

SAFETY DATA SHEET

ALBAclone® Anti-D Optimum

According to Regulation GB CLP

Revision date: 25-MAR-24

Supersedes date: N/A

Revision number: 01

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

1.1 Product identifier

Product Code Z039
Product Name ALBAclone® Anti-D Optimum

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

Identified Use For Immunohematology Testing
Uses advised against Use only for intended applications.

1.3 Details of the supplier of the safety data sheet

Manufacturer

Alba Bioscience Limited
Allan-Robb Campus
5 James Hamilton Way
Milton Bridge
Penicuik
EH26 0BF
United Kingdom

Tel: +44 (0) 0131 357 3333
email: customer.serviceeu@AliveDx.com

1.4 Emergency Telephone Number

Telephone: +44 (0) 131 357 3333
Persons available 09:00-17:00 Monday to Friday

- National Poisons Information Service

For medical advice or information, you should contact your GP or NHS 111 (or NHS 24 in Scotland) on 111 (for 24-hour health advice)

If you are a healthcare professional with an enquiry, please visit www.TOXBASE.org United Kingdom

2. Hazard Identification

2.1 Classification of the substance or mixture

Classification (EC 1272/2008)

Physical Hazards	Not Classified
Health Hazards	Not Classified
Environmental Hazards	Not Classified

2.2 Label Elements

Hazard Statements NC Not Classified

Supplemental Label Information EUH032 Contact with acids liberates very toxic gas.
EUH210 Safety data sheet available on request.

2.3 Other Hazards

This product does not contain any substances classified as PBT or vPvB.

Does not contain any substances on the Endocrine disrupters assessment list.

Sodium Azide may react with lead and copper plumbing to form highly explosive metal azides. No known test method can offer complete assurance that products derived from animal blood will not transmit infectious agents. Therefore, all blood derivatives should be considered potentially infectious. It is recommended that these reagents be handled using established good laboratory working practices.

3. Composition / Information on Ingredients

Bovine Serum Albumins, blood serum CAS number: 9048-46-8	EC number: 232-936-2	ATE Values Oral (mg/kg) = 500	1-<3%
Classification Acute Tox 4. – H302			

Sodium Azide CAS number: 26628-22-8 M factor (Acute) = 1 M Factor (Chronic) = 1	EC number: 247-852-1	ATE Values Oral (mg/kg) = 27 Dermal (mg/kg) = 18 Inhalation (dusts/mists mg/l) = 0.054	<1%
Classification Acute Tox. 2 - H300 Acute Tox. 1 - H310 Acute Tox. 2 - H330			

Sodium Azide		ATE Values	<1%
CAS number: 26628-22-8 M factor (Acute) = 1 M Factor (Chronic) = 1	EC number: 247-852-1	Oral (mg/kg) = 27 Dermal (mg/kg) = 18 Inhalation (dusts/mists mg/l) = 0.054	
Skin Irrit. 2 - H315 Eye Irrit. 2 - H319 STOT SE 1 - H370 STOT RE 2 - H373 Aquatic Acute 1 - H400 Aquatic Chronic 1 - H410 EUH032 Contact with acids liberates very toxic gas.			

The full text of all R-Phrases and Hazard Statements are displayed in Section 16.

Ingredient Notes Contains monoclonal antibody in supernatant with preservatives.

4. First Aid Measures

4.1 Description of first aid measures

General information Never give anything by mouth to an unconscious person. Show this Safety Data Sheet to the medical personnel.

Inhalation Move affected person to fresh air at once. If breathing stops, provide artificial respiration. Keep affected person warm and at rest. Get medical attention if symptoms are severe or persist.

Ingestion Do not induce vomiting. If vomiting occurs, the head should be kept low so that vomit does not enter the lungs. Remove affected person from source of contamination. Rinse mouth thoroughly with water. Move affected person to fresh air and keep warm and at rest in a position comfortable for breathing. Get medical attention if symptoms are severe or persist.

Skin contact Remove all contaminated clothing immediately and wash it before reuse. Wash skin thoroughly with soap and water. Get medical attention if symptoms are severe or persist.

