

# SAFETY DATA SHEET

SIEMENS

Immulite® 2000 HBsAg

MSDS no. : L2KHB2\_6

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

### 1.1 Product identifier

<b>Product name</b>	: Immulite® 2000 HBsAg	
<b>Product code</b>	: L2KHB2/6, 10381306, 10381328, 10374014	
<b>Product description</b>	: Not available.	
<b>Product type</b>	: Liquid.	
<b>Other means of identification</b>	: HBsAg Reagent Wedge A	L2HBA2A
	HBsAg Reagent Wedge B	L2HBA2B
	HBsAg Controls 1-3	LHBC1-3
	HBsAg Adjustor	LHBR

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

Not applicable.

### 1.3 Company/undertaking identification

**Manufactured/supplied** : Siemens Healthcare Diagnostics Limited  
Sir William Siemens Square  
Newton House  
Camberley  
Frimley  
Surrey  
GU16 8QD  
UK

Phone: +44 (0) 1276 696000  
Fax: +44 (0)1276 696133

**e-mail address of person responsible for this SDS** : dx.msds.healthcare@siemens.com

**1.4 Emergency telephone number** : Poison Control:  
In England and Wales:  
NHS Direct – 0845 4647 or 111  
In Scotland: NHS 24 – 08454 24 24 24  
In the Republic of Ireland: 01 809 2166

CHEMTREC: 0870-8200418 (UK only)  
00 + 1 + 703-527-3887 (UK & Ireland)  
(International calls to the United Kingdom)

## SECTION 2: Hazards identification

### 2.1 Classification of the substance or mixture

<b>Product definition</b>	:	HBsAg Reagent Wedge A	Mixture
		HBsAg Reagent Wedge B	Mixture
		HBsAg Controls 1-3	Mixture
		HBsAg Adjustor	Mixture

#### Classification according to Directive 1999/45/EC [DPD]

HBsAg Reagent Wedge A	The product is not classified as dangerous according to Directive 1999/45/EC and its amendments.
HBsAg Reagent Wedge B	The product is not classified as dangerous according to Directive 1999/45/EC and its amendments.
HBsAg Controls 1-3	The product is not classified as dangerous according to Directive 1999/45/EC and its amendments.
HBsAg Adjustor	The product is not classified as dangerous according to Directive 1999/45/EC and its amendments.

<b>Classification</b>	:	HBsAg Reagent Wedge A	Not classified.
		HBsAg Reagent Wedge B	Not classified.
		HBsAg Controls 1-3	Not classified.
		HBsAg Adjustor	Not classified.

<b>Physical/chemical hazards</b>	:	HBsAg Reagent Wedge A	Not applicable.
		HBsAg Reagent Wedge B	Not applicable.
		HBsAg Controls 1-3	Not applicable.
		HBsAg Adjustor	Not applicable.

<b>Human health hazards</b>	:	HBsAg Reagent Wedge A	Not applicable.
		HBsAg Reagent Wedge B	Not applicable.
		HBsAg Controls 1-3	Not applicable.
		HBsAg Adjustor	Not applicable.

<b>Environmental hazards</b>	:	HBsAg Reagent Wedge A	Not applicable.
		HBsAg Reagent Wedge B	Not applicable.
		HBsAg Controls 1-3	Not applicable.
		HBsAg Adjustor	Not applicable.

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

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

### 2.2 Label elements

#### Precautionary statements

**Indication of danger** :

<b>Risk phrases</b>	:	HBsAg Reagent Wedge A	This product is not classified as dangerous according to EU legislation.
		HBsAg Reagent Wedge B	This product is not classified as dangerous according to EU legislation.
		HBsAg Controls 1-3	This product is not classified as dangerous according to EU legislation.
		HBsAg Adjustor	This product is not classified as dangerous according to EU legislation.

<b>Safety phrases</b>	:	HBsAg Reagent Wedge A	Not applicable.
		HBsAg Reagent Wedge B	Not applicable.
		HBsAg Controls 1-3	Not applicable.
		HBsAg Adjustor	Not applicable.

<b>Supplemental label elements</b>	:	Not applicable.
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## SECTION 2: Hazards identification

**Annex XVII - Restrictions on the manufacture, placing on the market and use of certain dangerous substances, mixtures and articles** : HBsAg Reagent Wedge A Not applicable.  
 HBsAg Reagent Wedge B Not applicable.  
 HBsAg Controls 1-3 Not applicable.  
 HBsAg Adjustor Not applicable.

