

Printing date 11/23/2015 Reviewed on 11/23/2015

1: Identification

· Product identifier

· Trade name: CREATININE REAGENT 1

· Article number: 77331A / 79331A

· Synonyms EON 100 CREATININE R1/ EON 300 CREATININE R1.

· Relevant identified uses of the substance or mixture and uses advised against

Application of the substance / the mixture Reagent for IN VITRO diagnostic

Reagent for IN VITRO diagno

Product included in kit(s):

- Kit composed of two reagents: 77331 / 79331

 \cdot Details of the supplier of the safety data sheet

 $\cdot \textit{Manufacturer/Supplier:}$

ELITech Clinical Systems SAS

Zone Industrielle 61500 Sées • France Tel: +33 (0)2 33 81 21 00 Fax: +33 (0)2 33 28 77 51

www.elitechgroup.com MSDS.ECS-SAS@elitechgroup.com

· Information department: Product safety department

· Emergency telephone number: Contact your distributor or poison control center in your country.

2: Hazard(s) identification

- \cdot Classification of the substance or mixture
- · Classification according to Regulation (EC) No 1272/2008



Acute Tox. 3 H301 Toxic if swallowed.

Acute Tox. 3 H311 Toxic in contact with skin.



GHS08

STOT SE 2 H371 May cause damage to organs.

STOT RE 2 H373 May cause damage to organs through prolonged or repeated exposure.



GHS05

Met. Corr.1 H290 May be corrosive to metals.

Skin Corr. 1B H314 Causes severe skin burns and eye damage.

Eye Dam. 1 H318 Causes serious eye damage.

Aquatic Chronic 3 H412 Harmful to aquatic life with long lasting effects.

· Label elements

- · Labelling according to Regulation (EC) No 1272/2008 The product is classified and labeled according to the CLP regulation.
- · Hazard pictograms







GHS05 GHS06 GHS08

· Signal word Danger

 $\cdot \textit{Hazard-determining components of labeling:}$

tetramethylammonium hydroxide

· Hazard statements

May be corrosive to metals.

Toxic if swallowed or in contact with skin.

Causes severe skin burns and eye damage.

May cause damage to organs.

May cause damage to organs through prolonged or repeated exposure.

Harmful to aquatic life with long lasting effects.

Precautionary statements

Wear protective gloves/protective clothing/eye protection/face protection.

Do not breathe mist/vapours/spray.

Avoid release to the environment.

IF exposed or concerned: Call a POISON CENTER/doctor.

Get medical advice/attention if you feel unwell.

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Absorb spillage to prevent material damage.

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3: Composition/information on ingredients

- · Chemical characterization: Mixtures
- · Description:

Mixture of substances.

Aqueous solution.

•	tetramethylammonium hydroxide Acute Tox. 2, H300; Acute Tox. 1, H310; STOT SE 1, H370; STOT RE 1, H372; Skin Corr. 1B, H314; Aquatic Chronic 2, H411	2.5-10%
10043-35-3	boric acid Repr. 1B, H360FD	< 1.0%
	sodium dodecyl sulphate	< 1.0%
SVHC		

4: First-aid measures

· Description of first aid measures

· General information:

Immediately remove any clothing soiled by the product.

IF exposed or concerned: Get medical advice/attention.

Show this safety data sheet to the doctor in attendance.

· After inhalation:

Supply fresh air.

Move out of dangerous area.

If required, provide artificial respiration.

Seek medical advice.

· After skin contact:

Immediately wash with water and soap and rinse thoroughly.

Seek medical advice.

· After eye contact:

Protect unharmed eye.

Remove contact lenses, if present and easy to do.

Rinse opened eye for several minutes under running water. Then consult a doctor.

After swallowing:

Never give anything by mouth to an unconscious person.

Rinse out mouth.

Do not induce vomiting.

Seek immediate advice from a doctor or a poison control center.

- · Information for doctor:
- · Most important symptoms and effects, both acute and delayed

May cause damage to organs.

May cause damage to organs through prolonged or repeated exposure.

· Indication of any immediate medical attention and special treatment needed Data not available

5: Fire-fighting measures

- $\cdot \ Extinguishing \ media$
- · Suitable extinguishing agents:

CO2, extinguishing powder or water spray. Fight larger fires with water spray or alcohol resistant foam.

