

U/CSF Protein

Version 1.3

Revision Date 09-18-2014

Print Date 12-06-2014

SECTION 1. IDENTIFICATION

Product name : U/CSF Protein

Mat.-No./ Genisys-No. : 11877801160

Manufacturer or supplier's detailsCompany 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 element

Hazard pictograms :



Signal word : Warning

Hazard statements : H290 May be corrosive to metals.
H315 Causes skin irritation.
H319 Causes serious eye irritation.Precautionary statements : **Prevention:**
P234 Keep only in original container.
P264 Wash skin thoroughly after handling.
P280 Wear protective gloves/ eye protection/ face protection.
Response:
P302 + P352 IF ON SKIN: Wash with plenty of soap and water.
P305 + P351 + P338 IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.
P332 + P313 If skin irritation occurs: Get medical advice/ attention.
P337 + P313 If eye irritation persists: Get medical advice/ attention.
P362 Take off contaminated clothing and wash before reuse.

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P390 Absorb spillage to prevent material damage.

Storage:

P406 Store in corrosive resistant stainless steel container with a resistant inner liner.

Other hazards

None known.

SECTION 3. COMPOSITION/INFORMATION ON INGREDIENTS**R1(A / B)****GHS Classification**

Corrosive to metals, Category 1

H290: May be corrosive to metals.

Hazardous components

Chemical Name	CAS-No.	Concentration (%)
Edetic acid disodium salt dihydrate (EDTA-2Na-2H ₂ O)	6381-92-6	>= 1 - < 5
sodium hydroxide	1310-73-2	>= 1 - < 5

R2 (C)**GHS Classification**

Skin irritation, Category 2

H315: Causes skin irritation.

Eye irritation, Category 2A

H319: Causes serious eye irritation.

Hazardous components

Chemical Name	CAS-No.	Concentration (%)
benzethonium chloride	121-54-0	>= 1 - < 5

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 : Move to fresh air.
If unconscious place in recovery position and seek medical advice.
If symptoms persist, call a physician.
- In case of skin contact : Immediate medical treatment is necessary as untreated wounds from corrosion of the skin heal slowly and with difficulty.
If on skin, rinse well with water.
If on clothes, remove clothes.
- In case of eye contact : Small amounts splashed into eyes can cause irreversible tissue damage and blindness.
In the case of contact with eyes, rinse immediately with plenty

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- 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 : 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.
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.
Local authorities should be advised if significant spillages cannot be contained.
- Methods and materials for containment and cleaning up : Soak up with inert absorbent material (e.g. sand, silica gel, acid binder, universal binder, sawdust).

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Keep in suitable, closed containers for disposal.

SECTION 7. HANDLING AND STORAGE

- Advice on safe handling : Do not breathe vapours/dust.
Avoid contact with skin and eyes.
For personal protection see section 8.
Smoking, eating and drinking should be prohibited in the application area.
Dispose of rinse water in accordance with local and national regulations.
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.
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**R1(A / B)****Components with workplace control parameters**

Components	CAS-No.	Value type (Form of exposure)	Control parameters / Permissible concentration	Basis
sodium hydroxide	1310-73-2	C	2 mg/m ³	ACGIH
		C	2 mg/m ³	NIOSH REL
		TWA	2 mg/m ³	OSHA Z-1
		C	2 mg/m ³	OSHA P0

R2 (C)**Components with workplace control parameters**

Contains no substances with occupational exposure limit values.

Personal protective equipment

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

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Eye protection	: discussed with the producers of the protective gloves. : 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***R1(A / B)***

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
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.