### 2.3 Other hazards

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

## SECTION 3: Composition/information on ingredients

**Substance/mixture** : HBsAg Reagent Wedge A Mixture  
 HBsAg Reagent Wedge B Mixture  
 HBsAg Controls 1-3 Mixture  
 HBsAg Adjustor Mixture

Product/ingredient name	Identifiers	%	Classification		Type
			67/548/EEC	Regulation (EC) No. 1272/2008 [CLP]	
HBsAg Reagent Wedge A aminocaproic acid	EC: 200-469-3 CAS: 60-32-2	>=1, <5	Not classified.	Eye Irrit. 2, H319	[1]
HBsAg Reagent Wedge B aminocaproic acid	EC: 200-469-3 CAS: 60-32-2	>=1, <5	Not classified.	Eye Irrit. 2, H319  <b>See Section 16 for the full text of the H statements declared above.</b>	[1]

There are no additional ingredients present which, within the current knowledge of the supplier and in the concentrations applicable, are classified as hazardous to health or the environment, are PBTs or vPvBs or have been assigned a workplace exposure limit and hence require reporting in this section.

#### Type

- [1] Substance classified with a health or environmental hazard
- [2] Substance with a workplace exposure limit
- [3] Substance meets the criteria for PBT according to Regulation (EC) No. 1907/2006, Annex XIII
- [4] Substance meets the criteria for vPvB according to Regulation (EC) No. 1907/2006, Annex XIII
- [5] Substance of equivalent concern

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

## SECTION 4: First aid measures

### 4.1 Description of first aid measures

**Eye contact** : HBsAg 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.  
 HBsAg 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

**SECTION 4: First aid measures**

		HBsAg Controls 1-3	attention if irritation occurs. 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.
		HBsAg Adjustor	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>	:	HBsAg 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.
		HBsAg 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.
		HBsAg Controls 1-3	Remove victim to fresh air and keep at rest in a position comfortable for breathing. Get medical attention if symptoms occur.
		HBsAg Adjustor	Remove victim to fresh air and keep at rest in a position comfortable for breathing. Get medical attention if symptoms occur.
<b>Skin contact</b>	:	HBsAg Reagent Wedge A	Flush contaminated skin with plenty of water. Remove contaminated clothing and shoes. Get medical attention if symptoms occur.
		HBsAg Reagent Wedge B	Flush contaminated skin with plenty of water. Remove contaminated clothing and shoes. Get medical attention if symptoms occur.
		HBsAg Controls 1-3	Flush contaminated skin with plenty of water. Remove contaminated clothing and shoes. Get medical attention if symptoms occur.
		HBsAg Adjustor	Flush contaminated skin with plenty of water. Remove contaminated clothing and shoes. Get medical attention if symptoms occur.
<b>Ingestion</b>	:	HBsAg Reagent Wedge A	Wash out mouth with water. Remove victim to fresh air and keep at rest in a position comfortable for breathing. If material has been swallowed and the exposed person is conscious, give small quantities of water to drink. Do not induce vomiting unless directed to do so by medical personnel. Get medical attention if symptoms occur.
		HBsAg Reagent Wedge B	Wash out mouth with water. Remove victim to fresh air and keep at rest in a position comfortable for breathing. If material has been swallowed and the

**SECTION 4: First aid measures**

HBsAg Controls 1-3

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 victim to fresh air and keep at rest in a position comfortable for breathing. If material has been swallowed and the exposed person is conscious, give small quantities of water to drink. Do not induce vomiting unless directed to do so by medical personnel. Get medical attention if symptoms occur.

HBsAg Adjustor

Wash out mouth with water. Remove victim to fresh air and keep at rest in a position comfortable for breathing. If material has been swallowed and the exposed person is conscious, give small quantities of water to drink. Do not induce vomiting unless directed to do so by medical personnel. Get medical attention if symptoms occur.

**Protection of first-aiders** : No action shall be taken involving any personal risk or without suitable training.

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

**Potential acute health effects**

**Eye contact**

: HBsAg Reagent Wedge A

No known significant effects or critical hazards.

HBsAg Reagent Wedge B

No known significant effects or critical hazards.

HBsAg Controls 1-3

No known significant effects or critical hazards.

HBsAg Adjustor

No known significant effects or critical hazards.

**Inhalation**

: HBsAg Reagent Wedge A

Exposure to decomposition products may cause a health hazard. Serious effects may be delayed following exposure.

HBsAg Reagent Wedge B

Exposure to decomposition products may cause a health hazard. Serious effects may be delayed following exposure.

HBsAg Controls 1-3

No known significant effects or critical hazards.

HBsAg Adjustor

No known significant effects or critical hazards.

**Skin contact**

: HBsAg Reagent Wedge A

No known significant effects or critical hazards.

HBsAg Reagent Wedge B

No known significant effects or critical hazards.

