iLite® Assay Ready Cells containing cryoprotective medium from Lonza

BM4050

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

1.1 Product identifier

Product name:	**iLite® GM-CSF Assay Ready Cells**
Product description	**iLite Assay Ready Cells containing cryoprotective medium from Lonza (cat no 12-132A)**
Product code	**BM4050**

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

Use of the product	Laboratory chemicals. 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 the Regulation (EC) No. 1272/2008 (CLP):
The mixture is not to be classified according to CLP.
The mixture is covered by Directive 2009/41/EC on the contained use of genetically modified micro-organisms and classified as a Class 1 Genetically Modified Microorganism.
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 Fetal Bovine serum, which is derived from cattle. The Certificate of Analysis for FBS show that the substance has been analyzed for Bluetongue Virus, Bovine Adenovirus, Bovine Parvovirus, Rabies Virus, Reovirus, BRSV Fluorescent Antibody, Cytopathogenic agents and Hemadsorbing agents with a negative result. 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 substances are 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

3.2 Mixtures

Assay Ready Cells suspended in RPMI 1640 medium with:

No	Product/ingredient name	EC-number	CAS-number	REACH registration number	Conc. (%w/w)	Classification Regulation (EC) No. 1272/2008 [CLP]
	Fetal Bovine Serum (Heat inactivated FBS)	--	--	--	20	None

Mixed 1:1 with cryoprotective medium from Lonza (cat no 12-132A) containing the following substance:

	Dimethyl Sulfoxid (DMSO)	200-664-3	67-68-5	--	15	None

SECTION 4: FIRST-AID MEASURES

4.1 Description of first aid measures

On suspicion of possible infection from biological agents – seek medical advice!

Inhalation: Move to fresh air. Keep at rest and under surveillance. If needed: seek medical advice.

Skin contact: Remove contaminated clothing at once. Flush skin and wash thoroughly with soap and water.

Eye contact: Keep eyelids well apart. Rinse with water for a couple of minutes, remember to remove contact lenses if any. If irritation persists: Seek medical advice.

Ingestion Rinse mouth and drink plenty of water. If needed or if larger amounts has been swallowed: Seek medical advice.

4.2 Most important symptoms and effects, both acute and delayed

Skin contact: May cause irritation of skin.

Eye contact: May cause irritation of eyes.

Inhalation Prolonged or frequent exposure to vapours of volatile organic compounds may result in damage on liver, kidneys, blood or central nervous system (including brain damage).

4.3 Indication of any immediate medical attention and special treatment needed

Show this safety data sheet to a physician or emergency ward

SECTION 5: FIREFIGHTING MEASURES

5.1 Extinguishing media

Suitable extinguishing media Use water spray, carbon dioxide, dry chemical or foam.

Unsuitable extinguishing media Waterjet

5.2 Special hazards arising from the substance or mixture

Hazards from the substance or mixture None

Hazardous thermal decomposition products Decomposition products may include the following materials: oxides of carbon and sulphur.

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. No action shall be taken involving any personal risk or without suitable training. Evacuate surrounding areas. Keep unnecessary and unprotected personnel from entering. Do not touch or walk through spilt material. The employees or the company's occupational health and safety organization must be informed immediately of any accident or incident that may have resulted in the release of biological agents, which may cause disease in humans.
For emergency responders	If specialized clothing is required to deal with the spillage, take note of any information in Section 8 on suitable and unsuitable materials. See also Section 8 for additional information on hygiene measures.

6.2 Environmental precautions

Do not empty into drains – see section 12. Inform appropriate authorities in accordance with local regulations.

6.3 Methods and material for containment and cleaning up

Small spill	Stop leak if without risk. Move containers from spill area. Wipe up spillage etc. with paper towels. Use wet towels to finish cleaning up. Follow the laboratory's general decontamination procedure for infectious waste. Flush area of decontamination with water. Further handling of spillage – see section 13.
Large spill	Stop leak if without risk. Move containers from spill area. Prevent entry into sewers, water courses, basements or confined areas. Contain and collect spillage with absorbent material as vermiculite. Further handling of spillage – see section 13.

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	Before use, a workplace assessment of the safety and health conditions at the working place must be carried out according to the general specifications mentioned in the EU Directive 2000/54/EC on biological agents and work. Work must be planned, organized and carried out so that the influence of biological agents is avoided as much as possible. Use laboratory facilities, which generally qualify for handling of biological agents. No tool or used material should after end use be placed on tables or similar but collected immediately in special sealed containers. Recycling of tools should only take place after proper disinfecting and purification. If appliances are contaminated, washing must be made with appropriate disinfectant before further use.
Advice on general occupational hygiene	Eating, drinking and smoking should be prohibited in areas where this material is handled. Avoid contact with skin, eyes and clothing. Always wash hands with soap and water after completing work, and when leaving the laboratory (e.g. before going to the toilet and at the end of the workday). 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 cells are frozen. Immediately transfer to -80 °C (do not store at any other temperature). Cells should be used within 30 min of thawing and should be diluted immediately after thawing.
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

Occupational exposure limits - DMSO

European Union: None
UK: None
Sweden:

NGV	KGV	Comments
50 ppm = 150 g/cm^3	150 ppm = 500 g/cm^3	H,V
H: Skin permeable	V: Indicative short-term exposure limit	

Germany, MAK: 50 ppm = 160 mg/m^3
Denmark: 50 ppm = 160 mg/m^3
Finland: 50 ppm (8h)
Austria: 50 ppm = 160 mg/m^3
Switzerland: 50 ppm = 160 mg/m^3

