Cyclosporine Direct RIA – KIPB3679

Safety Data sheet

According to regulation (EU) 2020/878

Date of issue: 02.07.2025 | Revision date: - | Version/Replaced version: 1.0/-

The Safety Date Sheet is usable for:

KIPB3679 Cyclosporine Direct RIA

Refer to the instructions for the full list of product components

Single components with dangerous ingredients :

REF	Name	Symbol	Version
B32414	Calibrator 0	- CAL 0	1.0
B32414	Calibrator 1	- CAL 1	1.0
B32414	Calibrator 2	- CAL 2	1.0
B32414	Calibrator 3	- CAL 3	1.0
B32414	Calibrator 4	- CAL 4	1.0
B32414	Calibrator 5	- CAL 5	1.0
B32447	^{125}I-labeled cyclosporine	Ag 125I	1.0

Read the MSDS for the component on the following pages.

Single components for single use :

REF	Name	Symbol
B32412	Coated tubes	

Not listed single components contain no hazardous substances in concentrations to be declared, a labelling is not required.

1 Identification of substance/mixture and company

1.1 Product identifier

Product form : Mixture

Product name : Control 1 CONTROL 1

Control 2 CONTROL 2

Catalog # : B32413 REF

1.2 Relevant identified uses of substance or mixture and uses advised against

1.2.1 Relevant identified uses

Use of the substance/mixture : Laboratory reagent, Immunoassays

Use by professionals

1.2.2 Uses advised against

No additional information available

1.3 Details of the supplier of the safety data sheet

Supplier/Manufacturer

DIAsource ImmunoAssays S.A.

Rue du Bosquet, 2

B-1348 Louvain-la-Neuve

Belgium

Tel. Nr. +32 (0)10/84.99.11

E-mail: products.support@diasource.be

1.4 Emergency telephone number

DIAsource (only office hours) : +32 (0)10/84.99.23

Centre Anti-Poisons (BE) : 070 245 245

Please refer to your local Anti-Poison Center!

2 Hazards identification

2.1 Classification of the substance or mixture

Classification according to Regulation (EC) N° 1272/2008 (CLP)

Not classified as hazardous

According to EC directives or corresponding national laws, the product does not need to be classified or labelled

2.2 Label element

Labelling according to Regulation (EC) N° 1272/2008 (CLP)

Hazard symbol (CLP) : Not classified as hazardous

Signal word (CLP) : Not classified as hazardous

Hazard statement (CLP) : Not hazard statement

Precaution statement (CLP) : P280 Wear protective gloves, protective clothing, eye protection, face protection

P305+P351+P338 If in eyes: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing

2.3 Other hazards

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.

3 Composition/information on ingredients

3.1 Substances

Not applicable

3.2 Mixtures

No components need to be disclosed according to the applicable regulations.

Full text of H-statements: see section16

4 First aid measures

4.1 Description of first aid measures

First-aid measures general : Get medical advice/attention if you feel unwell. If possible show him this sheet. Failing this, show him the packaging or label. Never give anything by mouth to an unconscious person. Place the affected person in the recovery position.

First-aid measures after inhalation : If product is inhaled, move exposed individual to fresh air. If individual is not breathing, begin artificial respiration immediately and obtain medical attention.

First-aid measures after skin contact : In case of skin contact, remove any contaminated clothing. Wash affected area with plenty of soap and water for at least 15 minutes. If pain or irritation occur, obtain medical attention.

First-aid measures after eye contact : If product enters eyes, wash eyes gently under running water for 15 minutes or longer, making sure that the eyelids are held open. If pain or irritation occur, obtain medical attention.

First-aid measures after ingestion : If ingested, wash mouth out with water. If irritation or discomfort occurs, seek medical attention.

4.2 Most important symptom and effects, both acute and delayed

Symptoms/effects : 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.

5 Firefighting measures

5.1 Extinguishing media

Suitable extinguishing media : In case of fire use carbon dioxide (CO_2), dry chemical, water spray or foam. Use extinguishing media suitable for surrounding fire.

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

5.2 Special hazards arising from the substance or mixture

Hazardous decomposition products in case of fire : No special hazards determined.
Combustion products may contain minute amounts of mercury.

5.3 Advice for firefighters

Firefighting instructions : Prevent firefighting water from entering the environment. Use water spray or fog for cooling exposed containers.

Protection during firefighting : Self-contained breathing apparatus is recommended for firefighters in all chemical fire situations.

6 Accidental release measures

6.1 Personal precautions, protective equipment and emergency procedures

General measures : This product contains a material of animal origin. Observe general safety guidelines for protection during clean up procedures. Wear protective gloves, protective clothing and eye/face protection.

6.1.1 For non-emergency personnel

Emergency procedures : Evacuate unnecessary personnel.

6.1.2 For emergency responders

Protective equipment : Use personal protective equipment as required. In case of inadequate ventilation wear respiratory protection.

6.2 Environmental precautions

Contain spill to prevent migration. Do not allow the undiluted product to enter sewers/surface or ground water. Dispose of contents/container in accordance with local regulations.

6.3 Methods and material for containment and cleaning up

Methods for cleaning up : As a precautionary measure, treat spilled material with a 1:10 bleach/water solution. Absorb liquid and place in container suitable for disposal. Avoid generation of aerosols during clean up. Comply with applicable waste disposal regulations.
Carefully sweep up spilled material and place in a container suitable for disposal.
Avoid generating dust.
Dispose of all waste material in accordance with local guidelines

6.4 Reference to other sections

Exposure controls and personal protection, see section 8. Concerning disposal elimination after cleaning, see section 13.

7 Handling and storage

7.1 Precautions for safe handling

Precautions for safe handling : This product should be handled as though capable of transmitting infectious diseases. Universal precautions should be followed when using this product.

Hygiene measures : Handle in accordance with good industrial hygiene and safety procedures. When using do not eat, drink or smoke. Wash hands and other exposed areas with mild soap and water before eating, drinking or smoking and when leaving work.

7.2 Conditions for safe storage, including any incompatibilities

Storage conditions : Store at 2 to 8°C, as directed on the product label. To maintain product quality, store according to the instructions in the product labeling.

Prohibitions on mixed storage : Store away from strong acids, strong bases, strong oxidizers and incompatible materials (section 10).

Incompatible materials : No additional information available.

7.3 Specific end use(s)

Laboratory reagent, Immunoassays

8 Exposure controls/personnel protection

8.1 Control parameters

Exposure limits	
US OSHA	None established
ACGIH	None established
ACGIH Biological Exposure Indices (BEI)	None established
DFG MAK	None established
Ireland	None established
IOELVs	None established
NIOSH	None established
China	None established
Croatia	None established
Japan	None established
Sweden (AFS 2015:7 and amendments	None established
Turkey	None established

8.2 Exposure controls

Appropriate engineering controls : Place vial behind a metal shield, away from the user.

Hand protection : Wear suitable gloves (EN 374). Nitrile rubber, 0.35 mm. Butyl rubber, 0.5 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 : Safety glasses or chemical goggles should be worn to prevent eye contact. Refer U.S. OSHA 29 CFR 1910.133, European Standard EN166 or appropriate government standards.

Skin and body protection : Impervious gloves, such as Nitrile or equivalent, should be worn to prevent skin .contact.

Refer U.S. OSHA 29 CFR 1910.138, European Standard EN374 or appropriate government standards.

Respiratory protection : Under normal conditions, the use of this product 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.

Environmental exposure controls : Avoid release to the environment.

9 Physical and chemical properties

9.1 Information on basic physical and chemical properties

Physical state : Lyophilized Powder – Liquid after reconstitution

Colour : Yellowish

Odor : Odorless

Melting point/freezing point : No data available

Boiling point or initial boiling point and boiling range : No data available

Flammability : No data available

Lower and upper explosion limit : No data available

Flash point : No data available

Auto-ignition temperature : No data available

Decomposition temperature : No data available

pH : 7.4 @ 20°C

Kinematic viscosity : No data available

Solubility : Miscible

Partition coefficient n-octanol/water (log value) : Not applicable

Vapour pressure : No data available

Density and/or relative density : 1.02 @ 20°C

Relative vapour density : No data available

Particle size : Not applicable

9.2 Other information

9.2.1 Information with regard to physical hazard classes

Explosive properties : No explosive properties

Oxidising properties : No oxidising properties

9.2.2 Other safety characteristics

No additional information available

10 Stability and reactivity

10.1 Reactivity

No further relevant information available.