HBsAg Controls 1-3

No known significant effects or critical hazards.

HBsAg Adjustor

No known significant effects or critical hazards.

**Ingestion**

: HBsAg Reagent Wedge A

No known significant effects or critical hazards.

HBsAg Reagent Wedge B

No known significant effects or critical hazards.

HBsAg Controls 1-3

No known significant effects or critical hazards.

HBsAg Adjustor

No known significant effects or critical hazards.

## SECTION 4: First aid measures

### Over-exposure signs/symptoms

<b>Eye contact</b>	: HBsAg Reagent Wedge A HBsAg Reagent Wedge B HBsAg Controls 1-3 HBsAg Adjustor	No specific data. No specific data. No specific data. No specific data.
<b>Inhalation</b>	: HBsAg Reagent Wedge A HBsAg Reagent Wedge B HBsAg Controls 1-3 HBsAg Adjustor	No specific data. No specific data. No specific data. No specific data.
<b>Skin contact</b>	: HBsAg Reagent Wedge A HBsAg Reagent Wedge B HBsAg Controls 1-3 HBsAg Adjustor	No specific data. No specific data. No specific data. No specific data.
<b>Ingestion</b>	: HBsAg Reagent Wedge A HBsAg Reagent Wedge B HBsAg Controls 1-3 HBsAg Adjustor	No specific data. No specific data. No specific data. No specific data.

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

<b>Notes to physician</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.
<b>Specific treatments</b>	: No specific treatment.

## SECTION 5: Firefighting measures

### 5.1 Extinguishing media

<b>Suitable extinguishing media</b>	: Use dry chemical, CO <sub>2</sub> , water spray (fog) or foam.
<b>Unsuitable extinguishing media</b>	: None known.

### 5.2 Special hazards arising from the substance or mixture

<b>Hazards from the substance or mixture</b>	: In a fire or if heated, a pressure increase will occur and the container may burst.
<b>Hazardous thermal decomposition products</b>	: 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

<b>Special protective actions for fire-fighters</b>	: 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.
<b>Special protective equipment for fire-fighters</b>	: Fire-fighters should wear appropriate protective equipment and self-contained breathing apparatus (SCBA) with a full face-piece operated in positive pressure mode. Clothing for fire-fighters (including helmets, protective boots and gloves) conforming to European standard EN 469 will provide a basic level of protection for chemical incidents.

## SECTION 6: Accidental release measures

### 6.1 Personal precautions, protective equipment and emergency procedures

- For non-emergency personnel** : No action shall be taken involving any personal risk or without suitable training. Evacuate surrounding areas. Keep unnecessary and unprotected personnel from entering. Do not touch or walk through spilt material. Put on appropriate personal protective equipment.
- For emergency responders** : If specialised clothing is required to deal with the spillage, take note of any information in Section 8 on suitable and unsuitable materials. See also Section 8 for additional information on hygiene measures.

- 6.2 Environmental precautions** : Avoid dispersal of spilt material and runoff and contact with soil, waterways, drains and sewers. Inform the relevant authorities if the product has caused environmental pollution (sewers, waterways, soil or air).

### 6.3 Methods and materials 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. 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. Dispose of via a licensed waste disposal contractor.

- 6.4 Reference to other sections** : See Section 1 for emergency contact information.  
See Section 8 for information on appropriate personal protective equipment.  
See Section 13 for additional waste treatment information.

## SECTION 7: Handling and storage

The information in this section contains generic advice and guidance. The list of Identified Uses in Section 1 should be consulted for any available use-specific information provided in the Exposure Scenario(s).

### 7.1 Precautions for safe handling

- Protective measures** : Put on appropriate personal protective equipment (see Section 8).
- 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.

### 7.3 Specific end use(s)

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

## SECTION 8: Exposure controls/personal protection

The information in this section contains generic advice and guidance. Information is provided based on typical anticipated uses of the product. Additional measures might be required for bulk handling or other uses that could significantly increase worker or exposure or environmental releases.

### 8.1 Control parameters

#### Occupational exposure limits

No exposure limit value known.

**Recommended monitoring procedures** : If this product contains ingredients with exposure limits, personal, workplace atmosphere or biological monitoring may be required to determine the effectiveness of the ventilation or other control measures and/or the necessity to use respiratory protective equipment. Reference should be made to monitoring standards, such as the following: European Standard EN 689 (Workplace atmospheres - Guidance for the assessment of exposure by inhalation to chemical agents for comparison with limit values and measurement strategy) European Standard EN 14042 (Workplace atmospheres - Guide for the application and use of procedures for the assessment of exposure to chemical and biological agents) European Standard EN 482 (Workplace atmospheres - General requirements for the performance of procedures for the measurement of chemical agents) Reference to national guidance documents for methods for the determination of hazardous substances will also be required.

