

ALBAclone® Anti-M

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

1.1 - Product identifier

Trade name/designation ALBAclone® Anti-M
Chemical name N/A
Product-type Mixture
Product code EU (Z171), US (Z171U)

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

Relevant identified uses - For Immunohematology Testing.

Uses advised against - Use only for intended applications

1.3 - Details of the supplier of the safety data sheet

Alba Bioscience Limited
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Milton Bridge, Penicuik
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Distributor

EU Authorised Representative
Emergo Europe B.V.
Westervoortedijk 60
6827 AT, Arnhem
The Netherlands
Tel: + 31 (0)70 345 85 70

Manufacturer

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

1.4 - Emergency telephone number

SECTION 2: Hazards identification

2.1 - Classification of the substance or mixture

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

Aquatic Chronic 3	Hazardous to the aquatic environment - Aquatic Chronic 3
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2.2 - Label elements

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

Signal word : None
Pictograms : None

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Hazard statements

H412	Harmful to aquatic life with long lasting effects
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Precautionary statements

P273	Avoid release to the environment.
P501	Dispose of in accordance with national regulation.

EUH-phrases

EUH032	Contact with acids liberates very toxic gas
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2.3 - Other hazards

PBT-substance.

- The substances in the mixture do not meet the PBT/vPvB criteria according to REACH, annex XIII.

Other hazards which do not result in classification

- 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.
- This product does not contain a substance that has endocrine disrupting properties with respect to humans as no components meets the criteria.
- This product does not contain a substance that has endocrine disrupting properties with respect to non-target organisms as no components meets the criteria.

SECTION 3: Composition / information on ingredients

3.1 - Substances

Not applicable

3.2 - Mixtures

Chemical name	No	%	Class(es)	Specific concentration limit
sodium azide	CAS No. : 26628-22-8 Index No. : 011-004-00-7 EC No. : 247-852-1	< 1	Acute Tox. 1 Dermal - H310 Acute Tox. 2 Inhalation - H330 Acute Tox. 2 Oral - H300 Aquatic Acute 1 - H400 Aquatic Chronic 1 - H410 Eye Irrit. 2 - H319 Skin Irrit. 2 - H315 STOT RE 2 - H373 STOT SE 1 - H370	M-factor: 1 / 1 ATE oral 27 ATE dermal 18 ATE Inhalation Dust/Mist 0.054

- Full text of H- and EUH-statements: see section 16.
- Contains:
- Substance with a Community workplace exposure limit
- See section 8.
- Contains monoclonal antibody in supernatant with preservatives.

SECTION 4: First aid measures

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4.1 - Description of first aid measures

<u>Following inhalation</u>	<ul style="list-style-type: none">- Remove casualty to fresh air and keep warm and at rest.- If breathing is irregular or stopped, administer artificial respiration.- When in doubt or if symptoms are observed, get medical advice.
<u>Following skin contact</u>	<ul style="list-style-type: none">- After contact with skin, wash immediately with plenty of water and soap.- Remove contaminated, saturated clothing immediately.- When in doubt or if symptoms are observed, get medical advice.- Injection: Encourage bleeding and seek medical advice.
<u>After eye contact</u>	<ul style="list-style-type: none">- Rinse immediately carefully and thoroughly with eye-bath or water.- In case of eye irritation consult an ophthalmologist.
<u>After ingestion</u>	<ul style="list-style-type: none">- Never give anything by mouth to an unconscious person or a person with cramps.- Rinse mouth thoroughly with water.- When in doubt or if symptoms are observed, get medical advice.- Do NOT induce vomiting.

4.2 - Most important symptoms and effects, both acute and delayed

<u>Symptoms and effects - Following inhalation</u>	- May be harmful if inhaled.
<u>Symptoms and effects - Following skin contact</u>	- May be harmful in contact with skin.
<u>Symptoms and effects - After eye contact</u>	- No information available.
<u>Symptoms and effects - After ingestion</u>	- No information available.

4.3 - Indication of any immediate medical attention and special treatment needed

- Treat symptomatically.
- Symptoms may develop several hours following exposure; medical observation therefore necessary for at least 48 hours.

SECTION 5: Firefighting measures

5.1 - Extinguishing media

<u>Suitable extinguishing media</u>	<ul style="list-style-type: none">- ABC-powder- Carbon dioxide (CO₂)- Foam- Extinguishing powder- Water spray
<u>Unsuitable extinguishing media</u>	- Full water jet

5.2 - Special hazards arising from the substance or mixture

<u>Special hazards arising from the substance or mixture</u>	- No information available.
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<u>Hazardous decomposition products</u>	- Hazardous combustion products
	- Carbon monoxide
	- Carbon dioxide (CO ₂)
	- Metal oxide smoke, toxic
	- Nitrogen oxides (NO _x)

5.3 - Advice for firefighters

- Co-ordinate fire-fighting measures to the fire surroundings.
- Move undamaged containers from immediate hazard area if it can be done safely.
- Use water spray jet to protect personnel and to cool endangered containers.
- Wear a self-contained breathing apparatus and chemical protective clothing.
- Do not allow run-off from fire-fighting to enter drains or water courses.