Recommended monitoring procedure	Not relevant

Derived effect levels

Product/ingredient name	Type	Exposure	Value	Population	Effects
--	--	--	--	--	--

Predicted effect concentrations	Not available
PNEC Summary	Not available – No CSR

8.2 Exposure controls

Appropriate engineering controls	Sufficient ventilation.
Hygiene measures	Wash hands thoroughly after handling chemical products, before eating, drinking, smoking and using the lavatory and at the end of the working period. Appropriate techniques should be used to remove potentially contaminated clothing. Wash contaminated clothing before reusing. Ensure that eyewash stations and safety showers are close to the workstation location.
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 available information

10.2 Chemical stability Stabile at recommended storage conditions – see section 7.

10.3 Possibility of hazardous reactions No available information.

10.4 Condition to avoid No available information.

10.5 Incompatible materials No available information.

10.6 Hazardous decomposition products When heated to high temperatures (decomposition) toxic fumes are emitted: Oxides of carbon and sulphur.

SECTION 11: TOXICOLOGICAL INFORMATION

In addition to the hazardous properties mentioned below, the risk of infection from the biological agents present in the product must also be taken into account.

11.1 Information on toxicological effects

Hazard class	Data (DMSO)	Test	Reference
Acute toxicity: Inhalation Dermal Oral	 LD_{50} (rat) > 2 mg/l/4h LD_{Lo} (rat) > 40000 mg/kg LD_{50} (rat) = 14500 mg/kg	 No information No information No information	 IUCLID IUCLID IUCLID
Corrosion/irritation	Mild eye and skin irritation, rabbit	OECD 404, EU Method B.5	ECHA
Sensitization	No skin sensitization, guinea pig	Buehler	IUCLID
CMR	No mutagenicity, carcinogenicity, genotoxicity	Several	Merck/IUCLID

Acute toxicity
Assessment for other reagents than DMSO: No data available.

Irritation/Corrosion
Assessment for other reagents than DMSO: No data available.

Sensitization by inhalation/skin contact
Assessment for other reagents than DMSO: No data available.

Germ cell mutagenicity
Assessment for other reagents than DMSO: The chemical structure of the different reagents doesn't indicate any mutagenic effects.

Carcinogenicity
Assessment for other reagents than DMSO: The chemical structure of the different reagents doesn't indicate any carcinogenic effects.

Reproduction toxicity
Assessment for other reagents than DMSO: The chemical structure of the different reagents doesn't indicate any reproduction toxic effects.

Developmental toxicity
Assessment for other reagents than DMSO: The chemical structure of the different reagents doesn't indicate any teratogenic effects.

Specific target organ toxicity (single exposure)
STOT assessment single dose toxicity: No data available.

Repeated dose toxicity and specific organ toxicity (repeated exposure)
Prolonged or frequent exposure to vapours of volatile organic compounds may result in damage on liver, kidneys, blood or central nervous system (including brain damage).

11.2. Information on other hazards:
None known.

SECTION 12: ECOLOGICAL INFORMATION

12.1 Toxicity

12.1.1 Acute toxicity in the aquatic environment for DMSO

Test	Value/unit (mg/l)	Test method	Exp. time (h)	Species
Fish LC_{50}	32000	Static (FW)	96	Oncorhynchus mykiss
Daphnia EC_{50}	7000	No info. (FW)	24	Daphnia sp.
Algae EC_{50}	12350-25500	No info. (SW)	96	Skeletonema costatum

12.1.2 Acute toxicity in the aquatic environment other reagents than DMSO

No data available.

12.1.3 Ecotoxicity

No data available.

12.2 Persistence and degradability

Conclusion/Summary DMSO is not readily degradable (3.1% after 14 days in OECD 301C test).

12.3 Bioaccumulative potential

Conclusion/Summary DMSO: Log K_{ow} -1,35 – No significant bioaccumulation.

12.4 Mobility in soil

Soil/water partition coefficient (KOC) DMSO: K_{oc} (calculated) < 10 – Very high mobility expected in soil environments.

Mobility No available data

12.5 Results of PBT and vPvB assessment

PBT The substance is not considered PBT according to criteria in Annex XIIII.

vPvB The substance is not considered vPvB according to criteria in Annex XIIII.

12.6. Endocrine disrupting properties

None known.

12.7 Other adverse effects

None known.

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	Waste containing used biological agents may be considered as dangerous goods; **UN 3291, CLINICAL WASTE, UNSPECIFIED; N.O.S., or (BIO) MEDICAL WASTE N.O.S. or REGULATED MEDICAL WASTE, N.O.S. Class 6.2 Packing Group II**			

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 2009/41/EC on the contained use of genetically modified micro-organisms
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:

BRSV = Bovine Respiratory Syncytial Virus
CMR = Carcinogenicy, Mutagenicity, and Reproduction toxicity
CSR = Chemical Safety Report
DNEL = Derived No-Effect Level
EC50 – Half maximal effective concentration
FW = Fresh Water (Färskvatten)
KGV = Korttidsvärde (Swedish for short term exposure limit)
LC50 = Lethal Concentration 50 %
LD50 = Lethal Dose 50 %
MAK = Maximale Arbeitsplatzkonzentrationen (German for maximum workplace concentration)
NGV = Nivågränsvärde (Swedish for exposure limit)
PBT = Persistent, Bioaccumulative, Toxic
PNEC = Predicted No-Effect Concentration
vPvB = very Persistent, very Bioaccumulative

Literature:

Merck (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	14-Mar-2019	New document
2.0	20-Sep-2021	Transfer of BM3060, BM3071, BM4012, and BM4023 to LABEL-DOC-0448. Template updated in compliance with Regulation 2020/878