#### DNELs/DMELs

No DNELs/DMELs available.

#### PNECs

No PNECs available

### 8.2 Exposure controls

**Appropriate engineering controls** : Good general ventilation should be sufficient to control worker exposure to airborne contaminants.

#### Individual protection measures

**Hygiene measures** : Wash hands, forearms and face thoroughly after handling chemical products, before eating, smoking and using the lavatory and at the end of the working period. Appropriate techniques should be used to remove potentially contaminated clothing. Wash contaminated clothing before reusing. Ensure that eyewash stations and safety showers are close to the workstation location.

**Eye/face protection** : Safety eyewear complying with an approved standard should be used when a risk assessment indicates this is necessary to avoid exposure to liquid splashes, mists or dusts. If contact is possible, the following protection should be worn, unless the assessment indicates a higher degree of protection: safety glasses with side-shields.

#### Skin protection

**Hand protection** : Chemical-resistant, impervious gloves complying with an approved standard should be worn at all times when handling chemical products if a risk assessment indicates this is necessary.

**Body protection** : Personal protective equipment for the body should be selected based on the task being performed and the risks involved and should be approved by a specialist before handling this product.

**Other skin protection** : Appropriate footwear and any additional skin protection measures should be selected based on the task being performed and the risks involved and should be approved by a specialist before handling this product.

**Respiratory protection** : Use a properly fitted, air-purifying or air-fed respirator complying with an approved standard if a risk assessment indicates this is necessary. Respirator selection must be based on known or anticipated exposure levels, the hazards of the product and the safe working limits of the selected respirator.

**Environmental exposure controls** : Emissions from ventilation or work process equipment should be checked to ensure they comply with the requirements of environmental protection legislation. In some cases, fume scrubbers, filters or engineering modifications to the process equipment will be necessary to reduce emissions to acceptable levels.



**SECTION 9: Physical and chemical properties****9.1 Information on basic physical and chemical properties****Appearance**

<b>Physical state</b>	:	HBsAg Reagent Wedge A HBsAg Reagent Wedge B HBsAg Controls 1-3 HBsAg Adjustor	Liquid. Liquid. Liquid. Liquid.
<b>Colour</b>	:	HBsAg Reagent Wedge A HBsAg Reagent Wedge B HBsAg Controls 1-3 HBsAg Adjustor	Colourless. Colourless. Colourless. Colourless.
<b>Odour</b>	:	HBsAg Reagent Wedge A HBsAg Reagent Wedge B HBsAg Controls 1-3 HBsAg Adjustor	Odorless. Odorless. Odorless. Odorless.
<b>pH</b>	:	HBsAg Reagent Wedge A HBsAg Reagent Wedge B HBsAg Controls 1-3 HBsAg Adjustor	7.35 to 7.45 7.95 to 8.05 Not applicable. Not applicable.
<b>Melting point/freezing point</b>	:	HBsAg Reagent Wedge A HBsAg Reagent Wedge B HBsAg Controls 1-3 HBsAg Adjustor	Not available. Not available. Not available. Not available.
<b>Initial boiling point and boiling range</b>	:	HBsAg Reagent Wedge A HBsAg Reagent Wedge B HBsAg Controls 1-3 HBsAg Adjustor	Not available. Not available. Not available. Not available.
<b>Flash point</b>	:	HBsAg Reagent Wedge A HBsAg Reagent Wedge B HBsAg Controls 1-3 HBsAg Adjustor	Not available. Not available. Not available. Not available.
<b>Evaporation rate</b>	:	HBsAg Reagent Wedge A HBsAg Reagent Wedge B HBsAg Controls 1-3 HBsAg Adjustor	Not available. Not available. Not available. Not available.
<b>Flammability (solid, gas)</b>	:	HBsAg Reagent Wedge A HBsAg Reagent Wedge B HBsAg Controls 1-3 HBsAg Adjustor	Not available. Not available. Not available. Not available.
<b>Burning time</b>	:	HBsAg Reagent Wedge A HBsAg Reagent Wedge B HBsAg Controls 1-3 HBsAg Adjustor	Not applicable. Not applicable. Not applicable. Not applicable.
<b>Burning rate</b>	:	HBsAg Reagent Wedge A HBsAg Reagent Wedge B HBsAg Controls 1-3 HBsAg Adjustor	Not applicable. Not applicable. Not applicable. Not applicable.
<b>Upper/lower flammability or explosive limits</b>	:	HBsAg Reagent Wedge A HBsAg Reagent Wedge B HBsAg Controls 1-3 HBsAg Adjustor	Not available. Not available. Not available. Not available.
<b>Vapour pressure</b>	:	HBsAg Reagent Wedge A HBsAg Reagent Wedge B HBsAg Controls 1-3 HBsAg Adjustor	Not available. Not available. Not available. Not available.
<b>Solubility in water</b>	:	HBsAg Reagent Wedge A HBsAg Reagent Wedge B HBsAg Controls 1-3 HBsAg Adjustor	Not available. Not available. Not available. Not available.

