Safety Data Sheet (According to 1272/2008/EC)

Trade name:	Antithrombin III
Article number:	R3330000032, A-R1100002501
Product Description:	Antithrombin III - Reagent R1 (buffer)

1 Identification of the substance / preparation and the company

1.1	Product identifiers	
Produ	uct REF:	Refer to the Header
Produ	uct Description:	Refer to the Header

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

In vitro diagnostics.

1.3 Details of the supplier of the safety data sheet

Identification company:	I.S.E. S.r.l.	
	Via delle Driadi, 45	
	00133 Roma - Italia	
	Tel. +39 0774+ 579365; FAX +39 07	74 579305
	E-mail: info@logotech-ise.com	www.logotech-ise.com
Additional information from:	I.S.E. S.r.l Regulatory Affairs E-m	ail: info@logotech-ise.com

1.4 Emergency telephone number

Emergency information:As above or callPoliclinico A. Gemelli - Largo Agostino Gemelli, 8 - Roma - Italy - Tel. + 39 063054343

2 Hazards identification

2.1 Classification of the substance or mixture

Classification according to EC regulation 1272/2008

Void

For the full text of the H-Statements mentioned in the Section, see Section 16

Hazard designation: Void

2.2 Label elements

Labelling according to EC regulation 1272/2008

Label:	Void
Signal word:	Void
Hazard statements:	Void
Precautionary statements:	Void
Information pertaining to	Void
particular dangers for man and	
environment:	





	Antithrombin III-Reagent R1 SDS		SDS	(6	-90-
2		R3330000032			- 60
-	REF	A-R1100002501		IVD	A.V
					Re 22

2.3 Other hazards

Hazardous properties cannot be excluded.

Sodium azide can form explosive azides when containing heavy metals such as copper or lead.

3 Composition / information on ingredients

3.1 Substances

Not applicable.

3.2 Mixtures

Chemical characterization: Mixture

Description:

Mixture of the substances listed below with harmless products

Sodium azide	CAS: 26628-22-8	<u>Acc.1272/2008:</u>
< 0.1%	EC: 247-852-1	Acute Tox Oral CAT 4; H302
	Index Number:	Acute Aquatic Tox CAT 3; H412
	011-004-00-7	

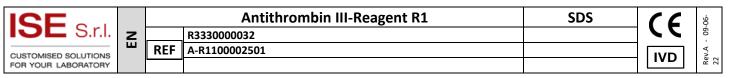
Additional information:For the wording of the listed phrases refer to Section 16This reagent contains Sodium Azide as a preservative

4 First aid measures

4.1 Description of first aid measures

General information:	Remove contaminated clothing
After inhalation:	Supply fresh air, consult doctor in case breathing problems develop. Unconscious: maintain adequate airway and respiration.
After skin contact:	Wash with soap and water. If symptoms persists, consult doctor.
After eye contact:	Rinse opened eye for several minutes under running water. If symptoms persists, consult doctor. Do not apply neutralizing agents.
After swallowing:	Rinse out mouth and then drink plenty of water. In case of persistent symptoms, consult doctor.





4.2 Most important symptoms and effects, both acute and delayed

After eye contact: May cause irritations.

4.3 Indication of any immediate medical attention and special treatment needed

Treat symptomatically.

5 Fire fighting measures

5.1 Extinguishing media

Suitable extinguishing agents:	Carbon dioxide (CO2), extinguishing powder or water spray/fog. Fight larger fires with
	water spray/fog or alcohol-resistant foam.

For safety reasons unsuitable None. extinguishing agents:

5.2 Special hazards arising from the substance or mixture

Special hazard caused by the	Nitrogen oxides (Nox), Oxides of phosphorus (PxOy)
material, its products of	Carbon monoxide (CO) and Carbon dioxide (CO2)
combustion or flue gases:	

5.3 Advice for firefighters

Protective equipment:	Put on breathing apparatus. Gas-tight suit.
Additional information:	Collect contaminated firefighting water separately. It must not enter drains.

6 Accidental release measures

6.1 Personal precautions, protective equipment and emergency procedures

Person-related safety	Wear protective clothing. Do not breathe vapors. Avoid skin and eye contact. See
precautions:	Section 8.

6.2 Environmental precautions

Measures for environmental	Do not allow to enter drainage system, surface or ground water. Discharge according
protection:	local regulations.

