Safety Data Sheet
acc. to OSHA HCS

Printing date 09/14/2015 Reviewed on 09/14/2015

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1: Identification

· **Product identifier**

· ***Trade name:*** **Total Bilirubin Reagent 1**

· *Article number:* 77270A / 79270A / BITV-0850R1.
· *Synonyms* EON 100 TOTAL BILIRUBIN R1 / EON 300 TOTAL BILIRUBIN R1 / TOTAL BILIRUBIN ENVOY R1.
· ***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 : 55270 / 77270 / 79270.

· **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***


GHS05

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


GHS07

Eye Irrit. 2 H319 Causes serious eye irritation.

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


GHS05

· *Signal word* Warning
· *Hazard statements*
May be corrosive to metals.
Causes serious eye irritation.
· *Precautionary statements*
Wear protective gloves / eye protection / face protection.
Keep only in original container.
Wash thoroughly after handling.
IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.
If eye irritation persists: Get medical advice/attention.
Absorb spillage to prevent material damage.

3: Composition/information on ingredients

· **Chemical characterization: Mixtures**
· ***Description:***
Mixture of substances.
Aqueous solution.

· ***Dangerous components:***

· *CAS NO.*	*Description*	*%*
7647-01-0	hydrochloric acid Skin Corr. 1B, H314; STOT SE 3, H335	2.5-10%
57-09-0	cetrimonium bromide Eye Dam. 1, H318; Aquatic Acute 1, H400; Acute Tox. 4, H302; Skin Irrit. 2, H315; STOT SE 3, H335	≤ 2.5%

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Trade name: Total Bilirubin Reagent 1

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4: First-aid measures

· **Description of first aid measures**
· ***General information:***
Immediately remove any clothing soiled by the product.
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:***
Immediately remove any clothing soiled by the product.
Immediately 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.
Do not induce vomiting.
Rinse out mouth and then drink plenty of water.
· ***Information for doctor:***
· *Most important symptoms and effects, both acute and delayed*
Irritating effect.
A corrosive effect cannot be ruled out because of the pH value.
· *Indication of any immediate medical attention and special treatment needed* Treat symptomatically.

5: Fire-fighting measures

· **Extinguishing media**
· ***Suitable extinguishing agents:***
CO_2, 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.
Hydrogen bromide (HBr)
Hydrogen chloride (HCl)
Nitrogen oxides (NOx)
Carbon oxides (COx)
· **Advice for firefighters**
· ***Protective equipment:*** As in any fire, wear a respiratory protective device, and full protective gear.
· **Additional information** Non-combustible liquid.

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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.
Avoid formation of gas/mist/vapours.
Avoid breathing gas/mist/vapours.
· **Environmental precautions:** Do not allow to enter sewers/ surface or ground water.
· **Methods and material for containment and cleaning up:**
Absorb spillage to prevent material damage.
Absorb with liquid-binding material (sand, diatomite, acid binders, 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.

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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.
Avoid formation of gas/mist/vapours.

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Avoid breathing gas/mist/vapours.
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:*
Store in a cool location.
Keep only in original container.
Unsuitable material for receptacle: metals.
· *Information about storage in one common storage facility:* Do not store together with alkalis (caustic solutions).
· *Further information about storage conditions:*
Keep container tightly closed.
Protect the product from light. Avoid exposure to heat.
Do not freeze.
· *Recommended storage temperature:* 2-8 °C
· **Specific end use(s)** Data not available.

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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:***	
7647-01-0 hydrochloric acid	
PEL (USA)	Ceiling limit value: 7 mg/m³, 5 ppm
REL (USA)	Ceiling limit value: 7 mg/m³, 5 ppm
TLV (USA)	Ceiling limit value: 2.98 mg/m³, 2 ppm

· *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.
Immediately remove all soiled and contaminated clothing.
Avoid contact with the eyes and skin.
Avoid physical contact with material.
Avoid formation of gas/mist/vapours.
Avoid breathing gas/mist/vapours.
The type of protective equipment must be selected according to the concentration and amount of the dangerous substance at the specific workplace.
· *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.
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*
Recommended thickness of the material: ≥ 0.11 mm
Nitrile rubber, NBR
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*
Penetration time : > 480 mm
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

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9: Physical and chemical properties

