### SAFETY DATA SHEET

SIEMENS : Healthineers :

IMMULITE® Free Beta HCG Control Module

SDS no.: LFBCM

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

1.1 Product identifier

Product name : IMMULITE® Free Beta HCG Control Module

Product code : LFBCM, 10385385

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

Identified uses Immulite® Free Beta-HCG Controls Diagnostic agents.

**Restrictions on use** For professional users only.

Supplier : Siemens Healthcare Diagnostics Limited

Park View, Watchmoor Park, Camberley, Surrey, GU15 3YL United Kingdom

Phone: +44 (0) 345 600 1955

e-mail address of person responsible for this SDS

: dx.msds.healthcare@siemens-healthineers.com

1.4 Emergency telephone number

CHEMTREC: +44 20 3807 3798

#### **SECTION 2: Hazards identification**

#### 2.1 Classification of the substance or mixture

Product definition : Immulite® Free Beta-HCG Controls Mixture

Classification according to UK CLP/GHS Immulite® Free Beta-HCG Controls

Aquatic Chronic 3, H412

The product is classified as hazardous according to UK CLP Regulation SI 2019/720 as amended.

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

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

2.2 Label elements

Signal word : Immulite® Free Beta-HCG Controls No signal word.

**Hazard statements** : Immulite® Free Beta-HCG Controls H412 - Harmful to aquatic life with long

lasting effects.

**Precautionary statements** 

**Prevention**: Immulite® Free Beta-HCG Controls P273 - Avoid release to the environment.

Response : Immulite® Free Beta-HCG Controls Not applicable.

Storage : Immulite® Free Beta-HCG Controls Not applicable.

Disposal : Immulite® Free Beta-HCG Controls P501 - Dispose of contents and

container in accordance with all local, regional, national and international

regulations.

### SECTION 2: Hazards identification

Supplemental label

elements

: Immulite® Free Beta-HCG Controls

Not applicable.

**Annex XVII - Restrictions** on the manufacture.

placing on the market and use of certain dangerous substances, mixtures and

: Immulite® Free Beta-HCG Controls

Not applicable.

articles

2.3 Other hazards

Product meets the criteria for PBT or vPvB according to Regulation (EC) No. 1907/2006, Annex XIII

: Immulite® Free Beta-HCG Controls

This mixture does not contain any substances that are assessed to be a

PBT or a vPvB.

Other hazards which do not result in classification : Immulite® Free Beta-HCG Controls

None known.

**Additional information** : Potentially biohazardous material.

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

azides.

### SECTION 3: Composition/information on ingredients

3.1 Substances : Immulite® Free Beta-HCG Controls Mixture

Product/ingredient name	Identifiers	%	Classification	Туре
Immulite® Free Beta-HCG Controls sodium azide	EC: 247-852-1 CAS: 26628-22-8 Index: 011-004-00-7	<1	Acute Tox. 2, H300 Acute Tox. 1, H310 Aquatic Acute 1, H400 (M=1) Aquatic Chronic 1, H410 (M=1)	[1] [2]
			See Section 16 for the full text of the H statements declared above.	

#### Type

- [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.

#### **SECTION 4: First aid measures**

#### 4.1 Description of first aid measures

Eye contact : Immulite® Free Beta-HCG Controls Immediately flush eyes with plenty of

water, occasionally lifting the upper and lower eyelids. Check for and remove any contact lenses. Get medical

attention if irritation occurs.

Inhalation : Immulite® Free Beta-HCG Controls Remove victim to fresh air and keep at

rest in a position comfortable for

breathing.

Skin contact : Immulite® Free Beta-HCG Controls Flush contaminated skin with plenty of

water. Remove contaminated clothing and shoes. Get medical attention if

symptoms occur.

#### **SECTION 4: First aid measures**

Ingestion : Immulite® Free Beta-HCG Controls Wash out mouth with water. If material

> has been swallowed and the exposed person is conscious, give small quantities of water to drink. Do not induce vomiting unless directed to do so

by medical personnel.

