SAFETY DATA SHEET

SIEMENS

MSDS no.

Immulite® Thyroid Autoantibody

LAACM

1. Identification of the substance/preparation and company/undertaking

<u>Identific</u>	<u>ation of</u>	the su	<u>bstance</u>	or pre	<u>paration</u>

Product name	: Immulite® Thyroid Autoantibody
Product code	: LAACM
Product type	: Liquid.
Use of the substance/preparation	: Diagnostic Agents
	dification.

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	: dx.msds.healthcare@siemens.com

Emergency telephone number : +49 6131 - 19240; [24x7x365] (with hours of operation)

2. Hazards identification

The product is classified as dangerous according to Directive 1999/45/EC and its amendments.

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Classification	R25 2 R51/53	
Physical/chemical hazards	nulite® Autoantibodies Controls Not applicable.	
Human health hazards	nulite® Autoantibodies Controls Toxic if swallow	ved.
Environmental hazards		c organisms, may cause erse effects in the aquatic

Potentially biohazardous material.

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

3. Composition/information on ingredients

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Substance/preparation

3. Composition/information on ingredients

Ingredient name	CAS number	%	EC number	Classification
Immulite® Autoantibodies Controls Sodium azide	26628-22-8	4.04	247-852-1	T+; R28 [1] [2]
2-methyl-2H-isothiazol-3-one	2682-20-4	0.41	220-239-6	R32 N; R50/53 Xn; R20/22 [1]
				C; R34 R43 N; R50
See section 16 for the full text of the R-phrases declared above				

There are no ingredients present which, within the current knowledge of the supplier and in the concentrations applicable, are classified as hazardous to health or the environment and hence require reporting in this section.

[1] Substance classified with a health or environmental hazard

[2] Substance with a workplace exposure limit

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

4. First-aid measures

First-aid measures

Inhalation	:	Get medical attention immediately. Move exposed person to fresh air. Keep person warm and at rest. 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.
Ingestion	-	Get medical attention immediately. Wash out mouth with water. Remove dentures if any. Move exposed person to fresh air. Keep person warm and at rest. 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.
Skin contact	:	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 reuse. Clean shoes thoroughly before reuse.
Eye contact		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.

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

5. Fire-fighting measures

Extinguishing media	
Suitable	: Use dry chemical, CO ₂ , water spray (fog) or foam.
Not suitable	: None known.
Special exposure hazards	: In a fire or if heated, a pressure increase will occur and the container may burst.
	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 toxic to aquatic organisms. Fire water contaminated with this material must be contained and prevented from being discharged to any waterway, sewer or drain.
Hazardous combustion products	: Decomposition products may include the following materials: carbon dioxide carbon monoxide nitrogen oxides phosphorus oxides halogenated compounds metal oxide/oxides
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.

6. Accidental release measures

Personal precautions	:	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. Do not breathe vapour or mist. Provide adequate ventilation. Wear appropriate respirator when ventilation is inadequate. Put on appropriate personal protective equipment (see section 8).
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.
Small spill	:	Stop leak if without risk. Move containers from spill area. Dilute with water and mop up if water-soluble or absorb with an inert dry material and place in an appropriate waste disposal container. Dispose of via a licensed waste disposal contractor.

7. Handling and storage

Handling	: Put on appropriate personal protective equipment (see section 8). 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. Do not get in eyes or on skin or clothing. Do not breathe vapour or mist. Do not ingest. Avoid release to the environment. Refer to special instructions/safety data sheet. If during normal use the material presents a respiratory hazard, use only with adequate ventilation or wear appropriate respirator. Keep in the original container or an approved alternative made from a compatible material, kept tightly closed when not in use. Keep away from acids. Empty containers retain product residue and can be hazardous. Do not reuse container.
Storage	: 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. Separate from acids. 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.
Packaging materials	
Recommended	: Use original container.
Date of issue/Date of	: 7/13/2010. 3/11

8. Exposure controls/personal protection

Ingredient name	Occupational exposure limits
Immulite® Autoantibodies C	
Sodium azide	EH40/2005 WELs (United Kingdom (UK), 8/2007). Absorbed through skin. Notes: as NaN3 STEL: 0.3 mg/m ³ , (as NaN3) 15 minute(s). TWA: 0.1 mg/m ³ , (as NaN3) 8 hour(s).
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 European Standard EN 689 for methods for the assessment of exposure by inhalation to chemical agents and national guidance documents for methods for the determination of hazardous substances.
Exposure controls	
Occupational exposure controls	: If user operations generate dust, fumes, gas, vapour or mist, use process enclosures, local exhaust ventilation or other engineering controls to keep worker exposure to airborne contaminants below any recommended or statutory limits. Engineering controls may be required to control the primary or secondary risks associated with this product.
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.
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.
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.
Eye 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.
Skin 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.
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.

