

# SAFETY DATA SHEET

IMMULITE® 2000 H. pylori IgG

**SIEMENS**  
**Healthineers** 

SDS no.:

L2KHPG2\_6

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

### 1.1 Product identifier

**Product name** : IMMULITE® 2000 H. pylori IgG  
**Product code** : L2KHPG2/6, 10381336, 10381335

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

<b>Identified uses</b>	H. Pylori IgG Reagent Wedge A	Diagnostic agents.
	H. pylori IgG Reagent Wedge B.	Diagnostic agents.
	H. Pylori IgG Adjustors	Diagnostic agents.
	IMMULITE® H. Pylori IgG Control Module	Diagnostic agents.
	H. pylori IgG 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>	H. Pylori IgG Reagent Wedge A	Mixture
	H. pylori IgG Reagent Wedge B.	Mixture
	H. Pylori IgG Adjustors	Mixture
	IMMULITE® H. Pylori IgG Control Module	Mixture
	H. pylori IgG Sample Diluent	Mixture

#### Classification according to UK CLP/GHS

##### **H. Pylori IgG Reagent Wedge A**

Skin Sens. 1, H317

##### **H. pylori IgG Reagent Wedge B.**

Skin Sens. 1, H317

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

**Hazard pictograms** :



**SECTION 2: Hazards identification**

<b>Signal word</b>	: H. Pylori IgG Reagent Wedge A H. pylori IgG Reagent Wedge B. H. Pylori IgG Adjustors IMMULITE® H. Pylori IgG Control Module H. pylori IgG Sample Diluent	Warning Warning No signal word. No signal word. No signal word.
<b>Hazard statements</b>	: H. Pylori IgG Reagent Wedge A  H. pylori IgG Reagent Wedge B.  H. Pylori IgG Adjustors  IMMULITE® H. Pylori IgG Control Module  H. pylori IgG Sample Diluent	H317 - May cause an allergic skin reaction. H317 - May cause an allergic skin reaction. No known significant effects or critical hazards. No known significant effects or critical hazards. No known significant effects or critical hazards.
<b><u>Precautionary statements</u></b>		
<b>Prevention</b>	: H. Pylori IgG Reagent Wedge A  H. pylori IgG Reagent Wedge B.  H. Pylori IgG Adjustors IMMULITE® H. Pylori IgG Control Module H. pylori IgG Sample Diluent	P280 - Wear protective gloves/protective clothing/eye protection/face protection. P280 - Wear protective gloves/protective clothing/eye protection/face protection. Not applicable. Not applicable. Not applicable.
<b>Response</b>	: H. Pylori IgG Reagent Wedge A          H. pylori IgG Reagent Wedge B.     H. Pylori IgG Adjustors IMMULITE® H. Pylori IgG Control Module H. pylori IgG Sample Diluent	P302 + P352 - IF ON SKIN: IF ON SKIN: Wash with plenty of soap and water. P333 + P313 - If skin irritation or rash occurs: If skin irritation or rash occurs: Get medical advice/attention. P362 + P364 - Take off contaminated clothing and wash it before reuse. P302 + P352 - IF ON SKIN: IF ON SKIN: Wash with plenty of soap and water. P333 + P313 - If skin irritation or rash occurs: If skin irritation or rash occurs: Get medical advice/attention. P362 + P364 - Take off contaminated clothing and wash it before reuse. Not applicable. Not applicable. Not applicable.
<b>Storage</b>	: H. Pylori IgG Reagent Wedge A H. pylori IgG Reagent Wedge B. H. Pylori IgG Adjustors IMMULITE® H. Pylori IgG Control Module H. pylori IgG Sample Diluent	Not applicable. Not applicable. Not applicable. Not applicable. Not applicable.
<b>Disposal</b>	: H. Pylori IgG Reagent Wedge A H. pylori IgG Reagent Wedge B. H. Pylori IgG Adjustors IMMULITE® H. Pylori IgG Control Module H. pylori IgG Sample Diluent	Not applicable. Not applicable. Not applicable. Not applicable. Not applicable.
<b>Supplemental label elements</b>	: H. Pylori IgG Reagent Wedge A H. pylori IgG Reagent Wedge B. H. Pylori IgG Adjustors IMMULITE® H. Pylori IgG Control Module H. pylori IgG Sample Diluent	Not applicable. Not applicable. Not applicable. Not applicable. Not applicable.