10.2 Chemical stability

The product is stable in accordance with recommended storage conditions.

10.3 Possibility of hazardous reactions

Sodium azide forms explosive compounds with heavy metals. Repeated contact of low concentrations of azide with lead and copper commonly found in plumbing drains may result in the build up of shock sensitive compounds.

10.4 Conditions to avoid

Avoid contact with incompatible materials. Avoid exposure to heat and direct sunlight.

10.5 Incompatible materials

Metals and metallic compounds.

10.6 Hazardous decomposition products

No decomposition products posing significant hazards would be expected from this product (an aqueous solution).

11 Toxicological information

11.1 Information on hazard classes as defined in Regulation (EC) No 1272/2008

Primary routes of exposure : Common routes of entry include inhalation, ingestion and eye/skin contact. Specific paths of concern for potentially infectious materials are skin puncture, contact with broken skin, contact with mucous membranes and inhalation of aerosolized material.

Acute toxicity : Not classified

Skin corrosion/irritation : Not classified

Based on available data, the classification criteria are not met

Serious eye damage/irritation : Not classified

Based on available data, the classification criteria are not met

Respiratory or skin sensitization : 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 : This product does not contain a reportable concentration (≥ 0.1%) of any ingredient listed as carcinogen by ACGIH, IARC, NTP, OSHA or 1272/2008 EC regulation

Reproductive toxicity : Not classified

Based on available data, the classification criteria are not met

Specific target organ toxicity (single exposure) : Not classified

Based on available data, the classification criteria are not met

Specific target organ toxicity (repeated exposure) : Not classified

Based on available data, the classification criteria are not met

Aspiration hazard : Not classified

Based on available data, the classification criteria are not met

11.2 Information on other hazards

Endocrine disrupting properties : This product does not have substance(s) of endocrine disrupting properties for health according to REACH Article 57(f)

Other information : This product contains material(s) of animal origin. Observe general safety guidelines for protection when handling this product

12 Ecological information

12.1 Toxicity

Soduim Azide (CAS N° 26628-22-6)	
Fresh water species	LC50 96 h Oncorhynchus mykiss: 0.8 mg/L LC50 96 h Lepomis macrochirus: 0.7 mg/L LC50 96 h Pimephales promelas: 5.46 mg/L [flow-through]
Microtox/organisms	No information available

Water flea	No information available
Fresh water algae	No information available

12.2 Persistence and degradability

Not required for inorganic substances.

12.3 Bioaccumulative potential

Not required for inorganic substances.

12.4 Mobility in soil

No additional information available.

12.5 Results of PBT and vPvB assessment

Not fulfilling Persistent, Bioaccumulative and Toxic (PBT), very Persistent and very Bioaccumulative (vPvB) criteria.

12.6 Endocrine disrupting properties

This product does not have substance(s) of endocrine disrupting properties for environment according to REACH Article 57(f).

12.7 Other adverse effects

This product contains environmentally hazardous substance below the cutoff level. Refer section 3 for ingredient information. Do not allow undiluted product to enter sewer/surface or ground water.

13 Disposal considerations

13.1 Waste treatment methods

Regional legislation (waste) : Dispose in a safe manner in accordance with local/national regulations.

Waste treatment methods : Do not empty into drains. Dispose of this material and its container in a safe way.

Waste code : The waste code number according to the Ordinance on the European Waste Catalogue depends on the waste producer and can therefore vary for any given product. The waste code number is therefore to be gleaned separately from each waste producer.

14 Transport information

In accordance with ADR / IMDG / IATA

14.1 UN number or ID number

UN-No. (ADR) : Not applicable

UN-No. (IMDG) : Not applicable

UN-No. (IATA) : Not applicable

14.2 UN proper shipping name

Proper Shipping Name (ADR) : Not applicable

Proper Shipping Name (IMDG) : Not applicable

Proper Shipping Name (IATA) : Not applicable

14.3 Transport hazard class(es)

Transport hazard class(es) (ADR) : Not applicable

Transport hazard class(es) (IMDG) : Not applicable

Transport hazard class(es) (IATA) : Not applicable

14.4 Packing group

Packing group (ADR) : Not applicable

Packing group (IMDG) : Not applicable

Packing group (IATA) : Not applicable

14.5 Environmental hazards

Dangerous for the environment : No

Marine pollutant : No

Other information : No supplementary information available

14.6 Special precautions for user

Overland transport : Not applicable

Transport by sea : Not applicable

Air transport : Not applicable

14.7 Maritime transport in bulk according to IMO instruments

Not applicable

15 Regulatory information

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

15.1.1 EU-Regulations

Contains no substance on the REACH candidate list.

Contains no REACH Annex XIV substances.

15.1.2 National regulations

Comply with applicable local regulations.

15.2 Chemical safety assessment

No chemical safety assessment has been carried out.

16 Other information

Data sources : REGULATION (EC) No 1272/2008 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 16 December 2008 on classification, labelling and packaging of substances and mixtures, amending and repealing Directives 67/548/EEC and 1999/45/EC, and amending Regulation (EC) No 1907/2006.

Change compared to the previous version : -

Abbreviations and acronyms:

ACGIH	American Conference of Governmental Industrial Hygienists
ADR	European Agreement concerning the International Carriage of Dangerous Goods by Road
CLP	Regulation (EC) No 1272/2008 on classification, labelling and packaging of substances and mixtures
DFGMAK	Republic Germany's maximum exposure limit
DMEL	Derived Minimal Effect Level
DNEL	Derived No-Effect Level
EC50	The effective concentration of substance that causes 50% of the maximum response (Median Effective Concentration)
GHS	Globally Harmonized System of Classification and Labelling of Chemicals
HCS	Hazard Communication Standard
IARC	International Agency for Research on Cancer
IATA	International Air Transport Association
ICAO	International Civil Aviation Organization
IDLH	Immediately Dangerous to Life or Health
IMDG	International Maritime Dangerous Goods Code" for the transport of dangerous goods by sea
IMO	International Maritime Orga
IOELVs	European Unions' Indicative Occupational Exposure Limit Values
LC50	Lethal Concentration to 50 % of a test population (Median Lethal Concentration)
LD50	Lethal Dose to 50% of a test population (Median Lethal Dose)
LOAEL	Lowest Observed Adverse Effect Level
NIOSH	National Institute for Occupational Safety and Health
NOAEC/L	No Observed Adverse Effect Concentration/Level
NOEC/L	No Observed Effect Concentration/Level
NTP	National Toxicology Program
OECD	Organisation for Economic Cooperation and Development
OSHA	Occupational Safety and Health Administration
PBT	Persistent, Bioaccumulative and Toxic substance
PEL	Permissible Exposure Limit
PNEC	Predicted No-Effect Concentration
REACH	Regulation (EC) No 1907/2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals
SARA	Superfund Amendments and Reauthorization Act
SDS	Safety Data Sheet
STEL	Short Term Exposure Limit
STLV	Short Term Limit Value
STP	Sewage Treatment Plant
STV	Short Term Value
TDG	Canadian Transportation of Dangerous Goods Regulations

TLV	Threshold Limit Value
TWA	Time Weighted Average
UFI	Unique Formula Identifier
UN GHS	United Nations Globally Harmonized System
US DOT	United States Department of Transportation
US OSHA	United States Occupational Safety and Health Administration
vPvB	Very Persistent and Very Bioaccumulative
WHMIS	Workplace Hazardous Material Information System

SDS EU (REACH Annex II)

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.