SECTION 6: Accidental release measures

6.1 - Personal precautions, protective equipment and emergency procedures

<u>For non-emergency personnel</u>	- Remove persons to safety.
	- Use personal protection equipment.
	- Avoid contact with skin, eyes and clothes.
	- Avoid breathing dust/fume/gas/mist/vapours/spray.
	- 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.

<u>For emergency responders</u>	- Remove persons to safety.
	- Wear personal protection equipment (refer to section 8).
	- Avoid contact with skin, eyes and clothes.
	- Avoid breathing dust/fume/gas/mist/vapours/spray.
	- Provide adequate ventilation.

6.2 - Environmental precautions

- Do not allow to enter into surface water or drains.
- Ensure waste is collected and contained.

6.3 - Methods and material for containment and cleaning up

<u>Methods and material for cleaning up</u>	- Small amounts of spillages:
	- Wipe up with absorbent material (eg. cloth, fleece).
	- Collect in closed and suitable containers for disposal.
	- Large amounts of spillages:
	- Absorb with liquid-binding material (sand, diatomaceous earth, acid- or universal binding agents).
	- Collect in closed and suitable containers for disposal.
	- Clear contaminated areas thoroughly.
	- Clean with disinfectants.

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- 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.

Inappropriate techniques - No information available.

6.4 - Reference to other sections

- Disposal: see section 13
- Safe handling: see section 7
- Personal protection equipment: see section 8

SECTION 7: Handling and storage

7.1 - Precautions for safe handling

Recommendation

- Avoid contact with skin, eyes and clothes.
- Handle as a potentially infectious material.

Advices on general occupational hygiene

- Thorough skin-cleansing after handling the product.
- Wash hands before breaks and after work.
- Avoid breathing dust/fume/gas/mist/vapours/spray.
- Work in well-ventilated zones or use proper respiratory protection.
- When using do not eat, drink, smoke, sniff.

7.2 - Conditions for safe storage, including any incompatibilities

- Keep container tightly closed in a cool, well-ventilated place.
- Keep away from heat, hot surfaces, sparks, open flames and other ignition sources. No smoking.
- Avoid high temperatures or direct sunlight.

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- exposure to cold. Do not freeze
- Keep away from: Oxidising agent
- Do not mix with acids.

7.3 - Specific end use(s)

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

SECTION 8: Exposure controls/personal protection

8.1 - Control parameters

sodium azide (26628-22-8)	
IOELV TWA mg/m ³ (UE)	0.1 mg/m ³ Skin (as NaN ₃)
IOELV STEL mg/m ³ (UE)	0.3 mg/m ³ Skin (as NaN ₃)
TWA EH40 mg/m ³ (UK)	0.1 mg/m ³ (as NaN ₃) Skin
STEL EH40 mg/m ³ (UK)	0.3 mg/m ³ (as NaN ₃) Skin

- NaN₃: Sodium Azide
- Skin =
- H: skin resorptive
- May be absorbed through the skin.
- IOELV=Indicative occupational exposure limit values
- TWA = Time weighted average
- STEL = Short term exposure limit

DNEL / PNEC

sodium azide (26628-22-8)			
Type	Value	User	Effect
DNEL long-term inhalative	0.493 mg/m ³	Workers	Systemic
DNEL long-term dermal	0.14 mg/kg bw/day	Workers	Systemic
PNEC aquatic, freshwater	0.00035 mg/l		
PNEC sediment, freshwater	0.0167 mg/kg		
PNEC sediment, marine water	0.00072 mg/kg		
PNEC sewage treatment plant (STP)	0.03 mg/l		

8.2 - Exposure controls

Appropriate engineering controls

- Provide adequate ventilation as well as local exhaust at critical locations.

Individual protection measures, such as personal protective equipment

- Tested protective gloves must be worn



- When handling with chemical substances, protective gloves must be worn with the CE-label including the four control digits.

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- For special purposes, it is recommended to check the resistance to chemicals of the protective gloves mentioned above together with the supplier of these gloves.
- Breakthrough times and swelling properties of the material must be taken into consideration.

