

Printing date 23.02.2024 Version number 1 Revision: 18.08.2023

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

· 1.1 Product identifier

· Trade name: AlphaLISA Insulin Analyte

· Product number: AL3184S

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

· Product category PC21 Laboratory chemicals

· Application of the substance / the mixture Laboratory chemicals

· 1.3 Details of the supplier of the safety data sheet

· Manufacturer/Supplier:

Revvity, Inc 549 Albany Street Boston, MA 02118

· Further information obtainable from:

US Technical Support 800-762-4000

· 1.4 Emergency telephone number:

If inside USA, call CHEMTREC at 1-800-424-9300 If outside USA, call CHEMTREC at 1-703-527-3887

SECTION 2: Hazards identification

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

Skin Irrit. 2 H315 Causes skin irritation.

Eye Irrit. 2 H319 Causes serious eye irritation.

Skin Sens. 1 H317 May cause an allergic skin reaction.

Aquatic Chronic 2 H411 Toxic to aquatic life with long lasting effects.

• 2.1.3 Additional information: For the wording of the relevant risk phrases refer to section 16.

- · 2.2 Label elements
- · Labelling according to Regulation (EC) No 1272/2008

The product is classified and labelled according to the CLP regulation.

· Hazard pictograms





GHS07 GHS09

- · Signal word Warning
- · Hazard-determining components of labelling:

5-chloro-2-methyl-2H-isothiazol-3-one

· Hazard statements

H315 Causes skin irritation.

H319 Causes serious eye irritation.

H317 May cause an allergic skin reaction.

H411 Toxic to aquatic life with long lasting effects.

· Precautionary statements

Avoid breathing dust/fume/gas/mist/vapours/spray.

P273 Avoid release to the environment.

P280 Wear protective gloves / 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.

(Contd. on page 2)

Printing date 23.02.2024 Version number 1 Revision: 18.08.2023

Trade name: AlphaLISA Insulin Analyte

(Contd. of page 1)

P333+P313 If skin irritation or rash occurs: Get medical advice/attention.

P501 Dispose of contents/container in accordance with local/regional/national/international

regulations.

· 2.3 Other hazards

· Results of PBT and vPvB assessment

· **PBT:** Not applicable. · **vPvB:** Not applicable.

SECTION 3: Composition/information on ingredients

- · 3.2 Mixtures
- Description: Mixture of substances listed below with nonhazardous additions.

Dangerous components:			
	5-chloro-2-methyl-2H-isothiazol-3-one	<0.1%	
EINECS: 247-500-7	Acute Tox. 3, H301; Acute Tox. 2, H310; Acute Tox. 2, H330; Skin Corr. 1C, H314; Eye Dam. 1, H318; Aquatic Acute 1, H400 (M=100); Aquatic		
	1C, H314; Eye Dam. 1, H318; 🚯 Aquatic Acute 1, H400 (M=100); Aquatic		
	Chronic 1, H410 (M=100); 🔥 Škin Sens. 1A, H317		
	Specific concentration limits: Skin Corr. 1C; H314: C ≥ 0.6 %		
	Skin Irrit. 2; H315: 0.06 % ≤ C < 0.6 %		
	Eye Dam. 1; H318: C ≥ 0.6 %		
	Eye Irrit. 2; H319: $0.06\% \le C < 0.6\%$		
	Škin Sens. 1A; H317: C ≥ 0.0015 %		

· Additional information: For the wording of the relevant risk phrases refer to section 16.

SECTION 4: First aid measures

- · 4.1 Description of first aid measures
- · General information: Immediately remove any clothing soiled by the product.
- · After inhalation:

Supply fresh air and to be sure call for a doctor.

In case of unconsciousness place patient stably in side position for transportation.

· After eye contact:

Rinse opened eye for several minutes under running water. If symptoms persist, consult a doctor.

- · After swallowing: If symptoms persist consult doctor.
- 4.2 Most important symptoms and effects, both acute and delayed No further relevant information available.
- · 4.3 Indication of any immediate medical attention and special treatment needed

No further relevant information available.

SECTION 5: Firefighting measures

- · 5.1 Extinguishing media
- · Suitable extinguishing agents: Use fire extinguishing methods suitable to surrounding conditions.
- 5.2 Special hazards arising from the substance or mixture No further relevant information available.
- · 5.3 Advice for firefighters
- · **Protective equipment:** Wear self-contained respiratory protective device.

