

1: Identification

- **Product identifier**
- **Trade name:** Direct Bilirubin Reagent 1
- **Article number:** 77260A / 79260A / BIDV-0850R1.
- **Synonyms** EON 100 DIRECT BILIRUBIN R1 / EON 300 DIRECT BILIRUBIN R1 / DIRECT 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 : 55260 / 77260 / 79260.
- **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**



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

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



- **Signal word** Warning
- **Hazard statements**
 May be corrosive to metals.
- **Precautionary statements**
 Keep only in original container.
 Absorb spillage to prevent material damage.

3: Composition/information on ingredients

- **Chemical characterization:** Mixtures
- **Description:**
 Mixture of substances.
 Aqueous solution.
- **Dangerous components:** No dangerous component in reportable quantity.

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.

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- **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* 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:**
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.
Nitrogen oxides (NO_x)
Sulfur oxides (SO_x)
- **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 clothing.
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.
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.
Unsuitable material for receptacle: metals.
Keep only in original container.
- **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:**
The product does not contain any relevant quantities of materials with critical values that have to be monitored at the workplace.
- **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.
Take off contaminated clothing and wash before reuse.
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.

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**

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:**



Tightly sealed goggles

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

Color: Colorless

- **Odor:** Odorless

- **Odour threshold:** Not determined.

- **pH-value at 25 °C (77 °F):** 1.1

- **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.

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· Vapor pressure:	Data not available
· Density:	
Relative density at 20 °C (68 °F)	1.0103 g/cm ³ (8.431 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.
 - Nitrogen oxides (NOx)
 - Sulfur oxides (SOx)
- **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 (rat)
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· 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.
- May cause irritating effect.

· 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) Available information lists no component.

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

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

· **Mobility in soil** Data not available

· Ecotoxicological effects:

· **Remark:** Can lead to changes in pH and deterioration of aquatic life.

· 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.

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· **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 · ADR · IMDG, IATA	Corrosive liquid, acidic, inorganic, n.o.s. (Sulfamic acid mixture) 3264 Corrosive liquid, acidic, inorganic, n.o.s. (Sulfamic acid mixture) CORROSIVE LIQUID, ACIDIC, INORGANIC, N.O.S. (SULPHAMIC ACID MIXTURE)
· Transport hazard class(es) · DOT	
	
· Class · Label	8 Corrosive substances 8
· ADR, IMDG, IATA	
	
· Class · Label	8 Corrosive substances 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. (Sulfamic acid mixture), 8, III

15: Regulatory information

- **SARA**
- **Section 302/304 (40CFR355.30 / 40CFR355.40):** Available information lists none.
- **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.

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- **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** Available information lists none.

- **NJ-RTK**

5329-14-6	sulphamic acid
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- **MA-RTK** Available information lists none.
- **RI-RTK** Available information lists none.
- **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:**
- 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

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

USA

1: Identification

- **Product identifier**
- **Trade name:** Direct Bilirubin Reagent 2
- **Article number:** 77260B / 79260B / BIDV-0850R2.
- **Synonyms** EON 100 DIRECT BILIRUBIN R2 / EON 300 DIRECT BILIRUBIN R2 / DIRECT 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 : 55260 / 77260 / 79260.
- **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.

- **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.
- **Precautionary statements**
Keep only in original container.
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			2.5-10%

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.

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- 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* 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:**
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.
Hydrogen chloride (HCl)
Nitrogen oxides (NO_x)
Sulfur oxides (SO_x)
- **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 clothing.
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.
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.
Unsuitable material for receptacle: metals.
Keep only in original container.
- *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

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· 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**

PEL (USA)	Ceiling limit value: 7 mg/m ³ , 5 ppm
REL (USA)	Ceiling limit value: 7 mg/m ³ , 5 ppm
TLV (USA)	Ceiling limit value: 2.98 mg/m ³ , 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.

Take off contaminated clothing and wash before reuse.

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.

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**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:**

Tightly sealed goggles

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

Color: Colorless

· **Odor:** Odorless· **Odour threshold:** Not determined.· **pH-value at 25 °C (77 °F):** 0.1· **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.

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· 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)	1.0142 g/cm ³ (8.463 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)
 - Nitrogen oxides (NOx)
 - Sulfur oxides (SOx)
- **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 (rabbit)
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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:* May cause irritating effect.

Inhalation:

- May be harmful by inhalation.
- May cause irritating effect.

Ingestion:

- May be harmful if swallowed.
- May cause irritating effect.

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	3
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· NTP (National Toxicology Program) Available information lists no component.

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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
- *Mobility in soil* Data not available
- **Ecotoxicological effects:**
- *Remark:* Can lead to changes in pH and deterioration of aquatic life.
- **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

- **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

<ul style="list-style-type: none"> · UN-Number · <i>DOT, ADR, IMDG, IATA</i> 	UN3264
<ul style="list-style-type: none"> · UN proper shipping name · <i>DOT</i> · <i>ADR</i> · <i>IMDG, IATA</i> 	Corrosive liquid, acidic, inorganic, n.o.s. (Hydrochloric acid mixture) 3264 Corrosive liquid, acidic, inorganic, n.o.s. (Hydrochloric acid mixture) CORROSIVE LIQUID, ACIDIC, INORGANIC, N.O.S. (HYDROCHLORIC ACID MIXTURE)
<ul style="list-style-type: none"> · Transport hazard class(es) · <i>DOT</i> 	<div style="text-align: center;">  </div>
<ul style="list-style-type: none"> · <i>Class</i> · <i>Label</i> 	8 Corrosive substances 8
<ul style="list-style-type: none"> · <i>ADR, IMDG, IATA</i> 	<div style="text-align: center;">  </div>
<ul style="list-style-type: none"> · <i>Class</i> · <i>Label</i> 	8 Corrosive substances 8
<ul style="list-style-type: none"> · Packing group · <i>DOT, ADR, IMDG, IATA</i> 	III
<ul style="list-style-type: none"> · Environmental hazards: · <i>Marine pollutant:</i> 	No
<ul style="list-style-type: none"> · Special precautions for user · <i>Danger code (Kemler):</i> · <i>EMS Number:</i> · <i>Segregation groups</i> 	Warning: Corrosive substances 80 F-A,S-B Acids
<ul style="list-style-type: none"> · Transport in bulk according to Annex II of MARPOL73/78 and the IBC Code 	Not applicable.
<ul style="list-style-type: none"> · Transport/Additional information: · <i>ADR</i> · <i>Excepted quantities (EQ)</i> 	Code: E1 Maximum net quantity per inner packaging: 30 ml Maximum net quantity per outer packaging: 1000 ml

(Contd. on page 6)

USA

Safety Data Sheet

acc. to OSHA HCS

Printing date 09/10/2015

Reviewed on 09/10/2015

Trade name: Direct Bilirubin Reagent 2

(Contd. of page 5)

<ul style="list-style-type: none"> · 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
<ul style="list-style-type: none"> · 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
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- 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			A4
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- 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
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- **NJ-RTK**

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

7647-01-0	hydrochloric acid
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- **RI-RTK**

7647-01-0	hydrochloric acid
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- **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**

H314 Causes severe skin burns and eye damage.

H335 May cause respiratory irritation.

- **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

Skin Corr. 1B: Skin corrosion/irritation, Hazard Category 1B

STOT SE 3: Specific target organ toxicity - Single exposure, Hazard Category 3

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