1 Identification of substance/mixture and company

1.1 Product identifier

Product form : Mixture

Product name : Calibrator 0 CAL 0

Calibrator 1 CAL 1

Calibrator 2 CAL 2

Calibrator 3 CAL 3

Calibrator 4 CAL 4

Calibrator 5 CAL 5

Catalog # : B32414 REF

1.2 Relevant identified uses of substance or mixture and uses advised against

1.2.1 Relevant identified uses

Use of the substance/mixture : Laboratory reagent, Immunoassays

Use by professionals

1.2.2 Uses advised against

No additional information available

1.3 Details of the supplier of the safety data sheet

Supplier/Manufacturer

DIAsource ImmunoAssays S.A.

Rue du Bosquet, 2

B-1348 Louvain-la-Neuve

Belgium

Tel. Nr. +32 (0)10/84.99.11

E-mail: products.support@diasource.be

1.4 Emergency telephone number

DIAsource (only office hours) : +32 (0)10/84.99.23

Centre Anti-Poisons (BE) : 070 245 245

Please refer to your local Anti-Poison Center!

2 Hazards identification

2.1 Classification of the substance or mixture

Classification according to Regulation (EC) N° 1272/2008 (CLP)

Not classified as hazardous

According to EC directives or corresponding national laws, the product does not need to be classified or labelled

2.2 Label element

Labelling according to Regulation (EC) N° 1272/2008 (CLP)

Hazard symbol (CLP) : Not classified as hazardous

Signal word (CLP) : Not classified as hazardous

Hazard statement (CLP) : Not hazard statement

Precaution statement (CLP) : P280 Wear protective gloves, protective clothing, eye protection, face protection

P305+P351+P338 If in eyes: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing

P309+310 IF exposed or if you feel unwell: Call a POISON CENTER or doctor/physician

2.3 Other hazards

This product contains concentrations of azide below the hazardous level which with repeated contact with lead and copper commonly found in plumbing drains may result in the build up of shock sensitive compounds. Sodium azide forms explosive compounds with heavy metals.

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.

3 Composition/information on ingredients

3.1 Substances

Not applicable

3.2 Mixtures

Name	Product identifier	%	Classification according to Regulation (EC) No. 1272/2008 [CLP]
Sodium Azide	(CAS N°) 26628-22-8 (EC N°) 247-852-1 (EC Index N°) 011-004-00-7	≤ 0,1	Acute Tox. Oral 2, H300 Aquatic Acute 1, H400 Aquatic Chronic 1, H410
1,4-Dioxane	(CAS N°) 123-91-1 (EC N°) 204-661-8 (EC Index N°) 603-024-00-5	< 0.001	Carc. 1B, H350 Eye Irrit. 2, H319 Flam. Liq. 2, H225 STOT SE 3, H335
Ethylene Oxide	(CAS N°) 75-21-8 (EC N°) 200-849-9 (EC Index N°) 603-023-00-X	< 0.001	Acute Tox. Inhal. 3, H331 Acute Tox. Oral 3, H301 Carc. 1B, H350 Eye Dam. 1, H318 Flam. Gas 1, H220 Muta. 1B, H340 Press. Gas [CG], H280 Repr. 1B, H360 STOT RE 1, H372 STOT SE 3 , H335, H336 Skin Corr. 1, H314

Full text of H-statements: see section16

4 First aid measures

4.1 Description of first aid measures

First-aid measures general : Get medical advice/attention if you feel unwell. If possible show him this sheet. Failing this, show him the packaging or label. Never give anything by mouth to an unconscious person. Place the affected person in the recovery position.

First-aid measures after inhalation : If product is inhaled, move exposed individual to fresh air. If individual is not breathing, begin artificial respiration immediately and obtain medical attention.

First-aid measures after skin contact : In case of skin contact, remove any contaminated clothing. Wash affected area with plenty of soap and water for at least 15 minutes. If pain or irritation occur, obtain medical attention.

First-aid measures after eye contact : If product enters eyes, wash eyes gently under running water for 15 minutes or longer, making sure that the eyelids are held open. If pain or irritation occur, obtain medical attention.

First-aid measures after ingestion : If ingested, wash mouth out with water. If irritation or discomfort occurs, seek medical attention.

4.2 Most important symptom and effects, both acute and delayed

Symptoms/effects : 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.

5 Firefighting measures

5.1 Extinguishing media

Suitable extinguishing media : In case of fire use carbon dioxide (CO_2), dry chemical, water spray or foam. Use extinguishing media suitable for surrounding fire.

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

5.2 Special hazards arising from the substance or mixture

Hazardous decomposition products in case of fire : No combustion products posing significant hazards are expected from this product (an aqueous solution).

5.3 Advice for firefighters

Firefighting instructions : Prevent firefighting water from entering the environment. Use water spray or fog for cooling exposed containers.

Protection during firefighting : Self-contained breathing apparatus is recommended for firefighters in all chemical fire situations.

6 Accidental release measures

6.1 Personal precautions, protective equipment and emergency procedures

General measures : This product contains a material of animal origin. Observe general safety guidelines for protection during clean up procedures. Wear protective gloves, protective clothing and eye/face protection.

6.1.1 For non-emergency personnel

Emergency procedures : Evacuate unnecessary personnel.

6.1.2 For emergency responders

Protective equipment : Use personal protective equipment as required. In case of inadequate ventilation wear respiratory protection.

6.2 Environmental precautions

Contain spill to prevent migration. Isolate area and absorb spill with sand, vermiculite or other inert absorbent material. Place absorbed material in container suitable for disposal. Do not allow the undiluted product to enter sewers/surface or ground water. Dispose of all waste material in accordance with local and facility guidelines.

6.3 Methods and material for containment and cleaning up

Methods for cleaning up : As a precautionary measure, treat spilled material with a 1:10 bleach/water solution. Absorb liquid and place in container suitable for disposal. Avoid generation of aerosols during clean up. Comply with applicable waste disposal regulations.

Dispose of all waste material in accordance with local guidelines.

6.4 Reference to other sections

Exposure controls and personal protection, see section 8. Concerning disposal elimination after cleaning, see section 13.

7 Handling and storage

7.1 Precautions for safe handling

Precautions for safe handling : This product should be handled as though capable of transmitting infectious diseases. Universal precautions should be followed when using this product.

Hygiene measures : Handle in accordance with good industrial hygiene and safety procedures. When using do not eat, drink or smoke. Wash hands and other exposed areas with mild soap and water before eating, drinking or smoking and when leaving work.

7.2 Conditions for safe storage, including any incompatibilities

Storage conditions : Store at 2 to 8°C, as directed on the product label. To maintain product quality, store according to the instructions in the product labeling.

Prohibitions on mixed storage : Store away from strong acids, strong bases, strong oxidizers and incompatible materials (section 10).

Incompatible materials : No additional information available.

7.3 Specific end use(s)

Laboratory reagent, Immunoassays

8 Exposure controls/personnel protection

8.1 Control parameters

Exposure limits : Sodium Azide (CAS N° 26628-22-8)	
US OSHA	None established
ACGIH	0.29 mg/m³ Ceiling (as Sodium azide); 0.11 ppm Ceiling (as Hydrazoic acid vapor)
ACGIH Biological Exposure Indices (BEI)	None established
DFG MAK	0.4 mg/m³ Peak (inhalable fraction); 0.2 mg/m3 TWA MAK (inhalable fraction)
Ireland	0.1 mg/m³ TWA; 0.3 mg/m3 STEL; Potential for cutaneous absorption
IOELVs	Possibility of significant uptake through the skin; 0.1 mg/m³ TWA; 0.3 mg/m³ STEL
NIOSH	None established
China	0.3 mg/m³ Ceiling MAC
Croatia	Skin Notation; 0.1 mg/m³ TWA [GVI]; 0.3 mg/m³ STEL [KGVI]
Japan	
Sweden (AFS 2015:7 and amendments	0.1 mg/m³ TLV NGV; 0.3 mg/m³ Binding STEL Bindande KGV
Turkey	0.3 mg/m³ STEL; Skin notation; 0.1 mg/m³ TWA