· **Information on basic physical and chemical properties**	
· ***General Information***	
· *Appearance:*	
Form:	Liquid
Color:	Colorless
· *Odor:*	Odorless
· *Odour threshold:*	Not determined.
· ***pH-value at 25 °C (77 °F):***	0.75-0.85
· ***Change in condition***	
Melting point/Melting range:	Not applicable
Boiling point/Boiling range:	Data not available
Solidification point:	Data not available
· ***Flash point:***	Not applicable.
· ***Flammability (solid, gaseous):***	Not applicable.
· ***Ignition temperature:***	Data not available
· *Decomposition temperature:*	Data not available
· ***Auto igniting:***	Product is not selfigniting.
· ***Danger of explosion:***	Product does not present an explosion hazard.
· ***Vapor pressure:***	Data not available
· ***Density:***	
Relative density at 20 °C (68 °F)	1.0124 g/cm³ (8.448 lbs/gal)
Vapour density	Data not available
Evaporation rate	Data not available
· ***Solubility in / Miscibility with***	
Water:	Fully miscible.
· ***Partition coefficient (n-octanol/water):***	Data not available
· ***Viscosity:***	
Dynamic:	Data not available
· **Other information**	No further relevant information available.

*
10: Stability and reactivity

· **Reactivity** May be corrosive to metals.
· **Chemical stability** Stable under recommended storage conditions.
· ***Thermal decomposition / conditions to be avoided:*** Data not available
· **Possibility of hazardous reactions** No dangerous reactions if used according to specifications.
· **Conditions to avoid** Data not available
· **Incompatible materials:**
Bases.
Metals.
· **Hazardous decomposition products:**
Dangerous decomposition products may be formed.
Hydrogen bromide (HBr)
Hydrogen chloride (HCl)
Nitrogen oxides (NOx)
Carbon oxides (COx)
· **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:***

· *LD/LC50 values that are relevant for classification:*

ATE (Acute Toxicity Estimates)		
Oral	LD50	>5000 mg/kg

7647-01-0 hydrochloric acid		
Oral	LD50	900 mg/kg (rabbit)
Inhalative	LC50/1h	4.5 mg/l (rat)
57-09-0 cetrimonium bromide		
Oral	LD50	410 mg/kg (rat)

· *Primary irritant effect:*
· *on the skin:* May cause irritating effect.

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· *on the eye:*
Causes serious eye irritation.
· *Inhalation:*
May be harmful by inhalation.
May cause irritating effect.
· *Ingestion:* May be harmful if swallowed.
· *Sensitization:* Data not available
· ***Additional toxicological information:*** A corrosive effect cannot be ruled out because of the pH value.
· *Carcinogenic categories*

· *IARC (International Agency for Research on Cancer)*	
7647-01-0	hydrochloric acid

· *NTP (National Toxicology Program)* Available information lists no component.

*
12: Ecological information

· **Toxicity**
· ***Aquatic toxicity:***
Information on components:

57-09-0 cetrimonium bromide	
EC50/48h	0.03 mg/l (Daphnia)
LC50/96h	0.3 mg/l (Danio rerio)

· **Persistence and degradability** Data not available
· **Behavior in environmental systems:**
· ***Bioaccumulative potential*** Data not available
· ***Mobility in soil*** Data not available
· **Ecotoxical effects:**
· ***Remark:*** Can lead to changes in pH and deterioration of aquatic life.
· **Additional ecological information:**
· ***General notes:***
At present there are no ecotoxicological assessments.
Water hazard class 2 (Self-assessment): hazardous for water
Danger to drinking water if even small quantities leak into the ground.
Do not allow product 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

· **Waste treatment methods**
· ***Recommendation:*** Disposal must be made according to official regulations.

· **Uncleaned packagings:**
· ***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***	UN3264
· **UN proper shipping name**	
· ***DOT***	Corrosive liquid, acidic, inorganic, n.o.s. (Hydrochloric acid mixture)
· ***ADR***	3264 Corrosive liquid, acidic, inorganic, n.o.s. (Hydrochloric acid mixture)
· ***IMDG, IATA***	CORROSIVE LIQUID, ACIDIC, INORGANIC, N.O.S. (HYDROCHLORIC ACID MIXTURE)
· **Transport hazard class(es)**	
· ***DOT***	

· *Class*	8 Corrosive substances
· *Label*	8
· ***ADR, IMDG, IATA***	

· *Class*	8 Corrosive substances

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Trade name: Total Bilirubin Reagent 1

