.4A:

acetic acid	64-19-7	0.0099 %
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The following Hazardous Chemicals are listed under the U.S. CleanWater Act, Section 311, Table 117.3:

acetic acid	64-19-7	0.0099 %
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This product does not contain any toxic pollutants listed under the U.S. Clean Water Act Section 307

Massachusetts Right To Know

sodium azide	26628-22-8	0 - 0.1 %
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Pennsylvania Right To Know

water	7732-18-5	90 - 100 %
sodium azide	26628-22-8	0 - 0.1 %

New Jersey Right To Know

water	7732-18-5	90 - 100 %
Mangan(II)-acetate Tetrahydrate	6156-78-1	1 - 5 %

California Prop 65 : This product does not contain any chemicals known to State of California to cause cancer, birth defects, or any other reproductive harm.

CS4 - [MMX]**EPCRA - Emergency Planning and Community Right-to-Know Act****CERCLA Reportable Quantity**

Components	CAS-No.	Component RQ (lbs)	Calculated product RQ (lbs)
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Sodium azide	26628-22-8	1000	*
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*: Calculated RQ exceeds reasonably attainable upper limit.

SARA 304 Extremely Hazardous Substances Reportable Quantity

Components	CAS-No.	Component RQ (lbs)	Calculated product RQ (lbs)
Sodium azide	26628-22-8	1000	*

*: Calculated RQ exceeds reasonably attainable upper limit.

SARA 302 : No chemicals in this material are subject to the reporting requirements of SARA Title III, Section 302.

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 does not contain any hazardous air pollutants (HAP), as defined by the U.S. Clean Air Act Section 12 (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 SOCMi Intermediate or Final VOC's (40 CFR 60.489):

dimethyl sulfoxide	67-68-5	15.8 %
glycerol	56-81-5	14.4 %

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

Massachusetts Right To Know

glycerol	56-81-5	10 - 20 %
sodium azide	26628-22-8	0 - 0.1 %

Pennsylvania Right To Know

water	7732-18-5	50 - 70 %
dimethyl sulfoxide	67-68-5	10 - 20 %
glycerol	56-81-5	10 - 20 %
potassium acetate	127-08-2	1 - 5 %
sodium azide	26628-22-8	0 - 0.1 %

New Jersey Right To Know

water	7732-18-5	50 - 70 %
dimethyl sulfoxide	67-68-5	10 - 20 %
glycerol	56-81-5	10 - 20 %
potassium acetate	127-08-2	1 - 5 %
N-(tri(hydroxymethyl)methyl)glycine	5704-04-1	1 - 5 %

California Prop 65 : This product does not contain any chemicals known to State of California to cause cancer, birth defects, or any other reproductive harm.

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CTM (-)C (Human Plasma)

EPCRA - Emergency Planning and Community Right-to-Know Act

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 : No chemicals in this material are subject to the reporting requirements of SARA Title III, Section 302.

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 does not contain any hazardous air pollutants (HAP), as defined by the U.S. Clean Air Act Section 12 (40 CFR 61).

This product does not contain any chemicals listed under the U.S. Clean Air Act Section 112(r) for Accidental Release Prevention (40 CFR 68.130, Subpart F).

This product does not contain any chemicals listed under the U.S. Clean Air Act Section 111 SOCMI Intermediate or Final VOC's (40 CFR 60.489).

Clean Water Act

This product does not contain any Hazardous Substances listed under the U.S. CleanWater Act, Section 311, Table 116.4A.

This product does not contain any Hazardous Chemicals listed under the U.S. CleanWater Act, Section 311, Table 117.3.

This product does not contain any toxic pollutants listed under the U.S. Clean Water Act Section 307

Massachusetts Right To Know

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

Pennsylvania Right To Know

Human serum /-plasma / -hemolysate, liquid	Not Assigned	90 - 100 %
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New Jersey Right To Know

Human serum /-plasma / -hemolysate, liquid	Not Assigned	90 - 100 %
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California Prop 65 : This product does not contain any chemicals known to State of California to cause cancer, birth defects, or any other reproductive harm.

[HCV L(+)]C, v2.0] (Human Plasma)

EPCRA - Emergency Planning and Community Right-to-Know Act

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 : No chemicals in this material are subject to the reporting requirements of SARA Title III, Section 302.

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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 does not contain any hazardous air pollutants (HAP), as defined by the U.S. Clean Air Act Section 12 (40 CFR 61).

