

KIT CAP-G/CTM HCV 48 TESTS US-IVD

Version 1.3

Revision Date 09-18-2014

Print Date 03-12-2015

SECTION 1. IDENTIFICATION

Product name : KIT CAP-G/CTM HCV 48 TESTS US-IVD

Mat.-No./ Genisys-No. : 03568555190

Chemical nature : Handle as potentially infectious.

Manufacturer or supplier's details

Company name of supplier : Roche Diagnostics

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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 : H225 Highly flammable liquid and vapour.
H302 + H332 Harmful if swallowed or if inhaled
H315 Causes skin irritation.
H318 Causes serious eye damage.
H334 May cause allergy or asthma symptoms or breathing difficulties if inhaled.
H336 May cause drowsiness or dizziness.Precautionary statements : **Prevention:**
P210 Keep away from heat/sparks/open flames/hot surfaces. -
No smoking.
P233 Keep container tightly closed.
P240 Ground/bond container and receiving equipment.
P241 Use explosion-proof electrical/ ventilating/ lighting/
equipment.
P242 Use only non-sparking tools.

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P243 Take precautionary measures against static discharge.
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.
P271 Use only outdoors or in a well-ventilated area.
P280 Wear protective gloves/ protective clothing/ 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.

P303 + P361 + P353 IF ON SKIN (or hair): Remove/ Take off immediately all contaminated clothing. Rinse skin with water/ shower.

P304 + P340 IF INHALED: 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.

P370 + P378 In case of fire: Use dry sand, dry chemical or alcohol-resistant foam for extinction.

Storage:

P403 + P233 Store in a well-ventilated place. Keep container tightly closed.

P403 + P235 Store in a well-ventilated place. Keep cool.

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***Magnetic Glass Particles (MGPs) Suspension*****GHS Classification**

Flammable liquids, Category 2

H225: Highly flammable liquid and vapour.

Eye irritation, Category 2A

H319: Causes serious eye irritation.

Specific target organ toxicity - single exposure, Category 3 (Central nervous system)

H336: May cause drowsiness or dizziness.

Hazardous components

Chemical Name	CAS-No.	Concentration (%)
propan-2-ol	67-63-0	>= 90 - <= 100

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Lysis Buffer (R2 / LYS RGT / [HIV/HBV/HCV/DPX/MPX/MPX2 - CS2])**GHS Classification**

Acute toxicity (Oral), Category 4

H302: Harmful if swallowed.

Acute toxicity (Inhalation), Category 4

H332: Harmful if inhaled.

Skin irritation, Category 2

H315: Causes skin irritation.

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	>= 10 - < 20

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 (%)
glycerol	56-81-5	>= 50 - < 70
Subtilisin	9014-01-1	>= 10 - < 20

[CS3 - EB] / R3 / EB 2**GHS Classification**

Not a hazardous substance or mixture.

Hazardous components

No hazardous ingredients

[CS4 - HCV] 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

CS4 [Mn2+]**GHS Classification**

Not a hazardous substance or mixture.

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Hazardous components

No hazardous ingredients

[CS4 - HCV] QS**GHS Classification**

Not a hazardous substance or mixture.

Hazardous components

No hazardous ingredients

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 (Human Plasma)**GHS Classification**

Not a hazardous substance or mixture.

Chemical nature : Handle as potentially infectious.

Hazardous components

No hazardous ingredients

HCV H(+)C / V2 (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. |

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- 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.

SECTION 5. FIREFIGHTING MEASURES

- Suitable extinguishing media : Alcohol-resistant foam
Carbon dioxide (CO₂)
Dry chemical
- 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.
For safety reasons in case of fire, cans should be stored separately in closed containments.
Use a water spray to cool fully closed containers.
- Special protective equipment for firefighters : Wear self-contained breathing apparatus for firefighting if necessary.

SECTION 6. ACCIDENTAL RELEASE MEASURES

- Personal precautions, protective equipment and : Use personal protective equipment.
Ensure adequate ventilation.