Use fire fighting measures that suit the environment.

Special hazards arising from the substance or mixture

Formation of hazardous vapours/gases is possible during heating or in case of fire.

Boron oxides

Carbon oxides (COx)

Nitrogen oxides (NOx)

· Advice for firefighters

• Protective equipment: As in any fire, wear a respiratory protective device, and full protective gear.

6: Accidental release measures

· Personal precautions, protective equipment and emergency procedures

Wear protective equipment. Keep unprotected persons away.

Ensure adequate ventilation

Avoid physical contact with material.

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- · Environmental precautions: Prevent seepage into sewage system, workpits and cellars.
- · Methods and material for containment and cleaning up:

Absorb with liquid-binding material (sand, diatomite, universal binders, sawdust).

Clean the affected area carefully.

Send for recovery or disposal in suitable receptacles.

Reference to other sections

See Section 7 for information on safe handling.

See Section 8 for information on personal protection equipment.

See Section 13 for disposal information.

7: Handling and storage

· Handling:

Precautions for safe handling

Ensure good ventilation/exhaustion at the workplace.

Open and handle receptacle with care.

Do not handle until all safety precautions have been read and understood.

Prevent formation of aerosols.

Avoid physical contact with material.

Observe the warnings on the label.

- · Information about protection against explosions and fires: No special measures required.
- · Conditions for safe storage, including any incompatibilities
- · Storage
- · Requirements to be met by storerooms and receptacles: Keep only in original container.
- Information about storage in one common storage facility. Store away from incompatible materials (see section 10).
- · Further information about storage conditions:

Keep receptacle tightly sealed.

Protect the product from light. Avoid exposure to heat.

- · Recommended storage temperature: 15-25 °C
- · Specific end use(s) Data not available.

8: Exposure controls/personal protection

- · Additional information about design of technical systems: Eyewash fountain and safety shower in the area of storage and use.
- · Control parameters
- · Components with limit values that require monitoring at the workplace:

10043-35-3 boric acid

TLV (USA) Short-term value: 6* mg/m³ Long-term value: 2* mg/m³

*as inhalable fraction

- · Additional information: The lists that were valid during the creation were used as basis.
- $\cdot \ Exposure \ controls$
- $\cdot \textit{Personal protective equipment:}$
- · General protective and hygienic measures:

The usual precautionary measures for handling chemicals should be followed.

Do not eat, drink, smoke or sniff while working.

Take off contaminated clothing and wash before reuse.

Wash hands before breaks and at the end of work.

Do not handle until all safety precautions have been read and understood.

Do not inhale gases / fumes / aerosols.

Store protective clothing separately.

Avoid physical contact with material.

The type of protective equipment must be selected according to the concentration and amount of the dangerous substance at the specific workplace.

· Breathing equipment:

In case of brief exposure or low pollution use respiratory filter device. In case of intensive or longer exposure use respiratory protective device that is independent of circulating air.

Suitable respiratory protective device recommended.

Use equipment tested and approved under appropriate government standards such as NIOSH (US) or CEN (EU).

 \cdot Protection of hands:



Protective gloves

The glove material has to be impermeable and resistant to the product/ the substance/ the preparation.

Due to missing tests no recommendation to the glove material can be given for the product/ the preparation/ the chemical mixture.

Selection of the glove material on consideration of the penetration times, rates of diffusion and the degradation

Use equipment tested and approved under appropriate government standards such as NIOSH (US) or CEN (EU).

Material of gloves

The selection of the suitable gloves does not only depend on the material, but also on further marks of quality and varies from manufacturer to manufacturer. As the product is a preparation of several substances, the resistance of the glove material can not be calculated in advance and has therefore to be checked prior to the application.

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- Penetration time of glove material The exact break through time has to be found out by the manufacturer of the protective gloves and has to be observed.
- · Eye protection:



Wear face shield/eye protection.

Use equipment tested and approved under appropriate government standards such as NIOSH (US) or CEN (EU).

