

SAFETY DATA SHEET

SIEMENS

Immulite® Thyroglobulin Control Module

MSDS no. : LTYCM

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

1.1 Product identifier

Product name : Immulite® Thyroglobulin Control Module
Product code : LTYCM, 10385246, 10385247
Product description : Not available.
Product type : Solid.
Other means of identification : Immulite® Thyroglobulin Controls LTYC1-3

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 2: Hazards identification

2.1 Classification of the substance or mixture


Product definition	: Immulite® Thyroglobulin Controls	Mixture
<u>Classification according to Directive 1999/45/EC [DPD]</u>		
	Immulite® Thyroglobulin Controls	The product is classified as dangerous according to Directive 1999/45/EC and its amendments.
Classification	: Immulite® Thyroglobulin Controls	T; R25 R52/53
Physical/chemical hazards	: Immulite® Thyroglobulin Controls	Not applicable.
Human health hazards	: Immulite® Thyroglobulin Controls	Toxic if swallowed.
Environmental hazards	: Immulite® Thyroglobulin Controls	Harmful to aquatic organisms, may cause long-term adverse effects in the aquatic environment.

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

Precautionary statements

Hazard symbol or symbols : 

Indication of danger	: Toxic	
Risk phrases	: Immulite® Thyroglobulin Controls	R25- Toxic if swallowed. R52/53- Harmful to aquatic organisms, may cause long-term adverse effects in the aquatic environment.
Safety phrases	: Immulite® Thyroglobulin Controls	S28- After contact with skin, wash immediately with plenty of water. S45- In case of accident or if you feel unwell, seek medical advice immediately (show the label where possible).
Hazardous ingredients	: Immulite® Thyroglobulin Controls Sodium azide	
Supplemental label elements	: Not applicable.	
Annex XVII - Restrictions on the manufacture, placing on the market and use of certain dangerous substances, mixtures and articles	: Immulite® Thyroglobulin Controls	Not applicable.

2.3 Other hazards

Other hazards which do not result in classification : None known.
Potentially biohazardous material.

SECTION 3: Composition/information on ingredients

Substance/mixture : Immulite® Thyroglobulin Controls Mixture

Product/ingredient name	Identifiers	%	Classification		Type
			67/548/EEC	Regulation (EC) No. 1272/2008 [CLP]	
Immulite® Thyroglobulin Controls sodium azide	EC: 247-852-1 CAS: 26628-22-8 Index: 011-004-00-7	>=1, <2.5	T+; R28 R32 N; R50/53 See Section 16 for the full text of the R-phrases declared above.	Acute Tox. 2, H300 Acute Tox. 1, H310 Aquatic Acute 1, H400 Aquatic Chronic 1, H410 See Section 16 for the full text of the H statements declared above.	[1] [2]

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® Thyroglobulin 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® Thyroglobulin Controls

Get medical attention immediately. 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. 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. In case of inhalation of decomposition products in a fire, symptoms may be delayed. The exposed person may need to be kept under medical surveillance for 48 hours.

Skin contact : Immulite® Thyroglobulin Controls

Get medical attention immediately. Flush contaminated skin with plenty of water. Remove contaminated clothing and shoes. Wash contaminated clothing thoroughly with water before removing it, or wear gloves. Continue to rinse for at least 10 minutes. Wash clothing before

SECTION 4: First aid measures

Ingestion	: Immulite® Thyroglobulin Controls	reuse. Clean shoes thoroughly before reuse. Get medical attention immediately. 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. 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.
Protection of first-aiders	: 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.	

4.2 Most important symptoms and effects, both acute and delayed

Potential acute health effects

Eye contact	: Immulite® Thyroglobulin Controls	No known significant effects or critical hazards.
Inhalation	: Immulite® Thyroglobulin Controls	Exposure to decomposition products may cause a health hazard. Serious effects may be delayed following exposure.
Skin contact	: Immulite® Thyroglobulin Controls	No known significant effects or critical hazards.
Ingestion	: Immulite® Thyroglobulin Controls	Toxic if swallowed.