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· *Label*	8
· **Packing group** · ***DOT, ADR, IMDG, IATA***	III
· **Environmental hazards:** · ***Marine pollutant:***	No
· **Special precautions for user** · *Danger code (Kemler):* · *EMS Number:* · *Segregation groups*	Warning: Corrosive substances 80 F-A,S-B Acids
· **Transport in bulk according to Annex II of MARPOL73/78 and the IBC Code**	Not applicable.
· **Transport/Additional information:**	
· ***ADR*** · *Excepted quantities (EQ)*	Code: E1 Maximum net quantity per inner packaging: 30 ml Maximum net quantity per outer packaging: 1000 ml
· ***IMDG*** · *Limited quantities (LQ)* · *Excepted quantities (EQ)*	5L Code: E1 Maximum net quantity per inner packaging: 30 ml Maximum net quantity per outer packaging: 1000 ml
· **UN "Model Regulation":**	UN3264, Corrosive liquid, acidic, inorganic, n.o.s. (Hydrochloric acid mixture), 8, III

15: Regulatory information

· ***SARA***

· *Section 302/304 (40CFR355.30 / 40CFR355.40):*	
7647-01-0	hydrochloric acid

· *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:* Available information lists none.
· *Chemicals known to cause reproductive toxicity for females:* Available information lists none.
· *Chemicals known to cause reproductive toxicity for males:* Available information lists none.
· *Chemicals known to cause developmental toxicity:* Available information lists none.

· ***Carcinogenic categories***
· *EPA (Environmental Protection Agency)* Available information lists none.

· *TLV (Threshold Limit Value established by ACGIH)*	
7647-01-0	hydrochloric acid

· *NIOSH-Ca (National Institute for Occupational Safety and Health)* Available information lists none.
· *OSHA-Ca (Occupational Safety & Health Administration)* Available information lists none.
· **U. S. State Regulations:**

· ***PA-RTK***	
7647-01-0	hydrochloric acid

· ***NJ-RTK***	
7647-01-0	hydrochloric acid

· ***MA-RTK***	
7647-01-0	hydrochloric acid

· ***RI-RTK***	
7647-01-0	hydrochloric 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.

· *Relevant phrases*
H302 Harmful if swallowed.
H314 Causes severe skin burns and eye damage.
H315 Causes skin irritation.
H318 Causes serious eye damage.

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Trade name: Total Bilirubin Reagent 1

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H335 May cause respiratory irritation.
H400 Very toxic to aquatic life.

· **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.
Met. Corr.1: Corrosive to metals, Hazard Category 1
Acute Tox. 4: Acute toxicity, Hazard Category 4
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
Eye Irrit. 2: Serious eye damage/eye irritation, Hazard Category 2
STOT SE 3: Specific target organ toxicity - Single exposure, Hazard Category 3
Aquatic Acute 1: Hazardous to the aquatic environment - AcuteHazard, Category 1

· **** Data compared to the previous version altered.***

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*

1: Identification

· **Product identifier**

· ***Trade name:*** **Total Bilirubin Reagent 2**

· *Article number:* 77270B / 79270B / BITV-0850R2.
· *Synonyms* EON 100 TOTAL BILIRUBIN R2 / EON 300 TOTAL BILIRUBIN R2 / TOTAL BILIRUBIN ENVOY 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 : 55270 / 77270 / 79270.

· **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***


GHS05

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


GHS07

Eye Irrit. 2 H319 Causes serious eye irritation.

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


GHS05

· *Signal word* Warning
· *Hazard statements*
May be corrosive to metals.
Causes serious eye irritation.
· *Precautionary statements*
Wear protective gloves / eye protection / face protection.
Keep only in original container.
Wash thoroughly after handling.
IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.
If eye irritation persists: Get medical advice/attention.
Absorb spillage to prevent material damage.

3: Composition/information on ingredients

· **Chemical characterization: Mixtures**
· ***Description:***
Mixture of substances.
Aqueous solution.

· ***Dangerous components:***

· CAS NO.	Description	%		
9002-92-0	dodecan-1-ol, ethoxylated		Eye Dam. 1, H318; Acute Tox. 4, H302	2.5-10%
7647-01-0	hydrochloric acid		Skin Corr. 1B, H314; STOT SE 3, H335	< 1.0%

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Trade name: Total Bilirubin Reagent 2

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*
4: First-aid measures

· **Description of first aid measures**
· ***General information:***
Immediately remove any clothing soiled by the product.
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:***
Immediately remove any clothing soiled by the product.
Immediately 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.
Do not induce vomiting.
Rinse out mouth and then drink plenty of water.
· ***Information for doctor:***
· *Most important symptoms and effects, both acute and delayed*
Irritating effect.
A corrosive effect cannot be ruled out because of the pH value.
· *Indication of any immediate medical attention and special treatment needed* Treat symptomatically.

