

SAFETY DATA SHEET

Afinion™ HbA1c Control C II

1. identification of the substance/preparation and of the company/undertaking

Date issued	14.03.2008
Product name	Afinion™ HbA1c Control C II
Use of the substance/preparation	Control material for Afinion™ HbA1c (rapid in vitro test for the measurement of glycated hemoglobin in human blood).

Producer

Company name	Axis-Shield PoC AS
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2. hazards identification

Hazard description	<p>This safety data sheet is valid for the Afinion™ HbA1c Control C II.</p> <p>Regarded as having very low health hazard. Presents little hazard if spilled or in fire. No ecotoxicological data available.</p> <p>Human serum, from which this product has been derived, is from thoroughly controlled voluntary unpaid donors of Scandinavian Blood Centres. Each unit is tested negative for HbsAg, HCV, HIV-I and HIV-II antibodies by approved tests. No test method can offer complete assurance that products containing human source material will be absent of these and other infectious agents. Precautions should be taken as for any potentially bio hazardous materials.</p>
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3. composition/information on ingredients

Component name	Identification	Labelling/classification	Contents
Triton X-100	CAS no.: 9002-93-1		< 0.2 weight%
Sodium azide	CAS no.: 26628-22-8 EC no.: 247-852-1		< 0.05 weight%
Column headings	CAS no. = Chemical Abstracts Service; EU (Einecs or Elincs number) = European inventory of Existing Commercial Chemical Substances; Ingredient name = Name as specified in the substance list (substances that are not included in the substance list must be translated, if possible). Contents given in; %, %wt/wt, %vol/wt, %vol/vol, mg/m3, ppb, ppm, weight%, vol%		
HH/HF/HE	T+ = Very toxic, T = Toxic, C = Corrosive, Xn = Harmful, Xi = Irritating, E = Explosive, O = Oxidizing, F+ = Extremely flammable, F = Very flammable, N = Environmental hazard		
Component comments	Stabilized preparation from human whole blood.		
	All components are below limit of hazard classification.		

4. first-aid measures

General	Seek medical advice in case of persistent symptoms of health damage. Miscible with water.
Inhalation	Not applicable.
Skin contact	Wash with water.
Eye contact	Flush eyes with water for at least 10 minutes. If persistent irritation occurs, seek medical advice.
Ingestion	Wash mouth thoroughly with water and drink water. If substance has been swallowed, drink large quantities of water. Seek medical advice.

5. fire-fighting measures

Suitable extinguishing media	Use extinguishing media appropriate for surrounding fire.
Improper extinguishing media	None.
Fire and explosion hazards	Not flammable. This product does not present any fire or explosion hazard.

6. accidental release measures

Personal precautions	Wear gloves, other protection is not necessary, see section 7 and 8.
Environmental precautions	Rejection forbidden to the sewer and in natural environment.
Methods for cleaning	Clean up, contaminated area should be washed with soap and water.

7. handling and storage

Handling	Avoid spilling, skin and eye contact. Wear gloves.
Storage	Store in original container according to temperature stated on container. Avoid exposure to temperatures above 30°C and direct sunlight.
Special risks and properties	The product should be handled as potentially bio hazardous materials.

8. exposure controls/personal protection

Exposure controls

Occupational exposure controls	Eye Washing Station should be available.
Respiratory protection	Respiratory protection not required.
Hand protection	Hand protection is recommended. (Nitrile gloves).
Eye protection	Eye protection is not necessary.
Skin protection (other than of the hands)	Protective clothing is not necessary.

9. physical and chemical properties

Physical state	Liquid control material in a glass vial with polypropylen cap.
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10. stability and reactivity

Conditions to avoid	None.
Materials to avoid	None.
Hazardous decomposition products	No hazardous decomposition products are known.
Stability	Stable and not reactive under normal conditions.

11. toxicological information

Other information regarding health hazards

General	The product itself represents a very low health hazard.
Skin contact	Avoid skin contact.
Eye contact	Splash in eye may cause irritation.
Ingestion	May cause nausea.

12. ecological information

Toxicological Information:

Aquatic, comments	No potential for bioaccumulation.
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Other ecological information

Ecotoxicity	No ecotoxicological data available. Contains small amounts of sodium azide (< 0.05 %). Sodium azide in higher concentrations is toxic to aquatic organisms.
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13. disposal considerations

Specify the appropriate methods of disposal	To be disposed according to local regulations. Rejection forbidden to the sewer and in natural environment.
Other Information	Used device should be handled and disposed as potentially bio hazardous materials.

14. transport information

Other applicable information.	The product is not subject to transport regulation. Fragile containers, handle with care. Protect from freezing, direct sunlight and temperatures above 25°C.
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15. regulatory information

R phrases	Not classified.
References (laws/regulations)	EU Regulations, 2005. ADR, RID, IMDG, IATA.

16. other information

Recommended restrictions on use	For in vitro diagnostic use only.
Sources of key data used to compile the safety datasheet	Exact composition from the Manufacturer.
Supplier's notes	<p>The MSDS is according to current regulations. Manufacturer/importer given in section 1 is legally responsible for the content of the MSDS.</p> <p>The revision of this MSDS is carried out by Alfheim Kjemikalie Consult. Alfheim Kjemikalie Consult is not responsible for errors or lack in information given by the manufacturer/importer.</p>
Responsible for safety datasheet	Axis-Shield PoC AS