This product does not contain any chemicals listed under the U.S. Clean Air Act Section 112(r) for Accidental Release Prevention (40 CFR 68.130, Subpart F).

This product does not contain any chemicals listed under the U.S. Clean Air Act Section 111 SOCMI Intermediate or Final VOC's (40 CFR 60.489).

Clean Water Act

This product does not contain any Hazardous Substances listed under the U.S. CleanWater Act, Section 311, Table 116.4A.

This product does not contain any Hazardous Chemicals listed under the U.S. CleanWater Act, Section 311, Table 117.3.

This product does not contain any toxic pollutants listed under the U.S. Clean Water Act Section 307

Massachusetts Right To Know

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

Pennsylvania Right To Know

Human serum /-plasma / -hemolysate, liquid	Not Assigned	90 - 100 %
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New Jersey Right To Know

Human serum /-plasma / -hemolysate, liquid	Not Assigned	90 - 100 %
--	--------------	------------

California Prop 65

: This product does not contain any chemicals known to State of California to cause cancer, birth defects, or any other reproductive harm.

[HCV H(+)C, v2.0] (Human Plasma)

EPCRA - Emergency Planning and Community Right-to-Know Act

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

: No chemicals in this material are subject to the reporting requirements of SARA Title III, Section 302.

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 does not contain any hazardous air pollutants (HAP), as defined by the U.S. Clean Air Act Section 12 (40 CFR 61).

This product does not contain any chemicals listed under the U.S. Clean Air Act Section 112(r) for Accidental Release Prevention (40 CFR 68.130, Subpart F).

This product does not contain any chemicals listed under the U.S. Clean Air Act Section 111 SOCMI Intermediate or Final VOC's (40 CFR 60.489).

Clean Water Act

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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

Massachusetts Right To Know

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

Pennsylvania Right To Know

Human serum /-plasma / -hemolysate, liquid Not Assigned 90 - 100 %

New Jersey Right To Know

Human serum /-plasma / -hemolysate, liquid Not Assigned 90 - 100 %

California Prop 65

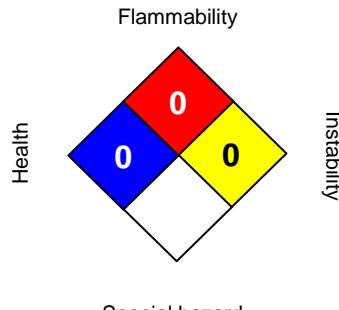
: This product does not contain any chemicals known to State of California to cause cancer, birth defects, or any other reproductive harm.

SECTION 16. OTHER INFORMATION

Further information

CS1 - [MGP] / MGP 2

NFPA:



HMIS III:

HEALTH	0
FLAMMABILITY	0
PHYSICAL HAZARD	0

0 = not significant, 1 =Slight,
2 = Moderate, 3 = High
4 = Extreme, * = Chronic

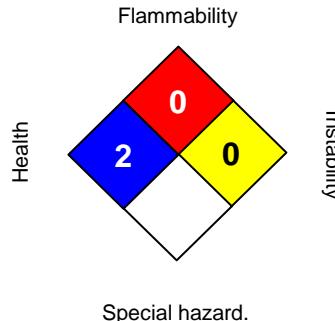
CS2 - [Lys]

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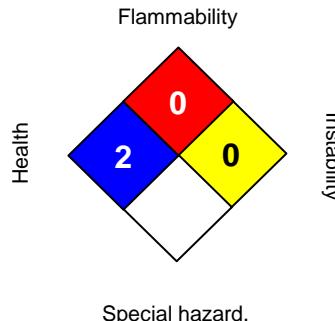
Revision Date 09-19-2014

Print Date 12-06-2014

NFPA:**HMIS III:**

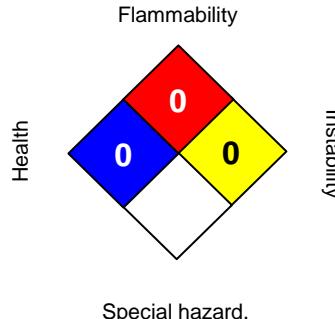
HEALTH	2
FLAMMABILITY	0
PHYSICAL HAZARD	0

0 = not significant, 1 =Slight,
 2 = Moderate, 3 = High
 4 = Extreme, * = Chronic

