

SAFETY DATA SHEET

SIEMENS

Immulite® Cytokine Control Module

MSDS no. :

LILCM

SECTION 1: Identification of the substance/mixture and of the company/undertaking

1.1 Product identifier

Product name : Immulite® Cytokine Control Module
Product code : LILCM, LILCM(D), 10385291, 10385389
Product description : Not available.

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

Not applicable.

1.3 Company/undertaking identification

Manufactured/supplied : Siemens Healthcare Diagnostics Limited
Sir William Siemens Square
Newton House
Camberley
Frimley
Surrey
GU16 8QD
UK

Phone: +44 (0) 1276 696000
Fax: +44 (0)1276 696133

e-mail address of person responsible for this SDS : dx.msds.healthcare@siemens.com

1.4 Emergency telephone number

: Poison Control:
In England and Wales:
NHS Direct – 0845 4647 or 111
In Scotland: NHS 24 – 08454 24 24 24
In the Republic of Ireland: 01 809 2166

CHEMTREC: 0870-8200418 (UK only)
00 + 1 + 703-527-3887 (UK & Ireland)
(International calls to the United Kingdom)

SECTION 1: Identification of the substance/mixture and of the company/undertaking

SECTION 2: Hazards identification

2.1 Classification of the substance or mixture

Product definition	: Immulate® Cytokine Controls	Mixture
<u>Classification according to Regulation (EC) No. 1272/2008 [CLP/GHS]</u>	Immulate® Cytokine Controls LONG-TERM AQUATIC HAZARD Immulate® Cytokine Controls	Category 3 The product is classified as hazardous according to Regulation (EC) 1272/2008 as amended.
Ingredients of unknown toxicity	: Immulate® Cytokine Controls	
Ingredients of unknown ecotoxicity	: Immulate® Cytokine Controls	
<u>Classification according to Directive 1999/45/EC [DPD]</u>	Immulate® Cytokine Controls	The product is not classified as dangerous according to Directive 1999/45/EC and its amendments.
Classification	: Immulate® Cytokine Controls	Not classified.
Physical/chemical hazards	: Immulate® Cytokine Controls	Not applicable.
Human health hazards	: Immulate® Cytokine Controls	Not applicable.
Environmental hazards	: Immulate® Cytokine Controls	Not applicable.

See Section 16 for the full text of the R phrases or H statements declared above.

See Section 11 for more detailed information on health effects and symptoms.

2.2 Label elements

Signal word	: Immulate® Cytokine Controls	No signal word.
Hazard statements	: Immulate® Cytokine Controls	H412 - Harmful to aquatic life with long lasting effects.
<u>Precautionary statements</u>		
Prevention	: Immulate® Cytokine Controls	P273 - Avoid release to the environment.
Response	: Immulate® Cytokine Controls	Not applicable.
Storage	: Immulate® Cytokine Controls	Not applicable.
Disposal	: Immulate® Cytokine Controls	P501 - Dispose of contents and container in accordance with all local, regional, and national regulations.
	:	
Supplemental label elements	: Immulate® Cytokine Controls	Not applicable.
Annex XVII - Restrictions on the manufacture, placing on the market and use of certain dangerous substances, mixtures and articles	: Immulate® Cytokine Controls	Not applicable.

2.3 Other hazards

Immulite® Cytokine Control Module

SECTION 2: Hazards identification

Other hazards which do not result in classification : Immulite® Cytokine Controls None known.

Additional information : Potentially biohazardous material.
Not available.

SECTION 3: Composition/information on ingredients

Substance/mixture : Immulite® Cytokine Controls Mixture

Product/ingredient name	Identifiers	%	Classification		Type
			67/548/EEC	Regulation (EC) No. 1272/2008 [CLP]	
Immulite® Cytokine Controls 2-methyl-2H-isothiazol-3-one	EC: 220-239-6 CAS: 2682-20-4	<0.1	Xn; R20/22 C; R34 R43 N; R50	Acute Tox. 3, H301 Acute Tox. 3, H311 Skin Corr. 1B, H314 Skin Sens. 1, H317 STOT SE 3, H335 Aquatic Acute 1, H400 Aquatic Chronic 1, H410	[1]
			See Section 16 for the full text of the R-phrases declared above.	See Section 16 for the full text of the H statements declared above.	