Eye contact Remove any contact lenses and open eyelids wide apart. Rinse immediately with plenty of water. Continue to rinse for at least 15 minutes. Get medical attention if symptoms are severe or persist after washing.

Injection Encourage bleeding and seek medical advice.

Protection of first aiders First aid personnel should wear appropriate protective equipment during any rescue.

4.2 Most important symptoms/effects, acute and delayed

Inhalation Vapour may irritate respiratory system/lungs.

Ingestion Hypotension (low blood pressure).

Skin contact Liquid may irritate skin.

Eye contact Prolonged contact may cause redness and/or tearing. May cause eye irritation.

4.3 Indication of immediate medical attention and special treatment needed, if necessary

Notes for the doctor Treat symptomatically.

Specific treatments Move affected person to fresh air and keep warm and at rest in a position comfortable for breathing. Keep affected person under observation. Effects may be delayed.

5. Fire Fighting Measures

5.1 Extinguishing media

Suitable extinguishing media

Use extinguishing measures that are appropriate to local circumstances and the surrounding environment.

Extinguishing Media Which Must not be Used for Safety Reasons

None known.

5.2 Special hazards arising from the substance or mixture

Specific Hazards

None known.

Hazardous combustion products

Thermal decomposition or combustion products may include the following substances: Oxides of carbon, Nitrous gases (NO_x), Toxic gases or vapours.

5.3 Advice for fire-fighters

Special protective actions during fire-fighting

Avoid breathing fire gases or vapours. Containers close to fire should be removed or cooled with water. Control run-off water by containing and keeping it out of sewers and watercourses. If risk of water pollution occurs, notify appropriate authorities.

Special protective equipment for firefighters

Wear positive-pressure self-contained breathing apparatus (SCBA) and appropriate protective clothing.

6. Accidental Release Measures

6.1 Personal precautions, protective equipment, and emergency procedures

For non-emergency personnel

Keep unnecessary and unprotected personnel away from the spillage. Wear appropriate clothing to prevent any possibility of skin contact. Do not touch or walk into spilled material. For personal protection, see Section 8. Keep upwind to avoid inhalation of gases, vapours, fumes and smoke. Avoid inhalation of vapours and spray/mists. Respiratory protection must be used if the airborne contamination exceeds the recommended occupational exposure limit. Provide adequate ventilation.

Handle all blood and materials in contact with blood as if capable of transmitting infectious agents. It is recommended that blood and materials in contact with blood be handled using established good laboratory practices.

For emergency responders

As above wear protective clothing as described in Section 8 of this safety data sheet.

6.2 Environmental precautions

Avoid discharge into drains or watercourses or onto the ground.

6.3 Methods and materials for containment and cleaning up

Methods for cleaning up

Provide adequate ventilation. Avoid contact with skin and eyes.

Small Spillages: Wipe up with an absorbent cloth and dispose of waste safely.

Large Spillages: Absorb in vermiculite, dry sand or earth and place into containers.

Store away from other materials. Clean contaminated surface thoroughly. Clean with disinfectants.

Sodium azide has been reported to form lead or copper azides in laboratory plumbing. These azides are potentially explosive. To prevent build up, flush plumbing with a large volume of water while disposing of these solutions in the sink. Select a disinfectant that is effective against bloodborne infectious agents. Commercial disinfectants must be used according to manufacturer directions.

Disinfectants are typically hazardous chemicals that react with many chemicals, materials and living tissues. Obtain and review the manufacturer's safety information before using the disinfectant. This product contains sodium azide, which reacts with acid to liberate hydrazoic acid, a very toxic gas.

Select a disinfectant with the following properties if disinfection of materials used to absorb a large volume of spilled product is required:

- Do not use any chemical or product with a pH below 6 to disinfect waste that contains sodium azide. Hydrazoic acid, a toxic gas, will be released when the pH is lower than 6.
- Do not use any chemical or product that contains mercury or any other metal to disinfect waste that contains sodium azide. This will create metal azide compounds, which can be highly explosive under pressure or shock (percussion).
- Select a disinfectant that does not bubble, effervesce or otherwise generate aerosols.
- Do not use excess disinfectant.
- Failure to follow manufacturer's directions may lead to unexpected reactions with the waste.
- Do not use a disinfectant if you do not have the proper facility, equipment and other appropriate protective measures available to work with it safely.