SECTION 6: Accidental release measures

• 6.1 Personal precautions, protective equipment and emergency procedures Not required.

(Contd. on page 3)

Printing date 23.02.2024 Version number 1 Revision: 18.08.2023

Trade name: AlphaLISA Insulin Analyte

(Contd. of page 2)

· 6.2 Environmental precautions:

Do not allow product to reach sewage system or any water course.

Inform respective authorities in case of seepage into water course or sewage system.

Dilute with plenty of water.

Do not allow to enter sewers/surface or ground water.

· 6.3 Methods and material for containment and cleaning up:

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

Dispose contaminated material as waste according to section 13.

Ensure adequate ventilation.

· 6.4 Reference to other sections

See Section 7 for information on safe handling.

See Section 8 for information on personal protection equipment.

See Section 13 for disposal information.

SECTION 7: Handling and storage

· 7.1 Precautions for safe handling

Ensure good ventilation/exhaustion at the workplace.

Prevent formation of aerosols.

- Information about fire and explosion protection: No special measures required.
- · 7.2 Conditions for safe storage, including any incompatibilities
- · Storage:
- · Requirements to be met by storerooms and containers: No special requirements.
- · Information about storage in one common storage facility: Not required.
- · Further information about storage conditions: Keep container tightly sealed.
- · Storage class: 12
- · 7.3 Specific end use(s) No further relevant information available.

SECTION 8: Exposure controls/personal protection

· 8.1 Control parameters

Ingredients with limit values that require monitoring at the workplace:

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

- · 8.2 Exposure controls
- · Appropriate engineering controls No further data; see section 7.
- · Individual protection measures, such as personal protective equipment
- General protective and hygienic measures:

Keep away from foodstuffs, beverages and feed.

Immediately remove all soiled and contaminated clothing

Wash hands before breaks and at the end of work.

Avoid contact with the eyes and skin.

· Respiratory protection:

In case of brief exposure or low pollution use respiratory filter device. In case of intensive or longer exposure use self-contained respiratory protective device.

Suitable respiratory protective device recommended.

· Hand protection



(Contd. on page 4)

Printing date 23.02.2024 Version number 1 Revision: 18.08.2023

Trade name: AlphaLISA Insulin Analyte

(Contd. of page 3

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

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

· Material of gloves

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

· Penetration time of glove material

The exact break through time has to be found out by the manufacturer of the protective gloves and has to be observed.

· Eye/face protection



Tightly sealed goggles

SECTION 9: Physical and chemical properties

· 9.1 Information on basic physical and chemical properties

· General Information

· Physical state Fluid

· Colour: According to product specification

Odour: CharacteristicOdour threshold: Not determined.

• Melting point/freezing point:

Undetermined.

· Boiling point or initial boiling point and boiling range 100 °C (7732-18-5 Water)

· Flammability Not applicable.

· Lower and upper explosion limit

Lower: Not determined.
 Upper: Not determined.
 Flash point: Not applicable.
 Decomposition temperature: Not determined.

• Decomposition temperature: Not determined. • pH Not determined.

· Viscosity:

Kinematic viscosity
 Dynamic:
 Not determined.
 Not determined.

· Solubility

water: Fully miscible.
 Partition coefficient n-octanol/water (log value) Not determined.

• Vapour pressure at 20 °C: 23 hPa (7732-18-5 Water)

Density and/or relative density

Density: Not determined.
 Relative density Not determined.
 Vapour density Not determined.

· 9.2 Other information

· Appearance:

· Form: Fluid

Important information on protection of health and environment, and on safety.

Ignition temperature: Product is not selfigniting.

• Explosive properties: Product does not present an explosion hazard.