There are no additional ingredients present which, within the current knowledge of the supplier and in the concentrations applicable, are classified as hazardous to health or the environment, are PBTs or vPvBs or have been assigned a workplace exposure limit and hence require reporting in this section.

Type

- [1] Substance classified with a health or environmental hazard
- [2] Substance with a workplace exposure limit
- [3] Substance meets the criteria for PBT according to Regulation (EC) No. 1907/2006, Annex XIII
- [4] Substance meets the criteria for vPvB according to Regulation (EC) No. 1907/2006, Annex XIII
- [5] Substance of equivalent concern

Occupational exposure limits, if available, are listed in Section 8.

SECTION 4: First aid measures

4.1 Description of first aid measures

Eye contact : Immulite® Cytokine Controls Immediately flush eyes with plenty of water, occasionally lifting the upper and lower eyelids. Check for and remove any contact lenses. Continue to rinse for at least 10 minutes. Get medical attention if irritation occurs.

Inhalation : Immulite® Cytokine Controls Remove victim to fresh air and keep at rest in a position comfortable for breathing. If not breathing, if breathing is irregular or if respiratory arrest occurs, provide artificial respiration or oxygen by trained personnel. It may be dangerous to the person providing aid to give mouth-to-mouth resuscitation. Get medical attention if adverse health

SECTION 4: First aid measures

effects persist or are severe. If unconscious, place in recovery position and get medical attention immediately. Maintain an open airway. Loosen tight clothing such as a collar, tie, belt or waistband.

Flush contaminated skin with plenty of water. Remove contaminated clothing and shoes. Get medical attention if symptoms occur. Wash clothing before reuse. Clean shoes thoroughly before reuse.

Wash out mouth with water. Remove dentures if any. Remove victim to fresh air and keep at rest in a position comfortable for breathing. If material has been swallowed and the exposed person is conscious, give small quantities of water to drink. Stop if the exposed person feels sick as vomiting may be dangerous. Do not induce vomiting unless directed to do so by medical personnel. If vomiting occurs, the head should be kept low so that vomit does not enter the lungs. Get medical attention if adverse health effects persist or are severe. Never give anything by mouth to an unconscious person. If unconscious, place in recovery position and get medical attention immediately. Maintain an open airway. Loosen tight clothing such as a collar, tie, belt or waistband.

No action shall be taken involving any personal risk or without suitable training. It may be dangerous to the person providing aid to give mouth-to-mouth resuscitation.

Skin contact : Immulate® Cytokine Controls

Ingestion : Immulate® Cytokine Controls

Protection of first-aiders : Immulate® Cytokine Controls

4.2 Most important symptoms and effects, both acute and delayed

Potential acute health effects

Eye contact : Immulate® Cytokine Controls

No known significant effects or critical hazards.

Inhalation : Immulate® Cytokine Controls

No known significant effects or critical hazards.

Skin contact : Immulate® Cytokine Controls

No known significant effects or critical hazards.

Ingestion : Immulate® Cytokine Controls

No known significant effects or critical hazards.

Over-exposure signs/symptoms

Eye contact : Immulate® Cytokine Controls

No specific data.

Inhalation : Immulate® Cytokine Controls

No specific data.

Skin contact : Immulate® Cytokine Controls

No specific data.

Ingestion : Immulate® Cytokine Controls

No specific data.

4.3 Indication of any immediate medical attention and special treatment needed

SECTION 4: First aid measures

- Notes to physician** : Immulite® Cytokine Controls Treat symptomatically. Contact poison treatment specialist immediately if large quantities have been ingested or inhaled.
- Specific treatments** : Immulite® Cytokine Controls No specific treatment.

SECTION 5: Firefighting measures

5.1 Extinguishing media

- Suitable extinguishing media** : Use dry chemical, CO₂, water spray (fog) or foam.
- Unsuitable extinguishing media** : None known.