Protection of first-aiders : Immulite® Free Beta-HCG Controls No action shall be taken involving any

personal risk or without suitable training.

#### 4.2 Most important symptoms and effects, both acute and delayed

#### Over-exposure signs/symptoms

Eye contact : Immulite® Free Beta-HCG Controls No specific data. Inhalation : Immulite® Free Beta-HCG Controls No specific data. Skin contact : Immulite® Free Beta-HCG Controls No specific data. Ingestion : Immulite® Free Beta-HCG Controls No specific data.

#### 4.3 Indication of any immediate medical attention and special treatment needed

Notes to physician : Immulite® Free Beta-HCG Controls Treat symptomatically. Contact poison

> treatment specialist immediately if large quantities have been ingested or inhaled.

Specific treatments : Immulite® Free Beta-HCG Controls No specific treatment.

> Immulite® Free Beta-HCG Controls Not available.

### SECTION 5: Firefighting measures

#### 5.1 Extinguishing media

Suitable extinguishing

media

: Use an extinguishing agent suitable for the surrounding fire.

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 combustion** 

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.

### 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. Put on appropriate personal protective equipment.

#### SECTION 6: Accidental release measures

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 material 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.

#### 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 (see Section 13). Dispose of via a licensed waste disposal contractor. Contaminated absorbent material may pose the same hazard as the spilt product. Note: see Section 1 for emergency contact information and Section 13 for waste disposal.

#### 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**

#### 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

#### 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. See Section 10 for incompatible materials before handling or use.

#### 7.3 Specific end use(s)

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

Date of issue/Date of revision

: 12/13/2022

Date of previous issue

: No previous validation

Version: 1

### **SECTION 8: Exposure controls/personal protection**

#### 8.1 Control parameters

#### Occupational exposure limits

Product/ingredient name	Exposure limit values
Immulite® Free Beta-HCG Controls sodium azide	EH40/2005 WELs (United Kingdom (UK), 1/2020). Absorbed through skin.  STEL: 0.3 mg/m³, (as NaN3) 15 minutes.  TWA: 0.1 mg/m³, (as NaN3) 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 appropriate monitoring standards. Reference to national guidance documents for methods for the determination of hazardous substances will also be required.

#### **DNELs/DMELs**

Product/ingredient name	Type	Exposure	Value	Population	Effects
Immulite® Free Beta-HCG					
Controls					
sodium azide	DNEL	Long term Oral	16.7 µg/kg bw/day	General population	Systemic
	DNEL	Long term Dermal	16.7 µg/kg bw/day	General population	Systemic
	DNEL	Long term Inhalation	29 μg/m³	General population	Systemic
	DNEL	Long term Dermal	46.7 µg/kg bw/day	Workers	Systemic
	DNEL	Long term Inhalation	0.164 mg/ m <sup>3</sup>	Workers	Systemic

#### **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.

### SECTION 8: Exposure controls/personal protection

**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.

: Appropriate footwear and any additional skin protection measures should be Other skin protection

selected based on the task being performed and the risks involved and should be

approved by a specialist before handling this product.

Respiratory protection Based on the hazard and potential for exposure, select a respirator that meets the

appropriate standard or certification. Respirators must be used according to a respiratory protection program to ensure proper fitting, training, and other important

aspects of use.

**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

The conditions of measurement of all properties are at standard temperature and pressure unless otherwise indicated.

#### 9.1 Information on basic physical and chemical properties

#### **Appearance**

Physical state : Immulite® Free Beta-HCG Controls Solid. Colour : Immulite® Free Beta-HCG Controls Off-white. Odour : Immulite® Free Beta-HCG Controls Odourless. **Odour threshold** : Not relevant/applicable due to nature of the product. Melting point/freezing point : Not relevant/applicable due to nature of the product. Softening point : Not relevant/applicable due to nature of the product.

**Sublimation temperature** : Not relevant/applicable due to nature of the product.

Initial boiling point and

boiling range

: Immulite® Free Beta-HCG Controls Not available.

: Immulite® Free Beta-HCG Controls Not relevant/applicable due to nature Flammability (solid, gas)

of the product.