IMMULITE® 2000 H. pylori IgG

**SECTION 2: Hazards identification**

<b>Annex XVII - Restrictions on the manufacture, placing on the market and use of certain dangerous substances, mixtures and articles</b>	: H. Pylori IgG Reagent Wedge A H. pylori IgG Reagent Wedge B. H. Pylori IgG Adjustors IMMULITE® H. Pylori IgG Control Module H. pylori IgG 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>	: H. Pylori IgG Reagent Wedge A  H. pylori IgG Reagent Wedge B.  H. Pylori IgG Adjustors  IMMULITE® H. Pylori IgG Control Module  H. pylori IgG 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>	: H. Pylori IgG Reagent Wedge A H. pylori IgG Reagent Wedge B. H. Pylori IgG Adjustors IMMULITE® H. Pylori IgG Control Module H. pylori IgG Sample Diluent	None known. None known. None known. None known. None known.
<b>Additional information</b>	: Not available.  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>	: H. Pylori IgG Reagent Wedge A H. pylori IgG Reagent Wedge B. H. Pylori IgG Adjustors IMMULITE® H. Pylori IgG Control Module H. pylori IgG Sample Diluent	Mixture Mixture Mixture Mixture Mixture
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Product/ingredient name	Identifiers	%	Classification	Type
<b>H. Pylori IgG Reagent Wedge A</b> aminocaproic acid	EC: 200-469-3 CAS: 60-32-2	≤3	Eye Irrit. 2, H319	[1]
3(2H)-Isothiazolone, 2-methyl-	EC: 220-239-6 CAS: 2682-20-4	<0.1	Acute Tox. 3, H301 Acute Tox. 3, H311 Acute Tox. 2, H330 Skin Corr. 1B, H314 Eye Dam. 1, H318 Skin Sens. 1A, H317 Aquatic Acute 1, H400 (M=10) Aquatic Chronic 1, H410 (M=1) EUH071	[1]
<b>H. pylori IgG Reagent Wedge B.</b> aminocaproic acid	EC: 200-469-3 CAS: 60-32-2	≤3	Eye Irrit. 2, H319	[1]
3(2H)-Isothiazolone, 2-methyl-	EC: 220-239-6 CAS: 2682-20-4	<0.1	Acute Tox. 3, H301 Acute Tox. 3, H311 Acute Tox. 2, H330	[1]

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

zinc chloride	EC: 231-592-0 CAS: 7646-85-7 Index: 030-003-00-2	<0.01	Skin Corr. 1B, H314 Eye Dam. 1, H318 Skin Sens. 1A, H317 Aquatic Acute 1, H400 (M=10) Aquatic Chronic 1, H410 (M=1) EUH071 Acute Tox. 4, H302 Skin Corr. 1B, H314 Eye Dam. 1, H318 STOT SE 3, H335 Aquatic Acute 1, H400 (M=10) Aquatic Chronic 1, H410 (M=1) <b>See Section 16 for the full text of the H statements declared above.</b>	[1] [2]
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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** : H. Pylori IgG Reagent Wedge A

Immediately flush eyes with plenty of water, occasionally lifting the upper and lower eyelids. Check for and remove any contact lenses. Continue to rinse for at least 10 minutes. Get medical attention if irritation occurs.

H. pylori IgG Reagent Wedge B.

Immediately flush eyes with plenty of water, occasionally lifting the upper and lower eyelids. Check for and remove any contact lenses. Continue to rinse for at least 10 minutes. Get medical attention if irritation occurs.

H. Pylori IgG Adjustors

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.

IMMULITE® H. Pylori IgG Control Module

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.

H. pylori IgG 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.

**Inhalation** : H. Pylori IgG Reagent Wedge A

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-

## SECTION 4: First aid measures

H. pylori IgG Reagent Wedge B.

H. Pylori IgG Adjustors

IMMULITE® H. Pylori IgG Control Module

H. pylori IgG Sample Diluent

### Skin contact

: H. Pylori IgG Reagent Wedge A

H. pylori IgG Reagent Wedge B.

to-mouth resuscitation. Get medical attention if adverse health effects persist or are severe. If unconscious, place in recovery position and get medical attention immediately. Maintain an open airway. Loosen tight clothing such as a collar, tie, belt or waistband. 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. 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 adverse health effects persist or are severe. If unconscious, place in recovery position and get medical attention immediately. Maintain an open airway. Loosen tight clothing such as a collar, tie, belt or waistband. 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. 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. Remove victim to fresh air and keep at rest in a position comfortable for breathing. Get medical attention if symptoms occur. 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. 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. In the event of any complaints or symptoms, avoid further exposure. 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,