Exposure limits : 1,4-Dioxane (CAS N° 123-91-1)	
US OSHA	100 ppm TWA; 360 mg/m³ TWA; prevent or reduce skin absorption
ACGIH	20 ppm TWA; Skin - potential significant contribution to overall exposure by the cutaneous route
ACGIH Biological Exposure Indices (BEI)	None established
DFG MAK	20 ppm Peak; 74 mg/m³ Peak; skin notation; 10 ppm TWA MAK; 37 mg/m³ TWA MAK
Ireland	20 ppm TWA (technical grade); 73 mg/m³ TWA (technical grade); 60 ppm STEL (calculated); 219 mg/m³ STEL (calculated); Potential for cutaneous absorption (technical grade)
IOELVs	20 ppm TWA; 73 mg/m³ TWA
NIOSH	500 ppm IDLH
China	Skin notation; 70 mg/m³ TWA
Croatia	20 ppm TWA [GVI]; 73 mg/m³ TWA [GVI]
Japan	1 ppm OEL; 3.6 mg/m³ OEL

Sweden (AFS 2015:7 and amendments	10 ppm TLV NGV; 35 mg/m³ TLV NGV; 25 ppm Indicative STEL Vägledande KGV; 90 mg/m³ Indicative STEL Vägledande KGV
Turkey	20 ppm TWA; 73 mg/m³ TWA

Exposure limits : Ethylene Oxide (CAS N° 75-21-8)	
US OSHA	1 ppm TWA; 5 ppm STEL (see 29 CFR 1910.1047)
ACGIH	1 ppm TWA
ACGIH Biological Exposure Indices (BEI)	5000 pmol HEV/g globin medium: blood time: not critical parameter: N-(2-Hydroxyethyl)valine (HEV) hemoglobin adducts (nonspecific); 5 µg HEMA/g creatinine medium: urine time: end of shift parameter: S-(2-Hydroxyethyl)mercapturic acid (HEMA) (nonspecific, population based)
DFG MAK	skin notation
Ireland	ppm TWA; 1.8 mg/m³ TWA; 3 ppm STEL (calculated); 5.4 mg/m³ STEL (calculated); Potential for cutaneous absorption
IOELVs	-
NIOSH	800 ppm IDLH; 0.1 ppm TWA (less than stated value); 0.18 mg/m³ TWA (less than stated value)
China	Skin notation; 2 mg/m³ TWA
Croatia	Skin Notation (significant contribution to the total body load possible exposure through the skin); 1 ppm TWA [GVI]; 1.8 mg/m³ TWA [GVI]; Carcinogen Category 1B; Mutagen Category 1B
Japan	1 ppm OEL; 1.8 mg/m³ OEL
Sweden (AFS 2015:7 and amendments	1 ppm TLV NGV; 1.8 mg/m³ TLV NGV; 5 ppm Binding STEL Bindande KGV; 9 mg/m³ Binding STEL Bindande KGV; Skin notation
Turkey	-

8.2 Exposure controls

Appropriate engineering controls : Place vial behind a metal shield, away from the user.

Hand protection : Wear suitable gloves (EN 374). Nitrile rubber, 0.35 mm. Butyl rubber, 0.5 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 : Safety glasses or chemical goggles should be worn to prevent eye contact. Refer U.S. OSHA 29 CFR 1910.133, European Standard EN166 or appropriate government standards.

Skin and body protection : Impervious gloves, such as Nitrile or equivalent, should be worn to prevent skin .contact. Refer U.S. OSHA 29 CFR 1910.138, European Standard EN374 or appropriate government standards.

Respiratory protection : Under normal conditions, the use of this product 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.

Environmental exposure controls : Avoid release to the environment.

9 Physical and chemical properties

9.1 Information on basic physical and chemical properties

Physical state : Liquid

Colour : Yellowish

Odor : Odorless

Melting point/freezing point : No data available

Boiling point or initial boiling point and boiling range : No data available

Flammability : No data available

Lower and upper explosion limit : No data available

Flash point : No data available

Auto-ignition temperature : No data available

Decomposition temperature : No data available

pH : 7.4 @ 20°C

Kinematic viscosity : No data available

Solubility : Miscible

Partition coefficient n-octanol/water (log value) : Not applicable

Vapour pressure : No data available

Density and/or relative density : 1.02 @ 20°C

Relative vapour density : No data available

Particle size : Not applicable

9.2 Other information

9.2.1 Information with regard to physical hazard classes

Explosive properties : No explosive properties

Oxidising properties : No oxidising properties

9.2.2 Other safety characteristics

No additional information available

10 Stability and reactivity

10.1 Reactivity

No further relevant information available.

10.2 Chemical stability

The product is stable in accordance with recommended storage conditions.

10.3 Possibility of hazardous reactions

Sodium azide forms explosive compounds with heavy metals. Repeated contact of low concentrations of azide with lead and copper commonly found in plumbing drains may result in the build up of shock sensitive compounds.

10.4 Conditions to avoid

Avoid contact with incompatible materials. Avoid exposure to heat and direct sunlight.

10.5 Incompatible materials

Metals and metallic compounds.

10.6 Hazardous decomposition products

No decomposition products posing significant hazards would be expected from this product (an aqueous solution).

11 Toxicological information

11.1 Information on hazard classes as defined in Regulation (EC) No 1272/2008

Soduim Azide (CAS N° 26628-22-6)	
LD50 dermal rabbit	20 mg/kg (NLM_HSDB)
LD50 oral rat	27 mg/kg (NZ_CCID)
LC50 inhalation rat	0.054 - 0.52 mg/L 4 h (dust)(ECHA_API)
1,4-Dioxane (CAS N° 123-91-1)	
LD50 dermal rabbit	7600 mg/kg (CHEMVIEW)
LD50 oral rat	5170 mg/kg (JAPAN_GHS)
LC50 inhalation rat	46 mg/L 2 h (vapor)(JAPAN_GHS)
Ethylene Oxide (CAS N° 75-25-8)	
LD50 oral rat	72 mg/kg (JAPAN_GHS)
LC50 inhalation rat	800 ppm 4 h (gas)(NLM_CIP)

Primary routes of exposure : Common routes of entry include inhalation, ingestion and eye/skin contact. Specific paths of concern for potentially infectious materials are skin puncture, contact with broken skin, contact with mucous membranes and inhalation of aerosolized material.

Acute toxicity : Not classified

Skin corrosion/irritation : Not classified

Based on available data, the classification criteria are not met

Serious eye damage/irritation : Not classified

Based on available data, the classification criteria are not met

Respiratory or skin sensitization : 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 : This product does not contain a reportable concentration (≥ 0.1%) of any ingredient listed as carcinogen by ACGIH, IARC, NTP, OSHA or 1272/2008 EC regulation

Reproductive toxicity : Not classified

Based on available data, the classification criteria are not met

Specific target organ toxicity (single exposure) : Not classified

Based on available data, the classification criteria are not met

Specific target organ toxicity (repeated exposure) : Not classified

Based on available data, the classification criteria are not met

Aspiration hazard : Not classified

Based on available data, the classification criteria are not met

11.2 Information on other hazards

Endocrine disrupting properties : This product does not have substance(s) of endocrine disrupting properties for health according to REACH Article 57(f)

Other information : This product contains material(s) of animal origin. Observe general safety guidelines for protection when handling this product

12 Ecological information

12.1 Toxicity

Soduim Azide (CAS N° 26628-22-6)	
Fresh water species	LC50 96 h Oncorhynchus mykiss: 0.8 mg/L LC50 96 h Lepomis macrochirus: 0.7 mg/L LC50 96 h Pimephales promelas: 5.46 mg/L [flow-through]
Microtox/organisms	No information available
Water flea	No information available
Fresh water algae	No information available
1,4-Dioxane (CAS N° 123-91-1)	
Fresh water species	LC50 96 h Lepomis macrochirus: >10000 mg/L [static] (EPA) LC50 96 h Lepomis macrochirus: >10000 mg/L [semi-static] (IUCLID) LC50 96 h Pimephales promelas: 9850 mg/L [flow-through] (EPA) LC50 96 h Pimephales promelas: 10306 - 14742 mg/L [static] (EPA) LC50 96 h Pimephales promelas: 9850 mg/L (IUCLID)
Microtox/organisms	No information available
Water flea	EC50 48 h water flea: 163 mg/L [Static]
Fresh water algae	No information available
Ethylene Oxide (CAS N° 75-25-8)	
Fresh water species	LC50 96 h Pimephales promelas: 73 - 96 mg/L (EPA)
Microtox/organisms	No information available
Water flea	LC50 48 h Daphnia magna: 137 - 300 mg/L (IUCLID)
Fresh water algae	No information available

12.2 Persistence and degradability

Not required for inorganic substances.

