

# SAFETY DATA SHEET



IMMULITE® 2000 Anti-HBc IgM

SDS no.:

L2KMC2\_6

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

### 1.1 Product identifier

**Product name** : IMMULITE® 2000 Anti-HBc IgM  
**Product code** : L2KMC2/6, 10381321, 10285814, 10488616

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

<b>Identified uses</b>	Anti-HBc IgM Reagent Wedge A	Diagnostic agents.
	Anti-HBc IgM Reagent Wedge B	Diagnostic agents.
	Anti-HBc IgM Adjustors	Diagnostic agents.
	Anti-HBc IgM Controls	Diagnostic agents.
	Anti-HBc IgM Sample Diluent	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

<b>Product definition</b>	: Anti-HBc IgM Reagent Wedge A	Mixture
	Anti-HBc IgM Reagent Wedge B	Mixture
	Anti-HBc IgM Adjustors	Mixture
	Anti-HBc IgM Controls	Mixture
	Anti-HBc IgM Sample Diluent	Mixture

#### Classification according to UK CLP/GHS

##### **Anti-HBc IgM Adjustors**

Acute Tox. 4, H302  
 Acute Tox. 3, H311  
 Aquatic Chronic 3, H412

##### **Anti-HBc IgM Controls**

Acute Tox. 4, H302  
 Acute Tox. 3, H311  
 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

## SECTION 2: Hazards identification

### Hazard pictograms

:



### Signal word

: Anti-HBc IgM Reagent Wedge A  
Anti-HBc IgM Reagent Wedge B  
Anti-HBc IgM Adjustors  
Anti-HBc IgM Controls  
Anti-HBc IgM Sample Diluent

No signal word.  
No signal word.  
Danger  
Danger  
No signal word.

### Hazard statements

: Anti-HBc IgM Reagent Wedge A  
  
Anti-HBc IgM Reagent Wedge B  
  
Anti-HBc IgM Adjustors  
  
Anti-HBc IgM Controls  
  
Anti-HBc IgM Sample Diluent

No known significant effects or critical hazards.  
No known significant effects or critical hazards.  
H302 - Harmful if swallowed.  
H311 - Toxic in contact with skin.  
H412 - Harmful to aquatic life with long lasting effects.  
H302 - Harmful if swallowed.  
H311 - Toxic in contact with skin.  
H412 - Harmful to aquatic life with long lasting effects.  
No known significant effects or critical hazards.

### Precautionary statements

#### Prevention

: Anti-HBc IgM Reagent Wedge A  
Anti-HBc IgM Reagent Wedge B  
Anti-HBc IgM Adjustors  
  
  
Anti-HBc IgM Controls

Not applicable.  
Not applicable.  
P264 - Wash hands thoroughly after handling.  
P280 - Wear protective gloves/protective clothing/eye protection/face protection.  
P273 - Avoid release to the environment.  
P264 - Wash hands thoroughly after handling.  
P280 - Wear protective gloves/protective clothing/eye protection/face protection.  
P273 - Avoid release to the environment.  
Not applicable.

#### Response

: Anti-HBc IgM Reagent Wedge A  
Anti-HBc IgM Reagent Wedge B  
Anti-HBc IgM Adjustors  
  
  
Anti-HBc IgM Controls

Not applicable.  
Not applicable.  
P312 - Call a POISON CENTER or doctor/physician if you feel unwell.  
P361 + P364 - Take off immediately all contaminated clothing and wash it before reuse.  
P312 - Call a POISON CENTER or doctor/physician if you feel unwell.  
P361 + P364 - Take off immediately all contaminated clothing and wash it before reuse.  
Not applicable.  
Not applicable.  
Not applicable.  
Not applicable.  
Not applicable.

#### Storage

: Anti-HBc IgM Reagent Wedge A  
Anti-HBc IgM Reagent Wedge B  
Anti-HBc IgM Adjustors  
Anti-HBc IgM Controls  
Anti-HBc IgM Sample Diluent

Not applicable.  
Not applicable.  
Not applicable.  
Not applicable.  
Not applicable.

**SECTION 2: Hazards identification**

<b>Disposal</b>	: Anti-HBc IgM Reagent Wedge A Anti-HBc IgM Reagent Wedge B Anti-HBc IgM Adjustors  Anti-HBc IgM Controls  Anti-HBc IgM Sample Diluent	Not applicable. Not applicable. P501 - Dispose of contents and container in accordance with all local, regional, and national regulations. P501 - Dispose of contents and container in accordance with all local, regional, and national regulations. Not applicable.
<b>Supplemental label elements</b>	: Anti-HBc IgM Reagent Wedge A Anti-HBc IgM Reagent Wedge B Anti-HBc IgM Adjustors Anti-HBc IgM Controls Anti-HBc IgM Sample Diluent	Safety data sheet available on request. Safety data sheet available on request. Not applicable. Not applicable. Safety data sheet available on request.
<b>Annex XVII - Restrictions on the manufacture, placing on the market and use of certain dangerous substances, mixtures and articles</b>	: Anti-HBc IgM Reagent Wedge A Anti-HBc IgM Reagent Wedge B Anti-HBc IgM Adjustors Anti-HBc IgM Controls Anti-HBc IgM Sample Diluent	Not applicable. Not applicable. Not applicable. Not applicable. Not applicable.
<b>2.3 Other hazards</b>		
<b>Product meets the criteria for PBT or vPvB according to Regulation (EC) No. 1907/2006, Annex XIII</b>	: Anti-HBc IgM Reagent Wedge A  Anti-HBc IgM Reagent Wedge B  Anti-HBc IgM Adjustors  Anti-HBc IgM Controls  Anti-HBc IgM Sample Diluent	This mixture does not contain any substances that are assessed to be a PBT or a vPvB. This mixture does not contain any substances that are assessed to be a PBT or a vPvB. This mixture does not contain any substances that are assessed to be a PBT or a vPvB. This mixture does not contain any substances that are assessed to be a PBT or a vPvB. This mixture does not contain any substances that are assessed to be a PBT or a vPvB.
<b>Other hazards which do not result in classification</b>	: Anti-HBc IgM Reagent Wedge A Anti-HBc IgM Reagent Wedge B Anti-HBc IgM Adjustors Anti-HBc IgM Controls Anti-HBc IgM Sample Diluent	None known. None known. None known. None known. None known.
<b>Additional information</b>	: Potentially biohazardous material.  Sodium azide may react with lead or copper plumbing to form highly explosive metal azides.	

