

iLite[®] Infliximab NAb Positive Control

BM3136

SECTION 1: IDENTIFICATION OF THE SUBSTANCE/MIXTURE AND OF THE COMPANY/UNDERTAKING

1.1 Product identifier

Product name: iLite[®] Infliximab NAb positive control

Product description iLite[®] Infliximab NAb positive control is a polyclonal rabbit antiserum with a neutralizing effect on Infliximab, diluted in RPMI 1640 with 40% heat-inactivated human serum

Product code BM3136

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

Use of the product Laboratory chemical. For research use only.

1.3 Details of the supplier of the safety data sheet

Company Svar Life Science AB
Address Lundvägen 151
Zip code/Place SE-212 24 Malmö, Sweden
Telephone +46 40 53 76 00
Website www.svarlifescience.com
E-mail info@svarlifescience.com

1.4 Emergency telephone number

Emergency telephone number (Sweden) Acute: 112 – Ask for "Giftinformation". If less acute call: +46 010 4566700.
Other countries: Please contact local emergency telephone number.

SECTION 2: HAZARDS IDENTIFICATION

2.1 Classification of the substance or mixture

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

The mixture is not to be classified according to CLP.

The mixture is covered by Directive 2000/54/EC of 18 September 2000 on the protection of workers from risks related to exposure to biological agents at work.

2.2 Label elements

None

2.3 Other hazards

Other hazards which do not result in classification Contain heat-inactivated human serum. The Certificate of Analysis for the human serum show that the substance has been tested and found negative for mycoplasma, HBsAg, HIV 1/2, anti-HCV, HCV-NAT, HIV-1 NAT, and syphilis in accordance with FDA regulations.



The products are considered to be biological agents in group 1 (ie. a biological agent that is unlikely to cause human infection). As a precaution, it is recommended that the work is carried out under measures similar to Group 2 in Council Directive 2000/54/EC.

Substance meets the criteria for PBT/ vPvB under Regulation EC No. 1907/2006, appendix XIII PBT/ vPvB: No

Endocrine disrupting properties

The substance is not identified as having endocrine disrupting properties in accordance with the criteria set out in Regulation 2017/2100 or Regulation 2018/605.

SECTION 3: COMPOSITION/INFORMATION ON INGREDIENTS

3.1 Mixtures

The product consists of RPMI 1640 medium with Glutamax added:

No	Product/ingredient name	EC-number	CAS-number	REACH registration number	Conc. (%w/w)	Classification Regulation (EC) No. 1272/2008 [CLP]
	Human type AB serum (heat-inactivated)	--	--	--	40	None
	Rabbit polyclonal antiserum towards Infliximab	--	--	--	0,3	None

SECTION 4: FIRST-AID MEASURES

4.1 Description of first aid measures

Inhalation:	Not expected to be an inhalation hazard under anticipated conditions of normal use of this material. Consult a physician if necessary.
Skin contact:	Remove contaminated clothing. Rinse skin with water. Immediate medical attention is not required.
Eye contact:	Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.
Ingestion	Not expected to present a significant ingestion hazard under anticipated conditions of normal use. If you feel unwell, seek medical advice.

4.2 Most important symptoms and effects, both acute and delayed

Skin contact:	None expected.
Eye contact:	None expected.
Inhalation	None expected.

4.3 Indication of any immediate medical attention and special treatment needed

None expected.

SECTION 5: FIREFIGHTING MEASURES

5.1 Extinguishing media

Suitable extinguishing media	Water spray. Carbon dioxide (CO ₂). Foam. Dry chemical.
Unsuitable extinguishing media	No information available.

5.2 Special hazards arising from the substance or mixture

Hazards from the substance or mixture	Not known
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5.3 Advice for firefighters

Special protective actions for fire-fighters	Promptly isolate the scene by removing all persons from the vicinity of the incident if there is a fire. No action shall be taken involving any personal risk or without suitable training.
Special protective equipment for fire-fighters	Fire-fighters should wear appropriate protective equipment and self-contained breathing apparatus (SCBA) with a full face-piece operated in positive pressure mode. Clothing for fire-fighters (including helmets, protective boots and gloves) conforming to European standard EN 469 will provide a basic level of protection for chemical incidents.
Further information	Not applicable

SECTION 6: ACCIDENTAL RELEASE MEASURES**6.1 Personal precautions, protective equipment and emergency procedures**

For non-emergency personnel Use personal protective equipment – see section 8.