· Body protection: Protective work clothing

9: Physical and chemical pro-	
General Information	themical properties
Appearance:	
Form:	Liquid
Color:	Colorless
· Odor:	Odorless
pH-value at 20 °C (68 °F):	13
Change in condition	
Melting point/Melting range:	Not applicable
Boiling point/Boiling range:	Not determined.
Solidification point:	Not determined
Flash point:	Not applicable.
Flammability (solid, gaseous):	Not applicable.
Ignition temperature:	Not determined
Decomposition temperature:	Not determined.
Auto igniting:	Product is not selfigniting.
Danger of explosion:	Product does not present an explosion hazard.
Vapor pressure:	Not determined.
Density:	
Relative density at 20 °C (68 °F)	1.017 g/cm ³ (8.487 lbs/gal)
Vapour density	Not determined.
Evaporation rate	Not determined
Solubility in / Miscibility with	
Water:	Miscible
Partition coefficient (n-octanol/wate	r): Not determined
Viscosity:	
Dynamic:	Not determined.
Other information	No further relevant information available.

10: Stability and reactivity

- · Reactivity See § Possibility of hazardous reactions.
- Chemical stability Stable under recommended storage conditions.
- Thermal decomposition / conditions to be avoided: Formation of hazardous vapours/gaz is possible during heating.
- · Possibility of hazardous reactions No dangerous reactions if used according to specifications.
- · Conditions to avoid No further relevant information available.
- · Incompatible materials:

Strong oxidizing agents, strong acids

Metallic aluminium

· Hazardous decomposition products:

Dangerous decomposition products may be formed.

Methanol

Amines

Nitrogen oxides (NOx)

Carbon oxides (COx)

Boron oxides

11: Toxicological information

- · Information on toxicological effects
- · Acute toxicity:

Toxic if swallowed or in contact with skin.

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		(Contd. of page 4)
· LD/LC50 v	alues that	are relevant for classification:
ATE (Acu	te Toxicity	y Estimates)
Oral	LD50	186 mg/kg (rat)
Dermal	LD50	619 mg/kg (rat)
Inhalative	LC50/4 h	350 mg/l (rat)
75-59-2 tet	tramethyla	ammonium hydroxide
Oral	LD50	7.5 mg/kg (rat)
Dermal	LD50	25 mg/kg (rat)
151-21-3 s	odium do	lecyl sulphate
Oral	LD50	1288 mg/kg (rat)
Inhalative	LC50/1h	>3900 mg/m3 (rat)
10043-35-3	3 boric aci	d
Oral	LD50	2660 mg/kg (rat)
Dermal	LD50	>2000 mg/kg (rabbit)
Inhalative	LC50/4 h	>2.03 mg/l (rat)
. Primary ir	witant offer	4.

- · Primary irritant effect:
- · on the skin:

Toxic if absorbed through skin.

Causes severe skin burns and eye damage.

· on the eye:

Causes serious eye damage.

· Inhalation:

May be harmful by inhalation.

May cause irritations or burns of mucous.

· Ingestion:

May cause irritations or burns of mucous.

Toxic if swallowed.

- · Sensitization: Based on available data, the classification criteria are not met.
- · Additional toxicological information:

May cause damage to organs.

May cause damage to organs through prolonged or repeated exposure.

A corrosive effect cannot be ruled out because of the pH value.

- · Carcinogenic categories
- · IARC (International Agency for Research on Cancer) None of the ingredient is listed.
- · NTP (National Toxicology Program) None of the ingredient is listed.
- · Aspiration hazard: Not classified.

12: Ecological information

- · Toxicity
- · Aquatic toxicity:

Information on components:

75-59-2 tetra	75-59-2 tetramethylammonium hydroxide		
EC50/48h	3 mg/l (Daphnia)		
LC50/96h	100 mg/l (Pimephales promelas)		
EC50/72h	96 mg/l (Pseudokirchneriella subcapitata)		
151-21-3 sod	lium dodecyl sulphate		
LC50/96h	3.6 mg/l (Onchorhyncus mykiss)		
NOEC - 7d	0.684 mg/L (Daphnia)		
10043-35-3 h	10043-35-3 boric acid		
	133 mg/l (Daphnia) ECOTOX Database		
	50-100 mg/l (Onchorhyncus mykiss) ECOTOX database		
	279 mg/l (Ptychocheilus lucius)		
LC0/96h	> 1021 mg/l (Lepomis macrochirus)		
LC50/21d	53.2 mg/L (Daphnia)		

- · Persistence and degradability Data not available
- · Behavior in environmental systems:
- · Bioaccumulative potential Data not available
- · Mobility in soil Data not available
- $\cdot \ Additional \ ecological \ information:$
- · General notes:

At present there are no ecotoxicological assessments.