## SECTION 9: Physical and chemical properties

<b>Partition coefficient: n-octanol/ water</b>	: HBsAg Reagent Wedge A HBsAg Reagent Wedge B HBsAg Controls 1-3 HBsAg Adjustor	Not available. Not available. Not available. Not available.
<b>Auto-ignition temperature</b>	: HBsAg Reagent Wedge A HBsAg Reagent Wedge B HBsAg Controls 1-3 HBsAg Adjustor	Not available. Not available. Not available. Not available.
<b>Decomposition temperature</b>	: HBsAg Reagent Wedge A HBsAg Reagent Wedge B HBsAg Controls 1-3 HBsAg Adjustor	Not available. Not available. Not available. Not available.
<b>Viscosity</b>	: HBsAg Reagent Wedge A HBsAg Reagent Wedge B HBsAg Controls 1-3 HBsAg Adjustor	Not available. Not available. Not available. Not available.
<b>Explosive properties</b>	: HBsAg Reagent Wedge A HBsAg Reagent Wedge B HBsAg Controls 1-3 HBsAg Adjustor	Not available. Not available. Not available. Not available.
<b>Oxidising properties</b>	: HBsAg Reagent Wedge A HBsAg Reagent Wedge B HBsAg Controls 1-3 HBsAg Adjustor	Not available. Not available. Not available. Not available.

### 9.2 Other information

<b>SADT</b>	: Not available.
<b><u>Aerosol product</u></b>	
<b>Type of aerosol</b>	: Not applicable.
<b>Heat of combustion</b>	: Not available.
<b>Ignition distance</b>	: Not applicable.
<b>Enclosed space ignition - Time equivalent</b>	: Not applicable.
<b>Enclosed space ignition - Deflagration density</b>	: Not applicable.
<b>Flame height</b>	: Not applicable.
<b>Flame duration</b>	: Not applicable.

## 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

**Conclusion/Summary** : Not available.

#### Acute toxicity estimates

Not available.

#### Irritation/Corrosion

Product/ingredient name	Result	Species	Score	Exposure	Observation
HBsAg Reagent Wedge A aminocaproic acid	Eyes - Mild irritant	Rabbit	-	24 hours 500 milligrams	-
HBsAg Reagent Wedge B aminocaproic acid	Eyes - Mild irritant	Rabbit	-	24 hours 500 milligrams	-

**Conclusion/Summary** : Not available.

#### Sensitisation

**Conclusion/Summary** : Not available.

#### Mutagenicity

**Conclusion/Summary** : Not available.

#### Carcinogenicity

**Conclusion/Summary** : Not available.

#### Reproductive toxicity

**Conclusion/Summary** : Not available.

#### Teratogenicity

**Conclusion/Summary** : Not available.

**Information on the likely routes of exposure** : Not available.

#### Potential acute health effects

<b>Eye contact</b>	: HBsAg Reagent Wedge A	No known significant effects or critical hazards.
	HBsAg Reagent Wedge B	No known significant effects or critical hazards.
	HBsAg Controls 1-3	No known significant effects or critical hazards.
	HBsAg Adjustor	No known significant effects or critical hazards.
<b>Inhalation</b>	: HBsAg Reagent Wedge A	Exposure to decomposition products may cause a health hazard. Serious effects may be delayed following exposure.
	HBsAg Reagent Wedge B	Exposure to decomposition products may cause a health hazard. Serious effects may be delayed following exposure.
	HBsAg Controls 1-3	No known significant effects or critical hazards.
	HBsAg Adjustor	No known significant effects or critical hazards.

## SECTION 11: Toxicological information

<b>Skin contact</b>	: HBsAg Reagent Wedge A	No known significant effects or critical hazards.
	HBsAg Reagent Wedge B	No known significant effects or critical hazards.
	HBsAg Controls 1-3	No known significant effects or critical hazards.
	HBsAg Adjustor	No known significant effects or critical hazards.
<b>Ingestion</b>	: HBsAg Reagent Wedge A	No known significant effects or critical hazards.
	HBsAg Reagent Wedge B	No known significant effects or critical hazards.
	HBsAg Controls 1-3	No known significant effects or critical hazards.
	HBsAg Adjustor	No known significant effects or critical hazards.