**SECTION 3: Composition/information on ingredients**

<b>3.1 Substances</b>	: Anti-HBc IgM Reagent Wedge A Anti-HBc IgM Reagent Wedge B Anti-HBc IgM Adjustors Anti-HBc IgM Controls Anti-HBc IgM Sample Diluent	Mixture Mixture Mixture Mixture Mixture
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**SECTION 3: Composition/information on ingredients**

Product/ingredient name	Identifiers	%	Classification	Type
<b>Anti-HBc IgM Reagent Wedge A</b> aminocaproic acid	EC: 200-469-3 CAS: 60-32-2	≤3	Eye Irrit. 2, H319	[1]
<b>Anti-HBc IgM Reagent Wedge B</b> aminocaproic acid	EC: 200-469-3 CAS: 60-32-2	≤3	Eye Irrit. 2, H319	[1]
<b>Anti-HBc IgM Adjustors</b> aminocaproic acid	EC: 200-469-3 CAS: 60-32-2	<10	Eye Irrit. 2, H319	[1]
sodium azide	EC: 247-852-1 CAS: 26628-22-8 Index: 011-004-00-7	<2.5	Acute Tox. 2, H300 Acute Tox. 1, H310 Aquatic Acute 1, H400 (M=1) Aquatic Chronic 1, H410 (M=1) EUH032	[1] [2]
<b>Anti-HBc IgM Controls</b> aminocaproic acid	EC: 200-469-3 CAS: 60-32-2	<10	Eye Irrit. 2, H319	[1]
sodium azide	EC: 247-852-1 CAS: 26628-22-8 Index: 011-004-00-7	<2.5	Acute Tox. 2, H300 Acute Tox. 1, H310 Aquatic Acute 1, H400 (M=1) Aquatic Chronic 1, H410 (M=1) EUH032	[1] [2]
<b>Anti-HBc IgM Sample Diluent</b> aminocaproic acid	EC: 200-469-3 CAS: 60-32-2	≤3	Eye Irrit. 2, H319  <b>See Section 16 for the full text of the H statements declared above.</b>	[1]

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** : Anti-HBc IgM Reagent Wedge A

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.

Anti-HBc IgM Reagent Wedge B

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.

Anti-HBc IgM Adjustors

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

## SECTION 4: First aid measures

	Anti-HBc IgM Controls	attention. 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.
	Anti-HBc IgM Sample Diluent	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.
<b>Inhalation</b>	: Anti-HBc IgM Reagent Wedge A	Remove victim to fresh air and keep at rest in a position comfortable for breathing. Get medical attention if symptoms occur. 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.
	Anti-HBc IgM Reagent Wedge B	Remove victim to fresh air and keep at rest in a position comfortable for breathing. Get medical attention if symptoms occur. 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.
	Anti-HBc IgM Adjustors	Remove victim to fresh air and keep at rest in a position comfortable for breathing. If not breathing, if breathing is irregular or if respiratory arrest occurs, provide artificial respiration or oxygen by trained personnel. It may be dangerous to the person providing aid to give mouth-to-mouth resuscitation. Get medical attention. If 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.
	Anti-HBc IgM Controls	Remove victim to fresh air and keep at rest in a position comfortable for breathing. If not breathing, if breathing is irregular or if respiratory arrest occurs, provide artificial respiration or oxygen by trained personnel. It may be dangerous to the person providing aid to give mouth-to-mouth resuscitation. Get medical attention. If 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.
	Anti-HBc IgM Sample Diluent	Remove victim to fresh air and keep at

**SECTION 4: First aid measures****Skin contact**

: Anti-HBc IgM Reagent Wedge A

Anti-HBc IgM Reagent Wedge B

Anti-HBc IgM Adjustors

Anti-HBc IgM Controls

Anti-HBc IgM Sample Diluent

**Ingestion**

: Anti-HBc IgM Reagent Wedge A

Anti-HBc IgM Reagent Wedge B

Anti-HBc IgM Adjustors

rest in a position comfortable for breathing. Get medical attention if symptoms occur. 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.

Flush contaminated skin with plenty of water. Remove contaminated clothing and shoes. Get medical attention if symptoms occur.

Flush contaminated skin with plenty of water. Remove contaminated clothing and shoes. Get medical attention if symptoms occur.

Wash with plenty of soap and 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. Get medical attention. If necessary, call a poison center or physician. Wash clothing before reuse. Clean shoes thoroughly before reuse.

Wash with plenty of soap and 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. Get medical attention. If necessary, call a poison center or physician. Wash clothing before reuse. Clean shoes thoroughly before reuse. Flush contaminated skin with plenty of water. Remove contaminated clothing and shoes. Get medical attention if symptoms occur.

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. Get medical attention if symptoms occur.

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. Get medical attention if symptoms occur.

Wash out mouth with water. Remove dentures if any. If material has been swallowed and the exposed person is conscious, give small quantities of water to drink. Stop if the exposed person feels sick as vomiting may be dangerous. Do not induce vomiting unless directed to do so by medical personnel. If vomiting occurs, the head should be kept low so that vomit does not enter the lungs. Get medical attention. If necessary, call a poison center or

## SECTION 4: First aid measures

### Anti-HBc IgM Controls

physician. 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.

Wash out mouth with water. Remove dentures if any. If material has been swallowed and the exposed person is conscious, give small quantities of water to drink. Stop if the exposed person feels sick as vomiting may be dangerous. Do not induce vomiting unless directed to do so by medical personnel. If vomiting occurs, the head should be kept low so that vomit does not enter the lungs. Get medical attention. If necessary, call a poison center or physician. 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.

### Anti-HBc IgM Sample Diluent

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. Get medical attention if symptoms occur.

**Protection of first-aiders** : Anti-HBc IgM Reagent Wedge A

Anti-HBc IgM Reagent Wedge B

Anti-HBc IgM Adjustors

No action shall be taken involving any personal risk or without suitable training. No action shall be taken involving any personal risk or without suitable training. 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. Wash contaminated clothing thoroughly with water before removing it, or wear gloves.

### Anti-HBc IgM Controls

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. Wash contaminated clothing thoroughly with water before removing it, or wear gloves.

### Anti-HBc IgM Sample Diluent

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** : Anti-HBc IgM Reagent Wedge A  
Anti-HBc IgM Reagent Wedge B  
Anti-HBc IgM Adjustors  
Anti-HBc IgM Controls  
Anti-HBc IgM Sample Diluent

No specific data.  
No specific data.  
No specific data.  
No specific data.  
No specific data.

**SECTION 4: First aid measures**

<b>Inhalation</b>	: Anti-HBc IgM Reagent Wedge A	No specific data.
	Anti-HBc IgM Reagent Wedge B	No specific data.
	Anti-HBc IgM Adjustors	No specific data.
	Anti-HBc IgM Controls	No specific data.
	Anti-HBc IgM Sample Diluent	No specific data.
<b>Skin contact</b>	: Anti-HBc IgM Reagent Wedge A	No specific data.
	Anti-HBc IgM Reagent Wedge B	No specific data.
	Anti-HBc IgM Adjustors	No specific data.
	Anti-HBc IgM Controls	No specific data.
	Anti-HBc IgM Sample Diluent	No specific data.
<b>Ingestion</b>	: Anti-HBc IgM Reagent Wedge A	No specific data.
	Anti-HBc IgM Reagent Wedge B	No specific data.
	Anti-HBc IgM Adjustors	No specific data.
	Anti-HBc IgM Controls	No specific data.
	Anti-HBc IgM Sample Diluent	No specific data.