Water hazard class 1 (Self-assessment): slightly hazardous for water

Do not allow undiluted product or large quantities of it to reach ground water, water course or sewage system.

Disposal procedures have to be respected, see Section 13.

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· Other adverse effects No further relevant information available.

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13: Disposal considerations

- · Waste treatment methods
- \cdot **Recommendation:** Disposal must be made according to official regulations.
- · Uncleaned packagings:
- \cdot **Recommendation:** Disposal must be made according to official regulations.
- · *Primary packaging:* Plastic vial (composed of polyethylene high density)

14: Transport information	
UN-Number DOT, ADR, IMDG, IATA	UN3267
UN proper shipping name	
· DOT	Corrosive liquid, basic, organic, n.o.s. (Tetramethylammonium hydroxide
	solution)
· ADR	3267 Corrosive liquid, basic, organic, n.o.s. (Tetramethylammonium
· IMDG, IATA	hydroxide solution) CORROSIVE LIQUID, BASIC, ORGANIC, N.O.S.
· IMDG, IATA	(TETRAMETHYLAMMONIUM HYDROXIDE SOLUTION)
· Transport hazard class(es)	
· DOT	
201	
<u> </u>	
· Class	8 Corrosive substances
. Label	Q
	0
· ADR, IMDG, IATA	
15 30-	
· Class · Label	8 Corrosive substances 8
	0
· Packing group	III
· DOT, ADR, IMDG, IATA	III
Environmental hazards:	N.
· Marine pollutant:	No
· Special precautions for user	Warning: Corrosive substances
· Danger code (Kemler): · EMS Number:	88 F-A,S-B
· EMS Number: · Segregation groups	F-A,S-B Alkalis
0 0 0 1	
· Transport in bulk according to Annex II of MARI Code	POL73/78 and the IBC Not applicable.
	**
· UN "Model Regulation":	UN3267, Corrosive liquid, basic, organic, n.o.s. (Tetramethylammonium hydroxide solution), 8, III

15: Regulatory information

- $\cdot \textit{SARA}$
- · Section 302/304 (40CFR355.30 / 40CFR355.40): None of the ingredients is listed.
- · Section 313 (Specific toxic chemical listings): Not regulated.
- TSCA (Toxic Substances Control Act): This product is regulated by the Food and Drug Administration; it is exempt from requirements of TSCA.
- Proposition 65
- · Chemicals known to cause cancer: None of the ingredients is listed.
- $\cdot \textit{Chemicals known to cause reproductive toxicity for females}. \textit{ None of the ingredients is listed}.$
- $\cdot \textit{Chemicals known to cause reproductive toxicity for males} : None \ of \ the \ ingredients \ is \ listed.$
- $\cdot \textit{Chemicals known to cause developmental toxicity:} \ \ None\ \ of\ the\ ingredient\ is\ listed.$

· Carcinogenic categories

· Carcinogenic categories	
· EPA (Environmental Protection Agency)	
10043-35-3 boric acid	I (oral)
· TLV (Threshold Limit Value established by ACGIH)	
10043-35-3 boric acid	A4
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- · NIOSH-Ca (National Institute for Occupational Safety and Health) None of the ingredient is listed.
- · OSHA-Ca (Occupational Safety & Health Administration) None of the ingredient is listed.
- · U. S. State Regulations:
- · PA-RTK None of the ingredient is listed.
- · NJ-RTK None of the ingredient is listed.
- · MA-RTK None of the ingredient is in reportable quantity.
- · RI-RTK None of the ingredient is in reportable quantity.
- · US Federal Regulation This mixture is a component of an FDA-regulated IN VITRO diagnostic medical device.
- · Chemical safety assessment: A Chemical Safety Assessment has not been carried out.

16: Other information

This information is based on our present knowledge. However, this shall not constitute a guarantee for any specific product features and shall not establish a legally valid contractual relationship.

· Relevant phrases

H228 Flammable solid.

Fatal if swallowed. H300 H302

Harmful if swallowed H310 Fatal in contact with skin.

