SAFETY DATA SHEET

1. IDENTIFICATION OF THE SUBSTANCE/PREPARATION AND THE COMPANY/UNDERTAKING

1.1 Product identifier

PRODUCT NAME:	iLite™ Insulin Assay Ready Cells iLite™ IL-23 Assay Ready Cells iLite™ IL-12 Assay Ready Cells iLite™ GM-CSF Assay Ready Cells iLite™ ADCC Effector (V) Assay Ready Cells iLite™ ADCC Target CD20(+) Assay Ready Cells iLite™ ADCC Target CD20(-) Assay Ready Cells iLite™ TLR4 Assay Ready Cells
Product description	iLite™ Assay Ready Cells
Product code	BM3060; BM4023, BM4012, BM4050, BM4001, BM4010, BM4015, BM4024

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	Euro Diagnostica AB
Address	Lundavägen 151
Zip code/Place	SE-212 24 Malmö, Sweden
Telephone	+46 40 53 76 00
Internet	www.eurodiagnostica.com
E-mail	info@eurodiagnostica.se

1.4 Emergency telephone number

Emergency telephone number	+46 (0)8-331231 (Poisson Information Centre), Sweden +44 844 892 0111 (24 hrs), UK

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.

2.2. Label elements:

No CLP labeling required.

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 of 18 September 2000 on the protection of workers from risks related to exposure to biological agents at work.
Substance meets the criteria for PBT/vPvB under Regulation EC No. 1907/2006, appendix XIII	PBT/vPvB: No (refers to substances containing)

3. COMPOSITION/INFORMATION ON INGREDIENTS

3.2 Mixtures:

Assay Ready Cells suspended in RPMI 1640 medium with:

% w/w	Substance name	CAS-no.	EC-no.	Index-no.	REACH-reg.no.	Classification
20	Fetal Bovin Serum (Heat inactivated FBS)	-	-	-	-	None
mixed 1:1 with cryoprotective medium from Lonza (Cat. No 12-132A) containing						
15	Dimethyl Sulfoxid (DMSO)	67-68-5	200-664-3	-	-	None

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:	Immediately flush with water or physiological salt water for at least 5 minutes, holding eye lids open, 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 potential acute health effects

Eye & Skin contact:	May cause irritation of skin and eyes.

4.3 Indication of any immediate medical attention and special treatment needed

Show this safety data sheet to a physician or emergency ward.

5. FIRE-FIGHTING MEASURES

5.1 Extinguishing media

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

5.2 Special hazards arising from the substance or mixture

Hazards from the substance or mixture	In case of fire, the product may form hazardous decomposition products such as oxides of carbon and sulphur.

5.3 Advice for firefighters

Advice for firefighters	When extinguishing surrounding fires use breathing apparatus with an independent source of air.

6. ACCIDENTAL RELEASE MEASURES

6.1 Personal precautions, protective equipment and emergency procedures

Use personal protective equipment - see section 8. The employees or the company's occupational health and safety organisation 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.

6.2 Environmental precautions

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

6.3 Methods and materials for containment and cleaning up

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.

6.4 Reference to other sections

See above.

7. HANDLING AND STORAGE

7.1 Precautions for safe handling

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. Do not ingest food and beverages in work places or similar areas. Avoid contact with skin, eyes and clothing. Good personal hygiene is necessary. Before washing your hands it is recommended that the hands are rinsed in cold running water. Always wash hands and contaminated areas with soap and water after completing work - even before eating, 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. Use laboratory facilities, which generally qualify for handling of biological agents.
The cleanliness of the laboratory: 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 sterilization and purification. If appliances are contamination, washing must be made with appropriate disinfectant before further use.

7.2 Conditions for safe storage, including any incompatibilities

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)** and are stable as supplied until the expiry date shown. Cells should be used within 30 min of thawing, and should be diluted immediately after thawing.

7.3 Specific end use(s)

See section 1.

8. EXPOSURE CONTROLS/PERSONAL PROTECTION

8.1 Control parameters

Occupational exposure limits

Ingredient name	CAS nr.	Range	ppm	mg/m³	Year	Remarks
--	--	--	--	--	--	--

Recommended monitoring procedures	Not relevant

DNEL / PNEC	Not available – No CSR.

8.2 Exposure controls

Appropriate engineering controls	Sufficient ventilation.

Personal protective equipment

Respiratory protection	Normally not required. In case of inadequate ventilation: Use an approved mask (EN140) with class A/P2 combination filter.
Eye/face protection	Use safety goggles (according to EN166) when there is risk of splashes.
Hand protection	Wear protective gloves (according to EN374) of nitrile rubber. It has not been possible to find information about the permeation time for the specific substances so it is recommended to change the gloves after use.
Body protection	Wear suitable protective clothing.

Environmental exposure controls	None particular.

9. PHYSICAL AND CHEMICAL PROPERTIES

9.1.1 Information on basic physical and chemical properties of the reagents

Physical state	Liquid
Colour	n.d.
Odour	n.d.
Odour threshold	n.d.
Solubility(ies)	n.d.
pH (product)	n.d.
Melting point/freezing point	n.d.
Initial boiling point and boiling range	n.d.
Flash point	n.d.
Evaporation rate (butyl acetate = 1)	n.d.
Flammability (solid, gas)	n.d.
Upper/lower flammability or explosive limits	n.d.
Combustion rate	n.d.
Upper/lower flammability or explosive limits	n.d.
Vapour pressure (at 20°C)	n.d.
Vapour density	n.d.
Relative density (Water = 1)	n.d.
Partition coefficient: n-octanol/water	n.d.
Autoignition temperature	n.d.
Decomposition temperature	n.d.
Viscosity	n.d.
Explosive properties	n.d.
Oxidising properties	n.d.

n.a = not applicable. n.d = not determined

9.2 Other information

None

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 Conditions 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.