HBV/CS3 [Pase] / P2**NFPA:****HMIS III:**

HEALTH	2*
FLAMMABILITY	0
PHYSICAL HAZARD	0

0 = not significant, 1 =Slight,
 2 = Moderate, 3 = High
 4 = Extreme, * = Chronic

CS3 - [EB]**NFPA:****HMIS III:**

HEALTH	0
FLAMMABILITY	0
PHYSICAL HAZARD	0

0 = not significant, 1 =Slight,
 2 = Moderate, 3 = High
 4 = Extreme, * = Chronic

CS4 [QS/IC]

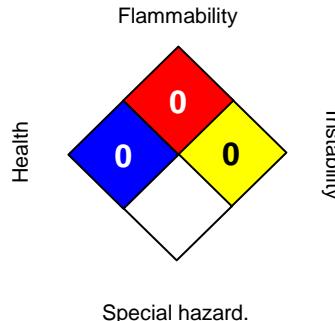
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NFPA:



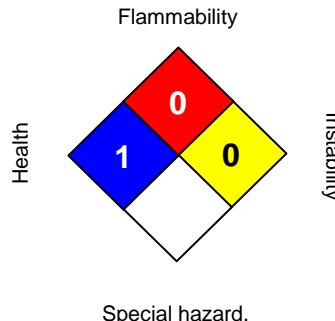
HMIS III:

HEALTH	0
FLAMMABILITY	0
PHYSICAL HAZARD	0

0 = not significant, 1 =Slight,
 2 = Moderate, 3 = High
 4 = Extreme, * = Chronic

CS4 - [CTM Mn2+]

NFPA:



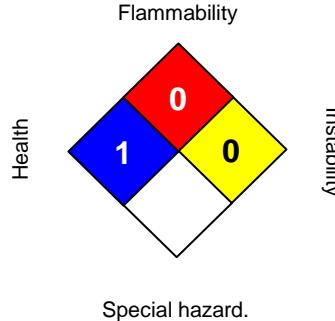
HMIS III:

HEALTH	2
FLAMMABILITY	0
PHYSICAL HAZARD	0

0 = not significant, 1 =Slight,
 2 = Moderate, 3 = High
 4 = Extreme, * = Chronic

CS4 - [MMX]

NFPA:



HMIS III:

HEALTH	0
FLAMMABILITY	0
PHYSICAL HAZARD	0

0 = not significant, 1 =Slight,
 2 = Moderate, 3 = High
 4 = Extreme, * = Chronic

CTM (-)C (Human Plasma)

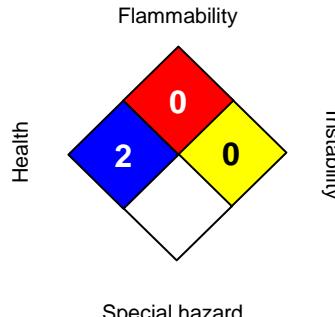
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NFPA:



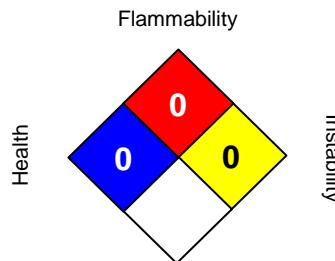
HMIS III:

HEALTH	2
FLAMMABILITY	0
PHYSICAL HAZARD	0

0 = not significant, 1 =Slight,
 2 = Moderate, 3 = High
 4 = Extreme, * = Chronic

[HCV L(+)C, v2.0] (Human Plasma)

NFPA:



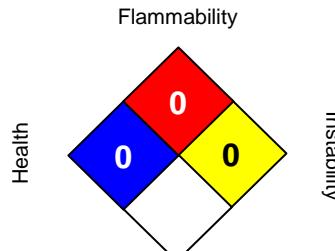
HMIS III:

HEALTH	0
FLAMMABILITY	0
PHYSICAL HAZARD	0

0 = not significant, 1 =Slight,
 2 = Moderate, 3 = High
 4 = Extreme, * = Chronic

[HCV H(+)C, v2.0] (Human Plasma)

NFPA:



HMIS III:

HEALTH	0
FLAMMABILITY	0
PHYSICAL HAZARD	0

0 = not significant, 1 =Slight,
 2 = Moderate, 3 = High
 4 = Extreme, * = Chronic

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: 09-19-2014

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.