Causes severe skin burns and eye damage. H314

H315 Causes skin irritation.

H318 Causes serious eye damage.

H332 Harmful if inhaled.

H335 May cause respiratory irritation.

H360FD May damage fertility. May damage the unborn child.

H370 Causes damage to organs.

H372 Causes damage to organs through prolonged or repeated exposure.

H411 Toxic to aquatic life with long lasting effects.

H412 Harmful to aquatic life with long lasting effects.

· Department issuing MSDS: Product safety department

· Contact: Product safety department

· Abbreviations and acronyms:

SVHC: Substances of Very High Concern
ADR: Accord européen sur le transport des marchandises dangereuses par Route (European Agreement concerning the International Carriage of Dangerous Goods by Road)
IMDG: International Maritime Code for Dangerous Goods

DOT: US Department of Transportation IATA: International Air Transport Association

GHS: Globally Harmonised System of Classification and Labelling of Chemicals ACGIH: American Conference of Governmental Industrial Hygienists

EINECS: European Inventory of Existing Commercial Chemical Substances ELINCS: European List of Notified Chemical Substances

CAS: Chemical Abstracts Service (division of the American Chemical Society)

LC50: Lethal concentration, 50 percent LD50: Lethal dose, 50 percent

NOEC: No Observed Effect Concentration EC50: Effective concentration, 50 percent

IC50 : Inhibitory concentration, 50 percent. Flam. Sol. 1: Flammable solids, Hazard Category 1

Met. Corr.1: Corrosive to metals, Hazard Category 1

Acute Tox. 2: Acute toxicity, Hazard Category 2
Acute Tox. 3: Acute toxicity, Hazard Category 3

Acute Tox. 4: Acute toxicity, Hazard Category 4 Acute Tox. 1: Acute toxicity, Hazard Category 1

Acute Tox. 1: Acute toxicity, Hazard Category 1
Skin Corr. 1B: Skin corrosion/irritation, Hazard Category 1B
Skin Irrit. 2: Skin corrosion/irritation, Hazard Category 2
Eye Dam. 1: Serious eye damage/eye irritation, Hazard Category 1
Repr. 1B: Reproductive toxicity, Hazard Category 1B
STOT SE 1: Specific target organ toxicity - Single exposure, Hazard Category 1
STOT SE 2: Specific target organ toxicity - Single exposure, Hazard Category 2
STOT SE 3: Specific target organ toxicity - Single exposure, Hazard Category 3
STOT RE 1: Specific target organ toxicity - Repeated exposure, Hazard Category 3
STOT RE 2: Specific target organ toxicity - Repeated exposure, Hazard Category 3
Aquatic Chronic 2: Hazardous to the aquatic environment - Chronic Hazard Category

Aquatic Chronic 2: Hazardous to the aquatic environment - Chronic Hazard, Category 2 Aquatic Chronic 3: Hazardous to the aquatic environment - Chronic Hazard, Category 3

* Data compared to the previous version altered.



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1: Identification

· Product identifier

· Trade name: CREATININE REAGENT 2

· Article number: 77331B / 79331B

· Synonyms EON 100 CREATININE R2 / EON 300 CREATININE R2.

- · Relevant identified uses of the substance or mixture and uses advised against
- · Application of the substance / the mixture

Reagent for IN VITRO diagnostic

Product included in kit(s):

- Kit composed of two reagents: 77331 / 79331
- \cdot Details of the supplier of the safety data sheet
- · Manufacturer/Supplier:

ELITech Clinical Systems SAS

Zone Industrielle 61500 Sées • France Tel: +33 (0)2 33 81 21 00 Fax: +33 (0)2 33 28 77 51 www.elitechgroup.com

MSDS.ECS-SAS@elitechgroup.com

- · Information department: Product safety department
- · Emergency telephone number: Contact your distributor or poison control center in your country.

2: Hazard(s) identification

- · Classification of the substance or mixture
- · Classification according to Regulation (EC) No 1272/2008 The product is not classified according to the CLP regulation.
- · Label elements
- · Labelling according to Regulation (EC) No 1272/2008 -
- · Hazard pictograms ·
- · Signal word -
- · Hazard statements -

3: Composition/information on ingredients

· Chemical characterization: Mixtures

· Description:

Mixture of substances. Aqueous solution.