## SECTION 4: First aid measures

		or wear gloves. Continue to rinse for at least 10 minutes. Get medical attention. In the event of any complaints or symptoms, avoid further exposure. 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.
	H. Pylori IgG Adjustors	Flush contaminated skin with plenty of water. Remove contaminated clothing and shoes. Get medical attention if symptoms occur.
	IMMULITE® H. Pylori IgG Control Module	Flush contaminated skin with plenty of water. Remove contaminated clothing and shoes. Get medical attention if symptoms occur.
	H. pylori IgG Sample Diluent	Flush contaminated skin with plenty of water. Remove contaminated clothing and shoes. Get medical attention if symptoms occur.
<b>Ingestion</b>	: H. Pylori IgG Reagent Wedge A	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 adverse health effects persist or are severe. 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.
	H. pylori IgG Reagent Wedge B.	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 adverse health effects persist or are severe. 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.
	H. Pylori IgG Adjustors	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.
	IMMULITE® H. Pylori IgG Control Module	Wash out mouth with water. If material has been swallowed and the exposed

**SECTION 4: First aid measures**

	H. pylori IgG Sample Diluent	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.
<b>Protection of first-aiders</b>	: H. Pylori IgG Reagent Wedge A	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.
	H. pylori IgG Reagent Wedge B.	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.
	H. Pylori IgG Adjustors	No action shall be taken involving any personal risk or without suitable training.
	IMMULITE® H. Pylori IgG Control Module	No action shall be taken involving any personal risk or without suitable training.
	H. pylori IgG 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**

<b>Eye contact</b>	: H. Pylori IgG Reagent Wedge A H. pylori IgG Reagent Wedge B. H. Pylori IgG Adjustors IMMULITE® H. Pylori IgG Control Module H. pylori IgG Sample Diluent	No specific data. No specific data. No specific data. No specific data. No specific data.
<b>Inhalation</b>	: H. Pylori IgG Reagent Wedge A H. pylori IgG Reagent Wedge B. H. Pylori IgG Adjustors IMMULITE® H. Pylori IgG Control Module H. pylori IgG Sample Diluent	No specific data. No specific data. No specific data. No specific data. No specific data.
<b>Skin contact</b>	: H. Pylori IgG Reagent Wedge A  H. pylori IgG Reagent Wedge B.  H. Pylori IgG Adjustors IMMULITE® H. Pylori IgG Control Module H. pylori IgG Sample Diluent	Adverse symptoms may include the following: irritation redness Adverse symptoms may include the following: irritation redness No specific data. No specific data. No specific data.
<b>Ingestion</b>	: H. Pylori IgG Reagent Wedge A H. pylori IgG Reagent Wedge B. H. Pylori IgG Adjustors IMMULITE® H. Pylori IgG Control Module H. pylori IgG Sample Diluent	No specific data. No specific data. No specific data. No specific data. No specific data.

**SECTION 4: First aid measures****4.3 Indication of any immediate medical attention and special treatment needed**

<b>Notes to physician</b>	: H. Pylori IgG 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.
	H. pylori IgG 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.
	H. Pylori IgG 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.
	IMMULITE® H. Pylori IgG Control Module	Treat symptomatically. Contact poison treatment specialist immediately if large quantities have been ingested or inhaled.
	H. pylori IgG 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>	: H. Pylori IgG Reagent Wedge A	No specific treatment.
	H. pylori IgG Reagent Wedge B.	No specific treatment.
	H. Pylori IgG Adjustors	No specific treatment.
	IMMULITE® H. Pylori IgG Control Module	No specific treatment.
	H. pylori IgG Sample Diluent	No specific treatment.
	H. Pylori IgG Reagent Wedge A	Not available.
	H. pylori IgG Reagent Wedge B.	Not available.
	H. Pylori IgG Adjustors	Not available.
	IMMULITE® H. Pylori IgG Control Module	Not available.
	H. pylori IgG Sample Diluent	Not available.

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

**Suitable extinguishing media** : Use an extinguishing agent suitable for the surrounding fire.

**Unsuitable extinguishing media** : None known.

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

**Hazards from the substance or mixture** : In a fire or if heated, a pressure increase will occur and the container may burst.

**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.



## SECTION 5: Firefighting measures

- 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. Avoid breathing vapour or mist. Provide adequate ventilation. Wear appropriate respirator when ventilation is inadequate. 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).

### 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). Persons with a history of skin sensitization problems should not be employed in any process in which this product is used. Do not get in eyes or on skin or clothing. Do not ingest. Avoid breathing vapour or mist. Keep in the original container or an approved alternative made from a compatible material, kept tightly closed when not in use. Empty containers retain product residue and can be hazardous. Do not reuse container.
- 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.