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

<b>Eye contact</b>	: HBsAg Reagent Wedge A	No specific data.
	HBsAg Reagent Wedge B	No specific data.
	HBsAg Controls 1-3	No specific data.
	HBsAg Adjustor	No specific data.
<b>Inhalation</b>	: HBsAg Reagent Wedge A	No specific data.
	HBsAg Reagent Wedge B	No specific data.
	HBsAg Controls 1-3	No specific data.
	HBsAg Adjustor	No specific data.
<b>Skin contact</b>	: HBsAg Reagent Wedge A	No specific data.
	HBsAg Reagent Wedge B	No specific data.
	HBsAg Controls 1-3	No specific data.
	HBsAg Adjustor	No specific data.
<b>Ingestion</b>	: HBsAg Reagent Wedge A	No specific data.
	HBsAg Reagent Wedge B	No specific data.
	HBsAg Controls 1-3	No specific data.
	HBsAg Adjustor	No specific data.

### Delayed and immediate effects and also chronic effects from short and long term exposure

#### Short term exposure

<b>Potential immediate effects</b>	: HBsAg Reagent Wedge A	Not available.
	HBsAg Reagent Wedge B	Not available.
	HBsAg Controls 1-3	Not available.
	HBsAg Adjustor	Not available.
<b>Potential delayed effects</b>	: HBsAg Reagent Wedge A	Not available.
	HBsAg Reagent Wedge B	Not available.
	HBsAg Controls 1-3	Not available.
	HBsAg Adjustor	Not available.

#### Long term exposure

<b>Potential immediate effects</b>	: HBsAg Reagent Wedge A	Not available.
	HBsAg Reagent Wedge B	Not available.
	HBsAg Controls 1-3	Not available.
	HBsAg Adjustor	Not available.
<b>Potential delayed effects</b>	: HBsAg Reagent Wedge A	Not available.
	HBsAg Reagent Wedge B	Not available.
	HBsAg Controls 1-3	Not available.
	HBsAg Adjustor	Not available.

#### Potential chronic health effects

Not available.

**Conclusion/Summary** : Not available.

## SECTION 11: Toxicological information

<b>General</b>	: HBsAg Reagent Wedge A HBsAg Reagent Wedge B HBsAg Controls 1-3 HBsAg Adjustor	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.
<b>Carcinogenicity</b>	: HBsAg Reagent Wedge A HBsAg Reagent Wedge B HBsAg Controls 1-3 HBsAg Adjustor	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.
<b>Mutagenicity</b>	: HBsAg Reagent Wedge A HBsAg Reagent Wedge B HBsAg Controls 1-3 HBsAg Adjustor	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.
<b>Teratogenicity</b>	: HBsAg Reagent Wedge A HBsAg Reagent Wedge B HBsAg Controls 1-3 HBsAg Adjustor	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.
<b>Developmental effects</b>	: HBsAg Reagent Wedge A HBsAg Reagent Wedge B HBsAg Controls 1-3 HBsAg Adjustor	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.
<b>Fertility effects</b>	: HBsAg Reagent Wedge A HBsAg Reagent Wedge B HBsAg Controls 1-3 HBsAg Adjustor	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.

**Other information** : Not available.

## SECTION 12: Ecological information

### 12.1 Toxicity

**Conclusion/Summary** : Not available.

### 12.2 Persistence and degradability

**Conclusion/Summary** : Not available.

### 12.3 Bioaccumulative potential

## SECTION 12: Ecological information

Product/ingredient name	LogP <sub>ow</sub>	BCF	Potential
HBsAg Reagent Wedge A aminocaproic acid	-2.95	-	low
HBsAg Reagent Wedge B aminocaproic acid	-2.95	-	low

### 12.4 Mobility in soil

**Soil/water partition coefficient (K<sub>oc</sub>)** : Not available.

**Mobility** : Not available.

### 12.5 Results of PBT and vPvB assessment

**PBT** : HBsAg Reagent Wedge A Not applicable.  
 HBsAg Reagent Wedge B Not applicable.  
 HBsAg Controls 1-3 Not applicable.  
 HBsAg Adjustor Not applicable.

**vPvB** : HBsAg Reagent Wedge A Not applicable.  
 HBsAg Reagent Wedge B Not applicable.  
 HBsAg Controls 1-3 Not applicable.  
 HBsAg Adjustor Not applicable.

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

## SECTION 13: Disposal considerations

The information in this section contains generic advice and guidance. The list of Identified Uses in Section 1 should be consulted for any available use-specific information provided in the Exposure Scenario(s).