· Dangerous components: No dangereous component in reportable quantity.

4: First-aid measures

- · Description of first aid measures
- \cdot General information: Show this safety data sheet to the doctor in attendance.
- · After inhalation:

Supply fresh air.

Move out of dangerous area.

If required, provide artificial respiration.

If symptoms appear, seek medical advice.

After skin contact:

Rinse with water.

If symptoms appear, seek medical advice.

· After eye contact:

Protect unharmed eye.

Remove contact lenses, if present and easy to do.

Rinse opened eye for several minutes under running water. If symptoms appear, seek medical advice.

· After swallowing:

Never give anything by mouth to an unconscious person.

Rinse out mouth.

Do not induce vomiting.

Seek advice from a doctor or a poison control center.

· Information for doctor:

- $\cdot \textit{Most important symptoms and effects, both acute and delayed } \textbf{Data not available}$
- $\cdot \textit{Indication of any immediate medical attention and special treatment needed } \textbf{Data not available}$

- USA

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5: Fire-fighting measures

· Extinguishing media

· Suitable extinguishing agents:

CO2, extinguishing powder or water spray. Fight larger fires with water spray or alcohol resistant foam.

Use fire fighting measures that suit the environment.

· Special hazards arising from the substance or mixture

Formation of toxic gases is possible during heating or in case of fire.

Carbon oxides (COx)

Nitrogen oxides (NOx)

· Advice for firefighters

· Protective equipment: As in any fire, wear a respiratory protective device, and full protective gear.

6: Accidental release measures

$\cdot \ Personal \ precautions, \ protective \ equipment \ and \ emergency \ procedures$

Ensure adequate ventilation

Wear protective clothing.

Avoid physical contact with material.

- · Environmental precautions: Prevent seepage into sewage system, workpits and cellars.
- · Methods and material for containment and cleaning up:

Absorb with liquid-binding material (sand, diatomite, universal binders, sawdust).

Do not allow to dry out

88-89-1 Picric acid (< 0.3 %): explosive when dry and forms very sensitive explosive metallic compounds whih metals.

Not mix with other waste.

Clean the affected area carefully.

\cdot Reference to other sections

See Section 7 for information on safe handling.

See Section 8 for information on personal protection equipment.

See Section 13 for disposal information.

7: Handling and storage

- · Handling:
- · Precautions for safe handling

Ensure good ventilation/exhaustion at the workplace.

Open and handle receptacle with care.

Avoid physical contact with material.

Observe the warnings on the label.

· Information about protection against explosions and fires:

88-89-1 Picric acid (< 1 %): explosive when dry and forms very sensitive explosive metallic compounds whih metals.

- $\cdot \ Conditions \ for \ safe \ storage, \ including \ any \ incompatibilities$
- · Storage:
- · Requirements to be met by storerooms and receptacles: No special requirements.
- · Information about storage in one common storage facility: Not required.
- $\cdot \textit{Further information about storage conditions} : \textit{Protect the product from light. Avoid exposure to heat}.$
- · Recommended storage temperature: 15-25 °C
- · Specific end use(s) No further relevant information available.

8: Exposure controls/personal protection

- $\cdot \textbf{Additional information about design of technical systems:} \ No \ further \ data; see \ item \ 7.$
- · Control parameters
- · Components with limit values that require monitoring at the workplace:

The product does not contain any relevant quantities of materials with critical values that have to be monitored at the workplace.

Information on components:

88-89-1 picric acid (<1%)		
PEL (USA)	Long-term value: 0.1 mg/m ³	
REL (USA)	Long-term value: 0.1 mg/m³ Short-term value: 0.3 mg/m³ Long-term value: 0.1 mg/m³ Long-term value: 0.1 mg/m³	
	Long-term value: 0.1 mg/m ³	
TLV (USA)	Long-term value: 0.1 mg/m ³	

· Additional information: The lists that were valid during the creation were used as basis.

- · Exposure controls
- · Personal protective equipment:
- · General protective and hygienic measures:

The usual precautionary measures for handling chemicals should be followed.

Wash hands before breaks and at the end of work.

Avoid physical contact with material.

The type of protective equipment must be selected according to the concentration and amount of the dangerous substance at the specific workplace.