**SECTION 7: Handling and storage****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
H. pylori IgG Reagent Wedge B. zinc chloride	<b>EH40/2005 WELs (United Kingdom (UK), 1/2020).</b> STEL: 2 mg/m <sup>3</sup> 15 minutes. Form: Fume TWA: 1 mg/m <sup>3</sup> 8 hours. Form: Fume

**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>H. Pylori IgG Reagent Wedge A</b> 3(2H)-Isothiazolone, 2-methyl-	DNEL	Long term Inhalation	0.021 mg/m <sup>3</sup>	General population	Local
	DNEL	Long term Inhalation	0.021 mg/m <sup>3</sup>	Workers	Local
	DNEL	Long term Oral	0.027 mg/kg bw/day	General population	Systemic
	DNEL	Short term Inhalation	0.043 mg/m <sup>3</sup>	General population	Local
	DNEL	Short term Inhalation	0.043 mg/m <sup>3</sup>	Workers	Local
	DNEL	Short term Oral	0.053 mg/kg bw/day	General population	Systemic
	DNEL	Long term Inhalation	0.021 mg/m <sup>3</sup>	General population	Local
	DNEL	Long term Inhalation	0.021 mg/m <sup>3</sup>	Workers	Local
	DNEL	Long term Oral	0.027 mg/kg bw/day	General population	Systemic
	DNEL	Short term Inhalation	0.043 mg/m <sup>3</sup>	General population	Local
	DNEL	Short term Inhalation	0.043 mg/m <sup>3</sup>	Workers	Local
<b>H. pylori IgG Reagent Wedge B.</b> 3(2H)-Isothiazolone, 2-methyl-  zinc chloride	DNEL	Short term Oral	0.053 mg/kg bw/day	General population	Systemic
	DNEL	Long term Oral	0.83 mg/kg bw/day	General population	Systemic
	DNEL	Long term Inhalation	1 mg/m <sup>3</sup>	Workers	Systemic
	DNEL	Long term Dermal	8.3 mg/kg bw/day	General population	Systemic
	DNEL	Long term Dermal	8.3 mg/kg bw/day	Workers	Systemic
	DNEL	Long term Inhalation	1.25 mg/m <sup>3</sup>	General population	Systemic

## SECTION 8: Exposure controls/personal protection

### 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. Contaminated work clothing should not be allowed out of the workplace. 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>	: H. Pylori IgG Reagent Wedge A	Liquid.
	H. pylori IgG Reagent Wedge B.	Liquid.
	H. Pylori IgG Adjustors	Liquid.
	IMMULITE® H. Pylori IgG Control Module	Liquid.
	H. pylori IgG Sample Diluent	Liquid.

**SECTION 9: Physical and chemical properties**

<b>Colour</b>	: H. Pylori IgG Reagent Wedge A	Colourless.
	H. pylori IgG Reagent Wedge B.	Colourless.
	H. Pylori IgG Adjustors	Colourless.
	IMMULITE® H. Pylori IgG Control Module	Colorless to light amber.
	H. pylori IgG Sample Diluent	Colourless.
<b>Odour</b>	: H. Pylori IgG Reagent Wedge A	Odourless.
	H. pylori IgG Reagent Wedge B.	Odourless.
	H. Pylori IgG Adjustors	Odourless.
	IMMULITE® H. Pylori IgG Control Module	Odourless.
	H. pylori IgG 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>	: H. Pylori IgG Reagent Wedge A	Not available.
	H. pylori IgG Reagent Wedge B.	Not available.
	H. Pylori IgG Adjustors	Not available.
	IMMULITE® H. Pylori IgG Control Module	Not available.
	H. pylori IgG Sample Diluent	Not available.
<b>Flammability (solid, gas)</b>	: H. Pylori IgG Reagent Wedge A	Not relevant/applicable due to nature of the product.
	H. pylori IgG Reagent Wedge B.	Not relevant/applicable due to nature of the product.
	H. Pylori IgG Adjustors	Not relevant/applicable due to nature of the product.
	IMMULITE® H. Pylori IgG Control Module	Not relevant/applicable due to nature of the product.
	H. pylori IgG Sample Diluent	Not relevant/applicable due to nature of the product.
<b>Upper/lower flammability or explosive limits</b>	: H. Pylori IgG Reagent Wedge A	Not available.
	H. pylori IgG Reagent Wedge B.	Not available.
	H. Pylori IgG Adjustors	Not available.
	IMMULITE® H. Pylori IgG Control Module	Not available.
	H. pylori IgG Sample Diluent	Not available.
<b>Flash point</b>	: H. Pylori IgG Reagent Wedge A	[Product does not sustain combustion.]
	H. pylori IgG Reagent Wedge B.	[Product does not sustain combustion.]
	H. Pylori IgG Adjustors	[Product does not sustain combustion.]
	IMMULITE® H. Pylori IgG Control Module	[Product does not sustain combustion.]
	H. pylori IgG Sample Diluent	[Product does not sustain combustion.]