5: Fire-fighting measures

· **Extinguishing media**
· ***Suitable extinguishing agents:***
CO_2, 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.
Hydrogen chloride (HCl)
Carbon oxides (COx)
Nitrogen oxides (NOx)
· **Advice for firefighters**
· ***Protective equipment:*** As in any fire, wear a respiratory protective device, and full protective gear.
· **Additional information** Non-combustible liquid.

*
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.
Avoid formation of gas/mist/vapours.
Avoid breathing gas/mist/vapours.
· **Environmental precautions:** Prevent seepage into sewage system, workpits and cellars.
· **Methods and material for containment and cleaning up:**
Absorb spillage to prevent material damage.
Absorb with liquid-binding material (sand, diatomite, acid binders, 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.
Avoid physical contact with material.
Avoid formation of gas/mist/vapours.
Avoid breathing gas/mist/vapours.

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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:*
Store in a cool location.
Keep only in original container.
Unsuitable material for receptacle: metals.
· *Information about storage in one common storage facility:* Do not store together with alkalis (caustic solutions).
· *Further information about storage conditions:*
Keep container tightly closed.
Protect the product from light. Avoid exposure to heat.
Do not freeze.
· *Recommended storage temperature:* 2-8 °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:***	
7647-01-0 hydrochloric acid (<1.0%)	
PEL (USA)	Ceiling limit value: 7 mg/m³, 5 ppm
REL (USA)	Ceiling limit value: 7 mg/m³, 5 ppm
TLV (USA)	Ceiling limit value: 2.98 mg/m³, 2 ppm

· *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.
Immediately remove all soiled and contaminated clothing.
Avoid contact with the eyes and skin.
Avoid physical contact with material.
Avoid formation of gas/mist/vapours.
Avoid breathing gas/mist/vapours.
The type of protective equipment must be selected according to the concentration and amount of the dangerous substance at the specific workplace.
· *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.
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*
Recommended thickness of the material: ≥ 0.11 mm
Nitrile rubber, NBR
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*
Penetration time : > 480 mm
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 properties

· **Information on basic physical and chemical properties**
· ***General Information***
· *Appearance:*
Form: Liquid

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Color:	Yellow up to reddish
· *Odor:*	Odorless
· *Odour threshold:*	Not determined.
· ***pH-value at 25 °C (77 °F):***	0.90-0.95
· ***Change in condition***	
Melting point/Melting range:	Not applicable
Boiling point/Boiling range:	Data not available
Solidification point:	Data not available
· ***Flash point:***	Not applicable.
· ***Flammability (solid, gaseous):***	Not applicable.
· ***Ignition temperature:***	Data not available
· *Decomposition temperature:*	Data not available
· ***Auto igniting:***	Product is not selfigniting.
· ***Danger of explosion:***	Product does not present an explosion hazard.
· ***Vapor pressure:***	Data not available
· ***Density:***	
Relative density at 20 °C (68 °F)	1.001 g/cm³ (8.353 lbs/gal)
Vapour density	Data not available
Evaporation rate	Data not available
· ***Solubility in / Miscibility with***	
Water:	Fully miscible.
· ***Partition coefficient (n-octanol/water):***	Data not available
· ***Viscosity:***	
Dynamic:	Data not available
· **Other information**	No further relevant information available.

*
10: Stability and reactivity

· **Reactivity** May be corrosive to metals.
· **Chemical stability** Stable under recommended storage conditions.
· ***Thermal decomposition / conditions to be avoided:*** Data not available
· **Possibility of hazardous reactions** No dangerous reactions if used according to specifications.
· **Conditions to avoid** Data not available
· **Incompatible materials:**
Bases.
Metals.
· **Hazardous decomposition products:**
Dangerous decomposition products may be formed.
Hydrogen chloride (HCl)
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:***

· *LD/LC50 values that are relevant for classification:*		
ATE (Acute Toxicity Estimates)		
Oral	LD50	>5000 mg/kg

9002-92-0 dodecan-1-ol, ethoxylated		
Oral	LD50	1000 mg/kg (rat)
7647-01-0 hydrochloric acid		
Oral	LD50	900 mg/kg (rabbit)
Inhalative	LC50/1h	4.5 mg/l (rat)

· *Primary irritant effect:*
· *on the skin:* May cause irritating effect.
· *on the eye:*
Causes serious eye irritation.
· *Inhalation:*
May be harmful by inhalation.
May cause irritating effect.
· *Ingestion:* May be harmful if swallowed.