### 13.1 Waste treatment methods

#### Product

**Methods of disposal** : The generation of waste should be avoided or minimised wherever possible. Disposal of this product, solutions and any by-products should at all times comply with the requirements of environmental protection and waste disposal legislation and any regional local authority requirements. Dispose of surplus and non-recyclable products via a licensed waste disposal contractor. Waste should not be disposed of untreated to the sewer unless fully compliant with the requirements of all authorities with jurisdiction.

**Hazardous waste** : Within the present knowledge of the supplier, this product is not regarded as hazardous waste, as defined by EU Directive 91/689/EEC.  
 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. Empty containers or liners may retain some product residues. Avoid dispersal of spilled material and runoff and contact with soil, waterways, drains and sewers.

## SECTION 14: Transport information

#### ADR/RID

**14.1 UN number** HBsAg Reagent Wedge A Not regulated.  
 HBsAg Reagent Wedge B Not regulated.  
 HBsAg Controls 1-3 Not regulated.  
 HBsAg Adjustor Not regulated.

**SECTION 14: Transport information**

<b>14.2 UN proper shipping name</b>	HBsAg Reagent Wedge A	-
	HBsAg Reagent Wedge B	-
	HBsAg Controls 1-3	-
	HBsAg Adjustor	-
<b>14.3 Transport hazard class(es)</b>	HBsAg Reagent Wedge A	-
	HBsAg Reagent Wedge B	-
	HBsAg Controls 1-3	-
	HBsAg Adjustor	-
<b>14.4 Packing group</b>	HBsAg Reagent Wedge A	-
	HBsAg Reagent Wedge B	-
	HBsAg Controls 1-3	-
	HBsAg Adjustor	-
<b>14.5 Environmental hazards</b>	HBsAg Reagent Wedge A	No.
	HBsAg Reagent Wedge B	No.
	HBsAg Controls 1-3	No.
	HBsAg Adjustor	No.
<b>Additional information</b>	HBsAg Reagent Wedge A	-
	HBsAg Reagent Wedge B	-
	HBsAg Controls 1-3	-
	HBsAg Adjustor	-

**ADN**

<b>14.1 UN number</b>	HBsAg Reagent Wedge A	Not regulated.
	HBsAg Reagent Wedge B	Not regulated.
	HBsAg Controls 1-3	Not regulated.
	HBsAg Adjustor	Not regulated.
<b>14.2 UN proper shipping name</b>	HBsAg Reagent Wedge A	-
	HBsAg Reagent Wedge B	-
	HBsAg Controls 1-3	-
	HBsAg Adjustor	-
<b>14.3 Transport hazard class(es)</b>	HBsAg Reagent Wedge A	-
	HBsAg Reagent Wedge B	-
	HBsAg Controls 1-3	-
	HBsAg Adjustor	-
<b>14.4 Packing group</b>	HBsAg Reagent Wedge A	-
	HBsAg Reagent Wedge B	-
	HBsAg Controls 1-3	-
	HBsAg Adjustor	-
<b>14.5 Environmental hazards</b>	HBsAg Reagent Wedge A	No.
	HBsAg Reagent Wedge B	No.
	HBsAg Controls 1-3	No.
	HBsAg Adjustor	No.
<b>Additional information</b>	HBsAg Reagent Wedge A	-
	HBsAg Reagent Wedge B	-
	HBsAg Controls 1-3	-
	HBsAg Adjustor	-

**IMDG**

<b>14.1 UN number</b>	HBsAg Reagent Wedge A	Not regulated.
	HBsAg Reagent Wedge B	Not regulated.
	HBsAg Controls 1-3	Not regulated.
	HBsAg Adjustor	Not regulated.

**SECTION 14: Transport information**

<b>14.2 UN proper shipping name</b>	HBsAg Reagent Wedge A	-
	HBsAg Reagent Wedge B	-
	HBsAg Controls 1-3	-
	HBsAg Adjustor	-
<b>14.3 Transport hazard class(es)</b>	HBsAg Reagent Wedge A	-
	HBsAg Reagent Wedge B	-
	HBsAg Controls 1-3	-
	HBsAg Adjustor	-
<b>14.4 Packing group</b>	HBsAg Reagent Wedge A	-
	HBsAg Reagent Wedge B	-
	HBsAg Controls 1-3	-
	HBsAg Adjustor	-
<b>14.5 Environmental hazards</b>	HBsAg Reagent Wedge A	No.
	HBsAg Reagent Wedge B	No.
	HBsAg Controls 1-3	No.
	HBsAg Adjustor	No.
<b>Additional information</b>	HBsAg Reagent Wedge A	-
	HBsAg Reagent Wedge B	-
	HBsAg Controls 1-3	-
	HBsAg Adjustor	-