Ingredient name	Closed cup			Open cup		
	°C	°F	Method	°C	°F	Method
H. Pylori IgG Reagent Wedge A Oxirane, 2-methyl-, polymer with oxirane	252	485.6				

Auto-ignition temperature :

**SECTION 9: Physical and chemical properties**

Ingredient name	°C	°F	Method
<b>H. pylori IgG Reagent Wedge B.</b> magnesium di(acetate)	310	590	EU A.16
<b>H. Pylori IgG Adjustors</b> sodium azide	309	588.2	EU A.16
<b>IMMULITE® H. Pylori IgG Control Module</b> sodium azide	309	588.2	EU A.16
<b>H. pylori IgG Sample Diluent</b> sodium azide	309	588.2	EU A.16

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

**pH** : H. Pylori IgG Reagent Wedge A 7.95 to 8.05  
H. pylori IgG Reagent Wedge B. 7.95 to 8.05  
H. Pylori IgG Adjustors 7.95 to 8.05  
IMMULITE® H. Pylori IgG Control Module 7.4  
H. pylori IgG Sample Diluent 7.95 to 8.05

**Viscosity** : H. Pylori IgG Reagent Wedge A Not available.  
H. pylori IgG Reagent Wedge B. Not available.  
H. Pylori IgG Adjustors Not available.  
IMMULITE® H. Pylori IgG Control Module Not available.  
H. pylori IgG 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
<b>H. Pylori IgG Reagent Wedge A</b> water	23.8	3.2				
<b>H. pylori IgG Reagent Wedge B.</b> water	23.8	3.2				
<b>H. Pylori IgG Adjustors</b> water	23.8	3.2				
<b>IMMULITE® H. Pylori IgG Control Module</b> sodium azide	0.0075	0.001				
<b>H. pylori IgG Sample Diluent</b> water	23.8	3.2				

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

**SECTION 9: Physical and chemical properties**

<b>Relative density</b>	: H. Pylori IgG Reagent Wedge A	1
	H. pylori IgG Reagent Wedge B.	1
	H. Pylori IgG Adjustors	1
	IMMULITE® H. Pylori IgG Control Module	1
	H. pylori IgG Sample Diluent	1
<b>Density</b>	: H. Pylori IgG Reagent Wedge A	Not available.
	H. pylori IgG Reagent Wedge B.	Not available.
	H. Pylori IgG Adjustors	Not available.
	IMMULITE® H. Pylori IgG Control Module	Not available.
	H. pylori IgG Sample Diluent	Not available.
<b>Vapour density</b>	: H. Pylori IgG Reagent Wedge A	Not available.
	H. pylori IgG Reagent Wedge B.	Not available.
	H. Pylori IgG Adjustors	Not available.
	IMMULITE® H. Pylori IgG Control Module	Not available.
	H. pylori IgG Sample Diluent	Not available.
<b>Explosive properties</b>	: H. Pylori IgG Reagent Wedge A	Not available.
	H. pylori IgG Reagent Wedge B.	Not available.
	H. Pylori IgG Adjustors	Not available.
	IMMULITE® H. Pylori IgG Control Module	Not available.
	H. pylori IgG Sample Diluent	Not available.
<b>Oxidising properties</b>	: H. Pylori IgG Reagent Wedge A	Not available.
	H. pylori IgG Reagent Wedge B.	Not available.
	H. Pylori IgG Adjustors	Not available.
	IMMULITE® H. Pylori IgG Control Module	Not available.
	H. pylori IgG Sample Diluent	Not available.
<b><u>Particle characteristics</u></b>		
<b>Median particle size</b>	: Not applicable.	
<b>9.2 Other information</b>		
<b>Fire point</b>	: H. Pylori IgG Reagent Wedge A	Not available.
	H. pylori IgG Reagent Wedge B.	Not available.
	H. Pylori IgG Adjustors	Not available.
	IMMULITE® H. Pylori IgG Control Module	Not available.
	H. pylori IgG 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****10.1 Reactivity** : No specific test data related to reactivity available for this product or its ingredients.**10.2 Chemical stability** : The product is stable.**10.3 Possibility of hazardous reactions** : Under normal conditions of storage and use, hazardous reactions will not occur.**10.4 Conditions to avoid** : No specific data.**10.5 Incompatible materials** : No specific data.**10.6 Hazardous decomposition products** : Under normal conditions of storage and use, hazardous decomposition products should not be produced.**SECTION 11: Toxicological information****11.1 Information on toxicological effects****Acute toxicity**