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· Breathing equipment:

Under normal conditions, the use of these products should not require respiratory protection. If overexposure should occur and ventilation is not adequate to maintain airborne concentrations at acceptable levels, the use of respiratory protection should be evaluated by a qualified professional. Use equipment tested and approved under appropriate government standards such as NIOSH (US) or CEN (EU).

· Protection of hands:



Protective gloves

The glove material has to be impermeable and resistant to the product/ the substance/ the preparation.

Due to missing tests no recommendation to the glove material can be given for the product/ the preparation/ the chemical mixture.

Selection of the glove material on consideration of the penetration times, rates of diffusion and the degradation

Use equipment tested and approved under appropriate government standards such as NIOSH (US) or CEN (EU).

· Material of gloves

The selection of the suitable gloves does not only depend on the material, but also on further marks of quality and varies from manufacturer to manufacturer. As the product is a preparation of several substances, the resistance of the glove material can not be calculated in advance and has therefore to be checked prior to the application.

- · Penetration time of glove material The exact break through time has to be found out by the manufacturer of the protective gloves and has to be observed.
- · Eye protection:

Goggles recommended during refilling.

Use equipment tested and approved under appropriate government standards such as NIOSH (US) or CEN (EU).

· Body protection: Protective work clothing

9: Physical and chemical pr	roperties
· Information on basic physical and · General Information · Appearance:	chemical properties
Form: Color:	Liquid Yellow
· Odor:	Odorless
· pH-value:	1.6
Change in condition Melting point/Melting range: Boiling point/Boiling range: Solidification point:	Not applicable Not determined. Not determined
· Flash point:	Not applicable.
· Flammability (solid, gaseous):	Not applicable.
· Ignition temperature:	Not determined
· Decomposition temperature:	Not determined
· Auto igniting:	Product is not selfigniting.
· Danger of explosion:	Product does not present an explosion hazard.
· Vapor pressure:	Not determined.
• Density: Relative density at 20 °C (68 °F) Vapour density Evaporation rate	0.996 g/cm³ (8.312 lbs/gal) Not determined Not determined
· Solubility in / Miscibility with Water:	Miscible
· Partition coefficient (n-octanol/wate	r): Not determined
· Viscosity: Dynamic: · Other information	Not determined No further relevant information available.

10: Stability and reactivity

- · Reactivity See § Possibility of hazardous reactions.
- · Chemical stability Stable under recommended storage conditions.
- · Thermal decomposition / conditions to be avoided: No decomposition if used according to specifications.
- · Possibility of hazardous reactions

Reacts with powdered metals.

88-89-1 Picric acid (< 1 %): explosive when dry and forms very sensitive explosive metallic compounds whih metals.

- · Conditions to avoid No further relevant information available.
- · Incompatible materials:

Bases

Risk of explosion with:

(Contd. on page 4)

(Contd. of page 3)

Safety Data Sheet acc. to OSHA HCS

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Trade name: CREATININE REAGENT 2

Metals.

Light metals.

Ammonia.

Amines, aromatic hydrocarbons, concrete.

· Hazardous decomposition products:

Formation of toxic gases is possible during heating or in case of fire.

Carbon oxides (COx)

Nitrogen oxides (NOx)

· Additional information: Stable at the recommended storage temperature and if protected from light. Avoid exposure to heat.

11: Toxicological information

- · Information on toxicological effects
- · Acute toxicity: Based on available data, the classification criteria are not met.
- · LD/LC50 values that are relevant for classification:

ATE (Acute Toxicity Estimates)

Oral	LD50	> 5000 mg/kg (-)
		> 5000 mg/kg (-)
Inhalative	LC50	475 mg/L (-)

- · Primary irritant effect:
- · on the skin: May cause irritating effect.
- · on the eye: May cause irritating effect.
- · Inhalation:

May be harmful by inhalation.

May cause irritating effect.

- · Ingestion: May be harmful if swallowed.
- · Sensitization: Based on available data, the classification criteria are not met.
- · Additional toxicological information:
- · Carcinogenic categories
- · IARC (International Agency for Research on Cancer) None of the ingredient is listed.
- · NTP (National Toxicology Program) None of the ingredient is listed.