5.2 Special hazards arising from the substance or mixture

- Hazards from the substance or mixture** : In a fire or if heated, a pressure increase will occur and the container may burst. This material is harmful to aquatic life with long lasting effects. Fire water contaminated with this material must be contained and prevented from being discharged to any waterway, sewer or drain.
- Hazardous thermal decomposition products** : No specific data.

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.

SECTION 6: Accidental release measures

6.1 Personal precautions, protective equipment and emergency procedures

- For non-emergency personnel** : 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. Avoid breathing vapour or mist. Provide adequate ventilation. Wear appropriate respirator when ventilation is inadequate. Put on appropriate personal protective equipment.
- For emergency responders** : If specialised clothing is required to deal with the spillage, take note of any information in Section 8 on suitable and unsuitable materials. See also the information in "For non-emergency personnel".

6.2 Environmental precautions

- : Avoid dispersal of spilt material and runoff and contact with soil, waterways, drains and sewers. Inform the relevant authorities if the product has caused environmental pollution (sewers, waterways, soil or air). Water polluting material. May be harmful to the environment if released in large quantities.

6.3 Methods and materials for containment and cleaning up

- Small spill** : Stop leak if without risk. Move containers from spill area. Dilute with water and mop up if water-soluble. Alternatively, or if water-insoluble, absorb with an inert dry material and place in an appropriate waste disposal container. Dispose of via a licensed waste disposal contractor.

SECTION 6: Accidental release measures

- Large spill** : Stop leak if without risk. Move containers from spill area. Approach the release from upwind. Prevent entry into sewers, water courses, basements or confined areas. Wash spillages into an effluent treatment plant or proceed as follows. Contain and collect spillage with non-combustible, absorbent material e.g. sand, earth, vermiculite or diatomaceous earth and place in container for disposal according to local regulations. Dispose of via a licensed waste disposal contractor. Contaminated absorbent material may pose the same hazard as the spilt product.
- 6.4 Reference to other sections** : See Section 1 for emergency contact information.
See Section 8 for information on appropriate personal protective equipment.
See Section 13 for additional waste treatment information.

SECTION 7: Handling and storage

The information in this section contains generic advice and guidance. The list of Identified Uses in Section 1 should be consulted for any available use-specific information provided in the Exposure Scenario(s).

7.1 Precautions for safe handling

- Protective measures** : Put on appropriate personal protective equipment (see Section 8). Do not ingest. Avoid contact with eyes, skin and clothing. Avoid breathing vapour or mist. Avoid release to the environment. Keep in the original container or an approved alternative made from a compatible material, kept tightly closed when not in use. Empty containers retain product residue and can be hazardous. Do not reuse container.
- Advice on general occupational hygiene** : Eating, drinking and smoking should be prohibited in areas where this material is handled, stored and processed. Workers should wash hands and face before eating, drinking and smoking. Remove contaminated clothing and protective equipment before entering eating areas. See also Section 8 for additional information on hygiene measures.

7.2 Conditions for safe storage, including any incompatibilities

Store in accordance with local regulations. Store in original container protected from direct sunlight in a dry, cool and well-ventilated area, away from incompatible materials (see Section 10) and food and drink. Keep container tightly closed and sealed until ready for use. Containers that have been opened must be carefully resealed and kept upright to prevent leakage. Do not store in unlabelled containers. Use appropriate containment to avoid environmental contamination.

7.3 Specific end use(s)

- Recommendations** : Not available.
- Industrial sector specific solutions** : Not available.

SECTION 8: Exposure controls/personal protection

The information in this section contains generic advice and guidance. Information is provided based on typical anticipated uses of the product. Additional measures might be required for bulk handling or other uses that could significantly increase worker or exposure or environmental releases.

8.1 Control parameters

Occupational exposure limits
No exposure limit value known.