Product/ingredient name	Result	Species	Dose	Exposure
H. pylori IgG Reagent Wedge B. zinc chloride	LD50 Oral	Rat	350 mg/kg	-

**Conclusion/Summary** : H. Pylori IgG Reagent Wedge A Not available.  
H. pylori IgG Reagent Wedge B. Not available.  
H. Pylori IgG Adjustors Not available.  
IMMULITE® H. Pylori IgG Control Module Not available.  
H. pylori IgG 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)
H. Pylori IgG Reagent Wedge A 3(2H)-Isothiazolone, 2-methyl-	100	300	N/A	0.5	N/A
H. pylori IgG Reagent Wedge B. 3(2H)-Isothiazolone, 2-methyl- zinc chloride	100 350	300 N/A	N/A N/A	0.5 N/A	N/A N/A

**Irritation/Corrosion**

Product/ingredient name	Result	Species	Score	Exposure	Observation
H. Pylori IgG Reagent Wedge A aminocaproic acid	Eyes - Mild irritant	Rabbit	-	24 hours 500 mg	-
H. pylori IgG Reagent Wedge B. aminocaproic acid	Eyes - Mild irritant	Rabbit	-	24 hours 500 mg	-
zinc chloride	Skin - Severe irritant	Rabbit	-	120 hours 1 %	-

**Conclusion/Summary**

IMMULITE® 2000 H. pylori IgG

**SECTION 11: Toxicological information**

<b>Skin</b>	: H. Pylori IgG Reagent Wedge A	Not available.
	H. pylori IgG Reagent Wedge B.	Not available.
	H. Pylori IgG Adjustors	Not available.
	IMMULITE® H. Pylori IgG Control Module	Not available.
	H. pylori IgG Sample Diluent	Not available.
<b>Eyes</b>	: H. Pylori IgG Reagent Wedge A	Not available.
	H. pylori IgG Reagent Wedge B.	Not available.
	H. Pylori IgG Adjustors	Not available.
	IMMULITE® H. Pylori IgG Control Module	Not available.
	H. pylori IgG Sample Diluent	Not available.
<b>Respiratory</b>	: H. Pylori IgG Reagent Wedge A	Not available.
	H. pylori IgG Reagent Wedge B.	Not available.
	H. Pylori IgG Adjustors	Not available.
	IMMULITE® H. Pylori IgG Control Module	Not available.
	H. pylori IgG Sample Diluent	Not available.

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

<b>Skin</b>	: H. Pylori IgG Reagent Wedge A	Not available.
	H. pylori IgG Reagent Wedge B.	Not available.
	H. Pylori IgG Adjustors	Not available.
	IMMULITE® H. Pylori IgG Control Module	Not available.
	H. pylori IgG Sample Diluent	Not available.
<b>Respiratory</b>	: H. Pylori IgG Reagent Wedge A	Not available.
	H. pylori IgG Reagent Wedge B.	Not available.
	H. Pylori IgG Adjustors	Not available.
	IMMULITE® H. Pylori IgG Control Module	Not available.
	H. pylori IgG Sample Diluent	Not available.

**Mutagenicity****Conclusion/Summary**

: H. Pylori IgG Reagent Wedge A	Not available.
H. pylori IgG Reagent Wedge B.	Not available.
H. Pylori IgG Adjustors	Not available.
IMMULITE® H. Pylori IgG Control Module	Not available.
H. pylori IgG Sample Diluent	Not available.

**Carcinogenicity****Conclusion/Summary**

: H. Pylori IgG Reagent Wedge A	Not available.
H. pylori IgG Reagent Wedge B.	Not available.
H. Pylori IgG Adjustors	Not available.
IMMULITE® H. Pylori IgG Control Module	Not available.
H. pylori IgG Sample Diluent	Not available.

**Reproductive toxicity****Conclusion/Summary**

: H. Pylori IgG Reagent Wedge A	Not available.
H. pylori IgG Reagent Wedge B.	Not available.
H. Pylori IgG Adjustors	Not available.
IMMULITE® H. Pylori IgG Control Module	Not available.
H. pylori IgG Sample Diluent	Not available.