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· *Sensitization:* Data not available
· ***Additional toxicological information:*** A corrosive effect cannot be ruled out because of the pH value.
· *Carcinogenic categories*

· *IARC (International Agency for Research on Cancer)*	
7647-01-0	hydrochloric acid

· *NTP (National Toxicology Program)* Available information lists no component.

12: Ecological information

· **Toxicity**
· ***Aquatic toxicity:***
Information on components:

9002-92-0 dodecan-1-ol, ethoxylated	
EC50	1-10 mg/l (Daphnia)

· **Persistence and degradability** Data not available
· **Behavior in environmental systems:**
· ***Bioaccumulative potential*** Data not available
· ***Mobility in soil*** Data not available
· **Ecotoxical effects:**
· ***Remark:*** Can lead to changes in pH and deterioration of aquatic life.
· **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.
· **Other adverse effects** No further relevant information available.

13: Disposal considerations

· **Waste treatment methods**
· ***Recommendation:*** Disposal must be made according to official regulations.

· **Uncleaned packagings:**
· ***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***	UN3264
· **UN proper shipping name**	
· ***DOT***	Corrosive liquid, acidic, inorganic, n.o.s. (Hydrochloric acid mixture)
· ***ADR***	3264 Corrosive liquid, acidic, inorganic, n.o.s. (Hydrochloric acid mixture)
· ***IMDG, IATA***	CORROSIVE LIQUID, ACIDIC, INORGANIC, N.O.S. (HYDROCHLORIC ACID MIXTURE)
· **Transport hazard class(es)**	
· ***DOT***	
	
· *Class*	8 Corrosive substances
· *Label*	8
· ***ADR, IMDG, IATA***	
	
· *Class*	8 Corrosive substances
· *Label*	8
· **Packing group**	
· ***DOT, ADR, IMDG, IATA***	III
· **Environmental hazards:**	
· ***Marine pollutant:***	No
· **Special precautions for user**	Warning: Corrosive substances

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· *Danger code (Kemler):*	80
· *EMS Number:*	F-A,S-B
· *Segregation groups*	Acids
· **Transport in bulk according to Annex II of MARPOL73/78 and the IBC Code**	Not applicable.
· **Transport/Additional information:**	
· ***ADR***	
· *Excepted quantities (EQ)*	Code: E1 Maximum net quantity per inner packaging: 30 ml Maximum net quantity per outer packaging: 1000 ml
· ***IMDG***	
· *Limited quantities (LQ)*	5L
· *Excepted quantities (EQ)*	Code: E1 Maximum net quantity per inner packaging: 30 ml Maximum net quantity per outer packaging: 1000 ml
· **UN "Model Regulation":**	UN3264, Corrosive liquid, acidic, inorganic, n.o.s. (Hydrochloric acid mixture), 8, III

15: Regulatory information

· ***SARA***

· *Section 302/304 (40CFR355.30 / 40CFR355.40):*	
7647-01-0	hydrochloric acid

· *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:* Available information lists none.
· *Chemicals known to cause reproductive toxicity for females:* Available information lists none.
· *Chemicals known to cause reproductive toxicity for males:* Available information lists none.
· *Chemicals known to cause developmental toxicity:* Available information lists none.

· ***Carcinogenic categories***
· *EPA (Environmental Protection Agency)* Available information lists none.
· *TLV (Threshold Limit Value established by ACGIH)* Available information lists none.
· *NIOSH-Ca (National Institute for Occupational Safety and Health)* Available information lists none.
· *OSHA-Ca (Occupational Safety & Health Administration)* Available information lists none.
· **U. S. State Regulations:**

· ***PA-RTK***	
7647-01-0	hydrochloric acid

· ***NJ-RTK***	
7647-01-0	hydrochloric acid

· ***MA-RTK***	
7647-01-0	hydrochloric acid

· ***RI-RTK***	
7647-01-0	hydrochloric 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.

· *Relevant phrases*
H302 Harmful if swallowed.
H318 Causes serious eye damage.

· **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

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LD50: Lethal dose, 50 percent
NOEC : No Observed Effect Concentration
EC50: Effective concentration, 50 percent
IC50 : Inhibitory concentration, 50 percent.
Met. Corr.1: Corrosive to metals, Hazard Category 1
Acute Tox. 4: Acute toxicity, Hazard Category 4
Eye Dam. 1: Serious eye damage/eye irritation, Hazard Category 1
Eye Irrit. 2: Serious eye damage/eye irritation, Hazard Category 2

· **** Data compared to the previous version altered.***