- Recommended monitoring procedures** : If this product contains ingredients with exposure limits, personal, workplace atmosphere or biological monitoring may be required to determine the effectiveness of the ventilation or other control measures and/or the necessity to use respiratory protective equipment. Reference should be made to monitoring standards, such as the following: European Standard EN 689 (Workplace atmospheres - Guidance for the assessment of exposure by inhalation to chemical agents for comparison with limit values and measurement strategy) European Standard EN 14042 (Workplace atmospheres - Guide for the application and use of procedures for the assessment

SECTION 8: Exposure controls/personal protection

of exposure to chemical and biological agents) European Standard EN 482 (Workplace atmospheres - General requirements for the performance of procedures for the measurement of chemical agents) Reference to national guidance documents for methods for the determination of hazardous substances will also be required.

DNELs/DMELs

No DNELs/DMELs available.

PNECs

No PNECs available

8.2 Exposure controls

Appropriate engineering controls : Good general ventilation should be sufficient to control worker exposure to airborne contaminants.

Individual protection measures

Hygiene measures : Wash hands, forearms and face thoroughly after handling chemical products, before eating, 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.

Eye/face protection : Safety eyewear complying with an approved standard should be used when a risk assessment indicates this is necessary to avoid exposure to liquid splashes, mists, gases or dusts. If contact is possible, the following protection should be worn, unless the assessment indicates a higher degree of protection: safety glasses with side-shields.

Skin protection

Hand protection : Chemical-resistant, impervious gloves complying with an approved standard should be worn at all times when handling chemical products if a risk assessment indicates this is necessary. Considering the parameters specified by the glove manufacturer, check during use that the gloves are still retaining their protective properties. It should be noted that the time to breakthrough for any glove material may be different for different glove manufacturers. In the case of mixtures, consisting of several substances, the protection time of the gloves cannot be accurately estimated.

Body protection : Personal protective equipment for the body should be selected based on the task being performed and the risks involved and should be approved by a specialist before handling this product.

Other skin protection : Appropriate footwear and any additional skin protection measures should be selected based on the task being performed and the risks involved and should be approved by a specialist before handling this product.

Respiratory protection : Use a properly fitted, air-purifying or air-fed respirator complying with an approved standard if a risk assessment indicates this is necessary. Respirator selection must be based on known or anticipated exposure levels, the hazards of the product and the safe working limits of the selected respirator.

Environmental exposure controls : Emissions from ventilation or work process equipment should be checked to ensure they comply with the requirements of environmental protection legislation. In some cases, fume scrubbers, filters or engineering modifications to the process equipment will be necessary to reduce emissions to acceptable levels.

SECTION 9: Physical and chemical properties

9.1 Information on basic physical and chemical properties

Appearance

Physical state	: Immulite® Cytokine Controls	Solid.
Colour	: Immulite® Cytokine Controls	Off-white.
Odour	: Immulite® Cytokine Controls	Odourless.
pH	: Immulite® Cytokine Controls	Not applicable.
Melting point/freezing point	: Immulite® Cytokine Controls	Not available.
Initial boiling point and boiling range	: Immulite® Cytokine Controls	Not available.
Flash point	: Immulite® Cytokine Controls	Not available.
Evaporation rate	: Immulite® Cytokine Controls	Not available.
Flammability (solid, gas)	: Immulite® Cytokine Controls	Not available.
Burning time	: Immulite® Cytokine Controls	Not available.
Burning rate	: Immulite® Cytokine Controls	Not available.
Upper/lower flammability or explosive limits	: Immulite® Cytokine Controls	Not available.
Vapour pressure	: Immulite® Cytokine Controls	Not available.
Solubility in water	: Immulite® Cytokine Controls	Not available.
Partition coefficient: n-octanol/water	: Immulite® Cytokine Controls	Not available.
Auto-ignition temperature	: Immulite® Cytokine Controls	Not available.
Decomposition temperature	: Immulite® Cytokine Controls	Not available.
Viscosity	: Immulite® Cytokine Controls	Not available.
Explosive properties	: Immulite® Cytokine Controls	Not available.
Oxidising properties	: Immulite® Cytokine Controls	Not available.