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

<b>Notes to physician</b>	: Anti-HBc IgM Reagent Wedge A	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.
	Anti-HBc IgM Reagent Wedge B	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.
	Anti-HBc IgM Adjustors	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.
	Anti-HBc IgM Controls	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.
	Anti-HBc IgM Sample Diluent	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.
<b>Specific treatments</b>	: Anti-HBc IgM Reagent Wedge A	No specific treatment.
	Anti-HBc IgM Reagent Wedge B	No specific treatment.
	Anti-HBc IgM Adjustors	No specific treatment.
	Anti-HBc IgM Controls	No specific treatment.
	Anti-HBc IgM Sample Diluent	No specific treatment.
	Anti-HBc IgM Reagent Wedge A	Not available.
	Anti-HBc IgM Reagent Wedge B	Not available.
	Anti-HBc IgM Adjustors	Not available.
	Anti-HBc IgM Controls	Not available.
	Anti-HBc IgM Sample Diluent	Not available.

**SECTION 5: Firefighting measures****5.1 Extinguishing media**

<b>Suitable extinguishing media</b>	: Use an extinguishing agent suitable for the surrounding fire.
<b>Unsuitable extinguishing media</b>	: None known.



## SECTION 5: Firefighting measures

### 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** : Decomposition products may include the following materials:  
carbon dioxide  
carbon monoxide  
nitrogen oxides  
sulfur oxides  
halogenated compounds  
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.
- 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.
- 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 container.
- Advice on general occupational hygiene** : Eating, drinking and smoking should be prohibited in areas where this material is handled, stored and processed. Workers should wash hands and face before eating, drinking and smoking. Remove contaminated clothing and protective equipment before entering eating areas. See also Section 8 for additional information on hygiene measures.

### 7.2 Conditions for safe storage, including any incompatibilities

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

### 7.3 Specific end use(s)

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

## SECTION 8: Exposure controls/personal protection

### 8.1 Control parameters

#### Occupational exposure limits

Product/ingredient name	Exposure limit values
<b>Anti-HBc IgM Adjustors</b> sodium azide	<b>EH40/2005 WELs (United Kingdom (UK), 1/2020). Absorbed through skin.</b> STEL: 0.3 mg/m <sup>3</sup> , (as NaN <sub>3</sub> ) 15 minutes. TWA: 0.1 mg/m <sup>3</sup> , (as NaN <sub>3</sub> ) 8 hours.
<b>Anti-HBc IgM Controls</b> sodium azide	<b>EH40/2005 WELs (United Kingdom (UK), 1/2020). Absorbed through skin.</b> STEL: 0.3 mg/m <sup>3</sup> , (as NaN <sub>3</sub> ) 15 minutes. TWA: 0.1 mg/m <sup>3</sup> , (as NaN <sub>3</sub> ) 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
<b>Anti-HBc IgM Adjustors</b> 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/m <sup>3</sup>	General population	Systemic
	DNEL	Long term Dermal	46.7 µg/kg	Workers	Systemic

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

<b>Anti-HBc IgM Controls</b> sodium azide	DNEL	Long term Inhalation	bw/day 0.164 mg/ m <sup>3</sup>	Workers	Systemic
	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/m <sup>3</sup>	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.

**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** : 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**

<b>Physical state</b>	Anti-HBc IgM Reagent Wedge A	Liquid.
	Anti-HBc IgM Reagent Wedge B	Liquid.
	Anti-HBc IgM Adjustors	Solid.
	Anti-HBc IgM Controls	Solid.
	Anti-HBc IgM Sample Diluent	Liquid.
<b>Colour</b>	Anti-HBc IgM Reagent Wedge A	Colourless.
	Anti-HBc IgM Reagent Wedge B	Colourless.
	Anti-HBc IgM Adjustors	Off-white.
	Anti-HBc IgM Controls	Off-white.
	Anti-HBc IgM Sample Diluent	Colourless.
<b>Odour</b>	Anti-HBc IgM Reagent Wedge A	Odourless.
	Anti-HBc IgM Reagent Wedge B	Odourless.
	Anti-HBc IgM Adjustors	Odourless.
	Anti-HBc IgM Controls	Odourless.
	Anti-HBc IgM Sample Diluent	Odourless.
<b>Odour threshold</b>	: Not relevant/applicable due to nature of the product.	
<b>Melting point/freezing point</b>	: Not relevant/applicable due to nature of the product.	
<b>Softening point</b>	: Not relevant/applicable due to nature of the product.	
<b>Sublimation temperature</b>	: Not relevant/applicable due to nature of the product.	
<b>Initial boiling point and boiling range</b>	Anti-HBc IgM Reagent Wedge A	Not available.
	Anti-HBc IgM Reagent Wedge B	Not available.
	Anti-HBc IgM Adjustors	Not available.
	Anti-HBc IgM Controls	Not available.
	Anti-HBc IgM Sample Diluent	Not available.
<b>Flammability (solid, gas)</b>	Anti-HBc IgM Reagent Wedge A	Not relevant/applicable due to nature of the product.
	Anti-HBc IgM Reagent Wedge B	Not relevant/applicable due to nature of the product.
	Anti-HBc IgM Adjustors	Not relevant/applicable due to nature of the product.
	Anti-HBc IgM Controls	Not relevant/applicable due to nature of the product.
	Anti-HBc IgM Sample Diluent	Not relevant/applicable due to nature of the product.
<b>Upper/lower flammability or explosive limits</b>	Anti-HBc IgM Reagent Wedge A	Not available.
	Anti-HBc IgM Reagent Wedge B	Not available.
	Anti-HBc IgM Adjustors	Not applicable.
	Anti-HBc IgM Controls	Not applicable.
	Anti-HBc IgM Sample Diluent	Not available.
<b>Flash point</b>	Anti-HBc IgM Reagent Wedge A	[Product does not sustain combustion.]
	Anti-HBc IgM Reagent Wedge B	[Product does not sustain combustion.]
	Anti-HBc IgM Adjustors	[Product does not sustain combustion.]
	Anti-HBc IgM Controls	[Product does not sustain combustion.]
	Anti-HBc IgM Sample Diluent	[Product does not sustain combustion.]
<b>Auto-ignition temperature</b>	:	

Ingredient name	°C	°F	Method
<b>Anti-HBc IgM Reagent Wedge A</b>			
sodium azide	309	588.2	EU A.16
<b>Anti-HBc IgM Reagent Wedge B</b>			
sodium azide	309	588.2	EU A.16
<b>Anti-HBc IgM Sample Diluent</b>			

IMMULITE® 2000 Anti-HBc IgM

**SECTION 9: Physical and chemical properties**

sodium azide	309	588.2	EU A.16
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**Decomposition temperature** : Not relevant/applicable due to nature of the product.