Upper/lower flammability or

explosive limits

: Immulite® Free Beta-HCG Controls

Not applicable.

Flash point : Immulite® Free Beta-HCG Controls [Product does not sustain combustion.]

**Decomposition temperature** 

Not relevant/applicable due to nature of the product. : Immulite® Free Beta-HCG Controls

Not applicable.

pН Immulite® Free Beta-HCG Controls **Viscosity** Not applicable.

Solubility(ies)

Not available.

Solubility in water

: Not relevant/applicable due to nature of the product.

Miscible with water

water

: Not relevant/applicable due to nature of the product. Partition coefficient: n-octanol/: Not relevant/applicable due to nature of the product.

Vapour pressure : Not available.

**Evaporation rate** : Not relevant/applicable due to nature of the product.

Immulite® Free Beta-HCG Controls Relative density

**Density** : Immulite® Free Beta-HCG Controls Not available. Not applicable. : Immulite® Free Beta-HCG Controls Vapour density : Immulite® Free Beta-HCG Controls Not available. **Explosive properties** Oxidising properties : Immulite® Free Beta-HCG Controls Not available.

**Particle characteristics** 

Median particle size : Not applicable.

Date of issue/Date of revision : 12/13/2022 Date of previous issue Version: 1 6/14 : No previous validation

### **SECTION 9: Physical and chemical properties**

#### 9.2 Other information

Fire point : Immulite® Free Beta-HCG Controls Not available. : Not relevant/applicable due to nature of the product. **Burning time Fundamental burning velocity** : Not relevant/applicable due to nature of the product. **Burning rate** : Not relevant/applicable due to nature of the product. **SADT** : Not relevant/applicable due to nature of the product. **SAPT** : Not relevant/applicable due to nature of the product. Heat of reaction : Not relevant/applicable due to nature of the product. **Heat of combustion** : Not relevant/applicable due to nature of the product. Flow time (ISO 2431) : Not relevant/applicable due to nature of the product. Molecular weight : Not relevant/applicable due to nature of the product.

### 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
Immulite® Free Beta-HCG	LD50 Dermal	Rabbit	20 mg/kg	-
Controls	LD50 Dermal	Rat	50 mg/kg	
sodium azide	LD50 Oral	Rat	27 mg/kg	

Conclusion/Summary: Immulite® Free Beta-HCG Controls Not available.

#### Acute toxicity estimates

Product/ingredient name	Oral (mg/ kg)	Dermal (mg/kg)	Inhalation (gases) (ppm)	Inhalation (vapours) (mg/l)	Inhalation (dusts and mists) (mg/l)
Immulite® Free Beta-HCG Controls Immulite® Free Beta-HCG Controls sodium azide	8437.5	6250	N/A	N/A	N/A
	27	20	N/A	N/A	N/A

#### Irritation/Corrosion

#### Conclusion/Summary

Skin: Immulite® Free Beta-HCG ControlsNot available.Eyes: Immulite® Free Beta-HCG ControlsNot available.Respiratory: Immulite® Free Beta-HCG ControlsNot available.

### **SECTION 11: Toxicological information**

**Sensitisation** 

Conclusion/Summary

Skin: Immulite® Free Beta-HCG ControlsNot available.Respiratory: Immulite® Free Beta-HCG ControlsNot available.

**Mutagenicity** 

Conclusion/Summary: Immulite® Free Beta-HCG Controls Not available.

**Carcinogenicity** 

Conclusion/Summary : Immulite® Free Beta-HCG Controls Not available.

Reproductive toxicity

Conclusion/Summary : Immulite® Free Beta-HCG Controls Not available.

**Teratogenicity** 

Conclusion/Summary : Immulite® Free Beta-HCG Controls Not available.

Specific target organ toxicity (single exposure)

Not available.

Specific target organ toxicity (repeated exposure)

Not available.

**Aspiration hazard** 

Not available.

Information on likely routes :

of exposure

: Immulite® Free Beta-HCG Controls

Not available.