6.4 Reference to other sections

Section 13 – disposal considerations.

7. Handling and Storage

7.1 Precautions for safe handling

Usage precautions

Handle as a potentially infectious material. Wear appropriate clothing to prevent any possibility of skin contact. Avoid contact with skin and eyes. Avoid inhalation of vapours and spray/mists. In case of insufficient ventilation, wear suitable respiratory equipment. Do not eat, drink or smoke when using

this product. Wash hands thoroughly after handling. Good personal hygiene procedures should be implemented.

7.2 Conditions for safe storage, including any incompatibilities

Storage precautions

Store in tightly-closed, original container in a dry, cool and well-ventilated place. Keep away from heat, hot surfaces, sparks, open flames and other ignition sources. No smoking. Protect from freezing. Keep containers upright. Store away from incompatible materials (see Section 10). Avoid contact with oxidising agents. Avoid contact with acids and alkalis.

7.3 Specific end uses

Specific end use(s)

The identified uses for this product are detailed in Section 1.2.

8. Exposure Controls / Personal Protection

8.1 Control parameters

Occupational Exposure Limits

Sodium Azide

Long-term exposure limit (8-hour TWA): WEL 0.1 mg/m³

Short-term exposure limit (15-minute): WEL 0.3 mg/m³

as NaN₃

Sk

WEL = Workplace Exposure Limit.

TWA = Time weighted average.

Sk = Can be absorbed through the skin.

Biological limit values Not listed.

SODIUM AZIDE (CAS: 26628-22-8)

DNEL Workers - Inhalation; Long term systemic effects: 0.493 mg/m³

Workers - Dermal; Long term systemic effects: 0.14 mg/kg bw/day

PNEC Fresh water; 0.00035 mg/L

STP; 0.030 mg/L

Sediment (Freshwater); 0.0167 mg/kg dw

Sediment (Marinewater); 0.00072 mg/kg dw

8.2 Exposure Controls

Appropriate Engineering Controls

Ensure adequate ventilation (general and / or local exhaust) to maintain exposure below exposure limits and to avoid inhalation of aerosols.

Personal protective equipment

Eye protection Eyewear complying with an approved standard should be worn if a risk assessment indicates eye contact is possible. The following protection should be worn: Chemical splash goggles or face shield. Personal protective equipment for eye and face protection should comply with European Standard EN166.

Hand protection Chemical-resistant, impervious gloves complying with an approved standard should be worn if a risk assessment indicates skin contact is possible. Wear protective gloves made of the following material: Nitrile rubber. The most suitable glove should be chosen in consultation with the glove supplier/manufacturer, who can provide information about the breakthrough time of the glove material.

Clothing Protective clothing such as coveralls / aprons or lab coats should be worn.

Hygiene measures Wash at the end of each work shift and before eating, smoking and using the toilet. Wash promptly with soap and water if skin becomes contaminated. Promptly remove any clothing that becomes contaminated. Use appropriate skin cream to prevent drying of skin. When handling, do not eat, drink or smoke in work area. Provide eyewash station.

Respiratory protection If ventilation is inadequate, suitable respiratory protection must be worn. Respiratory protection complying with an approved standard should be worn if a risk assessment indicates inhalation of contaminants is possible. Respiratory protection suitable for protection from aerosol containing biological agents should be worn if there is a risk of aerosols being generated and no local exhaust ventilation is possible.