9.2 Other information

SADT	: Not available.
Aerosol product	
Type of aerosol	: Not applicable.
Heat of combustion	: Not available.
Ignition distance	: Not applicable.
Enclosed space ignition - Time equivalent	: Not applicable.
Enclosed space ignition - Deflagration density	: Not applicable.
Flame height	: Not applicable.
Flame duration	: Not applicable.

SECTION 10: Stability and reactivity

10.1 Reactivity	: Immulite® Cytokine Controls	No specific test data related to reactivity available for this product or its ingredients.
10.2 Chemical stability	: Immulite® Cytokine Controls	The product is stable.

SECTION 10: Stability and reactivity

10.3 Possibility of hazardous reactions	: Immulite® Cytokine Controls	Under normal conditions of storage and use, hazardous reactions will not occur.
10.4 Conditions to avoid	: Immulite® Cytokine Controls	No specific data.
10.5 Incompatible materials	: Immulite® Cytokine Controls	No specific data.
10.6 Hazardous decomposition products	: Immulite® Cytokine Controls	Under normal conditions of storage and use, hazardous decomposition products should not be produced.

SECTION 11: Toxicological information

11.1 Information on toxicological effects

Acute toxicity

Conclusion/Summary : Immulite® Cytokine Controls Not available.

Acute toxicity estimates

Not available.

Irritation/Corrosion

Conclusion/Summary

Skin : Immulite® Cytokine Controls Not available.

Eyes : Immulite® Cytokine Controls Not available.

Respiratory : Immulite® Cytokine Controls Not available.

Sensitisation

Conclusion/Summary

Skin : Immulite® Cytokine Controls Not available.

Respiratory : Immulite® Cytokine Controls Not available.

Mutagenicity

Conclusion/Summary : Immulite® Cytokine Controls Not available.

Carcinogenicity

Conclusion/Summary : Immulite® Cytokine Controls Not available.

Reproductive toxicity

Conclusion/Summary : Immulite® Cytokine Controls Not available.

Teratogenicity

Conclusion/Summary : Immulite® Cytokine Controls Not available.

Specific target organ toxicity (single exposure)

Product/ingredient name	Category	Route of exposure	Target organs
Immulite® Cytokine Controls 2-methyl-2H-isothiazol-3-one	Category 3	Not applicable.	Respiratory tract irritation

Specific target organ toxicity (repeated exposure)

Not available.

Aspiration hazard

Not available.

Information on the likely routes of exposure : Not available.

SECTION 11: Toxicological information

Potential acute health effects

Eye contact	: Immulate® Cytokine Controls	No known significant effects or critical hazards.
Inhalation	: Immulate® Cytokine Controls	No known significant effects or critical hazards.
Skin contact	: Immulate® Cytokine Controls	No known significant effects or critical hazards.
Ingestion	: Immulate® Cytokine Controls	No known significant effects or critical hazards.

Symptoms related to the physical, chemical and toxicological characteristics

Eye contact	: Immulate® Cytokine Controls	No specific data.
Inhalation	: Immulate® Cytokine Controls	No specific data.
Skin contact	: Immulate® Cytokine Controls	No specific data.
Ingestion	: Immulate® Cytokine Controls	No specific data.

Delayed and immediate effects and also chronic effects from short and long term exposure

Short term exposure

Potential immediate effects	: Immulate® Cytokine Controls	Not available.
Potential delayed effects	: Immulate® Cytokine Controls	Not available.

Long term exposure

Potential immediate effects	: Immulate® Cytokine Controls	Not available.
Potential delayed effects	: Immulate® Cytokine Controls	Not available.

Potential chronic health effects

Not available.

Conclusion/Summary	: Immulate® Cytokine Controls	Not available.
General	: Immulate® Cytokine Controls	No known significant effects or critical hazards.
Carcinogenicity	: Immulate® Cytokine Controls	No known significant effects or critical hazards.
Mutagenicity	: Immulate® Cytokine Controls	No known significant effects or critical hazards.
Teratogenicity	: Immulate® Cytokine Controls	No known significant effects or critical hazards.
Developmental effects	: Immulate® Cytokine Controls	No known significant effects or critical hazards.
Fertility effects	: Immulate® Cytokine Controls	No known significant effects or critical hazards.
Interactive effects	:	
Other information	: Not available.	