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- emergency procedures Remove all sources of ignition.
Evacuate personnel to safe areas.
Refer to protective measures listed in sections 7 and 8.
Beware of vapours accumulating to form explosive concentrations. Vapours can accumulate in low areas.
- 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 : Contain spillage, and then collect with non-combustible absorbent material, (e.g. sand, earth, diatomaceous earth, vermiculite) and place in container for disposal according to local / national regulations (see section 13).

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.
Take precautionary measures against static discharges.
Provide sufficient air exchange and/or exhaust in work rooms.
Open drum carefully as content may be under pressure.
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 : No smoking.
Keep container tightly closed in a dry and well-ventilated place.
Containers which are opened must be carefully resealed and kept upright to prevent leakage.
Observe label precautions.
Electrical installations / working materials must comply with the technological safety standards.

SECTION 8. EXPOSURE CONTROLS/PERSONAL PROTECTION***Magnetic Glass Particles (MGPs) Suspension*****Components with workplace control parameters**

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

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propan-2-ol	67-63-0	TWA	200 ppm	ACGIH
		STEL	400 ppm	ACGIH
		TWA	400 ppm 980 mg/m ³	NIOSH REL
		ST	500 ppm 1,225 mg/m ³	NIOSH REL
		TWA	400 ppm 980 mg/m ³	OSHA Z-1
		TWA	400 ppm 980 mg/m ³	OSHA P0
		STEL	500 ppm 1,225 mg/m ³	OSHA P0

Biological occupational exposure limits

Components	CAS-No.	Control parameters	Biological specimen	Sampling time	Permissible concentration	Basis
Isopropanol	67-63-0	Acetone	Urine	End of shift at end of workweek	40 mg/l	ACGIH BEI

Lysis Buffer (R2 / LYS RGT / [HIV/HBV/HCV/DPX/MPX/MPX2 - CS2])**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/m ³	OSHA Z-1
		TWA (mist, total dust)	15 mg/m ³	OSHA Z-1
		TWA (Mist - total dust)	10 mg/m ³	OSHA P0
		TWA (Mist - respirable fraction)	5 mg/m ³	OSHA P0
Subtilisin	9014-01-1	C	0.00006 mg/m ³	OSHA P0
		C	0.00006 mg/m ³ (as crystalline active enzyme)	ACGIH
		ST	0.00006 mg/m ³	NIOSH REL

[CS3 - EB] / R3 / EB 2**Components with workplace control parameters**

Contains no substances with occupational exposure limit values.

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

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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/m ³	OSHA Z-1
		TWA (mist, total dust)	15 mg/m ³	OSHA Z-1
		TWA (Mist - total dust)	10 mg/m ³	OSHA P0
		TWA (Mist - respirable fraction)	5 mg/m ³	OSHA P0

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

Contains no substances with occupational exposure limit values.

[CS4 - HCV] QS**Components with workplace control parameters**

Contains no substances with occupational exposure limit values.

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

Contains no substances with occupational exposure limit values.

HCV L(+)C / V2 (Human Plasma)**Components with workplace control parameters**

Contains no substances with occupational exposure limit values.

HCV H(+)C / V2 (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.

Eye protection : Eye wash bottle with pure water

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	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***Magnetic Glass Particles (MGPs) Suspension***

Appearance	: liquid
Colour	: colourless black
Odour	: strong
Melting point/range	: -89 °C
Boiling point/boiling range	: 82 °C
Flash point	: 12 °C
Upper explosion limit	: 12 %(V)
Lower explosion limit	: 2 %(V)
Vapour pressure	: 42 hPa (20 °C)
Solubility(ies) Water solubility	: partly miscible
Auto-ignition temperature	: No data available
Thermal decomposition	: Hazardous decomposition products formed under fire conditions.
Oxidizing properties	: The substance or mixture is not classified as oxidizing.