9. Physical and Chemical Properties

9.1 Information on basic physical and chemical properties

Physical State	Liquid
Colour	Colourless
Odour	N/A
pH	7.0 – 7.4
Melting Point / Freezing Point	N/D
Boiling point or Initial Boiling Point and Boiling Range	N/D
Flash Point	N/A
Evaporation Rate	N/D
Flammability	N/A
Lower and upper explosion limit	N/A
Vapour Pressure	N/D
Relative vapour density	N/D
Density and/or relative density	N/D
Solubility(ies)	N/D
Partition coefficient: n-octanol/water	N/D
Auto ignition temperature	N/A
Decomposition temperature	N/D
Kinematic viscosity	N/D

N/A Not applicable

N/D Not determined

Information declared as "Not determined" or "Not applicable" is not considered to be relevant to the implementation of the proper control measures.

9.2 Other Information

Explosive properties	Not considered to be explosive.
Oxidising properties	There are no chemical groups present in the product that are associated with oxidising properties.
VOC Content (%)	No information available.

10. Stability and reactivity

10.1 Reactivity

There are no known reactivity hazards associated with this product.

10.2 Chemical stability

Stable at normal ambient temperatures.

10.3 Possibility of hazardous reactions

Sodium azide liberates very toxic gases when in contact with acid and may form highly explosive metal azides if it reacts with lead, copper, silver or brass.

10.4 Conditions to avoid

Avoid heat, flames and other sources of ignition. Avoid exposure to high temperatures.

10.5 Incompatible materials

Strong oxidising agents. Strong alkalis. Strong acids. Some metals. Copper. Lead. Silver. Brass.

10.6 Hazardous decomposition products

Thermal decomposition or combustion products may include the following substances: Toxic gases or vapours, Nitrous gases (NO_x), Carbon monoxide (CO) or Carbon dioxide (CO₂).

11. Toxicological Information

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

Acute toxicity - oral

Notes (oral LD₅₀) Based on available data the classification criteria are not met.

Acute toxicity - dermal

Notes (dermal LD₅₀) Based on available data the classification criteria are not met.

Acute toxicity - inhalation

Notes (inhalation LC₅₀) Based on available data the classification criteria are not met.

Skin corrosion/irritation

Skin corrosion/irritation Based on available data the classification criteria are not met.

Serious eye damage/irritation

Serious eye damage/irritation Based on available data the classification criteria are not met.

Respiratory sensitisation

Respiratory sensitisation Based on available data the classification criteria are not met.

Skin sensitisation

Skin sensitisation Based on available data the classification criteria are not met.

Germ cell mutagenicity

Genotoxicity - in vitro Based on available data the classification criteria are not met.

Carcinogenicity

Carcinogenicity Based on available data the classification criteria are not met.

Reproductive toxicity

Reproductive toxicity – fertility Based on available data the classification criteria are not met.

Specific target organ toxicity - single exposure

STOT - single exposure Based on available data the classification criteria are not met.

Specific target organ toxicity - repeated exposure

STOT - repeated exposure Based on available data the classification criteria are not met.

Aspiration hazard

Aspiration hazard Based on available data the classification criteria are not met.

Inhalation No significant hazard at normal ambient temperatures. Vapour may irritate respiratory system/lungs. May be harmful if inhaled.

Ingestion May cause discomfort if swallowed. Hypotension (low blood pressure). May be harmful if swallowed.

Skin contact Liquid may irritate skin. May be harmful in contact with skin. Contains components which may penetrate the skin.

Eye contact May irritate eyes.

Route of exposure Skin and/or eye contact, Inhalation, Ingestion.

Target organs Respiratory system, Lungs, Skin, Eyes, Heart & Cardiovascular System, Nervous System, Brain.

12. Ecological Information

Ecotoxicity effects

The product contains a substance which is very toxic to aquatic organisms, and which may cause long-term adverse effects in the aquatic environment. This preparation has not been classified as hazardous to the environment using the conventional method calculation. However, large or frequent spills may have hazardous effects on the environment.

12.1 Toxicity

Acute aquatic toxicity

Acute toxicity - fish Not known.

Acute toxicity - aquatic invertebrates Not known.

Acute toxicity - aquatic plants Not known.

12.2 Persistence and degradability

No information available.

12.3 Bioaccumulative potential

Bioaccumulative potential No information available.

Partition coefficient No information available.

12.4 Mobility in soil

No information available.

12.5 Results of PBT and vPvB assessment

This product does not contain any substances classified as PBT or vPvB.

