

### Safety Data Sheet

according to Regulation (EU) 2020/878 Issue date: 30/05/2023 Version: 1.0

### SECTION 1: Identification of the substance/mixture and of the company/undertaking

#### 1.1. Product identifier

Product form : Mixture

Trade name : G-6-PDH Reagent

Other means of identification : G-6-PDH Reagent, Component part number(s): 345-5, Kit part number(s): 345-B

#### 1.2. Relevant identified uses of the substance or mixture and uses advised against

#### 1.2.1. Relevant identified uses

Use of the substance/mixture : Medical Diagnostics

1.2.2. Uses advised against

Restrictions on use : No additional information available

#### 1.3. Details of the supplier of the safety data sheet

Trinity Biotech
I.D.A Business Park
Southern Cross Road
A98 H5C8 Bray, Co. Wicklow - Ireland
Technical Support Group 00353 1 276 9800
www.trinitybiotech.com
Clinicalchemistry.techsupport@trinitybiotech.com

#### 1.4. Emergency telephone number

Emergency number

: Contact your local Emergency Health Care Provider; Ireland-Technical Support Group 00353-1-276-9800 (operating hours 7:00-18:00)

Country	Organisation/Company	Address	Emergency number	Comment
Ireland	National Poisons Information Centre Beaumont Hospital	PO Box 1297 Beaumont Road 9	+353 1 809 2566 (Healthcare professionals- 24/7) +353 1 809 2166 (public, 8am - 10pm, 7/7)	

#### **SECTION 2: Hazards identification**

### 2.1. Classification of the substance or mixture

Classification according to Regulation (EC) No. 1272/2008 [CLP]

Not classified

Adverse physicochemical, human health and environmental effects

No additional information available

#### 2.2. Label elements

Labelling according to Regulation (EC) No. 1272/2008 [CLP]

EUH-statements : EUH208 - Contains maleimide(541-59-3). May produce an allergic reaction.

### 2.3. Other hazards

Contains no PBT/vPvB substances ≥ 0.1% assessed in accordance with REACH Annex XIII

The mixture does not contain substance(s) included in the list established in accordance with Article 59(1) of REACH for having endocrine disrupting properties, or is not identified as having endocrine disrupting properties in accordance with the criteria set out in Commission Delegated Regulation (EU) 2017/2100 or Commission Regulation (EU) 2018/605 at a concentration equal to or greater than 0,1 %

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### **SECTION 3: Composition/information on ingredients**

#### 3.1. Substances

Not applicable

#### 3.2. Mixtures

Name	Product identifier	Conc.	Classification according to Regulation (EC) No. 1272/2008 [CLP]
maleimide	CAS-No.: 541-59-3 EC-No.: 208-787-4	< 1	Acute Tox. 3 (Oral), H301 Skin Corr. 1B, H314 Skin Sens. 1, H317
sodium hydroxide	CAS-No.: 1310-73-2 EC-No.: 215-185-5 EC Index-No.: 011-002-00-6 REACH-no: 01-2119457892- 27	< 0.2	Met. Corr. 1, H290 Skin Corr. 1A, H314
acetone	CAS-No.: 67-64-1 EC-No.: 200-662-2 EC Index-No.: 606-001-00-8 REACH-no: 01-2119471330-	< 0.03	Flam. Liq. 2, H225 Eye Irrit. 2, H319 STOT SE 3, H336

Specific concentration limits:		
Name Product identifier		Specific concentration limits (Conc.)
sodium hydroxide	CAS-No.: 1310-73-2 EC-No.: 215-185-5 EC Index-No.: 011-002-00-6 REACH-no: 01-2119457892- 27	$(0.5 \le C < 2)$ Skin Irrit. 2, H315 $(0.5 \le C < 2)$ Eye Irrit. 2, H319 $(2 \le C < 5)$ Skin Corr. 1B, H314 $(5 \le C \le 100)$ Skin Corr. 1A, H314

Full text of H- and EUH-statements: see section 16

### **SECTION 4: First aid measures**

First-aid measures after skin contact

First-aid measures after eye contact

First-aid measures after ingestion

#### 4.1. Description of first aid measures

First-aid measures general : Never give anything by mouth to an unconscious person. Get medical advice/attention if you feel unwell.