6.3 Methods and material for containment and cleaning up

Measures for	Absorb with liquid-binding material (sand, diatomite, acid binders, universal binders,
cleaning/collecting:	sawdust).
	Dispose of contaminated material as waste according to item 13.
	Clean contaminated surfaces with an excess of water.
	Wash clothing and equipment after handling.





6.4 Reference to other sections

Refer additionally to section 8 and 13.

7 Handling and storage

7.1 Precautions for safe handling

Information for safe handling:	Observe normal to strict hygiene standards. Handle and open the container with care. Ensure good ventilation / exhaustion at the workplace. Do not inhale aerosols. Avoid prolonged or repeated skin contact. Avoid contact with eyes. Make sure that all applicable workplace limits are observed.
Information about protection	No special measures required.

against explosions and fires:

7.2 Conditions for safe storage, including any incompatibilities

Requirements to be met by storerooms and containers:	Observe all local and national regulations for storage of water polluting products.
Information about storage in one common storage facility:	Not required
Further information about storage conditions:	Keep container tightly sealed. Protect from heat and direct sunlight. Store in a cool place. Recommend storage temperature: 2 - 8 °C.

7.3 Specific end use(s)

Void.

8 Exposure controls / personal protection

8.1 Control parameters

Additional information about design of technical systems:

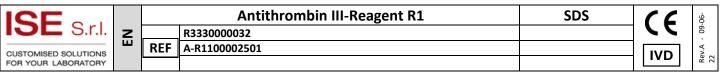
No further data; see item 7.

Components with critical values	Sodium azide	WEL (Great Britain)	Short-term value: 0.3 mg/m ³
that require monitoring at the			Long-term value: 0.1 mg/m ³
workplace:		TLV (European Union)	Short-term value: 0.3 mg/m ³
			Long-term value: 0.1 mg/m ³
			Skin



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Additional information:

The list that were valid during the compilation were used as basis.

8.2 Exposure controls

Personal protective equipment

General protective and hygienic measures:	Keep away from foodstuffs, beverages and food. Do not inhale gases / fumes / aerosols. Avoid close or long term contact with the skin. Avoid contact with the eyes. Wash hands during breaks and at the end of the work.
Breathing equipment:	If all workplace limits are observed and good ventilation is ensured, no special precautions necessary.
Protection of hands:	 Protective gloves. The glove material has to be impermeable and resistant to the product / the substance / the preparation. Selection of the glove material on consideration of the penetration times, rates of diffusion and the degradation. Check the permeability prior to each new use of the glove. To avoid skin problems reduce the wearing of gloves to the required minimum. Due to missing tests no recommendation to the glove material can be given for the product / the preparation / the chemical mixture.
Material of gloves:	The selection of the suitable gloves does not only depend on the material but also on further marks of quality varies from manufacturer to manufacturer. As the product is a preparation of several substances, the resistance of the glove material cannot be calculated in advance and has therefore to be checked prior to the application.
Penetration time of the glove:	The exact breakthrough time has to be found out by the manufacturer of the protective gloves and has to be observed.

9 Physical and chemical properties

9.1 Information on basic physical and chemical properties

General infomation

Liquid
Clear
Odourless
No data available
No data available





Change in condition:

Melting point / Melting range:	No data available
Boiling point / Boiling range:	No data available
Evaporation rate:	No data available
Flash point / Flash point range:	Not applicable
Self-inflammability:	Product is not self-igniting.
Danger of explosion:	Product is not explosive.
Density:	No data available
Solubility in / Miscibility with water:	Soluble

9.2 Other information

No data available

10	Stability and reactivity		
10.1	Reactivity		
		Stable reactivity until expiry date if stored in recommended conditions.	
10.2	Chemical stability		
		Stable until expiry date under recommended storage conditions.	
10.3	0.3 Possibility of hazardous reactions		
		No hazardous reactions known.	
10.4	Conditions to avoid		
	mal decomposition / litions to be avoided:	Sunlight Heat	
10.5	Incompatible products		
Mate	erials to be avoided:	Strong oxidizing agents Strong acids Heavy metals	



10.6 Hazardous decomposition products

Dangerous reactions may form very sensitive explosive metallic compounds.			
Dangerous products of	Nitrogen oxides (Nox), Oxides of phosphorus (PxOy)		
decomposition:	Carbon monoxide (CO) and Carbon dioxide (CO2)		

11 Toxicological information

11.1 Information on toxicological effects

Acute toxicity

LD/LC50 values that are relevant	Sodium azide	Oral	LD50	27 mg/kg (rat)
for classification:		Dermal	LD50	20 mg/kg (rabbit)

Primary irritant effect

on the skin:	No irritant effect.
on the eye:	No irritant effect.
Sensitization:	No sensitizing effect known.
Additional toxicological information:	The product is not object to classification according to the calculation method of the General EC Classification Guidelines for Preparations as issued in the latest version. When used and handled according to specifications, the product does not have any harmful effects according to our experience and the information provided to us.