12: Ecological information

- · Toxicity
- · Aquatic toxicity: At present there are no ecotoxicological assessments.
- · Persistence and degradability Data not available
- · Behavior in environmental systems:
- · Bioaccumulative potential Data not available
- \cdot **Mobility in soil** Data not available
- Additional ecological information:
- · General notes:

Water hazard class 1 (Self-assessment): slightly hazardous for water

Do not allow undiluted product or large quantities of it to reach ground water, water course or sewage system.

- Disposal procedures have to be respected, see Section 13.
- · Other adverse effects No further relevant information available.

13: Disposal considerations

- $\cdot \ Waste \ treatment \ methods$
- \cdot **Recommendation:** Disposal must be made according to official regulations.
- · Uncleaned packagings:
- \cdot **Recommendation:** Disposal must be made according to official regulations.
- · Primary packaging: Plastic vial (composed of polyethylene high density)

14: Transport information	
· UN-Number · DOT, ADR, ADN, IMDG, IATA	Not applicable
· UN proper shipping name · DOT, ADR, ADN, IMDG, IATA	-
· Transport hazard class(es)	
· DOT, ADR, ADN, IMDG, IATA · Class	-
· Packing group · DOT, ADR, IMDG, IATA	-

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Trade name: CREATININE REAGENT 2

		(Contd. of page 4)
· Environmental hazards: · Marine pollutant:	No	
· Special precautions for user	Not applicable.	
· Transport in bulk according to Annex II of MARK Code	POL73/78 and the IBC Not applicable.	
· UN "Model Regulation":	-	

15: Regulatory information

- · SARA
- · Section 302/304 (40CFR355.30 / 40CFR355.40): None of the ingredients is listed.
- · Section 313 (Specific toxic chemical listings): Not regulated.
- · TSCA (Toxic Substances Control Act): This product is regulated by the Food and Drug Administration; it is exempt from requirements of TSCA.
- · Proposition 65
- · Chemicals known to cause cancer: None of the ingredients is listed.
- · Chemicals known to cause reproductive toxicity for females: None of the ingredients is listed.
- · Chemicals known to cause reproductive toxicity for males: None of the ingredients is listed.
- · Chemicals known to cause developmental toxicity: None of the ingredient is listed.
- · Carcinogenic categories
- · EPA (Environmental Protection Agency) None of the ingredient is listed.
- · TLV (Threshold Limit Value established by ACGIH) None of the ingredient is listed.
- $\cdot \textit{NIOSH-Ca} \ (\textit{National Institute for Occupational Safety and Health}) \ \textit{None of the ingredient is listed}.$
- · OSHA-Ca (Occupational Safety & Health Administration) None of the ingredient is listed.

· U. S. State Regulations:
· PA-RTK
88-89-1 picric acid
· NJ-RTK
88-89-1 picric acid
MA DOW

88-89-1 picric acid

· RI-RTK

88-89-1 picric acid

- · US Federal Regulation This mixture is a component of an FDA-regulated IN VITRO diagnostic medical device.
- · Chemical safety assessment: A Chemical Safety Assessment has not been carried out.

16: Other information

This information is based on our present knowledge. However, this shall not constitute a guarantee for any specific product features and shall not establish a legally valid contractual relationship.

- · Department issuing MSDS: Product safety department
- · Contact: Product safety department
- Abbreviations and acronyms:

RID: Règlement international concernant le transport des marchandises dangereuses par chemin de fer (Regulations Concerning the International Transport of Dangerous Goods by Rail) ICAO: International Civil Aviation Organisation

ADR: Accord européen sur le transport des marchandises dangereuses par Route (European Agreement concerning the International Carriage of Dangerous Goods by Road)

IMDG: International Maritime Code for Dangerous Goods

DOT: US Department of Transportation

IATA: International Air Transport Association GHS: Globally Harmonised System of Classification and Labelling of Chemicals

ACGIH: American Conference of Governmental Industrial Hygienists EINECS: European Inventory of Existing Commercial Chemical Substances ELINCS: European List of Notified Chemical Substances

CAS: Chemical Abstracts Service (division of the American Chemical Society)

LC50: Lethal concentration, 50 percent

LD50: Lethal dose, 50 percent NOEC : No Observed Effect Concentration

EC50: Effective concentration, 50 percent IC50: Inhibitory concentration, 50 percent.

· * Data compared to the previous version altered.