For emergency responders No special handling advices are needed.

6.2 Environmental precautions

No special environmental precautions required.

6.3 Methods and material for containment and cleaning up

Small spill Soak up with inert absorbent material.

Large spill Not applicable.

6.4 Reference to other sections

See Section 8 for information on appropriate personal protective equipment. See Section 13 for additional waste treatment information.

SECTION 7: HANDLING AND STORAGE**7.1 Precautions for safe handling**

Protective measures Use laboratory facilities, which generally qualify for handling of biological agents.

Advice on general occupational hygiene Eating, drinking and smoking should be prohibited in areas where this material is handled. Do not pipette by mouth pipetting. See also Section 8 for additional information on hygiene measures.

7.2 Conditions for safe storage, including any incompatibilities

Storage: Upon receipt confirm that adequate dry-ice is present and the reagent is frozen. Store at -80 °C.

Further information: Not applicable

7.3 Specific end use(s)

Laboratory chemicals for research use only.

SECTION 8: EXPOSURE CONTROLS/PERSONAL PROTECTION**8.1 Control parameters**

Exposure Limits Contains no substances with occupational exposure limit values.

Engineering Measures Ensure adequate ventilation, especially in confined area

8.2 Exposure controls

Appropriate engineering controls Sufficient ventilation.

Hygiene measures Handle in accordance with good industrial hygiene and safety practice.

Respiratory protection Not relevant during normal condition.

Eye/face protection Use safety glasses (according to EN166) when there is risk of splashes.

Hand protection Wear protective gloves (according to EN374) of butyl rubber or nitrile rubber.

Body protection Wear suitable protective clothing.

Environmental exposure controls Not applicable

SECTION 9: PHYSICAL AND CHEMICAL PROPERTIES

9.1 Information on basic physical and chemical properties

Physical state:	Liquid
Colour:	n.d
Odour:	n.d
Melting point/freezing point (°C):	n.d
Boiling point or initial boiling point and boiling range (°C):	n.d
Flammability (solid, gas):	n.a
Lower and upper explosion limit (vol-%):	n.d
Flash point (°C):	n.d
Auto-ignition temperature (°C):	n.d
Decomposition temperature (°C):	n.d
pH:	n.d
Kinematic viscosity:	n.d
Solubility:	n.d
Partition coefficient n-octanol/water (log value):	n.d
Vapour pressure:	n.d
Density and/or relative density:	n.d
Relative vapour density:	n.d
Particle characteristics:	n.a

n.d = not determined

n.a = not applicable

9.2 Other information

Not applicable

SECTION 10: STABILITY AND REACTIVITY

10.1 Reactivity	No information available.
10.2 Chemical stability	Stable under normal conditions.
10.3 Possibility of hazardous reactions	No data available.
10.4 Condition to avoid	No information available.
10.5 Incompatible materials	No data available.
10.6 Hazardous decomposition products	No data available.

SECTION 11: TOXICOLOGICAL INFORMATION

11:1 Information on toxicological effects

Acute toxicity

No data available. Based on available data, the classification criteria are not met.

Irritation/Corrosion

No data available. Based on available data, the classification criteria are not met.

Sensitization by inhalation/skin contact

No data available. Based on available data, the classification criteria are not met.

Germ cell mutagenicity

No data available. Based on available data, the classification criteria are not met.

Carcinogenicity

No data available. Based on available data, the classification criteria are not met.

Reproductive toxicity

No data available. Based on available data, the classification criteria are not met.

Developmental toxicity

No data available. Based on available data, the classification criteria are not met.

Specific target organ toxicity (single exposure)

No data available. Based on available data, the classification criteria are not met.

Repeated dose toxicity and specific organ toxicity (repeated exposure)

No data available. Based on available data, the classification criteria are not met.