**pH** : Anti-HBc IgM Reagent Wedge A 7.95 to 8.05  
 Anti-HBc IgM Reagent Wedge B 7.95 to 8.05  
 Anti-HBc IgM Adjustors Not applicable.  
 Anti-HBc IgM Controls Not applicable.  
 Anti-HBc IgM Sample Diluent 7.95 to 8.05

**Viscosity** : Anti-HBc IgM Reagent Wedge A Not available.  
 Anti-HBc IgM Reagent Wedge B Not available.  
 Anti-HBc IgM Adjustors Not applicable.  
 Anti-HBc IgM Controls Not applicable.  
 Anti-HBc IgM Sample Diluent Not available.

**Solubility(ies)** :  
 Not available.

**Solubility in water** : Not relevant/applicable due to nature of the product.

**Miscible with water** : Not relevant/applicable due to nature of the product.

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

**Vapour pressure** :

Ingredient name	Vapour Pressure at 20°C			Vapour pressure at 50°C		
	mm Hg	kPa	Method	mm Hg	kPa	Method
Anti-HBc IgM Reagent Wedge A water	23.8	3.2				
Anti-HBc IgM Reagent Wedge B water	23.8	3.2				
Anti-HBc IgM Sample Diluent water	23.8	3.2				

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

**Relative density** : Anti-HBc IgM Reagent Wedge A 1  
 Anti-HBc IgM Reagent Wedge B 1  
 Anti-HBc IgM Adjustors 1  
 Anti-HBc IgM Controls 1  
 Anti-HBc IgM Sample Diluent 1

**Density** : Anti-HBc IgM Reagent Wedge A Not available.  
 Anti-HBc IgM Reagent Wedge B Not available.  
 Anti-HBc IgM Adjustors Not available.  
 Anti-HBc IgM Controls Not available.  
 Anti-HBc IgM Sample Diluent Not available.

**Vapour density** : Anti-HBc IgM Reagent Wedge A Not available.  
 Anti-HBc IgM Reagent Wedge B Not available.  
 Anti-HBc IgM Adjustors Not applicable.  
 Anti-HBc IgM Controls Not applicable.  
 Anti-HBc IgM Sample Diluent Not available.

**Explosive properties** : Anti-HBc IgM Reagent Wedge A Not available.  
 Anti-HBc IgM Reagent Wedge B Not available.  
 Anti-HBc IgM Adjustors Not available.  
 Anti-HBc IgM Controls Not available.  
 Anti-HBc IgM Sample Diluent Not available.

**SECTION 9: Physical and chemical properties**

<b>Oxidising properties</b>	: Anti-HBc IgM Reagent Wedge A	Not available.
	Anti-HBc IgM Reagent Wedge B	Not available.
	Anti-HBc IgM Adjustors	Not available.
	Anti-HBc IgM Controls	Not available.
	Anti-HBc IgM Sample Diluent	Not available.

**Particle characteristics**

<b>Median particle size</b>	: Not applicable.
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**9.2 Other information**

<b>Fire point</b>	: Anti-HBc IgM Reagent Wedge A	Not available.
	Anti-HBc IgM Reagent Wedge B	Not available.
	Anti-HBc IgM Adjustors	Not available.
	Anti-HBc IgM Controls	Not available.
	Anti-HBc IgM Sample Diluent	Not available.
<b>Burning time</b>	: Not relevant/applicable due to nature of the product.	
<b>Fundamental burning velocity</b>	: Not relevant/applicable due to nature of the product.	
<b>Burning rate</b>	: Not relevant/applicable due to nature of the product.	
<b>SADT</b>	: Not relevant/applicable due to nature of the product.	
<b>SAPT</b>	: Not relevant/applicable due to nature of the product.	
<b>Heat of reaction</b>	: Not relevant/applicable due to nature of the product.	
<b>Heat of combustion</b>	: Not relevant/applicable due to nature of the product.	
<b>Flow time (ISO 2431)</b>	: Not relevant/applicable due to nature of the product.	
<b>Molecular weight</b>	: Not relevant/applicable due to nature of the product.	

**SECTION 10: Stability and reactivity**

<b>10.1 Reactivity</b>	: No specific test data related to reactivity available for this product or its ingredients.
<b>10.2 Chemical stability</b>	: The product is stable.
<b>10.3 Possibility of hazardous reactions</b>	: Under normal conditions of storage and use, hazardous reactions will not occur.
<b>10.4 Conditions to avoid</b>	: No specific data.
<b>10.5 Incompatible materials</b>	: No specific data.
<b>10.6 Hazardous decomposition products</b>	: 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
<b>Anti-HBc IgM Adjustors</b> sodium azide	LD50 Dermal	Rabbit	20 mg/kg	-
	LD50 Dermal	Rat	50 mg/kg	-
	LD50 Oral	Rat	27 mg/kg	-
<b>Anti-HBc IgM Controls</b> sodium azide	LD50 Dermal	Rabbit	20 mg/kg	-
	LD50 Dermal	Rat	50 mg/kg	-
	LD50 Oral	Rat	27 mg/kg	-

IMMULITE® 2000 Anti-HBc IgM

**SECTION 11: Toxicological information**

<b>Conclusion/Summary</b>	: Anti-HBc IgM Reagent Wedge A	Not available.
	Anti-HBc IgM Reagent Wedge B	Not available.
	Anti-HBc IgM Adjustors	Not available.
	Anti-HBc IgM Controls	Not available.
	Anti-HBc IgM Sample Diluent	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)
<b>Anti-HBc IgM Adjustors</b> Anti-HBc IgM Adjustors sodium azide	1261.7 27	934.6 20	N/A N/A	N/A N/A	N/A N/A
<b>Anti-HBc IgM Controls</b> Anti-HBc IgM Controls sodium azide	1250.1 27	926 20	N/A N/A	N/A N/A	N/A N/A

**Irritation/Corrosion**

Product/ingredient name	Result	Species	Score	Exposure	Observation
<b>Anti-HBc IgM Reagent Wedge A</b> aminocaproic acid	Eyes - Mild irritant	Rabbit	-	24 hours 500 mg	-
<b>Anti-HBc IgM Reagent Wedge B</b> aminocaproic acid	Eyes - Mild irritant	Rabbit	-	24 hours 500 mg	-
<b>Anti-HBc IgM Adjustors</b> aminocaproic acid	Eyes - Mild irritant	Rabbit	-	24 hours 500 mg	-
<b>Anti-HBc IgM Controls</b> aminocaproic acid	Eyes - Mild irritant	Rabbit	-	24 hours 500 mg	-
<b>Anti-HBc IgM Sample Diluent</b> aminocaproic acid	Eyes - Mild irritant	Rabbit	-	24 hours 500 mg	-

**Conclusion/Summary**

<b>Skin</b>	: Anti-HBc IgM Reagent Wedge A	Not available.
	Anti-HBc IgM Reagent Wedge B	Not available.
	Anti-HBc IgM Adjustors	Not available.
	Anti-HBc IgM Controls	Not available.
	Anti-HBc IgM Sample Diluent	Not available.
<b>Eyes</b>	: Anti-HBc IgM Reagent Wedge A	Not available.
	Anti-HBc IgM Reagent Wedge B	Not available.
	Anti-HBc IgM Adjustors	Not available.
	Anti-HBc IgM Controls	Not available.
	Anti-HBc IgM Sample Diluent	Not available.
<b>Respiratory</b>	: Anti-HBc IgM Reagent Wedge A	Not available.
	Anti-HBc IgM Reagent Wedge B	Not available.
	Anti-HBc IgM Adjustors	Not available.
	Anti-HBc IgM Controls	Not available.
	Anti-HBc IgM Sample Diluent	Not available.

