SAFETY DATA SHEET



IMMULITE® C-Peptide Control Module

MSDS no. **PECM**

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

Identification of the substance or mixture

: IMMULITE® C-Peptide Control Module **Product name**

Product code : PECM: 10385589

Product type : Liquid.

Use of the substance/mixture : Diagnostic Agents

Company/undertaking identification

Manufactured/supplied : Siemens Healthcare Diagnostics Limited

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UK

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(with hours of operation)

Hazards identification

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

Classification : Xn; R22

R52/53

Physical/chemical hazards : C-Peptide Control Modules PEC1, PEC2 Not applicable.

& PEC3

Human health hazards : C-Peptide Control Modules PEC1, PEC2 Harmful if swallowed.

& PEC3

Environmental hazards : C-Peptide Control Modules PEC1, PEC2 Harmful to aquatic organisms, may cause

& PEC3

long-term adverse effects in the aquatic

environment.

Potentially biohazardous material.

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

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3. Composition/information on ingredients

Substance/preparation

	CAS number	%	EC number	Classification	
C-Peptide Control Modules PEC1, PEC2 & PEC3 sodium azide	26628-22-8	0.9	247-852-1	T+; R28 [1] [2] R32 N; R50/53	
See section 16 for the full text of the R-phrases 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 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

: 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. Get medical attention if adverse health 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.

Ingestion

: 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. Get medical attention. 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

: 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.

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, CO₂, 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.

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5. Fire-fighting measures

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.

Hazardous combustion products

: No specific data.

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. Avoid breathing 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.

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.

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 ingest. Avoid contact with eyes, skin and clothing. Avoid breathing vapour or mist. 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.

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. 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.

8. Exposure controls/personal protection

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Exposure controls/personal protection 8.

Ingredient name

Occupational exposure limits

C-Peptide Control Modules PEC1, PEC2 &

PEC3

sodium azide

EH40/2005 WELs (United Kingdom (UK), 1/2012). Absorbed through skin. Notes: as NaN3

STEL: 0.3 mg/m³. (as NaN3) 15 minute(s). TWA: 0.1 mg/m³, (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

: No special ventilation requirements. Good general ventilation should be sufficient to control worker exposure to airborne contaminants. If this product contains ingredients with exposure limits, use process enclosures, local exhaust ventilation or other engineering controls to keep worker exposure below any recommended or statutory limits.

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 evewash 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.

Physical and chemical properties 9.

General information

Appearance

Physical state : C-Peptide Control Modules PEC1, PEC2 &

Solid.

PFC3

Colour

: C-Peptide Control Off-white.

Modules PEC1, PEC2 &

PEC3

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9. Physical and chemical properties

Important health, safety and environmental information

pH : C-Peptide Control Not applicable.

Modules PEC1, PEC2 &

PEC3

Boiling point: C-Peptide Control Not available.

Modules PEC1, PEC2 &

PEC3

Melting point : C-Peptide Control Not available.

Modules PEC1, PEC2 &

PEC3

Flash point : C-Peptide Control Not available.

Modules PEC1, PEC2 &

PEC3

Explosion limits : C-Peptide Control Not available.

Modules PEC1, PEC2 &

PEC3

Vapour pressure : C-Peptide Control

Modules PEC1, PEC2 &

PEC3

Relative density : C-Peptide Control >

Modules PEC1, PEC2 &

PEC3

Octanol/water partition

coefficient

: C-Peptide Control

Modules PEC1, PEC2 &

PEC3

Viscosity : C-Peptide Control

Modules PEC1, PEC2 &

PEC3

Evaporation rate (butyl

acetate = 1)

: C-Peptide Control

Modules PEC1, PEC2 &

PEC3

Other information

Auto-ignition temperature

: C-Peptide Control

Not available.

Not available.

Not available.

Not available.

Not available.

Modules PEC1, PEC2 &

PEC3

10. Stability and reactivity

Stability : The product is stable.

Conditions to avoid : No specific data.

Materials to avoid : No specific data.

Hazardous decomposition

products

: Under normal conditions of storage and use, hazardous decomposition products

should not be produced.

11. Toxicological information

Potential acute health effects

Inhalation : No known significant effects or critical hazards.

Ingestion : Harmful if swallowed.

Skin contactNo known significant effects or critical hazards.Eye contactNo known significant effects or critical hazards.

Acute toxicity

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11. Toxicological information

Product/ingredient name C-Peptide Control Modules P PEC2 & PEC3	Result EC1,	Species	Dose	Exp	osure			
sodium azide	LD50 Dermal	ial Rat 50 mg/kg		-				
	LD50 Dermal	Rabbit	20 mg/kg	-				
	LD50 Intratracheal	Rat	47.5 mg/kg	-				
	LD50 Intratracheal	Rat	47500 ug/kg	j -				
	LD50 Oral	Rat	27 mg/kg	_				
	LD50 Subcutaneous	Rat	45 mg/kg	-				
	LD50 Subcutaneous	Rat	45100 ug/kg	j -				
	LDLo Intraperitoneal	Rat	30 mg/kg	-				
	LDLo Intraperitoneal	Rat	3 mg/kg	-				
Potential chronic health effects								
Chronic toxicity								
Product/ingredient name Not available.	Result	Species	Dose	Exposure				
Carcinogenicity								
Product/ingredient name Not available.	Result	Species	Dose	Exposure				
<u>Mutagenicity</u>								
Product/ingredient name Not available.	Test	Exper	Experiment		Result			
<u>Teratogenicity</u>								
Product/ingredient name Not available.	Result	Species	Dose	Exposure				
Reproductive toxicity								
Product/ingredient name	Maternal Fertili toxicity	ty Develop	mental Species	Dose	Exposure			
Not available.								
Chronic effects : No known significant effects or critical hazards.								
Carcinogenicity :	No known significant effect	ts or critical haza	ards.					