R2 (C)

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

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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.
Chemical stability	: Stable under normal conditions.
Possibility of hazardous reactions	: Reacts with the following substances: Acids No decomposition if stored and applied as directed.
Conditions to avoid	: No data available
Incompatible materials	: Acids
Hazardous decomposition products	: No data available

SECTION 11. TOXICOLOGICAL INFORMATION***R1(A / B)*****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 inhalation toxicity	: Acute toxicity estimate : > 10 mg/l Exposure time: 4 h Test atmosphere: dust/mist Method: Calculation method

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

Acute oral toxicity	: LD50 Oral (Rat): > 2,000 mg/kg Test substance: anhydrous substance LD50 Oral (Rabbit): 2,300 mg/kg
Acute inhalation toxicity	: LC50 (Rat): 1 - 5 mg/l Exposure time: 6 h Test atmosphere: dust/mist

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Method: OECD Test Guideline 403
Test substance: anhydrous substance

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

Skin corrosion/irritation

Not classified based on available information.

Product:

Remarks: Extremely corrosive and destructive to tissue.

Serious eye damage/eye irritation

Not classified based on available information.

Product:

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.

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

Genotoxicity in vitro : Test Type: Ames test
Remarks: In vitro tests did not show mutagenic effects

sodium hydroxide:

Genotoxicity in vitro : Test Type: Ames test
Result: negative

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.

Components:**sodium hydroxide:**

Effects on fertility :

Remarks: No data available

STOT - single exposure

Not classified based on available information.

Components:**sodium hydroxide:**

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:**sodium hydroxide:**

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

Aspiration toxicity

Not classified based on available information.

R2 (C)**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:****benzethonium chloride:**Acute oral toxicity : LD50 Oral (Rat): 368 mg/kg
Method: OECD Test Guideline 401**Skin corrosion/irritation**

Causes skin irritation.

Product:

Remarks: May cause skin irritation in susceptible persons.

Components:**benzethonium chloride:**

Result: Causes burns.

Remarks: Extremely corrosive and destructive to tissue.

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Serious eye damage/eye irritation

Causes serious eye irritation.

Product:

Remarks: May cause irreversible eye damage.

Components:**benzethonium chloride:**

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

Not classified based on available information.

Components:**benzethonium chloride:**

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

STOT - repeated exposure

Not classified based on available information.

Aspiration toxicity

Not classified based on available information.

Components:**benzethonium chloride:**

No data available

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SECTION 12. ECOLOGICAL INFORMATION***R1(A / B)*****Ecotoxicity****Product:**

Ecotoxicology Assessment

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

Other organisms relevant to the environment : No data available

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

Toxicity to fish : LC50 (Poecilia reticulata (guppy)): ca. 320 mg/l

Exposure time: 96 h

Test substance: anhydrous substance

LC50 (Leuciscus idus (Golden orfe)): > 500 mg/l

Exposure time: 96 h

Toxicity to daphnia and other aquatic invertebrates : EC50 (Daphnia (water flea)): > 100 mg/l

Exposure time: 24 h

Toxicity to algae : ErC50 (Desmodesmus subspicatus (green algae)): > 100 mg/l

Exposure time: 72 h

Toxicity to bacteria : EC50 (Pseudomonas putida): 56 mg/l

Exposure time: 8 h

Test substance: anhydrous substance

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

sodium hydroxide:

Toxicity to fish : LC50 (Oncorhynchus mykiss (rainbow trout)): 45.4 mg/l

Exposure time: 96 h

LC50 (Leuciscus idus (Golden orfe)): ca. 7 mg/l

Toxicity to daphnia and other aquatic invertebrates : EC50 (Daphnia magna (Water flea)): 40.38 mg/l

Exposure time: 48 h

Ecotoxicology Assessment

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

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

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

Biodegradability : Biodegradation: 3 %
Testing period: 30 d
Method: Directive 67/548/EEC Annex V, C.4.C.
Remarks: According to the results of tests of biodegradability this product is not readily biodegradable.

Biochemical Oxygen Demand (BOD) : 10 mg/g
Incubation time: 5 d

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).