- Suitable material: NBR (Nitrile rubber)

- Avoid contact with eyes.
- Suitable eye protection:
 - Eye glasses
 - Suitable protective clothing:
 - Barrier creams are not substitutes for body protection.
 - After contact with skin, wash immediately with plenty of water and soap.
 - Do not eat, drink or smoke when using this product.
 - Make available sufficient washing facilities
 - Provide eye shower and label its location conspicuously
 - Take off contaminated clothing and wash it before reuse.
 - Wash hands before breaks and after work.
 - In case of inadequate ventilation wear respiratory protection.
 - Respiratory protection necessary at: exceeding exposure limit values

SECTION 9: Physical and chemical properties

9.1 - Information on basic physical and chemical properties

<u>Physical state</u>	Liquid	<u>Appearance</u>	Liquid
<u>Colour</u>	Clear/Straw	<u>Odour</u>	odourless
Odour threshold	No data available		
pH	8.45 - 8.55		
Melting point	No data available		
Freezing point	No data available		
Boiling point	No data available		
Flash point	not applicable		
Evaporation rate	No data available		
flammability	not applicable		
Lower explosion limit	not applicable		
Upper explosion limit	not applicable		

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Vapour pressure	No data available
Vapour density	No data available
Relative density	No data available
Density	No data available
Solubility (Water)	No data available
Solubility (Ethanol)	No data available
Solubility (Acetone)	No data available
Solubility (Organic solvents)	No data available
Log KOC	No data available
Auto-ignition temperature	not applicable
Decomposition temperature	No data available
Kinematic viscosity	No data available
Dynamic viscosity	No data available

Particle characteristics

Particle size	not applicable
Dustiness	No data available
Specific surface area	No data available
Shape	No data available

9.2 - Other information

VOC content	No data available
Minimum ignition energy	No data available
Conductivity	No data available
Refractive index	No data available
Solids content	No data available
Surface tension	No data available
Saturation concentration	No data available

- Not oxidising.
- not explosive according to EU A.14
- Data obtained by expert judgement.
- Information declared as "Not available" or "Not applicable" is not considered to be relevant to the implementation of the proper control measures.

SECTION 10: Stability and reactivity

10.1 - Reactivity

- This material is considered to be non-reactive under normal use conditions.

10.2 - Chemical stability

- The product is chemically stable under recommended conditions of storage, use and temperature.

10.3 - Possibility of hazardous reactions

- No hazardous reaction when handled and stored according to provisions.
- Contact with acids liberates very toxic gas.
- May form highly explosive metal azides if it reacts with lead, copper, silver or brass.

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10.4 - Conditions to avoid

- Keep away from heat, hot surfaces, sparks, open flames and other ignition sources. No smoking.
- Avoid high temperatures or direct sunlight.

10.5 - Incompatible materials

- Oxidising agent, strong
- Strong acid
- Strong alkali
- metals
- Copper
- Lead
- silver
- Brass

10.6 - Hazardous decomposition products

- Does not decompose when used for intended uses.
- Thermal decomposition can lead to the escape of irritating gases and vapours.
- Carbon dioxide
- Carbon monoxide
- Metal oxide smoke, toxic
- Nitrogen oxides (NO_x)

SECTION 11: Toxicological information

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

Acute toxicity - Not classified

Toxicity : Mixture

LD50 oral (rat)	No data available
LD50 dermal (rat)	No data available
LD50 dermal (rabbit)	No data available
LC50 inhalation (rat)	No data available
LC50 inhalation dusts and mists (rat)	No data available
LC50 inhalation vapours (rat)	No data available

- Based on available data, the classification criteria are not met.
- Calculation method.
- May be absorbed through the skin.
- May be harmful in contact with skin.
- May be harmful if inhaled.

Toxicity : Substances

sodium azide (26628-22-8)	
LD50 oral (rat)	27 mg/kg
LD50 dermal (rat)	18 mg/kg
LC50 inhalation dusts and mists (rat)	0.054 mg/l

Skin corrosion/irritation - Not classified

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	- Based on available data, the classification criteria are not met. - Calculation method.
<u>Serious eye damage/eye irritation</u>	- Not classified
	- Based on available data, the classification criteria are not met. - Calculation method.
<u>Respiratory or skin sensitisation</u>	- Not classified
	- Based on available data, the classification criteria are not met. - Calculation method.
<u>Germ cell mutagenicity</u>	- Not classified
	- Based on available data, the classification criteria are not met.
<u>Carcinogenicity</u>	- Not classified
	- Based on available data, the classification criteria are not met.
<u>Reproductive toxicity</u>	- Not classified
	- Based on available data, the classification criteria are not met.
<u>STOT-single exposure</u>	- Not classified
	- Based on available data, the classification criteria are not met. - Calculation method.
<u>STOT-repeated exposure</u>	- Not classified
	- Based on available data, the classification criteria are not met. - Calculation method.
<u>Aspiration hazard</u>	- Not classified

11.2 - Information on other hazards

- This product does not contain a substance that has endocrine disrupting properties with respect to humans as no components meets the criteria.