First-aid measures after inhalation : If inhaled and if breathing is difficult, remove victim to fresh air and keep at rest in a position

comfortable for breathing. If experiencing respiratory symptoms: Call a poison center or a

: Remove affected clothing and wash all exposed skin area with mild soap and water,

followed by warm water rinse. Get medical attention if symptoms occur. Wash contaminated clothing before reuse.

: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. Get medical advice/attention if you feel unwell.

: Do NOT induce vomiting unless directed to do so by medical personnel. Rinse mouth out with water. Call a POISON CENTER/doctor if you feel unwell.

### 4.2. Most important symptoms and effects, both acute and delayed

Symptoms/effects after inhalation : Not expected to present a significant hazard under anticipated conditions of normal use. Symptoms/effects after skin contact : Repeated or prolonged skin contact may cause skin irritation and/or dermatitis and

: Repeated or prolonged skin contact may cause skin irritation and/or dermatitis and sensitization of susceptible persons.

Symptoms/effects after eye contact : Not expected to present a significant eye contact hazard under anticipated conditions of normal use.

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Symptoms/effects after ingestion : Not expected to present a significant hazard under anticipated conditions of normal use.

#### 4.3. Indication of any immediate medical attention and special treatment needed

Treat symptomatically.

### **SECTION 5: Firefighting measures**

#### 5.1. Extinguishing media

Suitable extinguishing media : Dry chemical, CO2, or water spray or regular foam. Use extinguishing agent suitable for

surrounding fire.

Unsuitable extinguishing media : Do not use a heavy water stream.

### 5.2. Special hazards arising from the substance or mixture

Fire hazard : Presents no particular fire or explosion hazard. Burning produces stinking and toxic fumes.

In case of fire and/or explosion do not breathe fumes.

Hazardous decomposition products in case of fire : Toxic fumes may be released.

### 5.3. Advice for firefighters

Firefighting instructions : Evacuate the danger area. Fight fire from safe distance and protected location. Move

containers from fire area if it can be done without personal risk. Use extinguishing media appropriate for surrounding fire. Use water spray or fog for cooling exposed containers.

Prevent fire fighting water from entering the environment.

Protection during firefighting : Wear a self contained breathing apparatus. Wear fire/flame resistant/retardant clothing. Do

not enter fire area without proper protective equipment, including respiratory protection.

### **SECTION 6: Accidental release measures**

### 6.1. Personal precautions, protective equipment and emergency procedures

General measures : Avoid all contact with skin, eyes, or clothing. Do not inhale vapour.

6.1.1. For non-emergency personnel

Protective equipment : Wear recommended personal protective equipment. Refer to section 8.2.

Emergency procedures : No action shall be taken without appropriate training or involving any personal risk. Do not

touch or walk on the spilled product. Evacuate unnecessary personnel. Ventilate spillage

area. Avoid contact with skin and eyes.

6.1.2. For emergency responders

Protective equipment : Do not attempt to take action without suitable protective equipment.

Emergency procedures : Stop leak if safe to do so. Ventilate area. Do not touch spilled material.

### 6.2. Environmental precautions

Avoid release to the environment. Notify authorities if product enters sewers or public waters.

### 6.3. Methods and material for containment and cleaning up

For containment : Stop leak without risks if possible. Contain any spills with dikes or absorbents to prevent migration and entry into sewers or streams. Caution : this product can cause the floor to be

slippery.

Methods for cleaning up : Move containers from spill area. Ventilate spillage area. Soak up spills with inert solids,

such as clay or diatomaceous earth as soon as possible. Clean contaminated surfaces with

an excess of water. Keep in suitable, closed containers for disposal.

Other information

Dispose of via an authorised person/ licensed waste disposal contract.

 Dispose of via an authorised person/ licensed waste disposal contractor or by other suitable waste treatment techniques. Dispose of materials or solid residues at an authorized site.

#### 6.4. Reference to other sections

For further information refer to section 13. For further information refer to section 8: "Exposure controls/personal protection".

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### **SECTION 7: Handling and storage**

#### 7.1. Precautions for safe handling

Precautions for safe handling

Do not get in eyes, on skin, or on clothing. Ensure good ventilation of the work station.
 Obtain special instructions before use. Do not breathe vapours, mist. Wear recommended personal protective equipment – refer to Section 8.2. Take all necessary technical measures to avoid or minimize the release of the product on the workplace. Provide local exhaust or general room ventilation.

