

Safety Data Sheet

according to Regulation (EC) No 1907/2006

Anti-A; Anti-B; Anti A,B; Anti-D Blend; Anti-Human-Globulin GREEN (IgG+C3d)

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

1.1. Product identifier

Anti-A; Anti-B; Anti A,B; Anti-D Blend; Anti-Human-Globulin GREEN (IgG+C3d)

Anti-A (Order-no. 6790, 6791)

Anti-B (Order-no. 6793, 6794)

Anti-AB (Order-no. 6796, 6797)

Anti-D Blend (Order-no. 6785, 6786)

Anti-Human-Globulin GREEN (IgG+C3d) (Order-no. 6912, 6913)

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

Use of the substance/mixture

Intended to be used in the detection and identification of certain properties of cell and serum components of blood prior to transfusion.

Note: All blood products should be treated as potentially infectious. Source material from which this product was derived was found negative when tested in accordance with current FDA required tests. No known test methods can offer assurance that products derived from human blood will not transmit infectious agents.

1.3. Details of the supplier of the safety data sheet

Company name: BAG Diagnostics GmbH
Street: Amtsgerichtsstr. 1-5
Place: D-35423 Lich
Telephone: +49 (0)6404 925-100
e-mail: info@bag-diagnostics.com
Contact person: Dr. Evelyn Sachsenberg
e-mail: e.sachsenberg@bag-diagnostics.com
Internet: www.bag-diagnostics.com

Telefax: +49 (0)6404 925-460

Telephone: +49 (0)6404 925-217

1.4. Emergency telephone number:

Extern: +49 (0)6131-19-240 Medizinische Klinik der Universität Mainz
Intern: +49 (0)171-2157379

SECTION 2: Hazards identification

2.1. Classification of the substance or mixture

Regulation (EC) No. 1272/2008

Hazard categories:

Acute toxicity: Acute Tox. 4

Hazard Statements:

Harmful if swallowed.

Hazardous Material Identification System (HMIS III)

| | |
|---------------------|---|
| HEALTH | 0 |
| FLAMMABILITY | 0 |
| PHYSICAL HAZARD | 0 |
| PERSONAL PROTECTION | B |

2.2. Label elements

Regulation (EC) No. 1272/2008

Signal word: Warning

Pictograms:



Hazard statements

H302 Harmful if swallowed.

Precautionary statements

P301+P310 IF SWALLOWED: Immediately call a POISON CENTER/doctor.
P264 Wash hands thoroughly after handling.

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 Do not eat, drink or smoke when using this product.
Use personal protective equipment as required.

SECTION 3: Composition/information on ingredients

3.2. Mixtures

Hazardous components

| CAS No | Chemical name | | | Quantity |
|------------|---|--------------|----------|----------|
| | EC No | Index No | REACH No | |
| | Classification according to Regulation (EC) No. 1272/2008 [CLP] | | | |
| 9048-46-8 | Bovine Albumin | | | 1-12 % |
| | | | | |
| 56-40-6 | Glycine | | | 0-2,0 % |
| | | | | |
| 9003-11-6 | Pluronic F68 | | | 0-1,0 % |
| | | | | |
| 26628-22-8 | sodium azide | | | < 1 % |
| | 247-852-1 | 011-004-00-7 | | |
| | Acute Tox. 2, Aquatic Acute 1, Aquatic Chronic 1; H300 H400 H410 EUH032 | | | |

Full text of H and EUH statements: see section 16.

SECTION 4: First aid measures

4.1. Description of first aid measures

After inhalation

Remove to fresh air. If not breathing, give artificial respiration. If breathing is difficult, give oxygen. Get medical attention immediately.

After contact with skin

Wipe off affected area and flush with plenty of soap and water for 15 minutes. Remove contaminated clothing and shoes. Seek medical attention. Wash clothing and shoes thoroughly before reuse.

After contact with eyes

Immediately flush eyes with plenty of water for at least 15 minutes, lifting lower and upper eyelids occasionally. Get medical attention immediately.

After ingestion

DO NOT induce vomiting unless directed by medical personnel. Never give anything by mouth to an unconscious person. Get medical attention immediately.

SECTION 5: Firefighting measures

5.1. Extinguishing media

Suitable extinguishing media

Use appropriate extinguishing media for surrounding fire: dry chemical, carbon dioxide, water spray or regular foam.

5.3. Advice for firefighters

Wear appropriate personal protective equipment. Fight fires only if properly trained. Move containers from fire area if it can be accomplished without risk. Use water to keep containers cool. Dike fire control water.

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Additional information

Avoid breathing vapors or dusts. Keep upwind.

SECTION 6: Accidental release measures

6.1. Personal precautions, protective equipment and emergency procedures

Action to Be Taken If Material Is Released or Spilled: Remove all sources of ignition. Do not touch spilled material. Stop the release if you can do it without risk. Isolate the area and deny entry. Absorb the spill and place used absorbent material into approved containers for later disposal. Decontaminate the area with an approved disinfectant. Cover the area with paper towels and pour disinfectant over the area. Wipe the area until clean and dry.

SECTION 7: Handling and storage

7.1. Precautions for safe handling

Advice on safe handling

HANDLING: Food and drink should not be consumed or tobacco products used, nor cosmetics applied in areas where chemicals are stored or handled.