12.3 Bioaccumulative potential

Not required for inorganic substances.

12.4 Mobility in soil

No additional information available.

12.5 Results of PBT and vPvB assessment

Not fulfilling Persistent, Bioaccumulative and Toxic (PBT), very Persistent and very Bioaccumulative (vPvB) criteria.

12.6 Endocrine disrupting properties

This product does not have substance(s) of endocrine disrupting properties for environment according to REACH Article 57(f).

12.7 Other adverse effects

This product contains environmentally hazardous substance below the cutoff level. Refer section 3 for ingredient information. Do not allow undiluted product to enter sewer/surface or ground water.

13 Disposal considerations

13.1 Waste treatment methods

Regional legislation (waste) : Dispose in a safe manner in accordance with local/national regulations.

Waste treatment methods : Do not empty into drains. Dispose of this material and its container in a safe way.

Waste code : The waste code number according to the Ordinance on the European Waste Catalogue depends on the waste producer and can therefore vary for any given product. The waste code number is therefore to be gleaned separately from each waste producer.

14 Transport information

In accordance with ADR / IMDG / IATA

14.1 UN number or ID number

UN-No. (ADR) : Not applicable

UN-No. (IMDG) : Not applicable

UN-No. (IATA) : Not applicable

14.2 UN proper shipping name

Proper Shipping Name (ADR) : Not applicable

Proper Shipping Name (IMDG) : Not applicable

Proper Shipping Name (IATA) : Not applicable

14.3 Transport hazard class(es)

Transport hazard class(es) (ADR) : Not applicable
Transport hazard class(es) (IMDG) : Not applicable
Transport hazard class(es) (IATA) : Not applicable

14.4 Packing group

Packing group (ADR) : Not applicable
Packing group (IMDG) : Not applicable
Packing group (IATA) : Not applicable

14.5 Environmental hazards

Dangerous for the environment : No
Marine pollutant : No
Other information : No supplementary information available

14.6 Special precautions for user

Overland transport : Not applicable
Transport by sea : Not applicable
Air transport : Not applicable

14.7 Maritime transport in bulk according to IMO instruments

Not applicable

15 Regulatory information

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

15.1.1 EU-Regulations

Contains no substance on the REACH candidate list.

Contains no REACH Annex XIV substances.

15.1.2 National regulations

Comply with applicable local regulations.

15.2 Chemical safety assessment

No chemical safety assessment has been carried out.

16 Other information

Data sources : REGULATION (EC) No 1272/2008 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 16 December 2008 on classification, labelling and packaging of substances and mixtures, amending and repealing Directives 67/548/EEC and 1999/45/EC, and amending Regulation (EC) No 1907/2006.

Change compared to the previous version : -

Abbreviations and acronyms:

ACGIH	American Conference of Governmental Industrial Hygienists
ADR	European Agreement concerning the International Carriage of Dangerous Goods by Road
CLP	Regulation (EC) No 1272/2008 on classification, labelling and packaging of substances and mixtures
DFGMAK	Republic Germany's maximum exposure limit
DMEL	Derived Minimal Effect Level
DNEL	Derived No-Effect Level
EC50	The effective concentration of substance that causes 50% of the maximum response (Median Effective Concentration)
GHS	Globally Harmonized System of Classification and Labelling of Chemicals
HCS	Hazard Communication Standard
IARC	International Agency for Research on Cancer
IATA	International Air Transport Association
ICAO	International Civil Aviation Organization
IDLH	Immediately Dangerous to Life or Health
IMDG	International Maritime Dangerous Goods Code" for the transport of dangerous goods by sea
IMO	International Maritime Orga
IOELVs	European Unions' Indicative Occupational Exposure Limit Values
LC50	Lethal Concentration to 50 % of a test population (Median Lethal Concentration)
LD50	Lethal Dose to 50% of a test population (Median Lethal Dose)

LOAEL	Lowest Observed Adverse Effect Level
NIOSH	National Institute for Occupational Safety and Health
NOAEC/L	No Observed Adverse Effect Concentration/Level
NOEC/L	No Observed Effect Concentration/Level
NTP	National Toxicology Program
OECD	Organisation for Economic Cooperation and Development
OSHA	Occupational Safety and Health Administration
PBT	Persistent, Bioaccumulative and Toxic substance
PEL	Permissible Exposure Limit
PNEC	Predicted No-Effect Concentration
REACH	Regulation (EC) No 1907/2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals
SARA	Superfund Amendments and Reauthorization Act
SDS	Safety Data Sheet
STEL	Short Term Exposure Limit
STLV	Short Term Limit Value
STP	Sewage Treatment Plant
STV	Short Term Value
TDG	Canadian Transportation of Dangerous Goods Regulations
TLV	Threshold Limit Value
TWA	Time Weighted Average
UFI	Unique Formula Identifier
UN GHS	United Nations Globally Harmonized System
US DOT	United States Department of Transportation
US OSHA	United States Occupational Safety and Health Administration
vPvB	Very Persistent and Very Bioaccumulative
WHMIS	Workplace Hazardous Material Information System

Full text of H- and EUH-phrases:

Acute Tox. Inhal. 3	Acute Toxicity Oral, Category 3
Acute Tox. Oral 2	Acute Toxicity Oral, Category 2
Acute Tox. Oral 3	Acute Toxicity Oral, Category 3
Aquatic Acute,1	Aquatic Hazard Acute, Category 1
Aquatic Longterm 1	Aquatic Hazard Long term, Category 1
Carc. 1B	Carcinogenicity, Category 1B
Eye Dam. 1	Eye Damage, Category 1
Eye Irrit. 2	Eye Irritation, Category 2
Flam. Gas 1	Flammable Gases (including chemically unstable gases), Category 1
Flam. Liq. 2	Flammable Liquids, Category 2
Muta. 1B	Germ Cell Mutagenicity, Category 1B
Press. Gas [CG]	Gases under pressure, Compressed Gas
Repr. 1B	Toxic to Reproductive, Category 1B
Skin Corr. 1	Skin Corrosion, Category 1
STOT RE 1	Specific Target Organ Toxicity Repeated Exposure, Category 1
STOT SE 3	Specific Target Organ Toxicity Single Exposure, Category 3
H220	Extremely flammable gas
H225	Highly flammable liquid and vapour
H280	Contains gas under pressure; may explode if heated
H300	Fatal if swallowed
H301	Toxic if swallowed
H314	Causes severe skin burns and eye damage
H318	Causes serious eye damage
H319	Causes serious eye irritation

H331	Toxic if inhaled
H335	May cause respiratory irritation
H336	May cause drowsiness or dizziness
H340	May cause genetic defects
H350	May cause cancer
H360	May damage fertility or the unborn chid
H372	Causes damage to organs through prolonged or repeated exposure
H400	Very toxic to aquatic life.
H410	Very toxic to aquatic life with long lasting effects.

SDS EU (REACH Annex II)

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.