(Contd. on page 5)

Printing date 23.02.2024 Version number 1 Revision: 18.08.2023

Trade name: AlphaLISA Insulin Analyte

		(Contd. of page
Solvent content:		
Water:	49.0 %	
Solids content:	5.5 %	
Change in condition		
Evaporation rate	Not determined.	
Information with regard to physical hazard cla	usses	
Explosives	Void	
Flammable gases	Void	
Aerosols	Void	
Oxidising gases	Void	
Gases under pressure	Void	
Flammable liquids	Void	
Flammable solids	Void	
Self-reactive substances and mixtures	Void	
Pyrophoric liquids	Void	
Pyrophoric solids	Void	
Self-heating substances and mixtures	Void	
Substances and mixtures, which emit flammab	ole gases	
in contact with water	Void	
Oxidising liquids	Void	
Oxidising solids	Void	
Organic peroxides	Void	
Corrosive to metals	Void	
Desensitised explosives	Void	

SECTION 10: Stability and reactivity

- · 10.1 Reactivity No further relevant information available.
- 10.2 Chemical stability
- Thermal decomposition / conditions to be avoided: No decomposition if used according to specifications.
- · 10.3 Possibility of hazardous reactions No dangerous reactions known.
- · 10.4 Conditions to avoid No further relevant information available.
- 10.5 Incompatible materials: No further relevant information available.
- 10.6 Hazardous decomposition products: No dangerous decomposition products known.

SECTION 11: Toxicological information

- · 11.1 Information on hazard classes as defined in Regulation (EC) No 1272/2008
- · Acute toxicity Based on available data, the classification criteria are not met.
- · Skin corrosion/irritation Causes skin irritation.
- · Serious eye damage/irritation Causes serious eye irritation.
- · Respiratory or skin sensitisation May cause an allergic skin reaction.
- · Germ cell mutagenicity Based on available data, the classification criteria are not met.
- · Carcinogenicity Based on available data, the classification criteria are not met.
- · Reproductive toxicity Based on available data, the classification criteria are not met.
- · STOT-single exposure Based on available data, the classification criteria are not met.
- · STOT-repeated exposure Based on available data, the classification criteria are not met.
- · Aspiration hazard Based on available data, the classification criteria are not met.

(Contd. on page 6)

Printing date 23.02.2024 Version number 1 Revision: 18.08.2023

Trade name: AlphaLISA Insulin Analyte

(Contd. of page 5)

· 11.2 Information on other hazards

· Endocrine disrupting properties

None of the ingredients is listed.

SECTION 12: Ecological information

- · 12.1 Toxicity
- · Aquatic toxicity: No further relevant information available.
- · 12.2 Persistence and degradability No further relevant information available.
- · 12.3 Bioaccumulative potential No further relevant information available.
- · 12.4 Mobility in soil No further relevant information available.
- · 12.5 Results of PBT and vPvB assessment
- · **PBT:** Not applicable.
- · vPvB: Not applicable.
- · 12.6 Endocrine disrupting properties

The product does not contain substances with endocrine disrupting properties.

- · 12.7 Other adverse effects
- · Remark: Toxic for fish

SECTION 13: Disposal considerations

- · 13.1 Waste treatment methods
- · Recommendation

Must not be disposed together with household garbage. Do not allow product to reach sewage system.

Hand over to hazardous waste disposers.

Must be specially treated adhering to official regulations.

- · Uncleaned packaging:
- · Recommendation: Disposal must be made according to official regulations.
- · Recommended cleansing agents: Water, if necessary together with cleansing agents.

· 14.1 UN number or ID number · ADR, IMDG, IATA	UN3082
· 14.2 UN proper shipping name	
$\cdot ADR$	3082 ENVIRONMENTALLY HAZARDOUS SUBSTANC
	LIQUID, N.O.S. (CYANOGEN BROMIDE)
· IMDG	ENVIRONMENTALLY HAZARDOUS SUBSTANCE
	LIQUID, N.O.S. (CYANOGEN BROMIDE), MARIN
	POLLUTANT
· IATA	ENVIRONMENTALLY HAZARDOUS SUBSTANCA
	LIQUID, N.O.S. (CYANOGEN BROMIDE)

(Contd. on page 7)