12	Ecological information
12.1	Toxicity

Ecotoxical effects

Aquatic toxicity:	Sodium Azide	LC50/96 h	0.7 mg/L (bluegill (lepomis macrochirus))

12.2 Persistence and degradability

No data available.

12.3 Bioaccumulative potential

No data available.

12.4 Mobility in soil

No data available.





12.5 Results of PBT and vPvB assessment

No data available.

12.6 Other adverse effects

Water hazard class 1	Slightly hazardous for water.
(self-assessment):	

13 Disposal considerations				
13.1 Waste treatment methods				
Product				
Recommendation:	Disposal must be made according to official regulations.			
European waste catalogue:	Waste disposal key numbers from EWC have to be assigned depending on origin and processing.			
Contaminated packaging				
Recommendation:	Disposal must be made according to official regulations.			
Recommended cleaning agent:	Water, if necessary with cleaning agent.			
14 Transport information 14.1 UN number				

14.2 UN proper shipping name	
ADR/RID, IMDG, IATA:	Not applicable

- ADR/RID, IMDG, IATA: Not restricted
- 14.3 Transport hazard class(es)
- ADR/RID, IMDG, IATA: Not applicable
- 14.4 Packaging group
- ADR/RID, IMDG, IATA: Not applicable
- 14.5 Environmental hazards
- Marine pollutant: No



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14.6 Special precautions for user

No dangerous goods in sense of these transport regulations.

14.7 Transport in bulk according to Annex II of MARPOL73/78 and the IBC Code

No data available.

15 Regulatory information				
15.1 Safety, health and evironmental regulations/legislation specific for the substance or mixture				
Designation according to EC guidelines:	The product needs to be classified and labelled in accordance with EC Directives / relevant national laws.			
National regulations				
Degree to be applied in case of technical fault:	-			
Water hazard class				
Water hazard class 1 (self-assessment):	Slightly hazardous for water			
15.2 Chemical Safety Assessment				
	Void			

16 Other information				
e) R-phrase(s) are of the ingredient(s) and of do(es) NOT represent the ication of the preparation.				
Very toxic if swallowed				
Contact with acids liberates very toxic gas				
Very toxic to aquatic organisms, may cause long-term adverse effects in the aquatic environment				
Harmful if swallowed				
Harmful to aquatic life with long lasting effects				
312 If swallowed, call a poison center/doctor/ if you feel unwell				
Rinse mouth				
Wash hands thoroughly after handling				



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- P270 Do not eat, drink or smoke when using this product
- P273 Avoid release to the environment
- P501 Dispose of content/container to ... in accordance with local/regional/national/international regulations

In vitro diagnostics use only.

Sodium azide is been used as preservative. Products containing Sodium azide must be handled with due caution: do not ingest or allow to contact skin or mucous membranes!

Sodium azide has been reported to form lead or copper azide in laboratory plumbing which may explode on percussion. Flush drains with water thoroughly after disposing of fluids containing sodium azide.

Each human donor unit used in the preparation of the standards and controls was found to be negative for the presence of HIV1 and HIV2 antibodies, as well as for the hepatitis B surface antigen and anti-hepatitis C antibodies, using a method approved by the FDA.

Department issuing SDS: I.S.E. S.r.l., Regulatory Affair Office

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Abbreviations and acronyms:

ADR: Accord relatif au transport international des marchandises dangereuses par route (European Agreement Concerning the International Carriage of Dangerous Goods by Road) IMDG: International Maritime Code for Dangerous Goods IATA: International Air Transport Association GHS: Globally Harmonised System of Classification and Labelling of Chemicals EINECS: European Inventory of Existing Commercial Chemical Substances ELINCS: European Inventory of Existing Commercial Chemical Substances CAS: Chemical Abstracts Service (division of the American Chemical Society) LC50: Lethal concentration, 50 percent LD50: Lethal dose, 50 percent PBT: Persistent, Bioaccumulative and Toxic vPvB: very Persistent and very Bioaccumulative Acute Tox. 4: Acute toxicity – Category 4 Skin Corr. 1B: Skin corrosion/irritation – Category 1 STOT SE 3: Specific target organ toxicity (single exposure) – Category 3