**Sensitisation****Conclusion/Summary**

**SECTION 11: Toxicological information**

<b>Skin</b>	: Anti-HBc IgM Reagent Wedge A Anti-HBc IgM Reagent Wedge B Anti-HBc IgM Adjustors Anti-HBc IgM Controls Anti-HBc IgM Sample Diluent	Not available. Not available. Not available. Not available. Not available.
<b>Respiratory</b>	: Anti-HBc IgM Reagent Wedge A Anti-HBc IgM Reagent Wedge B Anti-HBc IgM Adjustors Anti-HBc IgM Controls Anti-HBc IgM Sample Diluent	Not available. Not available. Not available. Not available. Not available.
<b><u>Mutagenicity</u></b>		
<b>Conclusion/Summary</b>	: Anti-HBc IgM Reagent Wedge A Anti-HBc IgM Reagent Wedge B Anti-HBc IgM Adjustors Anti-HBc IgM Controls Anti-HBc IgM Sample Diluent	Not available. Not available. Not available. Not available. Not available.
<b><u>Carcinogenicity</u></b>		
<b>Conclusion/Summary</b>	: Anti-HBc IgM Reagent Wedge A Anti-HBc IgM Reagent Wedge B Anti-HBc IgM Adjustors Anti-HBc IgM Controls Anti-HBc IgM Sample Diluent	Not available. Not available. Not available. Not available. Not available.
<b><u>Reproductive toxicity</u></b>		
<b>Conclusion/Summary</b>	: Anti-HBc IgM Reagent Wedge A Anti-HBc IgM Reagent Wedge B Anti-HBc IgM Adjustors Anti-HBc IgM Controls Anti-HBc IgM Sample Diluent	Not available. Not available. Not available. Not available. Not available.
<b><u>Teratogenicity</u></b>		
<b>Conclusion/Summary</b>	: Anti-HBc IgM Reagent Wedge A Anti-HBc IgM Reagent Wedge B Anti-HBc IgM Adjustors Anti-HBc IgM Controls Anti-HBc IgM Sample Diluent	Not available. Not available. Not available. Not available. Not available.
<b><u>Specific target organ toxicity (single exposure)</u></b>		
Not available.		
<b><u>Specific target organ toxicity (repeated exposure)</u></b>		
Not available.		
<b><u>Aspiration hazard</u></b>		
Not available.		
<b>Information on likely routes of exposure</b>	: Anti-HBc IgM Reagent Wedge A Anti-HBc IgM Reagent Wedge B Anti-HBc IgM Adjustors Anti-HBc IgM Controls Anti-HBc IgM Sample Diluent	Not available. Not available. Not available. Not available. Not available.
<b><u>Potential acute health effects</u></b>		
<b>Eye contact</b>	: Anti-HBc IgM Reagent Wedge A  Anti-HBc IgM Reagent Wedge B  Anti-HBc IgM Adjustors  Anti-HBc IgM Controls  Anti-HBc IgM Sample Diluent	No known significant effects or critical hazards. No known significant effects or critical hazards. No known significant effects or critical hazards. No known significant effects or critical hazards. No known significant effects or critical hazards.



**SECTION 11: Toxicological information**

<b>Inhalation</b>	: Anti-HBc IgM Reagent Wedge A	No known significant effects or critical hazards.
	Anti-HBc IgM Reagent Wedge B	No known significant effects or critical hazards.
	Anti-HBc IgM Adjustors	No known significant effects or critical hazards.
	Anti-HBc IgM Controls	No known significant effects or critical hazards.
	Anti-HBc IgM Sample Diluent	No known significant effects or critical hazards.
<b>Skin contact</b>	: Anti-HBc IgM Reagent Wedge A	No known significant effects or critical hazards.
	Anti-HBc IgM Reagent Wedge B	No known significant effects or critical hazards.
	Anti-HBc IgM Adjustors	Toxic in contact with skin.
	Anti-HBc IgM Controls	Toxic in contact with skin.
	Anti-HBc IgM Sample Diluent	No known significant effects or critical hazards.
<b>Ingestion</b>	: Anti-HBc IgM Reagent Wedge A	No known significant effects or critical hazards.
	Anti-HBc IgM Reagent Wedge B	No known significant effects or critical hazards.
	Anti-HBc IgM Adjustors	Harmful if swallowed.
	Anti-HBc IgM Controls	Harmful if swallowed.
	Anti-HBc IgM Sample Diluent	No known significant effects or critical hazards.

**Symptoms related to the physical, chemical and toxicological characteristics**

<b>Eye contact</b>	: Anti-HBc IgM Reagent Wedge A	No specific data.
	Anti-HBc IgM Reagent Wedge B	No specific data.
	Anti-HBc IgM Adjustors	No specific data.
	Anti-HBc IgM Controls	No specific data.
	Anti-HBc IgM Sample Diluent	No specific data.
<b>Inhalation</b>	: Anti-HBc IgM Reagent Wedge A	No specific data.
	Anti-HBc IgM Reagent Wedge B	No specific data.
	Anti-HBc IgM Adjustors	No specific data.
	Anti-HBc IgM Controls	No specific data.
	Anti-HBc IgM Sample Diluent	No specific data.
<b>Skin contact</b>	: Anti-HBc IgM Reagent Wedge A	No specific data.
	Anti-HBc IgM Reagent Wedge B	No specific data.
	Anti-HBc IgM Adjustors	No specific data.
	Anti-HBc IgM Controls	No specific data.
	Anti-HBc IgM Sample Diluent	No specific data.
<b>Ingestion</b>	: Anti-HBc IgM Reagent Wedge A	No specific data.
	Anti-HBc IgM Reagent Wedge B	No specific data.
	Anti-HBc IgM Adjustors	No specific data.
	Anti-HBc IgM Controls	No specific data.
	Anti-HBc IgM Sample Diluent	No specific data.

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

<b>Potential immediate effects</b>	: Anti-HBc IgM Reagent Wedge A	Not available.
	Anti-HBc IgM Reagent Wedge B	Not available.
	Anti-HBc IgM Adjustors	Not available.
	Anti-HBc IgM Controls	Not available.
	Anti-HBc IgM Sample Diluent	Not available.