7.2. Conditions for safe storage, including any incompatibilities

Further information on storage conditions

Store away from incompatible substances. Store in tightly closed containers. Avoid contact with open wounds and body fluids. Wash thoroughly after handling and before eating, drinking or smoking. Observe, federal, provincial and local regulations.

SECTION 8: Exposure controls/personal protection

8.1. Control parameters

Exposure limits (EH40)

| CAS No | Substance | ppm | mg/m ³ | fibres/ml | Category | Origin |
|------------|-------------------------------------|-----|-------------------|-----------|---------------|--------|
| 26628-22-8 | Sodium azide (as NaN ₃) | - | 0.1 | | TWA (8 h) | WEL |
| | | - | 0.3 | | STEL (15 min) | WEL |

8.2. Exposure controls

Eye/face protection

Use chemical safety goggles and/or full face shield where splashing of the solution is possible. Maintain eyewash fountain and quick drench facilities in the work area.

Hand protection

Protective gloves should be worn while handling materials and/or surfaces, which are potentially infectious.

Skin protection

CLOTHING: Clothing such as gowns, aprons, or lab coats should be worn when working with this material. HEAD/ FOOT PROTECTION: Hood, surgical caps, boots and shoe covers should be worn in areas with significant quantities of infectious materials.

Respiratory protection

A NIOSH/MSHA approved respirator should be worn where airborne exposures may exceed OSHA/ACGIH exposure limits.

Environmental exposure controls

Provide sufficient mechanical (general and/or local exhaust) ventilation to maintain exposure below permissible air concentrations.

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SECTION 9: Physical and chemical properties

9.1. Information on basic physical and chemical properties

| | |
|-----------------|--|
| Physical state: | liquid |
| Colour: | Anti-A: clear blue; Anti-B: clear yellow; Anti-A,B and Anti-D Blend: clear light amber; Anti-Human-Globulin GREEN (IgG+C3d): clear green |
| pH-Value: | 6-8 |

Changes in the physical state

| | |
|--|---------------------|
| Melting point: | 0 °C |
| Initial boiling point and boiling range: | 100 °C |
| Vapour pressure: | 24 hPa |
| Density: | 1 g/cm ³ |

9.2. Other information

Note: The following physical and chemical properties have no data available: Odor threshold; Melting point/freezing point; Flammability (solid, gas); Partition coefficient: n-octanol/ water; Auto-ignition temperature; Decomposition temperature; and Viscosity.

SECTION 10: Stability and reactivity

10.2. Chemical stability

Stable

10.4. Conditions to avoid

Fire and excessive heat. May decompose in heat.

10.5. Incompatible materials

Benzoyl chloride, potassium hydroxide, bromine, carbon disulfide, chromyl chloride, copper, dibromomalononitrile, dimethyl sulfate, lead, barium carbonate, sulfuric acid, nitric acid, strong acids and substances that react violently with water.

10.6. Hazardous decomposition products

Sodium azide when heated to decomposition liberates nitrogen gas and can cause an explosion. Carbon dioxide and carbon monoxide may form when bovine albumin is heated to decomposition.

Further information

Hazardous polymerisation: will not occur

SECTION 11: Toxicological information

11.1. Information on toxicological effects

Acute toxicity

| CAS No | Chemical name | | | | |
|------------|----------------|-------------|---------|--------|--------|
| | Exposure route | Dose | Species | Source | Method |
| 26628-22-8 | sodium azide | | | | |
| | oral | ATE 5 mg/kg | | | |

Further information

Acute Effects: This product is manufactured from human blood and therefore must be considered to be capable of transmitting disease. The substance irritates the eyes, the skin and the respiratory tract. Exposure above Occupational Exposure Limits could cause effects on the nervous system.

Chronic Effects: No information found.

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Listed Carcinogens: None

SECTION 12: Ecological information

12.1. Toxicity

N/A

SECTION 13: Disposal considerations

13.1. Waste treatment methods

Advice on disposal

Dispose in accordance with applicable federal, state, and local government regulations. Waste generators must determine whether a discarded material is classified as a hazardous waste. USEPA guidelines for the classification determination are listed in 40 CFR parts 261.3. Additionally, waste generators must consult state and local hazardous waste regulations to ensure complete and accurate classification.

SECTION 14: Transport information

SECTION 15: Regulatory information

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

National regulatory information

Additional information

Canada: These products have been classified in accordance with the hazard criteria of the Controlled Products Regulations and this SDS contains all information required by the Controlled Products Regulations.

SECTION 16: Other information

Relevant H and EUH statements (number and full text)

| | |
|--------|---|
| H300 | Fatal if swallowed. |
| H302 | Harmful if swallowed. |
| H400 | Very toxic to aquatic life. |
| H410 | Very toxic to aquatic life with long lasting effects. |
| EUH032 | Contact with acids liberates very toxic gas. |

Further Information

The information is based on present level of our knowledge. It does not, however, give assurances of product properties and establishes no contract legal rights. The receiver of our product is singularly responsible for adhering to existing laws and regulations.

Disclaimer

For in-vitro-diagnostic use only.

(The data for the hazardous ingredients were taken respectively from the last version of the sub-contractor's safety data sheet.)