Over-exposure signs/symptoms

Eye contact	: Immulite® Thyroglobulin Controls	No specific data.
Inhalation	: Immulite® Thyroglobulin Controls	No specific data.
Skin contact	: Immulite® Thyroglobulin Controls	No specific data.
Ingestion	: Immulite® Thyroglobulin Controls	No specific data.

4.3 Indication of any immediate medical attention and special treatment needed

Notes to physician	: In case of inhalation of decomposition products in a fire, symptoms may be delayed. The exposed person may need to be kept under medical surveillance for 48 hours.
Specific treatments	: No specific treatment.

SECTION 5: Firefighting measures

5.1 Extinguishing media

Suitable extinguishing media	: Use dry chemical, CO ₂ , 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	: No specific fire or explosion hazard.
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SECTION 5: Firefighting measures

Hazardous thermal decomposition products : Decomposition products may include the following materials:
nitrogen oxides
metal oxide/oxides

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. This material is harmful to aquatic organisms. Fire water contaminated with this material must be contained and prevented from being discharged to any waterway, sewer or drain.

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. 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 Section 8 for additional information on hygiene measures.

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.

6.3 Methods and materials for containment and cleaning up

Small spill : Move containers from spill area. Avoid dust generation. Do not dry sweep. Vacuum dust with equipment fitted with a HEPA filter and place in a closed, labeled waste container. Dispose of via a licensed waste disposal contractor.

Large spill : Move containers from spill area. Approach the release from upwind. Prevent entry into sewers, water courses, basements or confined areas. Avoid dust generation. Do not dry sweep. Vacuum dust with equipment fitted with a HEPA filter and place in a closed, labeled waste container. Dispose of via a licensed waste disposal contractor.

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 get in eyes or on skin or clothing. Do not ingest. 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.

SECTION 7: Handling and storage

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.

Seveso II Directive - Reporting thresholds (in tonnes)

Danger criteria

Category	Notification and MAPP threshold	Safety report threshold
Immulin® Thyroglobulin Controls C2: Toxic	50	200

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

Product/ingredient name	Exposure limit values
Immulin® Thyroglobulin Controls sodium azide	EH40/2005 WELs (United Kingdom (UK), 12/2011). Absorbed through skin. Notes: as NaN₃ STEL: 0.3 mg/m ³ , (as NaN ₃) 15 minutes. TWA: 0.1 mg/m ³ , (as NaN ₃) 8 hours.

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 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

SECTION 8: Exposure controls/personal protection

- 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 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, particulate filter 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	: Immulin® Thyroglobulin Controls	Solid.
Colour	: Immulin® Thyroglobulin Controls	Amber.
Odour	: Immulin® Thyroglobulin Controls	Odorless.
pH	: Immulin® Thyroglobulin Controls	Not applicable.
Melting point/freezing point	: Immulin® Thyroglobulin Controls	Not available.
Initial boiling point and boiling range	: Immulin® Thyroglobulin Controls	Not available.
Flash point	: Immulin® Thyroglobulin Controls	Not available.
Evaporation rate	: Immulin® Thyroglobulin Controls	Not available.
Flammability (solid, gas)	: Immulin® Thyroglobulin Controls	Not available.
Burning time	: Immulin® Thyroglobulin Controls	Not available.
Burning rate	: Immulin® Thyroglobulin Controls	Not available.
Upper/lower flammability or explosive limits	: Immulin® Thyroglobulin Controls	Not available.
Vapour pressure	: Immulin® Thyroglobulin Controls	Not available.
Solubility in water	: Immulin® Thyroglobulin Controls	Not available.
Partition coefficient: n-octanol/ water	: Immulin® Thyroglobulin Controls	Not available.
Auto-ignition temperature	: Immulin® Thyroglobulin Controls	Not available.