Potential acute health effects

**Eye contact**: Immulite® Free Beta-HCG Controls

No known significant effects or critical

hazards.

Inhalation : Immulite® Free Beta-HCG Controls No known significant effects or critical

hazards.

**Skin contact**: Immulite® Free Beta-HCG Controls

No known significant effects or critical

hazards.

Ingestion : Immulite® Free Beta-HCG Controls No known significant effects or critical

hazards.

Symptoms related to the physical, chemical and toxicological characteristics

Eye contact: Immulite® Free Beta-HCG ControlsNo specific data.Inhalation: Immulite® Free Beta-HCG ControlsNo specific data.Skin contact: Immulite® Free Beta-HCG ControlsNo specific data.Ingestion: Immulite® Free Beta-HCG ControlsNo specific data.

Delayed and immediate effects as well as chronic effects from short and long-term exposure

**Short term exposure** 

Potential immediate : Immulite® Free Beta-HCG Controls Not available.

effects

Potential delayed effects : Immulite® Free Beta-HCG Controls Not available.

Long term exposure

Potential immediate : Immulite® Free Beta-HCG Controls Not available.

effects

Potential delayed effects : Immulite® Free Beta-HCG Controls Not available.

Potential chronic health effects

Not available.

**Conclusion/Summary**: Immulite® Free Beta-HCG Controls Not available.

### **SECTION 11: Toxicological information**

General : Immulite® Free Beta-HCG Controls No known significant effects or critical

hazards

Carcinogenicity : Immulite® Free Beta-HCG Controls No known significant effects or critical

hazards.

Mutagenicity : Immulite® Free Beta-HCG Controls No known significant effects or critical

hazards.

Reproductive toxicity : Immulite® Free Beta-HCG Controls No known significant effects or critical

hazards.

Interactive effects : Immulite® Free Beta-HCG Controls Not available.

**Toxicokinetics** 

Absorption: Immulite® Free Beta-HCG ControlsNot available.Distribution: Immulite® Free Beta-HCG ControlsNot available.Metabolism: Immulite® Free Beta-HCG ControlsNot available.Elimination: Immulite® Free Beta-HCG ControlsNot available.

Other information : Immulite® Free Beta-HCG Controls Not available.

### **SECTION 12: Ecological information**

#### 12.1 Toxicity

Product/ingredient name	Result	Species	Exposure
Immulite® Free Beta-HCG Controls			
sodium azide	Acute EC50 9200 μg/l Marine water	Algae - Giant kelp - Macrocystis pyrifera	96 hours
	Acute EC50 6.4 mg/l Fresh water	Crustaceans - Water flea - Simocephalus serrulatus - Larvae	48 hours
	Acute EC50 4.2 mg/l Fresh water	Daphnia - Water flea - Daphnia pulex - Larvae	48 hours
	Acute LC50 0.68 mg/l Fresh water	Fish - Bluegill - Lepomis macrochirus	96 hours
	Chronic NOEC 5600 µg/l Marine water	Algae - Giant kelp - Macrocystis pyrifera	96 hours

**Conclusion/Summary**: Immulite® Free Beta-HCG Controls Not available.

12.2 Persistence and degradability

Conclusion/Summary: Immulite® Free Beta-HCG Controls Not available.

12.3 Bioaccumulative potential

Not available.

12.4 Mobility in soil

Soil/water partition : Immulite® Free Beta-HCG Controls Not available.

coefficient (Koc)

**Mobility** : Immulite® Free Beta-HCG Controls Not available.

12.5 Results of PBT and vPvB assessment

This mixture does not contain any substances that are assessed to be a PBT or a vPvB.