9. Physical and chemical properties

General information		
Appearance		
Physical state	: Immulite® Autoantibodies Controls	Solid.
Colour	: Immulite® Autoantibodies Controls	Off-white.
Important health, safety a	and environmental informatior	<u>l</u>
рН	: Immulite® Autoantibodies Controls	Not applicable.
Date of issue/Date of revision	: 7/13/2010.	4/11

9. Physical and chemical properties

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Boiling point	:	Immulite® Autoantibodies Controls	Not available.
Melting point	:	Immulite® Autoantibodies Controls	Not available.
Flash point	:	Immulite® Autoantibodies Controls	Not available.
Explosive properties	:	moisture.	e of the following materials or conditions: metals, acids and sence of the following materials or conditions: open flames, rge.
Explosion limits	:	Immulite® Autoantibodies Controls	Not available.
Vapour pressure	1	Immulite® Autoantibodies Controls	Not available.
Relative density	-	Immulite® Autoantibodies Controls	1
Octanol/water partition coefficient	1	Immulite® Autoantibodies Controls	Not available.
Viscosity	:	Immulite® Autoantibodies Controls	Not available.
Evaporation rate (butyl acetate = 1)	-	Immulite® Autoantibodies Controls	Not available.
Other information			
Auto-ignition temperature	:	Immulite® Autoantibodies Controls	Not available.

10. Stability and reactivity

Stability	The product is stable.	
Conditions to avoid	Avoid release to the environment. Refer to special instructions/safety data sheet.	
Materials to avoid	Reactive or incompatible with the following materials: acids	
Hazardous decomposition products	Contact with acids liberates very toxic gas.	

11. Toxicological information

Potential acute health effects

Inhalation		ure to decompositior e delayed following e		cause a health hazard	d. Serious effects
Ingestion	: Toxic i	if swallowed.			
Skin contact	: No kno	own significant effect	ts or critical haza	ards.	
Eye contact	: No kno	own significant effect	ts or critical haza	ards.	
Acute toxicity					
Product/ingredient name		Result	Species	Dose	Exposure
Sodium azide		LD50 Dermal	Rat	50 mg/kg	- '
		LD50 Dermal	Rabbit	20 mg/kg	-
		LD50 Intratracheal	Rat	47.5 mg/kg	-
		LD50 Intratracheal	Rat	47500 ug/kg	-
		LD50 Oral	Rat	27 mg/kg	-
		LD50 Subcutaneous	Rat	45100 ug/kg	-
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11. Toxicologica	l info	rmation					
		LD50		Rat	45 mg/kg	-	
		Subcuta		Det			
		LDLo Intraper		Rat	3 mg/kg	-	
		LDLo		Rat	30 mg/kg	-	
		Intraper	ritoneal		0.0		
Potential chronic health effe	ects						
Chronic toxicity							
Product/ingredient name Not available.		Result	\$	Species	Dose	Exp	osure
Carcinogenicity							
Product/ingredient name		Result	\$	Species	Dose	Exp	osure
Not available.							
Mutagenicity							
Product/ingredient name Not available.		Test		Expe	riment	Result	
Teratogenicity							
Product/ingredient name Not available.		Result	:	Species	Dose	Ехр	osure
Reproductive toxicity							
Product/ingredient name		Maternal toxicity	Fertility	Develop toxin	omental Species	Dose	Exposure
Not available.							
Chronic effects	: No k	nown significa	int effects o	r critical haz	ards.		
Carcinogenicity	: No k	nown significa	int effects of	r critical haz	ards.		
Mutagenicity	: No k	nown significa	int effects o	r critical haz	ards.		
Teratogenicity	: Nok	nown significa	int effects o	r critical haz	ards.		
Developmental effects	: Nok	nown significa	int effects of	r critical haz	ards.		
Fertility effects	: Nok	nown significa	int effects of	r critical haz	ards.		
Over-exposure signs/sympto	<u>oms</u>						
Inhalation	: No s	pecific data.					
Ingestion	: No s	pecific data.					
Skin	: No s	pecific data.					
Eyes	: No s	pecific data.					
Other adverse effects	: Imm Auto	ulite® antibodies Co		available.			

12. Ecological information

Environmental effects	:	Toxic to aquatic organi environment.	sms, may cause long-te	erm adverse effects	in the aquatic
Aquatic ecotoxicity					
Product/ingredient name Sodium azide		Test -	Result Acute EC50 6.4 to 8.9 mg/L Fresh water	Species Crustaceans - Water flea - Simocephalus serrulatus - LARVAE	Exposure 48 hours
		-	Acute EC50 4.2 to 6.2 mg/L	Daphnia - Water flea - Daphnia	48 hours