SECTION 9: Physical and chemical properties

Decomposition temperature	: Immulin® Thyroglobulin Controls	Not available.
Viscosity	: Immulin® Thyroglobulin Controls	Not available.
Explosive properties	: Immulin® Thyroglobulin Controls	Explosive in the presence of the following materials or conditions: metals, acids and moisture.
Oxidising properties	: Immulin® Thyroglobulin 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	: No specific test data related to reactivity available for this product or its ingredients.
10.2 Chemical stability	: The product is stable.
10.3 Possibility of hazardous reactions	: Under normal conditions of storage and use, hazardous reactions will not occur.
10.4 Conditions to avoid	: No specific data.
10.5 Incompatible materials	: No specific data.
10.6 Hazardous decomposition products	: 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

Product/ingredient name	Result	Species	Dose	Exposure
Immulin® Thyroglobulin Controls sodium azide	LD50 Dermal	Rabbit	20 mg/kg	-
	LD50 Dermal	Rat	50 mg/kg	-
	LD50 Oral	Rat	27 mg/kg	-

Conclusion/Summary : Not available.

Acute toxicity estimates

Route	ATE value
Immulin® Thyroglobulin Controls Oral Dermal	2093 mg/kg 1550.4 mg/kg

Irritation/Corrosion

SECTION 11: Toxicological information

Conclusion/Summary	:	Not available.	
<u>Sensitisation</u>			
Conclusion/Summary	:	Not available.	
<u>Mutagenicity</u>			
Conclusion/Summary	:	Not available.	
<u>Carcinogenicity</u>			
Conclusion/Summary	:	Not available.	
<u>Reproductive toxicity</u>			
Conclusion/Summary	:	Not available.	
<u>Teratogenicity</u>			
Conclusion/Summary	:	Not available.	
Information on the likely routes of exposure	:	Not available.	
<u>Potential acute health effects</u>			
Eye contact	:	Immulite® Thyroglobulin Controls	No known significant effects or critical hazards.
Inhalation	:	Immulite® Thyroglobulin Controls	Exposure to decomposition products may cause a health hazard. Serious effects may be delayed following exposure.
Skin contact	:	Immulite® Thyroglobulin Controls	No known significant effects or critical hazards.
Ingestion	:	Immulite® Thyroglobulin Controls	Toxic if swallowed.
<u>Symptoms related to the physical, chemical and toxicological characteristics</u>			
Eye contact	:	Immulite® Thyroglobulin Controls	No specific data.
Inhalation	:	Immulite® Thyroglobulin Controls	No specific data.
Skin contact	:	Immulite® Thyroglobulin Controls	No specific data.
Ingestion	:	Immulite® Thyroglobulin Controls	No specific data.
<u>Delayed and immediate effects and also chronic effects from short and long term exposure</u>			
<u>Short term exposure</u>			
Potential immediate effects	:	Immulite® Thyroglobulin Controls	Not available.
Potential delayed effects	:	Immulite® Thyroglobulin Controls	Not available.
<u>Long term exposure</u>			
Potential immediate effects	:	Immulite® Thyroglobulin Controls	Not available.
Potential delayed effects	:	Immulite® Thyroglobulin Controls	Not available.
<u>Potential chronic health effects</u>			
Not available.			
Conclusion/Summary	:	Not available.	
General	:	Immulite® Thyroglobulin Controls	No known significant effects or critical hazards.
Carcinogenicity	:	Immulite® Thyroglobulin Controls	No known significant effects or critical hazards.
Mutagenicity	:	Immulite® Thyroglobulin Controls	No known significant effects or critical hazards.
Teratogenicity	:	Immulite® Thyroglobulin Controls	No known significant effects or critical hazards.

SECTION 11: Toxicological information

- Developmental effects** : Immulite® Thyroglobulin Controls No known significant effects or critical hazards.
- Fertility effects** : Immulite® Thyroglobulin Controls No known significant effects or critical hazards.
- Other information** : Not available.

SECTION 12: Ecological information

12.1 Toxicity

Product/ingredient name	Result	Species	Exposure
Immulite® Thyroglobulin Controls sodium azide	Acute EC50 0.348 mg/l Fresh water	Algae - Pseudokirchneriella subcapitata	96 hours
	Acute EC50 4.2 to 6.2 mg/l Fresh water	Daphnia - Daphnia pulex - Larvae	48 hours
	Acute LC50 9000 µg/l Fresh water	Crustaceans - Gammarus lacustris	48 hours
	Acute LC50 0.68 mg/l Fresh water	Fish - Lepomis macrochirus	96 hours
	Chronic NOEC 5600 µg/l Marine water	Algae - Macrocystis pyrifera	96 hours

Conclusion/Summary : Not available.