**SECTION 11: Toxicological information**

<b>Potential delayed effects</b>	: Anti-HBc IgM Reagent Wedge A	Not available.
	Anti-HBc IgM Reagent Wedge B	Not available.
	Anti-HBc IgM Adjustors	Not available.
	Anti-HBc IgM Controls	Not available.
	Anti-HBc IgM Sample Diluent	Not available.

**Long term exposure**

<b>Potential immediate effects</b>	: Anti-HBc IgM Reagent Wedge A	Not available.
	Anti-HBc IgM Reagent Wedge B	Not available.
	Anti-HBc IgM Adjustors	Not available.
	Anti-HBc IgM Controls	Not available.
	Anti-HBc IgM Sample Diluent	Not available.

<b>Potential delayed effects</b>	: Anti-HBc IgM Reagent Wedge A	Not available.
	Anti-HBc IgM Reagent Wedge B	Not available.
	Anti-HBc IgM Adjustors	Not available.
	Anti-HBc IgM Controls	Not available.
	Anti-HBc IgM Sample Diluent	Not available.

**Potential chronic health effects**

Not available.

<b>Conclusion/Summary</b>	: Anti-HBc IgM Reagent Wedge A	Not available.
	Anti-HBc IgM Reagent Wedge B	Not available.
	Anti-HBc IgM Adjustors	Not available.
	Anti-HBc IgM Controls	Not available.
	Anti-HBc IgM Sample Diluent	Not available.

<b>General</b>	: Anti-HBc IgM Reagent Wedge A	No known significant effects or critical hazards.
	Anti-HBc IgM Reagent Wedge B	No known significant effects or critical hazards.
	Anti-HBc IgM Adjustors	No known significant effects or critical hazards.
	Anti-HBc IgM Controls	No known significant effects or critical hazards.
	Anti-HBc IgM Sample Diluent	No known significant effects or critical hazards.

<b>Carcinogenicity</b>	: Anti-HBc IgM Reagent Wedge A	No known significant effects or critical hazards.
	Anti-HBc IgM Reagent Wedge B	No known significant effects or critical hazards.
	Anti-HBc IgM Adjustors	No known significant effects or critical hazards.
	Anti-HBc IgM Controls	No known significant effects or critical hazards.
	Anti-HBc IgM Sample Diluent	No known significant effects or critical hazards.

<b>Mutagenicity</b>	: Anti-HBc IgM Reagent Wedge A	No known significant effects or critical hazards.
	Anti-HBc IgM Reagent Wedge B	No known significant effects or critical hazards.
	Anti-HBc IgM Adjustors	No known significant effects or critical hazards.
	Anti-HBc IgM Controls	No known significant effects or critical hazards.
	Anti-HBc IgM Sample Diluent	No known significant effects or critical hazards.

<b>Reproductive toxicity</b>	: Anti-HBc IgM Reagent Wedge A	No known significant effects or critical hazards.
	Anti-HBc IgM Reagent Wedge B	No known significant effects or critical hazards.
	Anti-HBc IgM Adjustors	No known significant effects or critical hazards.
	Anti-HBc IgM Controls	No known significant effects or critical hazards.

**SECTION 11: Toxicological information**

	Anti-HBc IgM Sample Diluent	No known significant effects or critical hazards.
<b>Interactive effects</b>	: Anti-HBc IgM Reagent Wedge A	Not available.
	Anti-HBc IgM Reagent Wedge B	Not available.
	Anti-HBc IgM Adjustors	Not available.
	Anti-HBc IgM Controls	Not available.
	Anti-HBc IgM Sample Diluent	Not available.
<b>Toxicokinetics</b>		
<b>Absorption</b>	: Anti-HBc IgM Reagent Wedge A	Not available.
	Anti-HBc IgM Reagent Wedge B	Not available.
	Anti-HBc IgM Adjustors	Not available.
	Anti-HBc IgM Controls	Not available.
	Anti-HBc IgM Sample Diluent	Not available.
<b>Distribution</b>	: Anti-HBc IgM Reagent Wedge A	Not available.
	Anti-HBc IgM Reagent Wedge B	Not available.
	Anti-HBc IgM Adjustors	Not available.
	Anti-HBc IgM Controls	Not available.
	Anti-HBc IgM Sample Diluent	Not available.
<b>Metabolism</b>	: Anti-HBc IgM Reagent Wedge A	Not available.
	Anti-HBc IgM Reagent Wedge B	Not available.
	Anti-HBc IgM Adjustors	Not available.
	Anti-HBc IgM Controls	Not available.
	Anti-HBc IgM Sample Diluent	Not available.
<b>Elimination</b>	: Anti-HBc IgM Reagent Wedge A	Not available.
	Anti-HBc IgM Reagent Wedge B	Not available.
	Anti-HBc IgM Adjustors	Not available.
	Anti-HBc IgM Controls	Not available.
	Anti-HBc IgM Sample Diluent	Not available.
<b>Other information</b>	: Anti-HBc IgM Reagent Wedge A	Not available.
	Anti-HBc IgM Reagent Wedge B	Not available.
	Anti-HBc IgM Adjustors	Not available.
	Anti-HBc IgM Controls	Not available.
	Anti-HBc IgM Sample Diluent	Not available.

**SECTION 12: Ecological information****12.1 Toxicity**

Product/ingredient name	Result	Species	Exposure
<b>Anti-HBc IgM Adjustors</b> 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
<b>Anti-HBc IgM Controls</b> 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	96 hours

**SECTION 12: Ecological information**

	Chronic NOEC 5600 µg/l Marine water	macrochirus Algae - Giant kelp - Macrocystis pyrifera	96 hours
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**Conclusion/Summary** : Anti-HBc IgM Reagent Wedge A Not available.  
 Anti-HBc IgM Reagent Wedge B Not available.  
 Anti-HBc IgM Adjustors Not available.  
 Anti-HBc IgM Controls Not available.  
 Anti-HBc IgM Sample Diluent Not available.

**12.2 Persistence and degradability**

**Conclusion/Summary** : Anti-HBc IgM Reagent Wedge A Not available.  
 Anti-HBc IgM Reagent Wedge B Not available.  
 Anti-HBc IgM Adjustors Not available.  
 Anti-HBc IgM Controls Not available.  
 Anti-HBc IgM Sample Diluent Not available.

**12.3 Bioaccumulative potential**

Product/ingredient name	LogP <sub>ow</sub>	BCF	Potential
<b>Anti-HBc IgM Reagent Wedge A</b> aminocaproic acid	-2.95	-	low
<b>Anti-HBc IgM Reagent Wedge B</b> aminocaproic acid	-2.95	-	low
<b>Anti-HBc IgM Adjustors</b> aminocaproic acid	-2.95	-	low
<b>Anti-HBc IgM Controls</b> aminocaproic acid	-2.95	-	low
<b>Anti-HBc IgM Sample Diluent</b> aminocaproic acid	-2.95	-	low

**12.4 Mobility in soil**

**Soil/water partition coefficient (K<sub>oc</sub>)** : Anti-HBc IgM Reagent Wedge A Not available.  
 Anti-HBc IgM Reagent Wedge B Not available.  
 Anti-HBc IgM Adjustors Not available.  
 Anti-HBc IgM Controls Not available.  
 Anti-HBc IgM Sample Diluent Not available.