**Teratogenicity****Conclusion/Summary**

: H. Pylori IgG Reagent Wedge A	Not available.
H. pylori IgG Reagent Wedge B.	Not available.
H. Pylori IgG Adjustors	Not available.
IMMULITE® H. Pylori IgG Control Module	Not available.
H. pylori IgG Sample Diluent	Not available.

**Specific target organ toxicity (single exposure)**

Product/ingredient name	Category	Route of exposure	Target organs
H. pylori IgG Reagent Wedge B. zinc chloride	Category 3	-	Respiratory tract irritation



**SECTION 11: Toxicological information****Specific target organ toxicity (repeated exposure)**

Not available.

**Aspiration hazard**

Not available.

<b>Information on likely routes of exposure</b>	H. Pylori IgG Reagent Wedge A	Not available.
	H. pylori IgG Reagent Wedge B.	Not available.
	H. Pylori IgG Adjustors	Not available.
	IMMULITE® H. Pylori IgG Control Module	Not available.
	H. pylori IgG Sample Diluent	Not available.

**Potential acute health effects**

<b>Eye contact</b>	H. Pylori IgG Reagent Wedge A	No known significant effects or critical hazards.
	H. pylori IgG Reagent Wedge B.	No known significant effects or critical hazards.
	H. Pylori IgG Adjustors	No known significant effects or critical hazards.
	IMMULITE® H. Pylori IgG Control Module	No known significant effects or critical hazards.
	H. pylori IgG Sample Diluent	No known significant effects or critical hazards.
<b>Inhalation</b>	H. Pylori IgG Reagent Wedge A	No known significant effects or critical hazards.
	H. pylori IgG Reagent Wedge B.	No known significant effects or critical hazards.
	H. Pylori IgG Adjustors	No known significant effects or critical hazards.
	IMMULITE® H. Pylori IgG Control Module	No known significant effects or critical hazards.
	H. pylori IgG Sample Diluent	No known significant effects or critical hazards.
<b>Skin contact</b>	H. Pylori IgG Reagent Wedge A	May cause an allergic skin reaction.
	H. pylori IgG Reagent Wedge B.	May cause an allergic skin reaction.
	H. Pylori IgG Adjustors	No known significant effects or critical hazards.
	IMMULITE® H. Pylori IgG Control Module	No known significant effects or critical hazards.
	H. pylori IgG Sample Diluent	No known significant effects or critical hazards.
<b>Ingestion</b>	H. Pylori IgG Reagent Wedge A	No known significant effects or critical hazards.
	H. pylori IgG Reagent Wedge B.	No known significant effects or critical hazards.
	H. Pylori IgG Adjustors	No known significant effects or critical hazards.
	IMMULITE® H. Pylori IgG Control Module	No known significant effects or critical hazards.
	H. pylori IgG Sample Diluent	No known significant effects or critical hazards.

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

<b>Eye contact</b>	H. Pylori IgG Reagent Wedge A	No specific data.
	H. pylori IgG Reagent Wedge B.	No specific data.
	H. Pylori IgG Adjustors	No specific data.
	IMMULITE® H. Pylori IgG Control Module	No specific data.
	H. pylori IgG Sample Diluent	No specific data.

**SECTION 11: Toxicological information**

<b>Inhalation</b>	: H. Pylori IgG Reagent Wedge A	No specific data.
	H. pylori IgG Reagent Wedge B.	No specific data.
	H. Pylori IgG Adjustors	No specific data.
	IMMULITE® H. Pylori IgG Control Module	No specific data.
	H. pylori IgG Sample Diluent	No specific data.
<b>Skin contact</b>	: H. Pylori IgG Reagent Wedge A	Adverse symptoms may include the following: irritation redness
	H. pylori IgG Reagent Wedge B.	Adverse symptoms may include the following: irritation redness
	H. Pylori IgG Adjustors	No specific data.
<b>Ingestion</b>	IMMULITE® H. Pylori IgG Control Module	No specific data.
	H. pylori IgG Sample Diluent	No specific data.
	: H. Pylori IgG Reagent Wedge A	No specific data.
	H. pylori IgG Reagent Wedge B.	No specific data.
	H. Pylori IgG Adjustors	No specific data.
	IMMULITE® H. Pylori IgG Control Module	No specific data.
	H. pylori IgG 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>	: H. Pylori IgG Reagent Wedge A	Not available.
	H. pylori IgG Reagent Wedge B.	Not available.
	H. Pylori IgG Adjustors	Not available.
	IMMULITE® H. Pylori IgG Control Module	Not available.
	H. pylori IgG Sample Diluent	Not available.
<b>Potential delayed effects</b>	: H. Pylori IgG Reagent Wedge A	Not available.
	H. pylori IgG Reagent Wedge B.	Not available.
	H. Pylori IgG Adjustors	Not available.
	IMMULITE® H. Pylori IgG Control Module	Not available.
	H. pylori IgG Sample Diluent	Not available.