Printing date 23.02.2024 Version number 1 Revision: 18.08.2023

Trade name: AlphaLISA Insulin Analyte

	(Contd. of page
14.3 Transport hazard class(es)	
· ADR, IMDG, IATA	
1 1 1 1 1 1 1 1 1 1	
· Class · Label	9 Miscellaneous dangerous substances and articles.9
· 14.4 Packing group · ADR, IMDG, IATA	III
· 14.5 Environmental hazards: · Marine pollutant: · Special marking (ADR): · Special marking (IATA):	Symbol (fish and tree) Symbol (fish and tree) Symbol (fish and tree)
· 14.6 Special precautions for user · Hazard identification number (Kemler code): · EMS Number: · Stowage Category	Warning: Miscellaneous dangerous substances and articles 90 F-A,S-F A
· 14.7 Maritime transport in bulk according to IM instruments	Not applicable.
Transport/Additional information:	
ADR Limited quantities (LQ) Excepted quantities (EQ) Transport category Tunnel restriction code	5L Code: E1 Maximum net quantity per inner packaging: 30 ml Maximum net quantity per outer packaging: 1000 ml 3 (-)
· IMDG · Limited quantities (LQ) · Excepted quantities (EQ)	5L Code: E1 Maximum net quantity per inner packaging: 30 ml Maximum net quantity per outer packaging: 1000 ml
· UN "Model Regulation":	UN 3082 ENVIRONMENTALLY HAZARDOU SUBSTANCE, LIQUID, N.O.S. (CYANOGEN BROMIDE), III

SECTION 15: Regulatory information

- · 15.1 Safety, health and environmental regulations/legislation specific for the substance or mixture
- · Directive 2012/18/EU
- · Named dangerous substances ANNEX I None of the ingredients is listed.
- · Seveso category E2 Hazardous to the Aquatic Environment
- \cdot Qualifying quantity (tonnes) for the application of lower-tier requirements 200 t
- Qualifying quantity (tonnes) for the application of upper-tier requirements 500 t

(Contd. on page 8)

Printing date 23.02.2024 Version number 1 Revision: 18.08.2023

Trade name: AlphaLISA Insulin Analyte

(Contd. of page 7)

- · REGULATION (EC) No 1907/2006 ANNEX XVII Conditions of restriction: 3
- DIRECTIVE 2011/65/EU on the restriction of the use of certain hazardous substances in electrical and electronic equipment Annex II

None of the ingredients is listed.

- · REGULATION (EU) 2019/1148
- · Annex I RESTRICTED EXPLOSIVES PRECURSORS (Upper limit value for the purpose of licensing under Article 5(3))

None of the ingredients is listed.

· Annex II - REPORTABLE EXPLOSIVES PRECURSORS

None of the ingredients is listed.

· Regulation (EC) No 273/2004 on drug precursors

7647-01-0 hydrochloric acid

3

· Regulation (EC) No 111/2005 laying down rules for the monitoring of trade between the Community and third countries in drug precursors

7647-01-0 hydrochloric acid

3

15.2 Chemical safety assessment: A Chemical Safety Assessment has not been carried out.

SECTION 16: Other information

The information provided in this safety data sheet is based on our current knowledge, and is believed to be correct at the date of publication. However, no representation is made concerning its accuracy and completeness. It is intended as guidance only, and is not to be regarded as a warranty or specification of quality. All materials may present unknown hazards and should be used with caution. Although certain hazards are described, we cannot guarantee that these are the only hazards that exist. Revvity, Inc. cannot be held liable for any damage resulting from handling or contact with the product.

· Abbreviations and acronyms:

ADR: Accord relatif au transport international des marchandises dangereuses par route (European Agreement Concerning the International Carriage of Dangerous Goods by Road)

IMDG: International Maritime Code for Dangerous Goods

IATA: International Air Transport Association

GHS: Globally Harmonised System of Classification and Labelling of Chemicals

EINECS: European Inventory of Existing Commercial Chemical Substances

ELINCS: European List of Notified Chemical Substances

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

PBT: Persistent, Bioaccumulative and Toxic

vPvB: very Persistent and very Bioaccumulative

Acute Tox. 3: Acute toxicity – Category 3

Acute Tox. 2: Acute toxicity – Category 2

Skin Corr. 1C: Skin corrosion/irritation - Category 1C

Skin Irrit. 2: Skin corrosion/irritation – Category 2

Eye Dam. 1: Serious eye damage/eye irritation - Category 1

Eye Irrit. 2: Serious eye damage/eye irritation – Category 2

Skin Sens. 1: Skin sensitisation – Category 1

Skin Sens. 1A: Skin sensitisation - Category 1A

Aquatic Acute 1: Hazardous to the aquatic environment - acute aquatic hazard - Category 1

Aquatic Chronic 1: Hazardous to the aquatic environment - long-term aquatic hazard - Category 1

Aquatic Chronic 2: Hazardous to the aquatic environment - long-term aquatic hazard - Category 2