12.2 Persistence and degradability

Conclusion/Summary : Not available.

12.3 Bioaccumulative potential

Not available.

12.4 Mobility in soil

Soil/water partition coefficient (K_{oc}) : Not available.

Mobility : Not available.

12.5 Results of PBT and vPvB assessment

- PBT** : Immulite® Thyroglobulin Controls Not applicable.
- vPvB** : Immulite® Thyroglobulin Controls Not applicable.

12.6 Other adverse effects : 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** : The classification of the product may meet the criteria for a hazardous waste. Sodium azide may react with lead or copper plumbing to form highly explosive metal azides.

SECTION 13: Disposal considerations

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

ADN

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

IMDG

14.1 UN number	Immulite® Thyroglobulin Controls	Not regulated.
14.2 UN proper shipping name	Immulite® Thyroglobulin Controls	-
14.3 Transport hazard class(es)	Immulite® Thyroglobulin Controls	-
14.4 Packing group	Immulite® Thyroglobulin Controls	-

SECTION 14: Transport information

14.5 Environmental hazards	Immulin® Thyroglobulin Controls	No.
Additional information	Immulin® Thyroglobulin Controls	-
IATA		
14.1 UN number	Immulin® Thyroglobulin Controls	Not regulated.
14.2 UN proper shipping name	Immulin® Thyroglobulin Controls	-
14.3 Transport hazard class(es)	Immulin® Thyroglobulin Controls	-
14.4 Packing group	Immulin® Thyroglobulin Controls	-
14.5 Environmental hazards	Immulin® Thyroglobulin Controls	No.
Additional information	Immulin® Thyroglobulin Controls	-
14.6 Special precautions for user	Immulin® Thyroglobulin 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 : Immulin® Thyroglobulin Controls Not applicable.

Other EU regulations

Europe inventory : Not determined.

Seveso II Directive

This product is controlled under the Seveso II Directive.

Danger criteria

SECTION 15: Regulatory information

Category

Immulin® Thyroglobulin Controls
C2: Toxic

15.2 Chemical Safety Assessment

: This product contains substances for which Chemical Safety Assessments are still required.

SECTION 16: Other information

Indicates information that has changed from previously issued version.

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

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

Immulin® Thyroglobulin Controls

Acute Tox. 4, H312

Aquatic Chronic 3, H412

Immulin® Thyroglobulin Controls

Acute Tox. 4, H312

Aquatic Chronic 3, H412

Calculation method

Calculation method

Full text of abbreviated H statements

: Immulin® Thyroglobulin Controls

H300

Fatal if swallowed.

H310

Fatal in contact with skin.

H312

Harmful in contact with skin.

H400

Very toxic to aquatic life.

H410

Very toxic to aquatic life with long lasting effects.

H412

Harmful to aquatic life with long lasting effects.

Full text of classifications [CLP/GHS]

: Immulin®

Thyroglobulin Controls

Acute Tox. 1, H310

ACUTE TOXICITY: SKIN - Category 1

Acute Tox. 2, H300

ACUTE TOXICITY: ORAL - Category 2

Acute Tox. 4, H312

ACUTE TOXICITY: SKIN - Category 4

Aquatic Acute 1, H400

ACUTE AQUATIC HAZARD - Category 1

Aquatic Chronic 1, H410

LONG-TERM AQUATIC HAZARD - Category 1

Aquatic Chronic 3, H412

LONG-TERM AQUATIC HAZARD - Category 3

Full text of abbreviated R phrases

: R28- Very toxic if swallowed.

R25- Toxic if swallowed.

R32- Contact with acids liberates very toxic gas.

R50/53- Very toxic to aquatic organisms, may cause long-term adverse effects in the aquatic environment.

R52/53- Harmful to aquatic organisms, may cause long-term adverse effects in the aquatic environment.

Full text of classifications [DSD/DPD]

: T+ - Very toxic

T - Toxic

N - Dangerous for the environment

Date of printing

: 2/18/2015.

Date of issue/ Date of revision

: 2/18/2015.

Date of previous issue

: No previous validation.

SECTION 16: Other information

Version : 1

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.