1 Identification of substance/mixture and company

1.1 Product identifier

Product form : Mixture

Product name : ^{125}I-labeled cyclosporine

Catalog # : B32447

1.2 Relevant identified uses of substance or mixture and uses advised against

1.2.1 Relevant identified uses

Use of the substance/mixture : Laboratory reagent, Immunoassays
Use by professionals

1.2.2 Uses advised against

No additional information available

1.3 Details of the supplier of the safety data sheet

Supplier/Manufacturer

DIAsource ImmunoAssays S.A.
Rue du Bosquet, 2
B-1348 Louvain-la-Neuve
Belgium
Tel. Nr. +32 (0)10/84.99.11
E-mail: products.support@diasource.be

1.4 Emergency telephone number

DIAsource (only office hours) : +32 (0)10/84.99.23

Centre Anti-Poisons (BE) : 070 245 245

Please refer to your local Anti-Poison Center!

2 Hazards identification

2.1 Classification of the substance or mixture

Classification according to Regulation (EC) N° 1272/2008 (CLP)

Flammable Liquids, Category 3 H226 Flammable liquid and vapour

(Full test of H-statements: see section16)

2.2 Label element

Labelling according to Regulation (EC) N° 1272/2008 (CLP)

Hazard symbol (CLP) :

Signal word (CLP) : Warning

Hazard statement (CLP) : H226 Flammable liquid and vapour

Precaution statement (CLP) : P210 Keep away from heat, hot surfaces, and sparks. No smoking
P233 Keep container tightly closed
P240 Ground container and receiving equipment
P241 Use explosion-proof electrical equipment
P242 Use non-sparking tools
P243 Take action to prevent static discharge
P280 Wear protective gloves, protective clothing and eye/face protection
P303+P361+P353 IF ON SKIN (or hair): Rinse skin with water
P370+P378 In case of fire: Use water spray for extinction
P403+P235 Store in a well-ventilated place. Keep cool
P501 Dispose of contents/container in accordance with local/national regulations

2.3 Other hazards

Radioactive material : This mixture contains Iodine-125, the activity of the mixture is indicated on the product label.Iodine-125 is a gamma-rays (35,5 keV) and X-rays (28 keV) emitter. Radiation can be protected by 1mm of lead. Half-life: 59.4 days.

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.

3 Composition/information on ingredients

3.1 Substances

Not applicable

3.2 Mixtures

Name	Product identifier	%	Classification according to Regulation (EC) No. 1272/2008 [CLP]
Ethyl Alcohol	(CAS N°) 64-17-5 (EC N°) 200-578-6 (EC Index N°) 603-002-00-5	10 - 20	Flam. Liq. 2, H225
1,4-Dioxane	(CAS N°) 123-91-1 (EC N°) 204-661-8 (EC Index N°) 603-024-00-5	< 0.001	Carc. 1B, H350 Eye Irrit. 2, H319 Flam. Liq. 2, H225 STOT SE 3, H335
Ethylene Oxide	(CAS N°) 75-21-8 (EC N°) 200-849-9 (EC Index N°) 603-023-00-X	< 0.001	Acute Tox. Inhal. 3, H331 Acute Tox. Oral 3, H301 Carc. 1B, H350 Eye Dam. 1, H318 Flam. Gas 1, H220 Muta. 1B, H340 Press. Gas [CG], H280 Repr. 1B, H360 STOT RE 1, H372 STOT SE 3 , H335, H336 Skin Corr. 1, H314

Full text of H-statements: see section16

4 First aid measures

4.1 Description of first aid measures

First-aid measures general : Get medical advice/attention if you feel unwell. If possible show him this sheet. Failing this, show him the packaging or label. Never give anything by mouth to an unconscious person. Place the affected person in the recovery position.

First-aid measures after inhalation : If product is inhaled, move exposed individual to fresh air. If individual is not breathing, begin artificial respiration immediately and obtain medical attention.

First-aid measures after skin contact : In case of skin contact, remove any contaminated clothing. Wash affected area with plenty of soap and water for at least 15 minutes. If pain or irritation occur, obtain medical attention.

First-aid measures after eye contact : If product enters eyes, wash eyes gently under running water for 15 minutes or longer, making sure that the eyelids are held open. If pain or irritation occur, obtain medical attention.

First-aid measures after ingestion : If ingested, wash mouth out with water. If irritation or discomfort occurs, seek medical attention.

4.2 Most important symptom and effects, both acute and delayed

Symptoms/effects : See Section 11 Toxicological Information for more detailed health information.

4.3 Indication of any immediate medical attention and special treatment needed

Treat symptomatically.

5 Firefighting measures

5.1 Extinguishing media

Suitable extinguishing media : In case of fire use carbon dioxide (CO_2), dry chemical, water spray or foam. Use extinguishing media suitable for surrounding fire.

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

5.2 Special hazards arising from the substance or mixture

Hazardous decomposition products in case of fire : No combustion products posing significant hazards are expected from this product (an aqueous solution).

5.3 Advice for firefighters

Firefighting instructions : Prevent firefighting water from entering the environment. Use water spray or fog for cooling exposed containers.

Protection during firefighting : Self-contained breathing apparatus is recommended for firefighters in all chemical fire situations.

6 Accidental release measures

6.1 Personal precautions, protective equipment and emergency procedures

General measures : This product contains a material of animal origin. Observe general safety guidelines for protection during clean up procedures. Wear protective gloves, protective clothing and eye/face protection.

6.1.1 For non-emergency personnel

Emergency procedures : Evacuate unnecessary personnel.

6.1.2 For emergency responders

Protective equipment : Use personal protective equipment as required. In case of inadequate ventilation wear respiratory protection.

6.2 Environmental precautions

Contain spill to prevent migration. Isolate area and absorb spill with sand, vermiculite or other inert absorbent material. Place absorbed material in container suitable for disposal. Do not allow the undiluted product to enter sewers/surface or ground water. Dispose of all waste material in accordance with local and facility guidelines.

6.3 Methods and material for containment and cleaning up

Methods for cleaning up : As a precautionary measure, treat spilled material with a 1:10 bleach/water solution. Absorb liquid and place in container suitable for disposal. Avoid generation of aerosols during clean up. Comply with applicable waste disposal regulations.

Dispose of all waste material in accordance with local guidelines.
Radioactive material is subject to the regulations of each country.
Dispose of all waste material in accordance with local guidelines

6.4 Reference to other sections

Exposure controls and personal protection, see section 8. Concerning disposal elimination after cleaning, see section 13.

7 Handling and storage

7.1 Precautions for safe handling

Precautions for safe handling : This product should be handled as though capable of transmitting infectious diseases. Universal precautions should be followed when using this product.

Hygiene measures : Handle in accordance with good industrial hygiene and safety procedures. When using do not eat, drink or smoke. Wash hands and other exposed areas with mild soap and water before eating, drinking or smoking and when leaving work.

7.2 Conditions for safe storage, including any incompatibilities

Storage conditions : Store at 2 to 8°C, as directed on the product label. To maintain product quality, store according to the instructions in the product labeling.

Prohibitions on mixed storage : Store away from strong acids, strong bases, strong oxidizers and incompatible materials (section 10).

Incompatible materials : No additional information available.

