SAFETY DATA SHEET

ALBAcyte® IgG Sensitised Cells

According to Regulation (EC) No. 2020/878

Revision date: 20-SEP-23 **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 Z441

Product Name ALBAcyte® IgG Sensitised Cells

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	EU Authorised Representative
Alba Bioscience Limited Allan-Robb Campus 5 James Hamilton Way Milton Bridge Penicuik EH26 0BF United Kingdom	Emergo Europe B.V. Westervoortedijk 60 6827 AT, Arnhem The Netherlands
Tel: +44 (0) 0131 357 3333 email: customer.serviceeu@quotientbd.com	Tel: + 31 (0)70 345 85 70

1.4 Emergency Telephone Number

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

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

A safety data sheet is not required for this product under Article 31 of REACH. This SDS has been created on a voluntary basis [to pass on relevant information required under Article 32].

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.

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

Mixtures	None of the ingredients are required to be listed.
Ingredient Notes	Contains human red blood cells in Modified Alsevers solution.

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 May be harmful if swallowed.

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.

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 firefighting

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. 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.
Clean contaminated surface thoroughly. Clean with disinfectants. 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.

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. Protect from freezing. Keep containers upright. Store away from incompatible materials (see Section 10).

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

Ingredient Comments No exposure limits known for ingredient(s).

Biological limit values Not listed.

8.2 Exposure Controls

Appropriate Engineering Controls

Provide adequate general and local exhaust ventilation.

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 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	Red cells in a clear solution
Odour	N/A
pH	N/A
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
Particle characteristics	N/A

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

Information with Regard to Physical Hazard Classes

Explosive properties	Not considered to be explosive.
Oxidising properties	There are no chemical groups present in the product that are associated with oxidising properties.

Other Safety Characteristics

VOC Content (%)	No information available.

Other Information

3–5%

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

None known.

10.4 Conditions to avoid

Avoid excessive heat for prolonged periods of time.

10.5 Incompatible materials

Strong oxidising agents. Strong alkalis. Strong acids.

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 (CO_2).

11. Toxicological Information

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

Acute toxicity - oral

Notes (oral LD_{50}) Based on available data the classification criteria are not met.

Acute toxicity - dermal

Notes (dermal LD_{50}) Based on available data the classification criteria are not met.

Acute toxicity - inhalation

Notes (inhalation LC_{50}) Based on available data the classification criteria are not met.

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

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

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

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 Based on available data the classification criteria are not met.

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

Specific target organ toxicity - single exposure

Based on available data the classification criteria are not met.

Specific target organ toxicity - repeated exposure

Based on available data the classification criteria are not met.

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.

Ingestion	May cause discomfort if swallowed. May be harmful if swallowed.
Skin contact	Liquid may irritate skin.
Eye contact	May irritate eyes.
Route of exposure	Skin and/or eye contact Inhalation Ingestion.
Target organs	Respiratory system, Lungs, Skin, Eyes.

11.2. Information on other hazards

Endocrine disrupting properties

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

12. Ecological Information

Ecotoxicity effects

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 Endocrine Disrupting Properties

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

12.7 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.

EU legislation According to Regulation (EC) No. 2020/878

SVHC REACH candidates None

Authorisations (Annex XIV) None

Restrictions (Annex XVII) None

15.2 Chemical Safety Assessment

Chemical safety assessments for substances in this mixture were not carried out.

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.
LC_{50}: Lethal Concentration to 50 % of a test population.
LD_{50}: Lethal Dose to 50% of a test population (Median Lethal Dose).
EC_{50}: 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
Hct: Hematocrit

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

References: company data, ECHA.

Classification procedures according to Regulation (EC) 1272/2008: 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