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

### **SECTION 13: Disposal considerations**

#### 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.

**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	Incomplified Fire a Reda LICO Construit	Nisk as mulsks d
14.1 UN number	Immulite® Free Beta-HCG Controls	Not regulated.
14.2 UN proper shipping name	Immulite® Free Beta-HCG Controls	-
14.3 Transport hazard class(es)	Immulite® Free Beta-HCG Controls	-
14.4 Packing group	Immulite® Free Beta-HCG Controls	-
14.5 Environmental hazards	Immulite® Free Beta-HCG Controls	No.
Additional information	Immulite® Free Beta-HCG Controls	-
<u>ADN</u>		
14.1 UN number	Immulite® Free Beta-HCG Controls	Not regulated.
14.2 UN proper shipping name	Immulite® Free Beta-HCG Controls	-
14.3 Transport hazard class(es)	Immulite® Free Beta-HCG Controls	-
14.4 Packing group	Immulite® Free Beta-HCG Controls	-
14.5 Environmental hazards	Immulite® Free Beta-HCG Controls	No.

### **SECTION 14: Transport information**

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

**14.6 Special precautions for** : Immulite® Free Beta-HCG Controls user

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.

spillage.

14.7 Transport in bulk according to IMO instruments

**Additional** 

information

Not applicable.

Immulite® Free Beta-HCG Controls

### **SECTION 15: Regulatory information**

## 15.1 Safety, health and environmental regulations/legislation specific for the substance or mixture UK (GB) /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.

#### Ozone depleting substances

Not listed.

#### **Prior Informed Consent (PIC)**

Not listed.

#### **Persistent Organic Pollutants**

Not listed.

Annex XVII - Restrictions on the manufacture,

placing on the market and use of certain

dangerous substances, mixtures and articles

#### **Seveso Directive**

This product is not controlled under the Seveso Directive.

**EU regulations** 

Industrial emissions (integrated pollution

: Immulite® Free Beta-HCG Controls

: Immulite® Free Beta-HCG Controls

: Immulite® Free Beta-HCG Controls

Not listed

Not listed

Not applicable.

prevention and control) -

Air

Industrial emissions

(integrated pollution

prevention and control) -

Water

#### **International regulations**

#### **Montreal Protocol**

Not listed.

#### Stockholm Convention on Persistent Organic Pollutants

Not listed.

#### Rotterdam Convention on Prior Informed Consent (PIC)

Not listed.

#### **UNECE Aarhus Protocol on POPs and Heavy Metals**

Not listed.

15.2 Chemical safety

: Not applicable.

assessment

#### **SECTION 16: Other information**

Indicates information that has changed from previously issued version.

**Abbreviations and** : ATE = Acute Toxicity Estimate

acronyms GB CLP = UK CLP (EC No 1272/2008) on the Classification, Labelling and

Packaging of Substances and Mixtures as amended by (EU Exit) Regulations 2019

No. 720 and amendments

DMEL = Derived Minimal Effect Level
DNEL = Derived No Effect Level

EUH statement = GB CLP-specific Hazard statement

N/A = Not available

PBT = Persistent, Bioaccumulative and Toxic PNEC = Predicted No Effect Concentration RRN = REACH Registration Number

SGG = Segregation Group

vPvB = Very Persistent and Very Bioaccumulative

### Procedure used to derive the classification

Classification	Justification
Immulite® Free Beta-HCG Controls	
Aquatic Chronic 3, H412	Calculation method

#### Full text of abbreviated H statements

Immulite® Free Beta-HCG Controls

H300 Fatal if swallowed.
H310 Fatal 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.
 EUH032 Contact with acids liberates very toxic gas.

#### Full text of classifications

Immulite® Free Beta-HCG Controls

Acute Tox. 1 ACUTE TOXICITY - Category 1
Acute Tox. 2 ACUTE TOXICITY - Category 2

Aquatic Acute 1 SHORT-TERM (ACUTE) AQUATIC HAZARD - Category 1
Aquatic Chronic 1 LONG-TERM (CHRONIC) AQUATIC HAZARD - Category 1
LONG-TERM (CHRONIC) AQUATIC HAZARD - Category 3

Date of printing : 12/13/2022 Date of issue/ Date of : 12/13/2022

revision

Date of previous issue : No previous validation

Version : 1

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.

Conforms to Regulation (EC) No. 1907/2006 (REACH), Annex II, as amended by UK REACH Regulation SI 2019/758

IMMULITE® Free Beta HCG Control Module