Chronic effects

: No known significant effects or critical hazards.

Carcinogenicity

: No known significant effects or critical hazards.

Mutagenicity

: No known significant effects or critical hazards.

Teratogenicity

: No known significant effects or critical hazards.

Developmental effects

: No known significant effects or critical hazards.

Fertility effects

: No known significant effects or critical hazards.

No known significant effects or critical hazards.

Over-exposure signs/symptoms

Inhalation: No specific data.Ingestion: No specific data.Skin: No specific data.Eyes: No specific data.

Other adverse effects : C-Peptide Control Modules PEC1, PEC2 Not available.

& PEC3

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12. Ecological information

Environmental effects

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

Aquatic ecotoxicity

Aquatic ecotoxicity				
Product/ingredient name C-Peptide Control Modules PEC1, PEC2 & PEC3	Test	Result	Species	Exposure
sodium azide	-	Acute EC50 6.4 to 8.9 mg/L Fresh water	Crustaceans - Water flea - Simocephalus serrulatus - Larvae - es7:k56s:7pt	48 hours
	-	Acute EC50 4.2 to 6.2 mg/L Fresh water	Daphnia - Water flea - Daphnia pulex - Larvae - es7:k56s:7pt	48 hours
	-	Acute EC50 0.348 mg/L Fresh water	Algae - Green algae - Pseudokirchneriella subcapitata	96 hours
	-	Acute EC50 9200 ug/L Marine water	Algae - Giant kelp - Macrocystis pyrifera	96 hours
	-	Acute LC50 0.8 mg/L Fresh water	Fish - Rainbow trout,donaldson trout - Oncorhynchus mykiss - 1.4 g	96 hours
	-	Acute LC50 0.68 mg/L Fresh water	Fish - Bluegill - Lepomis macrochirus - 0.6 g	96 hours
	-	Acute LC50 9000 ug/L Fresh water	Crustaceans -	48 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

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12. **Ecological information**

Chronic NOEC Algae - Giant 5600 ug/L Marine kelp -

Macrocystis water

pyrifera

96 hours

Conclusion/Summary

: Not available.

Biodegradability

Conclusion/Summary : Not available.

Other adverse effects : No known significant effects or critical hazards.

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.

Hazardous waste

: The classification of the product may meet the criteria for a hazardous waste.

European waste catalogue (EWC)

: Hazardous waste

18 01 06* chemicals consisting of or containing dangerous substances

Non-hazardous waste

18 01 07 chemicals other than those mentioned in 18 01 06

Sodium azide may react with lead or copper plumbing to form highly explosive metal azides.

Transport information 14.

International transport regulations

ADR/RID Class

C-Peptide Control Modules PEC1, PEC2 Not regulated. **UN number**

& PEC3

Proper shipping

C-Peptide Control Modules PEC1, PEC2 -

name

& PEC3

Classes

C-Peptide Control Modules PEC1, PEC2 -

& PEC3

PG*

C-Peptide Control Modules PEC1, PEC2 -

& PEC3

Label

Additional

C-Peptide Control Modules PEC1, PEC2 -

C-Peptide Control Modules PEC1, PEC2 -

& PEC3 information

ADN/ADNR Class

UN number C-Peptide Control Modules PEC1, PEC2 Not regulated.

& PEC3

Proper shipping

name & PEC3

Classes C-Peptide Control Modules PEC1, PEC2 -

& PEC3

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14. Transport information

PG* C-Peptide Control Modules PEC1, PEC2 -

& PEC3

Label

Additional C-Peptide Control Modules PEC1, PEC2 -

information & PEC3

IMDG Class

UN number C-Peptide Control Modules PEC1, PEC2 Not regulated.

& PEC3

Proper shipping C-Peptide Control Modules PEC1, PEC2 -

name & PEC3

Classes C-Peptide Control Modules PEC1, PEC2 -

& PEC3

PG* C-Peptide Control Modules PEC1, PEC2 -

& PEC3

Label

Additional C-Peptide Control Modules PEC1, PEC2 -

information & PEC3

IATA Class

UN number C-Peptide Control Modules PEC1, PEC2 Not regulated.

& PEC3

Proper shipping C-Peptide Control Modules PEC1, PEC2 -

name & PEC3

Classes C-Peptide Control Modules PEC1, PEC2 -

& PEC3

PG* C-Peptide Control Modules PEC1, PEC2 -

& PEC3

Label

Additional C-Peptide Control Modules PEC1, PEC2 -

information & PEC3

PG*: Packing group

15. Regulatory information

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.

Hazard symbol or symbols :



Harmful

Risk phrases : R22- Harmful if swallowed.

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

aquatic environment.

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 way.

Contains : C-Peptide Control Modules PEC1, PEC2 & PEC3

sodium azide 247-852-1

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Regulatory information

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. R22- Harmful 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 referred to in sections 2 and 3 - United Kingdom (UK)

: T+ - Very toxic Xn - Harmful

N - Dangerous for the environment

History

Date of issue/Date of

revision

: 1/25/2013.

Version

: 1.01

Prepared by

: Siemens Healthcare Diagnostics EHS Product Stewardship

Notice to reader

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.

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