Lysis Buffer (R2 / LYS RGT / [HIV/HBV/HCV/DPX/MPX/MPX2 - CS2])

Appearance	: liquid
Colour	: colourless
Odour	: none
pH	: 5.0
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	: completely miscible
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] / R3 / EB 2

Appearance	: liquid
pH	: 8.5
Melting point/range	: No data available
Boiling point/boiling range	: No data available
Flash point	: does not flash
Upper explosion limit	: No data available

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

[CS4 - HCV] MMX

Appearance	: liquid
Colour	: purple
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	: 1.0595 g/cm3
Solubility(ies)	
Water solubility	: completely miscible
Auto-ignition temperature	: No data available
Thermal decomposition	: No data available

CS4 [Mn2+]

Appearance	: liquid
pH	: 6.5
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	: 1.0 g/cm3

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Solubility(ies)
Water solubility : completely miscible

Auto-ignition temperature : No data available

Thermal decomposition : No data available

[CS4 - HCV] QS

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

Solubility(ies)
Water solubility : completely miscible

Auto-ignition temperature : No data available

Thermal decomposition : No data available

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

Solubility(ies)
Water solubility : completely miscible

Auto-ignition temperature : No data available

Thermal decomposition : No data available

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HCV L(+)/C / V2 (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/cm ³
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 (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/cm ³
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.

SECTION 10. STABILITY AND REACTIVITY

Reactivity	: No dangerous reaction known under conditions of normal use.
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Chemical stability	: Stable under normal conditions.
Possibility of hazardous reactions	: No decomposition if stored and applied as directed. Vapours may form explosive mixture with air.
Conditions to avoid	: No data available Heat, flames and sparks.
Incompatible materials	: No data available
Hazardous decomposition products	: No data available

SECTION 11. TOXICOLOGICAL INFORMATION***Magnetic Glass Particles (MGPs) Suspension*****Information on likely routes of exposure****Acute toxicity**

Not classified based on available information.

Product:

Acute oral toxicity : Acute toxicity estimate : 4,914 mg/kg
Method: Calculation method

Components:**propan-2-ol:**

Acute oral toxicity : LD50 Oral (Rat): 4,570 mg/kg
LD50 Oral (Mouse): 3,600 mg/kg
LD50 Oral (Rabbit): 6,410 mg/kg

Acute inhalation toxicity : LC50 (Rat): 30 mg/l, 16000 ppm
Exposure time: 4 h
LC50 (Mouse): 53 mg/l

Acute dermal toxicity : LD50 Dermal (Rabbit): 13,400 mg/kg

Skin corrosion/irritation

Not classified based on available information.

Product:

Remarks: May cause skin irritation in susceptible persons.

Components:**propan-2-ol:**

Remarks: May cause skin irritation in susceptible persons.

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Serious eye damage/eye irritation

Causes serious eye irritation.

Product:

Remarks: May cause irreversible eye damage.

Components:**propan-2-ol:**

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.

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

May cause drowsiness or dizziness.

Product:

Assessment: May cause drowsiness or dizziness.

Components:**propan-2-ol:**

Assessment: May cause drowsiness or dizziness.

STOT - repeated exposure

Not classified based on available information.

Product:

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

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repeated exposure.

Components:**propan-2-ol:**

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

Aspiration toxicity

Not classified based on available information.

Product:

No aspiration toxicity classification

Further information**Product:**

Remarks: Symptoms of overexposure may be headache, dizziness, tiredness, nausea and vomiting., Concentrations substantially above the TLV value may cause narcotic effects., Solvents may degrease the skin.

Lysis Buffer (R2 / LYS RGT / [HIV/HBV/HCV/DPX/MPX/MPX2 - CS2])**Information on likely routes of exposure****Acute toxicity**

Harmful if swallowed or if inhaled

Product:

Acute oral toxicity : Acute toxicity estimate : 1,266 mg/kg
Method: Calculation method

Acute inhalation toxicity : Acute toxicity estimate : 3.5 mg/l
Exposure time: 4 h
Test atmosphere: dust/mist
Method: Calculation method

Acute dermal toxicity : Acute toxicity estimate : 2,570 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

Polidocanol:

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

Skin corrosion/irritation

Causes skin irritation.