SECTION 12: Ecological information

12.1 - Toxicity

Toxicity : Mixture

EC50 48 hr crustacea	No data available
LC50 96 hr fish	No data available
ErC50 algae	No data available
ErC50 other aquatic plants	No data available
NOEC chronic fish	No data available
NOEC chronic crustacea	No data available
NOEC chronic algae	No data available
NOEC chronic other aquatic plants	No data available

ALBAclone® Anti-M

Toxicity : Substances

sodium azide (26628-22-8)

ErC50 algae

0.35 mg/l
Pseudokirchneriella
subcapitata

- Harmful to aquatic life with long lasting effects.

12.2 - Persistence and degradability

Biochemical oxygen demand (BOD)	No data available
Chemical oxygen demand (COD)	No data available
% of biodegradation in 28 days	No data available

- No information available.

12.3 - Bioaccumulative potential

Bioconcentration factor (BCF)	No data available
Log KOC	No data available

- No information available.

12.4 - Mobility in soil

- No information available.

12.5 - Results of PBT and vPvB assessment

- The substances in the mixture do not meet the PBT/vPvB criteria according to REACH, annex XIII.

12.6 - Endocrine disrupting properties

- This product does not contain a substance that has endocrine disrupting properties with respect to non-target organisms as no components meets the criteria.

12.7 - Other adverse effects

- Avoid release to the environment.

SECTION 13: Disposal considerations

13.1 - Waste treatment methods

Waste treatment methods

- Dispose of waste according to applicable legislation.
- Waste disposal according to directive 2008/98/EC, covering waste and dangerous waste.
- Handle contaminated packages in the same way as the substance itself.

Sewage disposal

- No information available.

Special precautions for waste treatment

- Collect the waste separately.
- Waste for disposal is to be classified and labelled.
- The waste is to be kept separate from other types of waste until its disposal.
- This material and its container must be disposed of as hazardous waste.
- Consult the appropriate local waste disposal expert about waste disposal.

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Community or national or regional provisions - The waste code has to be identified in agreement with the disposal company or the competent authority.

SECTION 14: Transport information

14.1 - UN number or ID number

Not applicable

14.2 - UN proper shipping name

Not applicable

14.3 - Transport hazard class(es)

Not applicable

14.4 - Packing group

Not applicable

14.5 - Environmental hazards

Not applicable

14.6 - Special precautions for user

Not applicable

14.7 - Maritime transport in bulk according to IMO instruments

Not applicable

SECTION 15: Regulatory information

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

Substances REACH candidates None

Substances Annex XIV None

Substances Annex XVII None

VOC content No data available

- Directive 98/24/EC of 7 April 1998 on the protection of the health and safety of workers from the risks related to chemical agents at work

- WGK 1

15.2 - Chemical Safety Assessment

Chemical safety assessment carried out for the product - Relevant exposure scenario information for the components of this mixture has been included in this Safety Data Sheet and therefore no annex is provided.

SECTION 16: Other information

SDS versions

Version	Issue date	Author	Description of the amendments
2.4	09/10/2024	J Waterfield	1.3
2.3	09/04/2024	J Waterfield	1.3, 9.1 (pH and colour)

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2.2	04/10/2023	J Waterfield	8.1.
2.1	02/06/2023	J Waterfield	.
2	26/10/2020	J Waterfield	
1	05/03/2020		

Abbreviations and acronyms

- For abbreviations and acronyms, see table at <http://abbrev.esdscom.eu>
- bw: body weight
- dw: dry weight
- Acute toxicity estimate (ATE)

Data sources: Material Safety Data Sheet, Misc. manufacturers.
ECHA

Texts of the regulatory sentences

Acute Tox. 1 Dermal	Acute toxicity (dermal) - Category 1
Acute Tox. 2 Inhalation	Acute toxicity (inhalative) - Category 2
Acute Tox. 2 Oral	Acute toxicity (oral) - Category 2
Aquatic Acute 1	Hazardous to the aquatic environment - Aquatic Acute 1
Aquatic Chronic 1	Hazardous to the aquatic environment - Aquatic Chronic 1
Aquatic Chronic 3	Hazardous to the aquatic environment - Aquatic Chronic 3
Eye Irrit. 2	Eye irritation - Category 2
H300	Fatal if swallowed.
H410	Very toxic to aquatic life with long lasting effects.
H412	Harmful to aquatic life with long lasting effects
Skin Irrit. 2	Irritation, Category 2
STOT RE 2	STOT-repeated exposure - Category 2
STOT SE 1	STOT-single exposure - Category 1

This information relates only to the specific material designated and may not be valid for such material used in combination with any other materials or in any process. Such information is, to the best of the company's knowledge and belief, accurate and reliable as of the date indicated. However, no warranty, guarantee or representation is made to its accuracy, reliability or completeness. It is the user's responsibility to satisfy himself as to the suitability of such information for his own particular use.

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