7.3 Specific end use(s)

Laboratory reagent, Immunoassays

8 Exposure controls/personnel protection

8.1 Control parameters

Exposure limits : Ethyl Alcohol (CAS N°64-17-5)	
US OSHA	1000 ppm TWA; 1900 mg/m³ TWA
ACGIH	1000 ppm STEL
ACGIH Biological Exposure Indices (BEI)	5000 pmol HEV/g globin medium: blood time: not critical parameter: N-(2-Hydroxyethyl)valine (HEV) hemoglobin adducts (nonspecific); 5 µg HEMA/g creatinine medium: urine time: end of shift parameter: S-(2-Hydroxyethyl)mercapturic acid (HEMA) (nonspecific, population based)
DFG MAK	800 ppm Peak; 1520 mg/m³ Peak; 200 ppm TWA MAK; 380 mg/m³ TWA MAK
Ireland	1000 ppm STEL
IOELVs	None established
NIOSH	3300 ppm IDLH (10% LEL); 1000 ppm TWA; 1900 mg/m³ TWA
China	None established
Croatia	1000 ppm TWA [GVI]; 1900 mg/m³ TWA [GVI]
Japan	None established
Sweden (AFS 2015:7 and amendments	500 ppm TLV NGV; 1000 mg/m³ TLV NGV; 1000 ppm Indicative STEL Vägledande KGV; 1900 mg/m³ Indicative STEL Vägledande KGV
Turkey	

Exposure limits : 1,4-Dioxane (CAS N° 123-91-1)	
US OSHA	100 ppm TWA; 360 mg/m³ TWA; prevent or reduce skin absorption
ACGIH	20 ppm TWA; Skin - potential significant contribution to overall exposure by the cutaneous route
ACGIH Biological Exposure Indices (BEI)	None established
DFG MAK	20 ppm Peak; 74 mg/m³ Peak; skin notation; 10 ppm TWA MAK; 37 mg/m³ TWA MAK
Ireland	20 ppm TWA (technical grade); 73 mg/m³ TWA (technical grade); 60 ppm STEL (calculated);

	219 mg/m³ STEL (calculated); Potential for cutaneous absorption (technical grade)
IOELVs	20 ppm TWA; 73 mg/m³ TWA
NIOSH	500 ppm IDLH
China	Skin notation; 70 mg/m³ TWA
Croatia	20 ppm TWA [GVI]; 73 mg/m³ TWA [GVI]
Japan	1 ppm OEL; 3.6 mg/m³ OEL
Sweden (AFS 2015:7 and amendments	10 ppm TLV NGV; 35 mg/m³ TLV NGV; 25 ppm Indicative STEL Vägledande KGV; 90 mg/m³ Indicative STEL Vägledande KGV
Turkey	20 ppm TWA; 73 mg/m³ TWA

Exposure limits : Ethylene Oxide (CAS N° 75-21-8)	
US OSHA	1 ppm TWA; 5 ppm STEL (see 29 CFR 1910.1047)
ACGIH	1 ppm TWA
ACGIH Biological Exposure Indices (BEI)	5000 pmol HEV/g globin medium: blood time: not critical parameter: N-(2-Hydroxyethyl)valine (HEV) hemoglobin adducts (nonspecific); 5 µg HEMA/g creatinine medium: urine time: end of shift parameter: S-(2-Hydroxyethyl)mercapturic acid (HEMA) (nonspecific, population based)
DFG MAK	skin notation
Ireland	ppm TWA; 1.8 mg/m³ TWA; 3 ppm STEL (calculated); 5.4 mg/m³ STEL (calculated); Potential for cutaneous absorption
IOELVs	-
NIOSH	800 ppm IDLH; 0.1 ppm TWA (less than stated value); 0.18 mg/m³ TWA (less than stated value)
China	Skin notation; 2 mg/m³ TWA
Croatia	Skin Notation (significant contribution to the total body load possible exposure through the skin); 1 ppm TWA [GVI]; 1.8 mg/m³ TWA [GVI]; Carcinogen Category 1B; Mutagen Category 1B
Japan	1 ppm OEL; 1.8 mg/m³ OEL
Sweden (AFS 2015:7 and amendments	1 ppm TLV NGV; 1.8 mg/m³ TLV NGV; 5 ppm Binding STEL Bindande KGV; 9 mg/m³ Binding STEL Bindande KGV; Skin notation
Turkey	-

8.2 Exposure controls

Appropriate engineering controls : Place vial behind a metal shield, away from the user.

Hand protection : Wear suitable gloves (EN 374). Nitrile rubber, 0.35 mm. Butyl rubber, 0.5 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 : Safety glasses or chemical goggles should be worn to prevent eye contact. Refer U.S. OSHA 29 CFR 1910.133, European Standard EN166 or appropriate government standards.

Skin and body protection : Impervious gloves, such as Nitrile or equivalent, should be worn to prevent skin .contact. Refer U.S. OSHA 29 CFR 1910.138, European Standard EN374 or appropriate government standards.

Respiratory protection : Under normal conditions, the use of this product 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.

Environmental exposure controls : Avoid release to the environment.

9 Physical and chemical properties

9.1 Information on basic physical and chemical properties

Physical state : Liquid

Colour : Red

Odor : Slight odor

Melting point/freezing point : No data available

Boiling point or initial boiling point and boiling range : No data available

Flammability : No data available

Lower and upper explosion limit : No data available

Flash point : 36°C

Auto-ignition temperature : No data available

Decomposition temperature : No data available

pH : 4.5 @ 20°C

Kinematic viscosity : No data available

Solubility : Miscible

Partition coefficient n-octanol/water (log value) : Not applicable

Vapour pressure	:	No data available
Density and/or relative density	:	1.02 @ 20°C
Relative vapour density	:	No data available
Particle size	:	Not applicable

9.2 Other information

9.2.1 Information with regard to physical hazard classes

Explosive properties	:	No explosive properties
Oxidising properties	:	No oxidising properties

9.2.2 Other safety characteristics

No additional information available

10 Stability and reactivity

10.1 Reactivity

No further relevant information available.

10.2 Chemical stability

The product is stable in accordance with recommended storage conditions.

10.3 Possibility of hazardous reactions

Sodium azide forms explosive compounds with heavy metals. Repeated contact of low concentrations of azide with lead and copper commonly found in plumbing drains may result in the build up of shock sensitive compounds.

10.4 Conditions to avoid

Avoid contact with incompatible materials. Avoid exposure to heat and direct sunlight.

10.5 Incompatible materials

Metals and metallic compounds.

10.6 Hazardous decomposition products

No decomposition products posing significant hazards would be expected from this product (an aqueous solution).

11 Toxicological information

11.1 Information on hazard classes as defined in Regulation (EC) No 1272/2008

Ethyl Alcohol (CAS N°64-17-5)	
LD50 oral rat	7060 mg/kg (NLM_CIP)
LC50 inhalation rat	116.9 mg/L 4 h (males)(vapor)(ECHA_API)
LC50 inhalation rat	133.8 mg/L 4 h (females)(vapor)(ECHA_API)
1,4-Dioxane (CAS N° 123-91-1)	
LD50 dermal rabbit	7600 mg/kg (CHEMVIEW)
LD50 oral rat	5170 mg/kg (JAPAN_GHS)
LC50 inhalation rat	46 mg/L 2 h (vapor)(JAPAN_GHS)
Ethylene Oxide (CAS N° 75-25-8)	
LD50 oral rat	72 mg/kg (JAPAN_GHS)
LC50 inhalation rat	800 ppm 4 h (gas)(NLM_CIP)

Primary routes of exposure	:	Common routes of entry include inhalation, ingestion and eye/skin contact. Specific paths of concern for potentially infectious materials are skin puncture, contact with broken skin, contact with mucous membranes and inhalation of aerosolized material.
Acute toxicity	:	Not classified
Skin corrosion/irritation	:	Not classified Based on available data, the classification criteria are not met
Serious eye damage/irritation	:	Not classified Based on available data, the classification criteria are not met
Respiratory or skin sensitization	:	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	:	This product does not contain a reportable concentration (≥ 0.1%) of any ingredient listed as carcinogen by ACGIH, IARC, NTP, OSHA or 1272/2008 EC regulation
Reproductive toxicity	:	Not classified Based on available data, the classification criteria are not met
Specific target organ toxicity (single exposure)	:	Not classified Based on available data, the classification criteria are not met

Specific target organ toxicity (repeated exposure) : Not classified
Based on available data, the classification criteria are not met

Aspiration hazard : Not classified
Based on available data, the classification criteria are not met

11.2 Information on other hazards

Endocrine disrupting properties : This product does not have substance(s) of endocrine disrupting properties for health according to REACH Article 57(f)

Other information : This product contains material(s) of animal origin. Observe general safety guidelines for protection when handling this product