**IATA**

<b>14.1 UN number</b>	HBsAg Reagent Wedge A	Not regulated.
	HBsAg Reagent Wedge B	Not regulated.
	HBsAg Controls 1-3	Not regulated.
	HBsAg Adjustor	Not regulated.
<b>14.2 UN proper shipping name</b>	HBsAg Reagent Wedge A	-
	HBsAg Reagent Wedge B	-
	HBsAg Controls 1-3	-
	HBsAg Adjustor	-
<b>14.3 Transport hazard class(es)</b>	HBsAg Reagent Wedge A	-
	HBsAg Reagent Wedge B	-
	HBsAg Controls 1-3	-
	HBsAg Adjustor	-
<b>14.4 Packing group</b>	HBsAg Reagent Wedge A	-
	HBsAg Reagent Wedge B	-
	HBsAg Controls 1-3	-
	HBsAg Adjustor	-
<b>14.5 Environmental hazards</b>	HBsAg Reagent Wedge A	No.
	HBsAg Reagent Wedge B	No.
	HBsAg Controls 1-3	No.
	HBsAg Adjustor	No.
<b>Additional information</b>	HBsAg Reagent Wedge A	-
	HBsAg Reagent Wedge B	-
	HBsAg Controls 1-3	-
	HBsAg Adjustor	-

**14.6 Special precautions for user** : HBsAg Reagent Wedge A

**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.

HBsAg Reagent Wedge B

**Transport within user's premises:**



## SECTION 14: Transport information

HBsAg Controls 1-3

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.

HBsAg Adjustor

**Transport within user's premises:**

always transport in closed containers that are upright and secure. Ensure that persons transporting the product know what to do in the event of an accident or spillage.

**14.7 Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code** : Not available.

## SECTION 15: Regulatory information

### 15.1 Safety, health and environmental regulations/legislation specific for the substance or mixture EU Regulation (EC) No. 1907/2006 (REACH)

Annex XIV - List of substances subject to authorisation

Annex XIV

None of the components are listed.

Substances of very high concern

None of the components are listed.

<b>Annex XVII - Restrictions on the manufacture, placing on the market and use of certain dangerous substances, mixtures and articles</b>	<b>:</b> HBsAg Reagent Wedge A	Not applicable.
	HBsAg Reagent Wedge B	Not applicable.
	HBsAg Controls 1-3	Not applicable.
	HBsAg Adjustor	Not applicable.

Other EU regulations


**Europe inventory** : Not determined.

Seveso II Directive

This product is not controlled under the Seveso II Directive.

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

## SECTION 16: Other information

 Indicates information that has changed from previously issued version.

**Abbreviations and acronyms** :

- ATE = Acute Toxicity Estimate
- CLP = Classification, Labelling and Packaging Regulation [Regulation (EC) No. 1272/2008]
- DMEL = Derived Minimal Effect Level
- DNEL = Derived No Effect Level
- EUH statement = CLP-specific Hazard statement
- PBT = Persistent, Bioaccumulative and Toxic
- PNEC = Predicted No Effect Concentration
- RRN = REACH Registration Number

**SECTION 16: Other information**

vPvB = Very Persistent and Very Bioaccumulative

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

Not classified.

Not classified.		
<b>Full text of abbreviated H statements</b>	<b>: HBsAg Reagent Wedge A</b> H319	Causes serious eye irritation.
	<b>HBsAg Reagent Wedge B</b> H319	Causes serious eye irritation.
<b>Full text of classifications [CLP/GHS]</b>	<b>: HBsAg Reagent Wedge A</b> Eye Irrit. 2, H319	SERIOUS EYE DAMAGE/ EYE IRRITATION - Category 2
	<b>HBsAg Reagent Wedge B</b> Eye Irrit. 2, H319	SERIOUS EYE DAMAGE/ EYE IRRITATION - Category 2
<b>Full text of abbreviated R phrases</b>	: Not applicable.	
<b>Full text of classifications [DSD/DPD]</b>	: Not applicable.	
<b>Date of printing</b>	: 2/17/2015.	
<b>Date of issue/ Date of revision</b>	: 2/17/2015.	
<b>Date of previous issue</b>	: No previous validation.	
<b>Version</b>	: 1	

[Notice to reader](#)

To the best of our knowledge, the information contained herein is accurate. However, neither the above-named supplier, nor any of its subsidiaries, assumes any liability whatsoever for the accuracy or completeness of the information contained herein.

Final determination of suitability of any material is the sole responsibility of the user. All materials may present unknown hazards and should be used with caution. Although certain hazards are described herein, we cannot guarantee that these are the only hazards that exist.