Hygiene measures

Handle in accordance with good industrial hygiene and safety procedures. Wash hands and other exposed areas with mild soap and water before eating, drinking or smoking and when leaving work. Do not eat, drink or smoke when using this product. Always wash hands after handling the product. Wash contaminated clothing before reuse.

### 7.2. Conditions for safe storage, including any incompatibilities

Storage conditions

: Keep only in the original container in a cool, well ventilated place away from : Direct sunlight, Incompatible materials, Protect from freezing, Avoid high temperatures. Keep away from food, drink and animal feedingstuffs. Keep container tightly closed. Containers which are opened should be properly resealed and kept upright to prevent leakage. Store in accordance with local, regional, national or international regulation.

### 7.3. Specific end use(s)

No additional information available

### **SECTION 8: Exposure controls/personal protection**

#### 8.1. Control parameters

### 8.1.1 National occupational exposure and biological limit values

sodium hydroxide (1310-73-2)			
Ireland - Occupational Exposure Limits			
Local name	Sodium hydroxide		
OEL STEL	2 mg/m³		
Regulatory reference	Chemical Agents Code of Practice 2021		
acetone (67-64-1)	acetone (67-64-1)		
EU - Indicative Occupational Exposure Limit (IOEL)			
Local name	Acetone		
IOEL TWA	1210 mg/m³		
IOEL TWA [ppm]	500 ppm		
Regulatory reference	COMMISSION DIRECTIVE 2000/39/EC		
Ireland - Occupational Exposure Limits	Ireland - Occupational Exposure Limits		
Local name	Acetone		
OEL TWA [1]	1210 mg/m³		
OEL TWA [2]	500 ppm		
Remark	IOELV (Indicative Occupational Exposure Limit Values)		
Regulatory reference	Chemical Agents Code of Practice 2021		
Ireland - Biological limit values			
Local name	Acetone		

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acetone (67-64-1)	
Ireland - BMGV	50 mg/l Parameter: acetone - Medium: urine - Sampling time: End of shift - Notations: Ns (Non-specific)
Regulatory reference	Biological Monitoring Guidelines (HSA, 2011)

#### 8.1.2. Recommended monitoring procedures

Monitoring methods	
Monitoring methods	Workplace exposure - General requirements for the performance of procedures for the measurement of chemical agents. Workplace atmospheres. Guide for the application and use of procedures for the assessment of exposure to chemical and biological agents. Workplace atmospheres. Guidance for the assessment of exposure by inhalation to chemical agents for comparison with limit values and measurement strategy. Refer to all applicable national, international and local regulations or provisions.

#### 8.1.3. Air contaminants formed

No additional information available

#### 8.1.4. DNEL and PNEC

No additional information available

#### 8.1.5. Control banding

No additional information available

### 8.2. Exposure controls

#### 8.2.1. Appropriate engineering controls

#### Appropriate engineering controls:

Ensure good ventilation of the work station. Handle in accordance with good industrial hygiene and safety procedures. Avoid all unnecessary exposure.

#### 8.2.2. Personal protection equipment

### Personal protective equipment:

Personal protective equipment should be chosen according to the CEN standards and in discussion with the supplier of the protective equipment. Wear recommended personal protective equipment.

#### 8.2.2.1. Eye and face protection

### Eye protection:

Even though no specific eye irritation data are available, wear eye protection appropriate to conditions of use when handling this material. ISO 16321-1

### 8.2.2.2. Skin protection

### Skin and body protection:

Skin protection appropriate to the conditions of use should be provided

#### Hand protection:

Wear suitable gloves resistant to chemical penetration. Please follow the instructions related to the permeability and the penetration time provided by the manufacturer. ISO 374-1

#### 8.2.2.3. Respiratory protection

#### Respiratory protection:

No respiratory protection needed under normal use conditions. Where excessive vapour, mist, or dust may result, use approved respiratory protection equipment. EN 149

#### 8.2.2.4. Thermal hazards

No additional information available

#### 8.2.3. Environmental exposure controls

#### **Environmental exposure controls:**

Avoid release to the environment.

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### **SECTION 9: Physical and chemical properties**

#### 9.1. Information on basic physical and chemical properties

Physical state : Liquid

Colour : According to product specification.