12 Ecological information

12.1 Toxicity

Ethyl Alcohol (CAS N°64-17-5)	
Fresh water species	LC50 96 h Oncorhynchus mykiss: 12.0 - 16.0 mL/L [static] (EPA) LC50 96 h Pimephales promelas: >100 mg/L [static] (EPA) LC50 96 h Pimephales promelas: 13400 - 15100 mg/L [flow-through] (EPA)
Microtox/organisms	LC50 48 h Eisenia foetida 0.1 - 1 mg/cm² [filter paper](IUCLID)
Water flea	LC50 48 h Daphnia magna: 9268 - 14221 mg/L (IUCLID) EC50 48 h Daphnia magna: 2 mg/L [Static] (EPA)
Fresh water algae	No information available
1,4-Dioxane (CAS N° 123-91-1)	
Fresh water species	LC50 96 h Lepomis macrochirus: >10000 mg/L [static] (EPA) LC50 96 h Lepomis macrochirus: >10000 mg/L [semi-static] (IUCLID) LC50 96 h Pimephales promelas: 9850 mg/L [flow-through] (EPA) LC50 96 h Pimephales promelas: 10306 - 14742 mg/L [static] (EPA) LC50 96 h Pimephales promelas: 9850 mg/L (IUCLID)
Microtox/organisms	No information available
Water flea	EC50 48 h water flea: 163 mg/L [Static]
Fresh water algae	No information available
Ethylene Oxide (CAS N° 75-25-8)	
Fresh water species	LC50 96 h Pimephales promelas: 73 - 96 mg/L (EPA)
Microtox/organisms	No information available
Water flea	LC50 48 h Daphnia magna: 137 - 300 mg/L (IUCLID)
Fresh water algae	No information available

12.2 Persistence and degradability

Not required for inorganic substances.

12.3 Bioaccumulative potential

Not required for inorganic substances.

12.4 Mobility in soil

No additional information available.

12.5 Results of PBT and vPvB assessment

Not fulfilling Persistent, Bioaccumulative and Toxic (PBT), very Persistent and very Bioaccumulative (vPvB) criteria.

12.6 Endocrine disrupting properties

This product does not have substance(s) of endocrine disrupting properties for environment according to REACH Article 57(f).

12.7 Other adverse effects

This product contains environmentally hazardous substance below the cutoff level. Refer section 3 for ingredient information. Do not allow undiluted product to enter sewer/surface or ground water.

13 Disposal considerations

13.1 Waste treatment methods

Regional legislation (waste) : Dispose in a safe manner in accordance with local/national regulations.

Waste treatment methods : Do not empty into drains. Dispose of this material and its container in a safe way.

Waste code : The waste code number according to the Ordinance on the European Waste Catalogue depends on the waste producer and can therefore vary for any given product. The waste code number is therefore to be gleaned separately from each waste producer.

14 Transport information

In accordance with ADR / IMDG / IATA

14.1 UN number or ID number

UN-No. (ADR) : Not applicable

UN-No. (IMDG) : Not applicable
UN-No. (IATA) : Not applicable

14.2 UN proper shipping name

Proper Shipping Name (ADR) : Not applicable
Proper Shipping Name (IMDG) : Not applicable
Proper Shipping Name (IATA) : Not applicable

14.3 Transport hazard class(es)

Transport hazard class(es) (ADR) : Not applicable
Transport hazard class(es) (IMDG) : Not applicable
Transport hazard class(es) (IATA) : Not applicable

14.4 Packing group

Packing group (ADR) : Not applicable
Packing group (IMDG) : Not applicable
Packing group (IATA) : Not applicable

14.5 Environmental hazards

Dangerous for the environment : No
Marine pollutant : No
Other information : No supplementary information available

14.6 Special precautions for user

Overland transport : Not applicable
Transport by sea : Not applicable
Air transport : Not applicable

14.7 Maritime transport in bulk according to IMO instruments

Not applicable

15 Regulatory information

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

15.1.1 EU-Regulations

Contains no substance on the REACH candidate list.
Contains no REACH Annex XIV substances.

15.1.2 National regulations

Comply with applicable local regulations.

15.2 Chemical safety assessment

No chemical safety assessment has been carried out.

16 Other information

Data sources : REGULATION (EC) No 1272/2008 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 16 December 2008 on classification, labelling and packaging of substances and mixtures, amending and repealing Directives 67/548/EEC and 1999/45/EC, and amending Regulation (EC) No 1907/2006.

Change compared to the previous version : -

Abbreviations and acronyms:

ACGIH	American Conference of Governmental Industrial Hygienists
ADR	European Agreement concerning the International Carriage of Dangerous Goods by Road
CLP	Regulation (EC) No 1272/2008 on classification, labelling and packaging of substances and mixtures
DFGMAK	Republic Germany's maximum exposure limit
DMEL	Derived Minimal Effect Level
DNEL	Derived No-Effect Level
EC50	The effective concentration of substance that causes 50% of the maximum response (Median Effective Concentration)
GHS	Globally Harmonized System of Classification and Labelling of Chemicals
HCS	Hazard Communication Standard
IARC	International Agency for Research on Cancer
IATA	International Air Transport Association
ICAO	International Civil Aviation Organization
IDLH	Immediately Dangerous to Life or Health

IMDG	International Maritime Dangerous Goods Code" for the transport of dangerous goods by sea
IMO	International Maritime Orga
IOELVs	European Unions' Indicative Occupational Exposure Limit Values
LC50	Lethal Concentration to 50 % of a test population (Median Lethal Concentration)
LD50	Lethal Dose to 50% of a test population (Median Lethal Dose)
LOAEL	Lowest Observed Adverse Effect Level
NIOSH	National Institute for Occupational Safety and Health
NOAEC/L	No Observed Adverse Effect Concentration/Level
NOEC/L	No Observed Effect Concentration/Level
NTP	National Toxicology Program
OECD	Organisation for Economic Cooperation and Development
OSHA	Occupational Safety and Health Administration
PBT	Persistent, Bioaccumulative and Toxic substance
PEL	Permissible Exposure Limit
PNEC	Predicted No-Effect Concentration
REACH	Regulation (EC) No 1907/2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals
SARA	Superfund Amendments and Reauthorization Act
SDS	Safety Data Sheet
STEL	Short Term Exposure Limit
STLV	Short Term Limit Value
STP	Sewage Treatment Plant
STV	Short Term Value
TDG	Canadian Transportation of Dangerous Goods Regulations
TLV	Threshold Limit Value
TWA	Time Weighted Average
UFI	Unique Formula Identifier
UN GHS	United Nations Globally Harmonized System
US DOT	United States Department of Transportation
US OSHA	United States Occupational Safety and Health Administration
vPvB	Very Persistent and Very Bioaccumulative
WHMIS	Workplace Hazardous Material Information System

Full text of H- and EUH-phrases:

Acute Tox. Inhal. 3	Acute Toxicity Oral, Category 3
Acute Tox. Oral 2	Acute Toxicity Oral, Category 2
Carc. 1B	Carcinogenicity, Category 1B
Eye Dam. 1	Eye Damage, Category 1
Eye Irrit. 2	Eye Irritation, Category 2
Flam. Gas 1	Flammable Gases (including chemically unstable gases), Category 1
Flam. Liq. 2	Flammable Liquids, Category 2
Muta. 1B	Germ Cell Mutagenicity, Category 1B
Press. Gas [CG]	Gases under pressure, Compressed Gas
Repr. 1B	Toxic to Reproductive, Category 1B
Skin Corr. 1	Skin Corrosion, Category 1
STOT RE 1	Specific Target Organ Toxicity Repeated Exposure, Category 1
STOT SE 3	Specific Target Organ Toxicity Single Exposure, Category 3
H220	Extremely flammable gas
H225	Highly flammable liquid and vapour
H280	Contains gas under pressure; may explode if heated
H301	Toxic if swallowed
H314	Causes severe skin burns and eye damage
H318	Causes serious eye damage

H319	Causes serious eye irritation
H331	Toxic if inhaled
H335	May cause respiratory irritation
H336	May cause drowsiness or dizziness
H340	May cause genetic defects
H350	May cause cancer
H360	May damage fertility or the unborn chid
H372	Causes damage to organs through prolonged or repeated exposure

SDS EU (REACH Annex II)

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.