12.6 Other adverse effects

No information available.

13. Disposal Considerations

13.1 Waste treatment methods

General information When handling waste, the safety precautions applying to handling of the product should be considered.

Disposal methods Dispose of waste to licensed waste disposal site in accordance with the requirements of the local Waste Disposal Authority.

Waste class The waste code classification is to be carried out according to the European Waste Catalogue (EWC).

14. Transport Information

The product is not covered by international regulations on the transport of dangerous goods (IMDG, IATA, ADR/RID).

14.1. UN number

Not applicable.

14.2. UN proper shipping name

Not applicable.

14.3. Transport hazard class(es)

No transport warning sign required.

14.4. Packing group

Not applicable.

14.5. Environmental hazards

Environmentally hazardous substance/marine pollutant

No.

14.6. Special precautions for user

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

National regulations Follow national regulation for work with chemical agents.

UK legislation According to Regulation GB CLP

SVHC REACH candidates None

Authorisations (Annex XIV) None

Restrictions (Annex XVII) None

15.2 Chemical Safety Assessment

Relevant exposure scenario information for the components of this mixture has been included in this Safety Data Sheet and therefore no annex is provided.

16. Other Information

Abbreviations and acronyms used in the safety data sheet

CAS: Chemical Abstracts Service.

PBT: Persistent, Bioaccumulative and Toxic substance.

vPvB: Very Persistent and Very Bioaccumulative.

DNEL: Derived No Effect Level.

PNEC: Predicted No Effect Concentration.

ATE: Acute Toxicity Estimate.

LC₅₀: Lethal Concentration to 50 % of a test population.

LD₅₀: Lethal Dose to 50% of a test population (Median Lethal Dose).

EC₅₀: 50% of maximal Effective Concentration.

IMDG: International Maritime Dangerous Goods.

IATA: International Air Transport Association.

ADR: European Agreement concerning the International Carriage of Dangerous Goods by Road.

UN: United Nations.

MARPOL 73/78: International Convention for the Prevention of Pollution From Ships, 1973 as modified by the Protocol of 1978.

IBC: International Code for the Construction and Equipment of Ships carrying Dangerous Chemicals in Bulk (International Bulk Chemical Code).

GHS: Globally Harmonized System.

REACH: Registration, Evaluation, Authorisation and Restriction of Chemicals Regulation (EC) No 1907/2006.

VOC: Volatile organic compounds

STP: Sewage Treatment Plant

NaN₃: Sodium Azide

dw: dry weight

bw: body weight

Classification abbreviations and acronyms

Acute Tox. = Acute toxicity

Aquatic Acute = Hazardous to the aquatic environment (acute)

Aquatic Chronic = Hazardous to the aquatic environment (chronic)

Eye Irrit. = Eye irritation

Skin Irrit. = Skin irritation

STOT RE = Specific target organ toxicity-repeated exposure

STOT SE = Specific target organ toxicity-single exposure

Significant changes from previous version: Sections 1, 2, 3, 9, 11 and 12 updated.

References: company data, ECHA, GB MCL list.

Full text of H-Statements referred to under section 2 and 3:

H300 Fatal if swallowed.

H302 Harmful if swallowed.

H310 Fatal in contact with skin.

H315 Causes skin irritation.

H319 Causes serious eye irritation.

H330 Fatal if inhaled.

H370 Causes damage to organs (Heart & cardiovascular system, Central nervous system, Gastro-intestinal tract).

H373 May cause damage to organs (Brain, Central nervous system) through prolonged or repeated exposure.

H400 Very toxic to aquatic life.

H410 Very toxic to aquatic life with long lasting effects.

Classification procedures according to GB CLP: Calculation Method

Disclaimer

The information provided on this SDS is correct to the best of our knowledge, information and belief at the date of its publication. The information given is designed only as a guide for safe handling, use, processing, storage, transportation, disposal and release and is not to be considered as a warranty or quality specification. The information relates only to the specific material designated and may not be valid for such material used in combination with any other material or in any process, unless specified in the text.

End of Safety Data Sheet