Appearance : clear.

Odour : According to product specification.

Odour threshold Not available Melting point Not available Freezing point Not available Boiling point : Not available Flammability : Not applicable Lower explosion limit : Not available Upper explosion limit : Not available Flash point : Not available Auto-ignition temperature : Not available : Not available Decomposition temperature рΗ : 7.57 – 7.67 Viscosity, kinematic : Not available Solubility : Not available Partition coefficient n-octanol/water (Log Kow) : Not available Vapour pressure : Not available Vapour pressure at 50°C : Not available Density : Not available Relative density : Not available Relative vapour density at 20°C : Not available Particle characteristics : Not applicable

#### 9.2. Other information

### 9.2.1. Information with regard to physical hazard classes

No additional information available

#### 9.2.2. Other safety characteristics

No additional information available

### **SECTION 10: Stability and reactivity**

#### 10.1. Reactivity

The product is non-reactive under normal conditions of use, storage and transport. No dangerous reactions known.

#### 10.2. Chemical stability

Stable under normal conditions.

### 10.3. Possibility of hazardous reactions

No dangerous reactions known under normal conditions of use. Hazardous polymerisation: Will not occur.

#### 10.4. Conditions to avoid

None under recommended storage and handling conditions (see section 7).

### 10.5. Incompatible materials

Strong bases. Strong acids. Strong oxidizing agents. Strong reducing agents.

#### 10.6. Hazardous decomposition products

Under normal conditions of storage and use, hazardous decomposition products should not be produced.

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### **SECTION 11: Toxicological information**

SECTION 11. Toxicological information		
11.1. Information on hazard classes as defined in Regulation (EC) No 1272/2008		
Acute toxicity (oral) Acute toxicity (dermal) Acute toxicity (inhalation)	<ul> <li>Not classified (Based on available data, the classification criteria are not met)</li> <li>Not classified (Based on available data, the classification criteria are not met)</li> <li>Not classified (Based on available data, the classification criteria are not met)</li> </ul>	
maleimide (541-59-3)		
LD50 oral	80 mg/kg mouse	
acetone (67-64-1)		
LD50 oral rat	5800 ml/kg (ECHA)	
LD50 dermal rabbit	20000 mg/kg (IUCLID)	
LC50 Inhalation - Rat	76 mg/l/4h	
Skin corrosion/irritation	: Not classified (Based on available data, the classification criteria are not met) pH: 7.57 – 7.67	
Serious eye damage/irritation	: Not classified (Based on available data, the classification criteria are not met) pH: 7.57 – 7.67	
Respiratory or skin sensitisation	: Not classified (Based on available data, the classification criteria are not met)	
Germ cell mutagenicity	: Not classified (Based on available data, the classification criteria are not met)	
Carcinogenicity	: Not classified (Based on available data, the classification criteria are not met)	
Reproductive toxicity	: Not classified (Based on available data, the classification criteria are not met)	
STOT-single exposure	: Not classified (Based on available data, the classification criteria are not met)	
acetone (67-64-1)		
STOT-single exposure	May cause drowsiness or dizziness.	

### 11.2. Information on other hazards

### 11.2.1. Endocrine disrupting properties

Adverse health effects caused by endocrine disrupting properties

: The mixture does not contain substance(s) included in the list established in accordance with Article 59(1) of REACH for having endocrine disrupting properties, or is not identified as having endocrine disrupting properties in accordance with the criteria set out in Commission Delegated Regulation (EU) 2017/2100 or Commission Regulation (EU) 2018/605 at a concentration equal to or greater than 0,1 %

: Not classified (Based on available data, the classification criteria are not met)

: Not classified (Based on available data, the classification criteria are not met)

#### 11.2.2. Other information

STOT-repeated exposure

Aspiration hazard

Other information

 No experimental study on the product is available. The information given is based on our knowledge of the components and the classification of the product is determined by calculation

### **SECTION 12: Ecological information**

#### 12.1. Toxicity

Hazardous to the aquatic environment, short–term (acute)

: Not classified (Based on available data, the classification criteria are not met)

Hazardous to the aquatic environment, long-term (chronic)

: Not classified (Based on available data, the classification criteria are not met)

Additional information

: No experimental study on the product is available. The information given is based on our knowledge of the components and the classification of the product is determined by calculation.