**Mobility** : Anti-HBc IgM Reagent Wedge A Not available.  
 Anti-HBc IgM Reagent Wedge B Not available.  
 Anti-HBc IgM Adjustors Not available.  
 Anti-HBc IgM Controls Not available.  
 Anti-HBc IgM Sample Diluent 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**

<b>14.1 UN number</b>	Anti-HBc IgM Reagent Wedge A	Not regulated.
	Anti-HBc IgM Reagent Wedge B	Not regulated.
	Anti-HBc IgM Adjustors	UN3288
	Anti-HBc IgM Controls	UN3288
	Anti-HBc IgM Sample Diluent	Not regulated.
<b>14.2 UN proper shipping name</b>	Anti-HBc IgM Reagent Wedge A	-
	Anti-HBc IgM Reagent Wedge B	-
	Anti-HBc IgM Adjustors	Toxic solid, inorganic, n.o.s. (sodium azide)
	Anti-HBc IgM Controls	Toxic solid, inorganic, n.o.s. (sodium azide)
	Anti-HBc IgM Sample Diluent	-
<b>14.3 Transport hazard class(es)</b>	Anti-HBc IgM Reagent Wedge A	-
	Anti-HBc IgM Reagent Wedge B	-
	Anti-HBc IgM Adjustors	6.1
	Anti-HBc IgM Controls	6.1
	Anti-HBc IgM Sample Diluent	-
<b>14.4 Packing group</b>	Anti-HBc IgM Reagent Wedge A	-
	Anti-HBc IgM Reagent Wedge B	-
	Anti-HBc IgM Adjustors	III
	Anti-HBc IgM Controls	III
	Anti-HBc IgM Sample Diluent	-
<b>14.5 Environmental hazards</b>	Anti-HBc IgM Reagent Wedge A	No.
	Anti-HBc IgM Reagent Wedge B	No.
	Anti-HBc IgM Adjustors	No.
	Anti-HBc IgM Controls	No.
	Anti-HBc IgM Sample Diluent	No.
<b>Additional information</b>	Anti-HBc IgM Reagent Wedge A	-
	Anti-HBc IgM Reagent Wedge B	-
	Anti-HBc IgM Adjustors	<b><u>Tunnel code</u></b> (E)
	Anti-HBc IgM Controls	<b><u>Tunnel code</u></b> (E)
	Anti-HBc IgM Sample Diluent	-

**ADN**

**SECTION 14: Transport information**

<b>14.1 UN number</b>	Anti-HBc IgM Reagent Wedge A	Not regulated.
	Anti-HBc IgM Reagent Wedge B	Not regulated.
	Anti-HBc IgM Adjustors	UN3288
	Anti-HBc IgM Controls	UN3288
	Anti-HBc IgM Sample Diluent	Not regulated.
<b>14.2 UN proper shipping name</b>	Anti-HBc IgM Reagent Wedge A	-
	Anti-HBc IgM Reagent Wedge B	-
	Anti-HBc IgM Adjustors	Toxic solid, inorganic, n.o.s. (sodium azide)
	Anti-HBc IgM Controls	Toxic solid, inorganic, n.o.s. (sodium azide)
	Anti-HBc IgM Sample Diluent	-
<b>14.3 Transport hazard class(es)</b>	Anti-HBc IgM Reagent Wedge A	-
	Anti-HBc IgM Reagent Wedge B	-
	Anti-HBc IgM Adjustors	6.1
	Anti-HBc IgM Controls	6.1
	Anti-HBc IgM Sample Diluent	-
<b>14.4 Packing group</b>	Anti-HBc IgM Reagent Wedge A	-
	Anti-HBc IgM Reagent Wedge B	-
	Anti-HBc IgM Adjustors	III
	Anti-HBc IgM Controls	III
	Anti-HBc IgM Sample Diluent	-
<b>14.5 Environmental hazards</b>	Anti-HBc IgM Reagent Wedge A	No.
	Anti-HBc IgM Reagent Wedge B	No.
	Anti-HBc IgM Adjustors	No.
	Anti-HBc IgM Controls	No.
	Anti-HBc IgM Sample Diluent	No.
<b>Additional information</b>	Anti-HBc IgM Reagent Wedge A	-
	Anti-HBc IgM Reagent Wedge B	-
	Anti-HBc IgM Adjustors	-
	Anti-HBc IgM Controls	-
	Anti-HBc IgM Sample Diluent	-

**IMDG**

<b>14.1 UN number</b>	Anti-HBc IgM Reagent Wedge A	Not regulated.
	Anti-HBc IgM Reagent Wedge B	Not regulated.
	Anti-HBc IgM Adjustors	UN3288
	Anti-HBc IgM Controls	UN3288
	Anti-HBc IgM Sample Diluent	Not regulated.
<b>14.2 UN proper shipping name</b>	Anti-HBc IgM Reagent Wedge A	-
	Anti-HBc IgM Reagent Wedge B	-
	Anti-HBc IgM Adjustors	Toxic solid, inorganic, n.o.s. (sodium azide)
	Anti-HBc IgM Controls	Toxic solid, inorganic, n.o.s. (sodium azide)
	Anti-HBc IgM Sample Diluent	-
<b>14.3 Transport hazard class(es)</b>	Anti-HBc IgM Reagent Wedge A	-
	Anti-HBc IgM Reagent Wedge B	-
	Anti-HBc IgM Adjustors	6.1
	Anti-HBc IgM Controls	6.1
	Anti-HBc IgM Sample Diluent	-
<b>14.4 Packing group</b>	Anti-HBc IgM Reagent Wedge A	-
	Anti-HBc IgM Reagent Wedge B	-
	Anti-HBc IgM Adjustors	III
	Anti-HBc IgM Controls	III
	Anti-HBc IgM Sample Diluent	-