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Product:

Remarks: May cause skin irritation in susceptible persons.

Components:**Polidocanol:**

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.

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.

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.

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:**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

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inhaled.

Components:**Subtilisin:**

Assessment: May cause sensitisation by inhalation.

Result: The product is a respiratory sensitiser, 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:**

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] / R3 / EB 2**Information on likely routes of exposure****Acute toxicity**

Not classified based on available information.

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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.

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.

Product:

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No aspiration toxicity classification

[CS4 - HCV] 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:

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

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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.

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 - Assessment : Mild eye irritation, Mild skin irritation

glycerol:

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

Aspiration toxicity

Not classified based on available information.

Components:

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dimethyl sulfoxide:

No data available

CS4 [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

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.

[CS4 - HCV] QS

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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.

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

Not classified based on available information.

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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.

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

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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.

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 (Human Plasma)**Information on likely routes of exposure**

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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.

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.

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SECTION 12. ECOLOGICAL INFORMATION***Magnetic Glass Particles (MGPs) Suspension*****Ecotoxicity****Product:**

Ecotoxicology Assessment

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

Other organisms relevant to the environment : No data available

Components:**propan-2-ol:**Toxicity to fish : LC0 (Oncorhynchus mykiss (rainbow trout)): 10,000 mg/l
Method: OECD Test Guideline 203LC50 (Oncorhynchus mykiss (rainbow trout)): 12,250 mg/l
Method: OECD Test Guideline 203LC100 (Oncorhynchus mykiss (rainbow trout)): 15,000 mg/l
Method: OECD Test Guideline 203Toxicity to daphnia and other aquatic invertebrates : EC50 (Daphnia magna (Water flea)): 9,500 mg/l
Exposure time: 24 hToxicity to algae : EC0 (Scenedesmus quadricauda (Green algae)): 1,800 mg/l
Exposure time: 168 h
Method: OECD Test Guideline 201Toxicity to bacteria : EC0 (Pseudomonas putida): 1,050 mg/l
Exposure time: 16 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:****propan-2-ol:**Biodegradability : Biodegradation: 99 %
Exposure time: 11 d
Method: OECD Test Guideline 302Biodegradation: 57 %
Exposure time: 5 d
Method: OECD Test Guideline 302**Bioaccumulative potential****Components:**

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propan-2-ol:

Partition coefficient: n-octanol/water : log Pow: 0.05

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).

Lysis Buffer (R2 / LYS RGT / [HIV/HBV/HCV/DPX/MPX/MPX2 - CS2])**Ecotoxicity****Product:**

Ecotoxicology Assessment

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

Other organisms relevant to the environment : No data available

Components:**guanidinium thiocyanate:**Toxicity to fish : LC50 (Poecilia reticulata (guppy)): 89.1 mg/l
Exposure time: 96 hToxicity to daphnia and other aquatic invertebrates : EC50 (Daphnia (water flea)): 42.4 mg/l
Exposure time: 48 h

Ecotoxicology Assessment

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

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

Other organisms relevant to the environment : No data available

Polidocanol:

M-Factor (Acute aquatic toxicity) : 1

Ecotoxicology Assessment

Acute aquatic toxicity : Toxic to aquatic life.

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

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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

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).

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:**

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

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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

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

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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).

[CS3 - EB] / R3 / EB 2**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).

[CS4 - HCV] 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 hToxicity to daphnia and other
aquatic invertebrates : EC50 (Daphnia magna (Water flea)): 24,600 mg/l
Exposure time: 48 h
Method: OECD Test Guideline 202Toxicity to bacteria : EC50 (Photobacterium phosphoreum): ca. 70,000 mg/l
Exposure time: 0.25 h

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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

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

Persistence and degradability**Components:****dimethyl sulfoxide:**Biodegradability : Biodegradation: 4 %
Exposure time: 1 dBiodegradation: 6 %
Exposure time: 8 dBiodegradation: 29 %
Exposure time: 15 dBiodegradation: 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- : log Pow: -1.35

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octanol/water

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).