R2 (C)**Ecotoxicity****Product:**

Ecotoxicology Assessment

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

Other organisms relevant to the environment : No data available

Components:**benzethonium chloride:**

Toxicity to fish : LC50 (Oncorhynchus mykiss (rainbow trout)): 1.15 mg/l
Exposure time: 96 h
Method: OECD Test Guideline 203

Toxicity to daphnia and other aquatic invertebrates : EC50 (Daphnia magna (Water flea)): 0.22 mg/l
Exposure time: 48 h
Method: OECD Test Guideline 202

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Toxicity to algae : IC50 (Pseudokirchneriella subcapitata (green algae)): 0.12 mg/l
Exposure time: 72 h
Method: OECD Test Guideline 201

Ecotoxicology Assessment
Chronic aquatic toxicity : Very toxic 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

Persistence and degradability**Components:****benzethonium chloride:**

Biodegradability : Biodegradation: 0 %
Exposure time: 28 d
Method: OECD Test Guideline 301B

Bioaccumulative potential**Components:****benzethonium chloride:**

Partition coefficient: n-octanol/water : log Pow: 1.08 (20 °C)
Method: OECD Test Guideline 107

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.

SECTION 13. DISPOSAL CONSIDERATIONS**Disposal methods**

Waste from residues : 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.

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Can be disposed as waste water, when in compliance with local regulations.

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

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

UN/ID No. : UN 1824
 Proper shipping name : Sodium hydroxide solution
 Class : 8
 Packing group : III
 Labels : Corrosives
 Packing instruction (cargo aircraft) : 856
 Packing instruction (passenger aircraft) : 852

IMDG-Code

UN number : UN 1824
 Proper shipping name : Sodium hydroxide solution
 Class : 8
 Packing group : III
 Labels : 8
 EmS Code : F-A, S-B
 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 1824
 Proper shipping name : Sodium hydroxide solution
 Class : 8
 Packing group : III
 Labels : Class 8 - Corrosive
 ERG Code : 154
 Marine pollutant : no

SECTION 15. REGULATORY INFORMATION**R1(A / B)****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 hydroxide	1310-73-2	1000	*

*: Calculated RQ exceeds reasonably attainable upper limit.

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

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

sodium hydroxide	1310-73-2	2.71 %
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The following Hazardous Chemicals are listed under the U.S. CleanWater Act, Section 311, Table 117.3:

sodium hydroxide	1310-73-2	2.71 %
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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 hydroxide	1310-73-2	1 - 5 %
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Pennsylvania Right To Know

water	7732-18-5	90 - 100 %
sodium hydroxide	1310-73-2	1 - 5 %

New Jersey Right To Know

water	7732-18-5	90 - 100 %
Edetic acid disodium salt dihydrate (EDTA-2Na-2H ₂ O)	6381-92-6	1 - 5 %
sodium hydroxide	1310-73-2	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.

R2 (C)

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.

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- 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

water	7732-18-5	90 - 100 %
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New Jersey Right To Know

water	7732-18-5	90 - 100 %
benzethonium chloride	121-54-0	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.

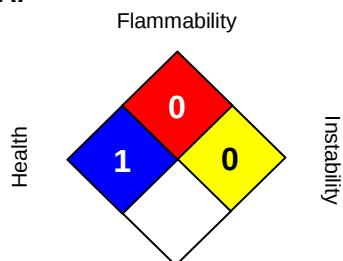
SECTION 16. OTHER INFORMATION**Further information****R1(A / B)**

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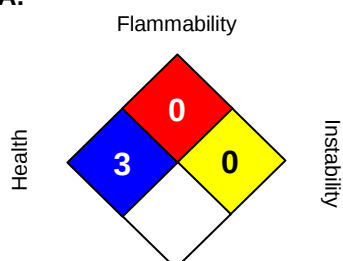
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NFPA:**HMIS III:**

HEALTH	1
FLAMMABILITY	0
PHYSICAL HAZARD	0

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

**R2 (C)
NFPA:****HMIS III:**

HEALTH	3
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.