**SECTION 14: Transport information**

<b>14.5 Environmental hazards</b>	Anti-HBc IgM Reagent Wedge A	No.
	Anti-HBc IgM Reagent Wedge B	No.
	Anti-HBc IgM Adjustors	No.
	Anti-HBc IgM Controls	No.
	Anti-HBc IgM Sample Diluent	No.
<b>Additional information</b>	Anti-HBc IgM Reagent Wedge A	-
	Anti-HBc IgM Reagent Wedge B	-
	Anti-HBc IgM Adjustors	-
	Anti-HBc IgM Controls	-
	Anti-HBc IgM Sample Diluent	-
<b>IATA</b>		
<b>14.1 UN number</b>	Anti-HBc IgM Reagent Wedge A	Not regulated.
	Anti-HBc IgM Reagent Wedge B	Not regulated.
	Anti-HBc IgM Adjustors	UN3288
	Anti-HBc IgM Controls	UN3288
	Anti-HBc IgM Sample Diluent	Not regulated.
<b>14.2 UN proper shipping name</b>	Anti-HBc IgM Reagent Wedge A	-
	Anti-HBc IgM Reagent Wedge B	-
	Anti-HBc IgM Adjustors	Toxic solid, inorganic, n.o.s. (sodium azide)
	Anti-HBc IgM Controls	Toxic solid, inorganic, n.o.s. (sodium azide)
	Anti-HBc IgM Sample Diluent	-
<b>14.3 Transport hazard class(es)</b>	Anti-HBc IgM Reagent Wedge A	-
	Anti-HBc IgM Reagent Wedge B	-
	Anti-HBc IgM Adjustors	6.1
	Anti-HBc IgM Controls	6.1
	Anti-HBc IgM Sample Diluent	-
<b>14.4 Packing group</b>	Anti-HBc IgM Reagent Wedge A	-
	Anti-HBc IgM Reagent Wedge B	-
	Anti-HBc IgM Adjustors	III
	Anti-HBc IgM Controls	III
	Anti-HBc IgM Sample Diluent	-
<b>14.5 Environmental hazards</b>	Anti-HBc IgM Reagent Wedge A	No.
	Anti-HBc IgM Reagent Wedge B	No.
	Anti-HBc IgM Adjustors	No.
	Anti-HBc IgM Controls	No.
	Anti-HBc IgM Sample Diluent	No.
<b>Additional information</b>	Anti-HBc IgM Reagent Wedge A	-
	Anti-HBc IgM Reagent Wedge B	-
	Anti-HBc IgM Adjustors	-
	Anti-HBc IgM Controls	-
	Anti-HBc IgM Sample Diluent	-

**14.6 Special precautions for user** : Anti-HBc IgM Reagent Wedge A

Anti-HBc IgM Reagent Wedge B

Anti-HBc IgM Adjustors

**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.

**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.

**Transport within user's premises:**

**SECTION 14: Transport information**

Anti-HBc IgM Controls

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.

**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.

Anti-HBc IgM Sample Diluent

**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 IMO instruments**

Not applicable.

**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**

: Anti-HBc IgM Reagent Wedge A Anti-HBc IgM Reagent Wedge B Anti-HBc IgM Adjustors Anti-HBc IgM Controls Anti-HBc IgM Sample Diluent
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Not applicable.  
Not applicable.  
Not applicable.  
Not applicable.  
Not applicable.

**Seveso Directive**

This product is not controlled under the Seveso Directive.

**National regulations****EU regulations**

**Industrial emissions (integrated pollution prevention and control) - Air**

: Anti-HBc IgM Reagent Wedge A Anti-HBc IgM Reagent Wedge B Anti-HBc IgM Adjustors Anti-HBc IgM Controls Anti-HBc IgM Sample Diluent
--

Not listed  
Not listed  
Not listed  
Not listed  
Not listed



IMMULITE® 2000 Anti-HBc IgM

## SECTION 15: Regulatory information

<b>Industrial emissions (integrated pollution prevention and control) - Water</b>	: Anti-HBc IgM Reagent Wedge A	Not listed
	Anti-HBc IgM Reagent Wedge B	Not listed
	Anti-HBc IgM Adjustors	Not listed
	Anti-HBc IgM Controls	Not listed
	Anti-HBc IgM Sample Diluent	Not listed

### 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 assessment** : Not applicable.

## SECTION 16: Other information

Indicates information that has changed from previously issued version.

**Abbreviations and acronyms** :

- ATE = Acute Toxicity Estimate
- 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
<b>Anti-HBc IgM Adjustors</b> Acute Tox. 4, H302 Acute Tox. 3, H311 Aquatic Chronic 3, H412	Calculation method Calculation method Calculation method
<b>Anti-HBc IgM Controls</b> Acute Tox. 4, H302 Acute Tox. 3, H311 Aquatic Chronic 3, H412	Calculation method Calculation method Calculation method

### Full text of abbreviated H statements

IMMULITE® 2000 Anti-HBc IgM

**SECTION 16: Other information****Anti-HBc IgM****Reagent****Wedge A**

H319 Causes serious eye irritation.

**Anti-HBc IgM****Reagent****Wedge B**

H319 Causes serious eye irritation.

**Anti-HBc IgM****Adjustors**

H300 Fatal if swallowed.  
 H302 Harmful if swallowed.  
 H310 Fatal in contact with skin.  
 H311 Toxic in contact with skin.  
 H319 Causes serious eye irritation.  
 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.

**Anti-HBc IgM****Controls**

H300 Fatal if swallowed.  
 H302 Harmful if swallowed.  
 H310 Fatal in contact with skin.  
 H311 Toxic in contact with skin.  
 H319 Causes serious eye irritation.  
 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.

**Anti-HBc IgM****Sample Diluent**

H319 Causes serious eye irritation.

**Full text of classifications****Anti-HBc IgM****Reagent Wedge A**

Eye Irrit. 2 SERIOUS EYE DAMAGE/EYE IRRITATION - Category 2

**Anti-HBc IgM****Reagent Wedge B**

Eye Irrit. 2 SERIOUS EYE DAMAGE/EYE IRRITATION - Category 2

**Anti-HBc IgM****Adjustors**

Acute Tox. 1 ACUTE TOXICITY - Category 1  
 Acute Tox. 2 ACUTE TOXICITY - Category 2  
 Acute Tox. 3 ACUTE TOXICITY - Category 3  
 Acute Tox. 4 ACUTE TOXICITY - Category 4  
 Aquatic Acute 1 SHORT-TERM (ACUTE) AQUATIC HAZARD - Category 1  
 Aquatic Chronic 1 LONG-TERM (CHRONIC) AQUATIC HAZARD - Category 1  
 Aquatic Chronic 3 LONG-TERM (CHRONIC) AQUATIC HAZARD - Category 3  
 Eye Irrit. 2 SERIOUS EYE DAMAGE/EYE IRRITATION - Category 2

**Anti-HBc IgM****Controls**

Acute Tox. 1 ACUTE TOXICITY - Category 1  
 Acute Tox. 2 ACUTE TOXICITY - Category 2  
 Acute Tox. 3 ACUTE TOXICITY - Category 3

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## SECTION 16: Other information

Acute Tox. 4	ACUTE TOXICITY - Category 4
Aquatic Acute 1	SHORT-TERM (ACUTE) AQUATIC HAZARD - Category 1
Aquatic Chronic 1	LONG-TERM (CHRONIC) AQUATIC HAZARD - Category 1
Aquatic Chronic 3	LONG-TERM (CHRONIC) AQUATIC HAZARD - Category 3
Eye Irrit. 2	SERIOUS EYE DAMAGE/EYE IRRITATION - Category 2

### Anti-HBc IgM

#### Sample Diluent

Eye Irrit. 2	SERIOUS EYE DAMAGE/EYE IRRITATION - Category 2
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### Notice to reader

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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.