12. Ecological information

	-	Fresh water Acute LC50 0.8 mg/L Fresh water	trout - Oncorhynchus	96 hours
	-	Acute LC50 0.68 mg/L Fresh water	9	96 hours
	-	Acute LC50 5460 to 5870 ug/L Fresh water		96 hours
	-	Acute LC50 3920 ug/L Fresh water		96 hours
	-	Acute LC50 2840 ug/L Fresh water		96 hours
	-	Acute LC50 2750 ug/L Fresh water		96 hours
2-methyl-2H-isothiazol-3-one	-	Acute EC50 0.18 to 0.19 ppm Fresh water	Daphnia - Water flea - Daphnia magna - <24 hours	48 hours
	-	Acute LC50 0.19 to 0.31 ppm Fresh water	Fish - Rainbow trout,donaldson trout - Oncorhynchus mykiss	96 hours
	-	Acute LC50 0.3 to 0.32 ppm Fresh water	Fish - Bluegill - Lepomis macrochirus	96 hours
	-	Acute LC50 0.07 to 0.09 ppm Fresh water	Fish - Rainbow trout,donaldson trout - Oncorhynchus mykiss	96 hours
	-	Acute LC50 0.056 to 0.084 ppm Marine water	Crustaceans - Calanoid copepod - Acartia tonsa	48 hours
Conclusion/Summary <u>Biodegradability</u> Conclusion/Summary	Not available.Not available.			
Date of issue/Date of revision	: 7/13/2010.			

12. Ecological information

Other adverse effects

: No known significant effects or critical hazards.

13. Disposal considerations

Methods of disposal	:	The generation of waste should be avoided or minimised wherever possible. Empty containers or liners may retain some product residues. This material and its container must be disposed of in a safe way. Dispose of surplus and non-recyclable products via a licensed waste disposal contractor. 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. Avoid dispersal of spilt material and runoff and contact with soil, waterways, drains and sewers.
European waste catalogue (EWC)		18 01 06* chemicals consisting of or containing dangerous substances
Hazardous waste	1	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.

14. Transport information

International transport regulations

ADR/RID Class

	UN number	Immulite® Autoantibodies Controls	UN3288
	Proper shipping name	Immulite® Autoantibodies Controls	Toxic solid, inorganic, n.o.s. (Sodium azide)
	Classes	Immulite® Autoantibodies Controls	6.1
	PG*	Immulite® Autoantibodies Controls	III
	Label	×××	
	Additional information	Immulite® Autoantibodies Controls	-
<u>ADN</u>	<u>R Class</u>		
	UN number	Immulite® Autoantibodies Controls	UN3288
	Proper shipping name	Immulite® Autoantibodies Controls	Toxic solid, inorganic, n.o.s. (Sodium azide)
	Classes	Immulite® Autoantibodies Controls	6.1
	PG*	Immulite® Autoantibodies Controls	III

14. Transport information

Label Q Immulite® **Additional** information Autoantibodies Controls **IMDG Class UN number Immulite**® UN3288 Autoantibodies Controls **Proper shipping** Immulite® Toxic solid, inorganic, n.o.s. (Sodium azide) name Autoantibodies Controls **Classes** Immulite® 6.1 Autoantibodies Controls PG* Immulite® Ш Autoantibodies Controls Label **Additional** Immulite® information Autoantibodies Controls **IATA Class** Immulite® UN3288 **UN number** Autoantibodies Controls Toxic solid, inorganic, n.o.s. (Sodium azide) **Proper shipping** Immulite® name **Autoantibodies** Controls Classes Immulite® 6.1 Autoantibodies Controls PG* Immulite® Ш Autoantibodies Controls Label **Additional** Immulite® information Autoantibodies Controls

PG* : Packing group

15. Regulatory information

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EU regulations

Classification and labeling have been determined according to EU Directives 67/548/EEC and 1999/45/EC (including amendments) and take into account the intended product use.



	Toxic, Dangerous for the environment	
Risk phrases	R25- Toxic if swallowed. R32- Contact with acids liberates very toxic gas. R51/53- Toxic to aquatic organisms, may cause long-term adverse aquatic environment.	e effects in the
Safety phrases	S28- After contact with skin, wash immediately with plenty of water S35- This material and its container must be disposed of in a safe S45- In case of accident or if you feel unwell, seek medical advice (show the label where possible).	way.
Contains	Immulite® Autoantibodies Controls Sodium azide 247	7-852-1
Product use	Industrial applications.	
Europe inventory	Not determined.	

16. Other information

Full text of R-phrases referred to in sections 2 and 3 - United Kingdom (UK)	 R28- Very toxic if swallowed. R25- Toxic if swallowed. R20/22- Harmful by inhalation and if swallowed. R34- Causes burns. R43- May cause sensitisation by skin contact. R32- Contact with acids liberates very toxic gas. R50- Very toxic to aquatic organisms. R50/53- Very toxic to aquatic organisms, may cause long-term adverse effects in the aquatic environment. R51/53- Toxic to aquatic organisms, may cause long-term adverse effects in the aquatic environment.
Full text of classifications referred to in sections 2 and 3 - United Kingdom (UK)	: T+ - Very toxic T - Toxic C - Corrosive Xn - Harmful N - Dangerous for the environment
<u>History</u>	
Date of issue/Date of revision	: 7/13/2010.
Version	: 1.01
Prepared by	: Siemens Healthcare Diagnostics EHS Product Stewardship

Notice to reader

16. Other information

To the best of our knowledge, the information contained herein is accurate. However, neither the abovenamed 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.