CS4 [Mn2+]**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).

[CS4 - HCV] QS**Ecotoxicity****Product:**

Ecotoxicology Assessment

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

Other organisms relevant to the environment : No data available

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).

CTM (-)C (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).

HCV L(+)C / V2 (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 H(+)/C / V2 (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).

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.
Do not re-use empty containers.
Do not burn, or use a cutting torch on, the empty drum.

SECTION 14. TRANSPORT INFORMATION**International Regulation****IATA-DGR**

- UN/ID No. : UN 1219
Proper shipping name : Isopropanol
Class : 3
Packing group : II
Labels : Flammable liquids
Packing instruction (cargo aircraft) : 364
Packing instruction (passenger aircraft) : 353

IMDG-Code

- UN number : UN 1219
Proper shipping name : Isopropanol
Class : 3
Packing group : II
Labels : 3
EmS Code : F-E, S-D
Marine pollutant : no

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**

- UN/ID/NA number : UN 1219
Proper shipping name : Isopropanol
Class : 3
Packing group : II
Labels : Class 3 - Flammable Liquid

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ERG Code : 129

Marine pollutant : no

SECTION 15. REGULATORY INFORMATION***Magnetic Glass Particles (MGPs) Suspension*****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 : The following components are subject to reporting levels established by SARA Title III, Section 313:

propan-2-ol	67-63-0	93 %
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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 SOCM1

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

propan-2-ol	67-63-0	93 %
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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

propan-2-ol	67-63-0	90 - 100 %
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Pennsylvania Right To Know

propan-2-ol	67-63-0	90 - 100 %
Magnetische Glaspartikel (MGP)	Not Assigned	5 - 10 %

New Jersey Right To Know

propan-2-ol	67-63-0	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.

Lysis Buffer (R2 / LYS RGT / [HIV/HBV/HCV/DPX/MPX/MPX2 - CS2])**EPCRA - Emergency Planning and Community Right-to-Know Act**

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

Clean Water Act

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

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

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

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	10 - 20 %

New Jersey Right To Know

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

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.

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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).

The following chemical(s) are listed under the U.S. Clean Air Act Section 111 SOCM 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] / R3 / EB 2**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).

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

Clean Water Act

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

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

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

Massachusetts Right To Know

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

Pennsylvania Right To Know

water	7732-18-5	90 - 100 %
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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 - HCV] MMX**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).

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

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dimethyl sulfoxide	67-68-5	14.31 %
glycerol	56-81-5	12.89 %

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 %
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.

CS4 [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.

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

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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	0.44 %
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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).

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

acetic acid	64-19-7	0.002 %
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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	0.002 %
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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	0.002 %
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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 %
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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 - HCV] QS
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.

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

Clean Water Act

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

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

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

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.

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

Clean Water Act

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

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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.

HCV L(+)/C / V2 (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 SOCM Intermediate or Final VOC's (40 CFR 60.489).

Clean Water Act

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

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

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

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

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

Clean Water Act

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

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

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

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.

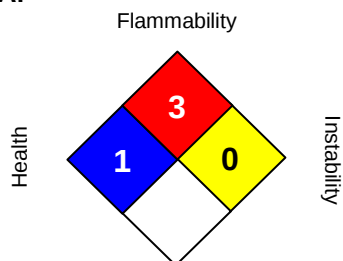
SECTION 16. OTHER INFORMATION**Further information****Magnetic Glass Particles (MGPs) Suspension**

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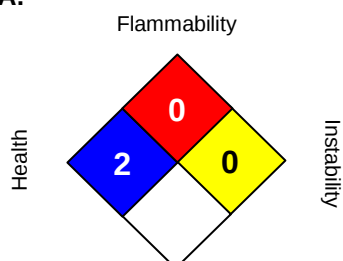
NFPA:

Special hazard.