sodium hydroxide (1310-73-2)		
	LC50 - Fish [1]	125 mg/l (96 h, Gambusia affinis)

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sodium hydroxide (1310-73-2)	
LC50 - Fish [2]	45.4 mg/l (96 h, Oncorhynchus mykiss)
EC50 - Crustacea [1]	40.38 mg/l (48 h, Daphnia)
acetone (67-64-1)	
LC50 - Fish [1]	6210 mg/l (96 h, Pimephales promelas, OECD 203, flow-through test)
EC50 - Crustacea [1]	8800 mg/l (48 h, Daphnia pulex, ECHA, static test)
EC50 - Other aquatic organisms [1]	61.15 mg/l (30 min, activated sludge, OECD 209)

### 12.2. Persistence and degradability

G-6-PDH Reagent	
Persistence and degradability	Biodegradability in water: no data available.

#### 12.3. Bioaccumulative potential

G-6-PDH Reagent	
Bioaccumulative potential	No data available concerning bioaccumulation.

### 12.4. Mobility in soil

G-6-PDH Reagent	
Ecology - soil	No additional information available.

### 12.5. Results of PBT and vPvB assessment

No additional information available

### 12.6. Endocrine disrupting properties

Adverse effects on the environment caused by endocrine disrupting properties

: The mixture does not contain substance(s) included in the list established in accordance with Article 59(1) of REACH for having endocrine disrupting properties, or is not identified as having endocrine disrupting properties in accordance with the criteria set out in Commission Delegated Regulation (EU) 2017/2100 or Commission Regulation (EU) 2018/605 at a concentration equal to or greater than 0,1 %.

### 12.7. Other adverse effects

Other adverse effects : No additional information available.

### **SECTION 13: Disposal considerations**

### 13.1. Waste treatment methods

Waste treatment methods : Dispose of contents/container in accordance with licensed collector's sorting instructions.

Disposal must be carried out using appropriate EWC code.

Product/Packaging disposal recommendations : Dispose in a safe manner in accordance with local/national regulations.

Ecology - waste materials : Avoid release to the environment.

### **SECTION 14: Transport information**

In accordance with ADR / IMDG / IATA / ADN / RID

ADR	IMDG	IATA	ADN	RID
14.1. UN number or ID number				
Not regulated for transport				

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ADR	IMDG	IATA	ADN	RID
Not regulated	Not regulated	Not regulated	Not regulated	Not regulated
14.2. UN proper shipping name				
Not regulated	Not regulated	Not regulated	Not regulated	Not regulated
14.3. Transport hazard class(es)				
Not regulated	Not regulated	Not regulated	Not regulated	Not regulated
14.4. Packing group				
Not regulated	Not regulated	Not regulated	Not regulated	Not regulated
14.5. Environmental hazards				
Not regulated	Not regulated	Not regulated	Not regulated	Not regulated
No supplementary information available				

### 14.6. Special precautions for user

#### **Overland transport**

Not regulated

#### Transport by sea

Not regulated

#### Air transport

Not regulated

#### Inland waterway transport

Not regulated

### Rail transport

Not regulated

### 14.7. Maritime transport in bulk according to IMO instruments

Not applicable

### **SECTION 15: Regulatory information**

### 15.1. Safety, health and environmental regulations/legislation specific for the substance or mixture

### 15.1.1. EU-Regulations

#### **REACH Annex XVII (Restriction List)**

Contains no substance(s) listed on REACH Annex XVII (Restriction Conditions)

### **REACH Annex XIV (Authorisation List)**

Contains no substance(s) listed on REACH Annex XIV (Authorisation List)

#### **REACH Candidate List (SVHC)**

Contains no substance(s) listed on the REACH Candidate List

### **PIC Regulation (Prior Informed Consent)**

Contains no substance(s) listed on the PIC list (Regulation EU 649/2012 concerning the export and import of hazardous chemicals)

### **POP Regulation (Persistent Organic Pollutants)**

Contains no substance(s) listed on the POP list (Regulation EU 2019/1021 on persistent organic pollutants)

### Ozone Regulation (1005/2009)

Contains no substance(s) listed on the Ozone Depletion list (Regulation EU 1005/2009 on substances that deplete the ozone layer)

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#### **Explosives Precursors Regulation (2019/1148)**

Contains substance(s) listed on the Explosives Precursors list (Regulation EU 2019/1148 on the marketing and use of explosives precursors)

#### ANNEX II REPORTABLE EXPLOSIVES PRECURSORS

List of substances on their own or in mixtures or in substances for which suspicious transactions and significant disappearances and thefts are to be reported to the relevant national contact point within 24 hours.