SECTION 12: Ecological information

12.1 Toxicity

Product/ingredient name	Result	Species	Exposure
Immulite® Cytokine Controls 2-methyl-2H-isothiazol-3-one	Acute EC50 0.18 ppm Fresh water Acute LC50 0.07 ppm Fresh water	Daphnia - Daphnia magna Fish - Oncorhynchus mykiss	48 hours 96 hours

Conclusion/Summary : Immulite® Cytokine Controls Not available.

12.2 Persistence and degradability

Conclusion/Summary : Immulite® Cytokine Controls Not available.

12.3 Bioaccumulative potential

Not available.

12.4 Mobility in soil

Soil/water partition coefficient (K_{oc}) : Immulite® Cytokine Controls Not available.

Mobility : Immulite® Cytokine Controls Not available.

12.5 Results of PBT and vPvB assessment

PBT : Immulite® Cytokine Controls Not applicable.

vPvB : Immulite® Cytokine Controls Not applicable.

12.6 Other adverse effects : Immulite® Cytokine Controls No known significant effects or critical hazards.

SECTION 13: Disposal considerations

The information in this section contains generic advice and guidance. The list of Identified Uses in Section 1 should be consulted for any available use-specific information provided in the Exposure Scenario(s).

13.1 Waste treatment methods

Product

Methods of disposal : The generation of waste should be avoided or minimised wherever possible. Disposal of this product, solutions and any by-products should at all times comply with the requirements of environmental protection and waste disposal legislation and any regional local authority requirements. Dispose of surplus and non-recyclable products via a licensed waste disposal contractor. Waste should not be disposed of untreated to the sewer unless fully compliant with the requirements of all authorities with jurisdiction.

Hazardous waste : Immulite® Cytokine Controls The classification of the product may meet the criteria for a hazardous waste.
Not available.

Packaging

Methods of disposal : The generation of waste should be avoided or minimised wherever possible. Waste packaging should be recycled. Incineration or landfill should only be considered when recycling is not feasible.

Special precautions : This material and its container must be disposed of in a safe way. Care should be taken when handling emptied containers that have not been cleaned or rinsed out. Empty containers or liners may retain some product residues. Avoid dispersal of spilt material and runoff and contact with soil, waterways, drains and sewers.

SECTION 14: Transport information

ADR/RID

14.1 UN number	Immulate® Cytokine Controls	Not regulated.
14.2 UN proper shipping name	Immulate® Cytokine Controls	-
14.3 Transport hazard class(es)	Immulate® Cytokine Controls	-
14.4 Packing group	Immulate® Cytokine Controls	-
14.5 Environmental hazards	Immulate® Cytokine Controls	No.
Additional information	Immulate® Cytokine Controls	-

ADN

14.1 UN number	Immulate® Cytokine Controls	Not regulated.
14.2 UN proper shipping name	Immulate® Cytokine Controls	-
14.3 Transport hazard class(es)	Immulate® Cytokine Controls	-
14.4 Packing group	Immulate® Cytokine Controls	-
14.5 Environmental hazards	Immulate® Cytokine Controls	No.
Additional information	Immulate® Cytokine Controls	-

IMDG

14.1 UN number	Immulate® Cytokine Controls	Not regulated.
14.2 UN proper shipping name	Immulate® Cytokine Controls	-
14.3 Transport hazard class(es)	Immulate® Cytokine Controls	-
14.4 Packing group	Immulate® Cytokine Controls	-
14.5 Environmental hazards	Immulate® Cytokine Controls	No.
Additional information	Immulate® Cytokine Controls	-

Immulite® Cytokine Control Module

SECTION 14: Transport information

IATA

14.1 UN number	Immulite® Cytokine Controls	Not regulated.
14.2 UN proper shipping name	Immulite® Cytokine Controls	-
14.3 Transport hazard class(es)	Immulite® Cytokine Controls	-
14.4 Packing group	Immulite® Cytokine Controls	-
14.5 Environmental hazards	Immulite® Cytokine Controls	No.
Additional information	Immulite® Cytokine Controls	-
14.6 Special precautions for user	: Immulite® Cytokine Controls	Transport within user's premises: always transport in closed containers that are upright and secure. Ensure that persons transporting the product know what to do in the event of an accident or spillage.
14.7 Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code	: Not available.	