11. TOXICOLOGICAL INFORMATION

In addition to the hazardous properties mentioned below, you should also take into account any viruses from biological agents and their additional hazardous properties.

11.1 Information on toxicological effects:

Hazard class	Data (DMSO)	Test	Reference
Acute toxicity:			
Inhalation	LC_{50} (rat) > 2 mg/l/4h	No information	IUCLID
Dermal	LD_{Lo} (rat) > 40000 mg/kg	No information	IUCLID
Oral	LD_{50} (rat) = 14500 mg/kg	No information	IUCLID
Corrosion/irritation:	Mild eye and skin irritation, rabbit	No information	IUCLID
Sensitization:	No skin sensitisation, guinea pig	Buehler	IUCLID
CMR:	No Mutagenicity, Carcinogenicity, Genotoxicity	Several	Merck/IUCLID

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

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

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

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

Carcinogenicity
Assessment of carcinogenicity for the different reagents:
The chemical structure of the different reagents don't indicate any carcinogenic effects.

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

Developmental toxicity
Assessment of teratogenicity for the different reagents:
The chemical structure of the different reagents don'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)
Based on available information an organ specific toxicity is not expected for the different reagents.

Information on likely routes of exposure: Skin, lungs and gastrointestinal tract.
Symptoms:

Inhalation:	May cause irritation.
Skin:	May cause irritation with redness.
Eyes:	May cause irritation with redness and pain.
Ingestion:	May cause irritation to the mouth, throat and gastrointestinal tract.
Chronic effects:	None known.

12. ECOLOGICAL INFORMATION

12.1 Toxicity

12.1.1 Acute toxicity in the aquatic environment of DMSO

Test	Value/unit (mg/l)	Test method	Datasource	Species
Fish LC_{50}, 96h	37000 - 37000 mg/l	Static (FW)	IUCLID	Oncorhynchus mykiss
Daphnia EC_{50}, 24h	7000	No info. (FW)	IUCLID	Daphnia sp.
Algae EC_{50}, 96h	12350-25500	No info (FW)	IUCLID	Skeletonema costatum

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	-

12.5 Results of PBT and vPvB assessment

The substance is not considered PBT/vPvB according to criteria in Annex XIII.

12.6 Other adverse effects

None known.

13. DISPOSAL CONSIDERATIONS

13.1 Waste treatment methods

Biological agents are considered hazardous waste. Observe local regulations.

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

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	(Absorbents, filter materials, wiping cloths, protective clothing).

Packaging

Method of disposal	Incineration. (Contaminated packaging material – see above)
Special precautions	None.

14. TRANSPORT INFORMATION

Product classified as dangerous goods: ☐ Yes ☒ No ☐ Not decided

	ADR/RID	ADN/ADNR	IMDG	IATA
14.1 UN number	Not regulated	Not regulated	Not regulated	Not regulated
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	Not available	Not available	Not available	Not available
Additional information	Waste containing used biological agents may be considered as dangerous goods; **UN 3291, Class 6.2 – CLINICAL WASTE, UNSPECIFIED, N.O.S, or (BIO) MEDICAL WASTE N.O.S. or REGULATED MEDICAL WASTE, N.O.S.**			

14.7 Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code
Not applicable

15. REGULATORY INFORMATION

15.1 Safety, health and environmental regulations/legislation specific for the substance or mixture

Directive 2009/41/EC on the contained use of genetically modified micro-organisms (Recast)
Directive 2000/54/EC - biological agents at work.
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.

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

15.2 Chemical Safety Assessment

No CSR has been issued.

16. OTHER INFORMATION

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

LIST OF HAZARD STATEMENTS MENTIONED UNDER SECTION 3
None.

Abbreviations:
CMR = Carcinogenicy, Mutagenicity and Reproduction toxicity.
CSR = Chemical Safety Report
DNEL = Derived No-Effect Level
EC50 = Half maximal effective concentration
FW = Fresh Water (Färskvatten)
LC50 = Lethal Concentration 50 %
LD50 = Lethal Dose 50 %
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

Training advice:
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.

Changes since the previous edition:
Not relevant.

Disclaimer: The above information is based on data available to us and is believed to be correct. Since the information may be applied under conditions beyond our control and with which we may be unfamiliar, we do not assume any responsibility for the results of its use and all persons receiving it must make their own determination of the effects, properties, protections and disposal which pertain to their particular conditions. No representation, warranty, or guarantee, express or implied (including a warranty of fitness or merchantability for a particular purpose), is made with respect to the materials, the accuracy of this information, the results to be obtained from the use thereof, or the hazards connected with the use of the material. Caution should be used in the handling and use of the material. The above information is offered in good faith and with the belief that it is accurate. As of the date of issuance, we are providing all information relevant to the foreseeable handling of the material. However, in the event of an adverse incident associated with this product, this Safety Data Sheet is not, and is not intended to be, a substitute for consultation with appropriately trained personnel.

Revision(s)

Version	Valid from (date)	Changes
00 EN	July 27th, 2016	New SDS according to Regulation (EC) No. 1907/2006 (REACH), Annex II.
01 EN	November 24th, 2016	Six new products have been added to section 1.1. Information regarding mixture content has been revised under section 3.2. Storage information under section 7.2 has been revised.