HMIS III:

HEALTH	2
FLAMMABILITY	3
PHYSICAL HAZARD	0

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

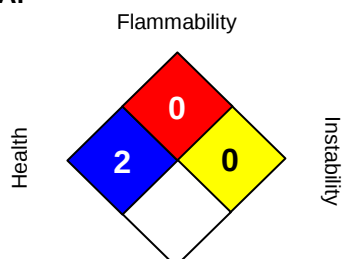
Lysis Buffer (R2 / LYS RGT / [HIV/HBV/HCV/DPX/MPX/MPX2 - CS2])
NFPA:

Special hazard.

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:

Special hazard.

HMIS III:

HEALTH	2*
FLAMMABILITY	0
PHYSICAL HAZARD	0

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

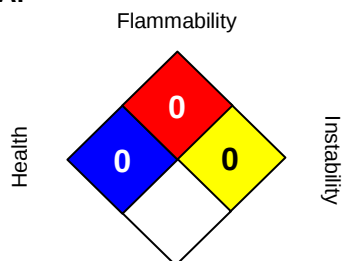
[CS3 - EB] / R3 / EB 2

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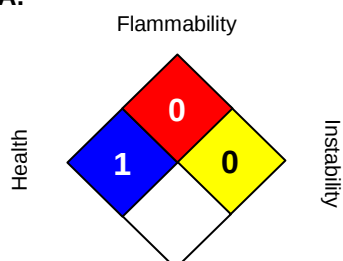
Revision Date 09-18-2014

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NFPA:**HMIS III:**

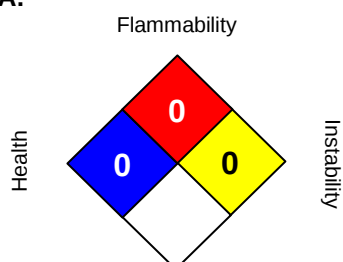
HEALTH	0
FLAMMABILITY	0
PHYSICAL HAZARD	0

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

[CS4 - HCV] MMX**NFPA:****HMIS III:**

HEALTH	0
FLAMMABILITY	0
PHYSICAL HAZARD	0

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

CS4 [Mn2+]**NFPA:****HMIS III:**

HEALTH	0
FLAMMABILITY	0
PHYSICAL HAZARD	0

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

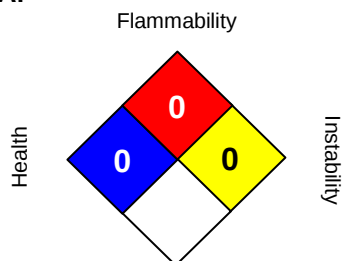
[CS4 - HCV] QS

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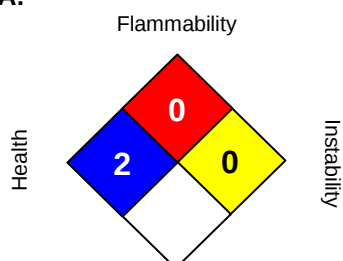
NFPA:

Special hazard.

HMIS III:

HEALTH	0
FLAMMABILITY	0
PHYSICAL HAZARD	0

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

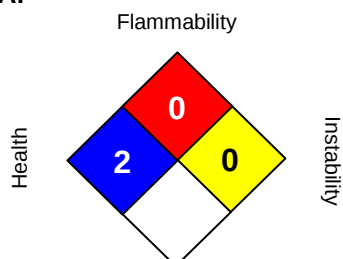
CTM (-)C (Human Plasma)**NFPA:**

Special hazard.

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 (Human Plasma)**NFPA:**

Special hazard.

HMIS III:

HEALTH	2
FLAMMABILITY	0
PHYSICAL HAZARD	0

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

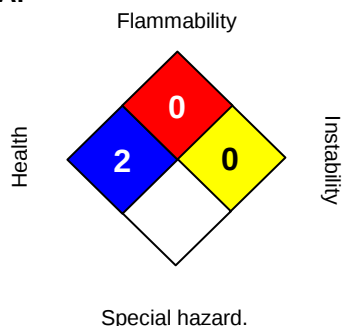
HCV H(+)C / V2 (Human Plasma)

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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

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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.