SECTION 15: Regulatory information

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

EU Regulation (EC) No. 1907/2006 (REACH)

Annex XIV - List of substances subject to authorisation

Annex XIV

None of the components are listed.

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 : Immulite® Cytokine Controls Not applicable.

Other EU regulations

Europe inventory : Not determined.

Seveso II Directive

Immulite® Cytokine Controls This product is not controlled under the Seveso II Directive.

International regulations

Immulite® Cytokine Control Module

SECTION 15: Regulatory information

Chemical Weapons Convention List Schedule I Chemicals	: Immulite® Cytokine Controls	Not listed
Chemical Weapons Convention List Schedule II Chemicals	: Immulite® Cytokine Controls	Not listed
Chemical Weapons Convention List Schedule III Chemicals	: Immulite® Cytokine Controls	Not listed

15.2 Chemical Safety Assessment : Not applicable.

SECTION 16: Other information

Abbreviations and acronyms : ATE = Acute Toxicity Estimate
 CLP = Classification, Labelling and Packaging Regulation [Regulation (EC) No. 1272/2008]
 DMEL = Derived Minimal Effect Level
 DNEL = Derived No Effect Level
 EUH statement = CLP-specific Hazard statement
 PBT = Persistent, Bioaccumulative and Toxic
 PNEC = Predicted No Effect Concentration
 RRN = REACH Registration Number
 vPvB = Very Persistent and Very Bioaccumulative

Immulite® Cytokine Controls Aquatic Chronic 3, H412		Calculation method
Full text of abbreviated H statements	: Immulite® Cytokine Controls H301 H311 H314 H317 H335 H400 H410 H412	Toxic if swallowed. Toxic in contact with skin. Causes severe skin burns and eye damage. May cause an allergic skin reaction. May cause respiratory irritation. Very toxic to aquatic life. Very toxic to aquatic life with long lasting effects. Harmful to aquatic life with long lasting effects.
Full text of classifications [CLP/GHS]	: Immulite® Cytokine Controls Acute Tox. 3, H301 Acute Tox. 3, H311 Aquatic Acute 1, H400 Aquatic Chronic 1, H410 Aquatic Chronic 3, H412 Skin Corr. 1B, H314 Skin Sens. 1, H317 STOT SE 3, H335	ACUTE TOXICITY: ORAL - Category 3 ACUTE TOXICITY: SKIN - Category 3 ACUTE AQUATIC HAZARD - Category 1 LONG-TERM AQUATIC HAZARD - Category 1 LONG-TERM AQUATIC HAZARD - Category 3 SKIN CORROSION/IRRITATION - Category 1B SKIN SENSITIZATION - Category 1 SPECIFIC TARGET ORGAN TOXICITY (SINGLE EXPOSURE) [Respiratory tract irritation] - Category 3
Full text of abbreviated R phrases	: R20/22- Harmful by inhalation and if swallowed. R34- Causes burns. R43- May cause sensitisation by skin contact. R50- Very toxic to aquatic organisms.	
Full text of classifications [DSD/DPD]	: C - Corrosive Xn - Harmful N - Dangerous for the environment	

SECTION 16: Other information

Date of printing : 1/15/2016.

Date of issue/ Date of revision : 1/15/2016.

Date of previous issue : 5/7/2015.

Version : 1.02

Notice to reader

To the best of our knowledge, the information contained herein is accurate. However, neither the above-named supplier, nor any of its subsidiaries, assumes any liability whatsoever for the accuracy or completeness of the information contained herein.

Final determination of suitability of any material is the sole responsibility of the user. All materials may present unknown hazards and should be used with caution. Although certain hazards are described herein, we cannot guarantee that these are the only hazards that exist.