11.2 Information on other hazards:


Not available

SECTION 12: ECOLOGICAL INFORMATION

12:1 Toxicity	Contains no substances known to be hazardous to the environment or not degradable in waste water treatment plants.
12:2 Persistence and degradability	No information available
12:3 Bioaccumulative potential	No information available
12:4 Mobility in soil	No information available
12:5 Results of PBT and vPvB assessment	This mixture does not contain any substances that are assessed to be a PBT or a vPvB.
12:6 Endocrine disrupting properties:	No information available
12:7 Other adverse effects	No information available

SECTION 13: DISPOSAL CONSIDERATIONS**13.1 Waste treatment methods**

Method of disposal Biological agents are considered hazardous waste. Disposal should be according to local, state or national legislation.

Note! Waste containers containing biological material must be labeled with:  (black symbol on yellow background).

The generation of waste should be avoided or minimized wherever possible. This material and its container must be disposed of in a safe way by incineration.

Hazardous waste Within the present knowledge of the supplier, this product is regarded as hazardous waste, as defined by EU Directive 2008/98/EC.

European Waste Catalogue (EWC)

EWC Waste Code	Type of waste
18 01 03	Wastes whose collection and disposal is subject to special requirements in order to prevent infection
15 02 02	Absorbent material containing residues of or contaminated by dangerous substances

Packaging

Method of disposal	Incineration.
Special precautions	None.

SECTION 14: TRANSPORT INFORMATION

Product is not classified as dangerous goods.

	ADR/RID	ADN/ADNR	IMDG	IATA
14.1 UN number or ID number	--	--	--	--
14.2 UN proper shipping name	--	--	--	--
14.3 Transport hazard class(es)	--	--	--	--
14.4 Packing Group	--	--	--	--
14.5 Environmental hazards	--	--	--	--
14.6 Special precautions for user	No	No	No	No
14.7 Maritime transport in bulk according to IMO instruments	Not applicable	Not applicable	Not applicable	Not applicable
Additional information	--			

SECTION 15: REGULATORY INFORMATION
15.1 Safety, health and environmental regulations/legislation specific for the substance or mixture

Must not be used by persons under 18 years of age (Directive 94/33/EC).

The employer shall assess the working conditions and, if there is any risk to the safety or health and any effects on the pregnancy or breastfeeding of workers, take the necessary measures to adjust the working conditions (Directive 92/85/EEC)

The mixture is covered by:

Directive 2000/54/EC – biological agents at work

EU Regulation (EC) No. 1272/2008 (CLP): Not classified.

EU Regulation (EC) No. 1907/2006 (REACH)
Annex XIV – List of substances subject to authorization
Substances of very high concern

None of the components are listed.

Annex XVII – Restrictions on the manufacture, placing on the market and use of certain dangerous substances, mixtures and articles

Not applicable

15.2 Chemical Safety Assessment

No CSR.

Other information

Tariff Code harmonized system	Not applicable
The EU Seveso Directive	Not applicable

International regulations

Chemical Weapons Convention List Schedule I Chemicals	Chemical Weapons Convention List Schedule II Chemicals	Chemical Weapons Convention List Schedule III Chemicals
Not regulated	Not regulated	Not regulated

SECTION 16: OTHER INFORMATION

Conforms to Regulation (EC) No. 1907/2006 (REACH), Annex II.

LIST OF HAZARD STATEMENTS MENTIONED UNDER SECTION 3: None

Abbreviations:

CSR = Chemical Safety Report

PBT = Persistent, Bioaccumulative, Toxic

vPvB = very Persistent, very Bioaccumulative

Literature:

MP Biomedicals and Thermofisher Scientific (Safety Data Sheet)

IUCLID = International Uniform Chemical Information Database

ECHA = European Chemicals Agency

Other information

No special training is required. However, the user should be well instructed in the execution of his/her task, be familiar with this Safety Data Sheet and have normal training in the use of personal protective equipment.

Revisions

Version	Valid from (date)	Changes
1.0	{{Effective date}}	New document