Name		Nomenclature	Combined Nomenclature code for mixture without constituents which would determine classification under another CN code
Acetone	67-64-1	2914 11 00	ex 3824 99 92

Please see https://ec.europa.eu/home-affairs/system/files/2021-11/list\_of\_competent\_authorities\_and\_national\_contact\_points\_en.pdf

#### **Drug Precursors Regulation (273/2004)**

Contains no substance(s) listed on the Drug Precursors list (Regulation EC 273/2004 on the manufacture and the placing on market of certain substances used in the illicit manufacture of narcotic drugs and psychotropic substances)

#### 15.1.2. National regulations

No additional information available

#### 15.2. Chemical safety assessment

No chemical safety assessment has been carried out

### **SECTION 16: Other information**

Abbreviations and acronyms:		
ADN	European Agreement concerning the International Carriage of Dangerous Goods by Inland Waterways	
ADR	European Agreement concerning the International Carriage of Dangerous Goods by Road	
ATE	Acute Toxicity Estimate	
BLV	Biological limit value	
CAS-No.	Chemical Abstract Service number	
CLP	Classification Labelling Packaging Regulation; Regulation (EC) No 1272/2008	
DMEL	Derived Minimal Effect level	
DNEL	Derived-No Effect Level	
EC50	Median effective concentration	
EC-No.	European Community number	
EN	European Standard	
IATA	International Air Transport Association	
IMDG	International Maritime Dangerous Goods	
LC50	Median lethal concentration	
LD50	Median lethal dose	
LOAEL	Lowest Observed Adverse Effect Level	
NOAEC	No-Observed Adverse Effect Concentration	
NOAEL	No-Observed Adverse Effect Level	
NOEC	No-Observed Effect Concentration	
OEL	Occupational Exposure Limit	
PBT	Persistent Bioaccumulative Toxic	
PNEC	Predicted No-Effect Concentration	

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Abbreviations and acronyms:		
REACH	Registration, Evaluation, Authorisation and Restriction of Chemicals Regulation (EC) No 1907/2006	
RID	Regulations concerning the International Carriage of Dangerous Goods by Rail	
SDS	Safety Data Sheet	
vPvB	Very Persistent and Very Bioaccumulative	
WGK	Water Hazard Class	

Data sources : ECHA (European Chemicals Agency). Regulation (EC) No 1272/2008 of the European

Parliament and of the Council of 16 December 2008 and all its amendments and

modifications. Supplier's safety documents.

Training advice : Training staff on good practice.

Full text of H- and EUH-statements:		
Acute Tox. 3 (Oral)	Acute toxicity (oral), Category 3	
EUH208	Contains maleimide(541-59-3). May produce an allergic reaction.	
Eye Irrit. 2	Serious eye damage/eye irritation, Category 2	
Flam. Liq. 2	Flammable liquids, Category 2	
H225	Highly flammable liquid and vapour.	
H290	May be corrosive to metals.	
H301	Toxic if swallowed.	
H314	Causes severe skin burns and eye damage.	
H315	Causes skin irritation.	
H317	May cause an allergic skin reaction.	
H319	Causes serious eye irritation.	
H336	May cause drowsiness or dizziness.	
Met. Corr. 1	Corrosive to metals, Category 1	
Skin Corr. 1A	Skin corrosion/irritation, Category 1, Sub-Category 1A	
Skin Corr. 1B	Skin corrosion/irritation, Category 1, Sub-Category 1B	
Skin Irrit. 2	Skin corrosion/irritation, Category 2	
Skin Sens. 1	Skin sensitisation, Category 1	
STOT SE 3	Specific target organ toxicity – Single exposure, Category 3, Narcosis	

Safety Data Sheet (SDS), EU

SDS prepared by: H2 Compliance

This information is based on our current knowledge and is intended to describe the product for the purposes of health, safety and environmental requirements only. It should not therefore be construed as guaranteeing any specific property of the product.