

# iLite<sup>®</sup> Adalimumab NAb positive control

BM3159

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

### 1.1 Product identifier

<b>Product name:</b>	iLite <sup>®</sup> Adalimumab NAb positive control
<b>Product description</b>	iLite <sup>®</sup> Adalimumab NAb positive control is a polyclonal rabbit antiserum with a neutralizing effect towards Adalimumab, diluted in RPMI 1640 containing 40% heat-inactivated human serum.
<b>Product code</b>	BM3159

### 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

<b>Company</b>	Svar Life Science AB
<b>Address</b>	Lundvägen 151
<b>Zip code/Place</b>	SE-212 24 Malmö, Sweden
<b>Telephone</b>	+46 40 53 76 00
<b>Website</b>	<a href="http://www.svarlifescience.com">www.svarlifescience.com</a>
<b>E-mail</b>	<a href="mailto:info@svarlifescience.com">info@svarlifescience.com</a>

### 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 Adalimumab	--	--	--	1.3	None

## SECTION 4: FIRST-AID MEASURES

### 4.1 Description of first aid measures

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

<b>Skin contact:</b>	None expected.
<b>Eye contact:</b>	None expected.
<b>Inhalation</b>	None expected.

### 4.3 Indication of any immediate medical attention and special treatment needed

None expected.

## SECTION 5: FIREFIGHTING MEASURES

### 5.1 Extinguishing media

<b>Suitable extinguishing media</b>	Water spray. Carbon dioxide (CO <sub>2</sub> ). Foam. Dry chemical.
<b>Unsuitable extinguishing media</b>	No information available.

### 5.2 Special hazards arising from the substance or mixture

<b>Hazards from the substance or mixture</b>	Not known
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### 5.3 Advice for firefighters

<b>Special protective actions for fire-fighters</b>	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.
<b>Special protective equipment for fire-fighters</b>	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.
<b>Further information</b>	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

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

n.d = not determined

n.a = not applicable

### 9.2 Other information

Not applicable

## SECTION 10: STABILITY AND REACTIVITY

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

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

<b>Method of disposal</b>	Incineration.
<b>Special precautions</b>	None.

**SECTION 14: TRANSPORT INFORMATION**

Product is not classified as dangerous goods.

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

**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**

<b>Tariff Code harmonized system</b>	Not applicable
<b>The EU Seveso Directive</b>	Not applicable

**International regulations**

<b>Chemical Weapons Convention List Schedule I Chemicals</b>	<b>Chemical Weapons Convention List Schedule II Chemicals</b>	<b>Chemical Weapons Convention List Schedule III Chemicals</b>
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