**Long term exposure**

<b>Potential immediate effects</b>	: H. Pylori IgG Reagent Wedge A	Not available.
	H. pylori IgG Reagent Wedge B.	Not available.
	H. Pylori IgG Adjustors	Not available.
	IMMULITE® H. Pylori IgG Control Module	Not available.
	H. pylori IgG Sample Diluent	Not available.
<b>Potential delayed effects</b>	: H. Pylori IgG Reagent Wedge A	Not available.
	H. pylori IgG Reagent Wedge B.	Not available.
	H. Pylori IgG Adjustors	Not available.
	IMMULITE® H. Pylori IgG Control Module	Not available.
	H. pylori IgG Sample Diluent	Not available.

**Potential chronic health effects**

Not available.

<b>Conclusion/Summary</b>	: H. Pylori IgG Reagent Wedge A	Not available.
	H. pylori IgG Reagent Wedge B.	Not available.
	H. Pylori IgG Adjustors	Not available.
	IMMULITE® H. Pylori IgG Control Module	Not available.
	H. pylori IgG Sample Diluent	Not available.

**SECTION 11: Toxicological information**

<b>General</b>	: H. Pylori IgG Reagent Wedge A	Once sensitized, a severe allergic reaction may occur when subsequently exposed to very low levels.
	H. pylori IgG Reagent Wedge B.	Once sensitized, a severe allergic reaction may occur when subsequently exposed to very low levels.
	H. Pylori IgG Adjustors	No known significant effects or critical hazards.
	IMMULITE® H. Pylori IgG Control Module	No known significant effects or critical hazards.
	H. pylori IgG Sample Diluent	No known significant effects or critical hazards.
<b>Carcinogenicity</b>	: H. Pylori IgG Reagent Wedge A	No known significant effects or critical hazards.
	H. pylori IgG Reagent Wedge B.	No known significant effects or critical hazards.
	H. Pylori IgG Adjustors	No known significant effects or critical hazards.
	IMMULITE® H. Pylori IgG Control Module	No known significant effects or critical hazards.
	H. pylori IgG Sample Diluent	No known significant effects or critical hazards.
<b>Mutagenicity</b>	: H. Pylori IgG Reagent Wedge A	No known significant effects or critical hazards.
	H. pylori IgG Reagent Wedge B.	No known significant effects or critical hazards.
	H. Pylori IgG Adjustors	No known significant effects or critical hazards.
	IMMULITE® H. Pylori IgG Control Module	No known significant effects or critical hazards.
	H. pylori IgG Sample Diluent	No known significant effects or critical hazards.
<b>Reproductive toxicity</b>	: H. Pylori IgG Reagent Wedge A	No known significant effects or critical hazards.
	H. pylori IgG Reagent Wedge B.	No known significant effects or critical hazards.
	H. Pylori IgG Adjustors	No known significant effects or critical hazards.
	IMMULITE® H. Pylori IgG Control Module	No known significant effects or critical hazards.
	H. pylori IgG Sample Diluent	No known significant effects or critical hazards.
<b>Interactive effects</b>	: H. Pylori IgG Reagent Wedge A	Not available.
	H. pylori IgG Reagent Wedge B.	Not available.
	H. Pylori IgG Adjustors	Not available.
	IMMULITE® H. Pylori IgG Control Module	Not available.
	H. pylori IgG Sample Diluent	Not available.
<b><u>Toxicokinetics</u></b>		
<b>Absorption</b>	: H. Pylori IgG Reagent Wedge A	Not available.
	H. pylori IgG Reagent Wedge B.	Not available.
	H. Pylori IgG Adjustors	Not available.
	IMMULITE® H. Pylori IgG Control Module	Not available.
	H. pylori IgG Sample Diluent	Not available.
<b>Distribution</b>	: H. Pylori IgG Reagent Wedge A	Not available.
	H. pylori IgG Reagent Wedge B.	Not available.
	H. Pylori IgG Adjustors	Not available.
	IMMULITE® H. Pylori IgG Control Module	Not available.
	H. pylori IgG Sample Diluent	Not available.

IMMULITE® 2000 H. pylori IgG

**SECTION 11: Toxicological information**

<b>Metabolism</b>	: H. Pylori IgG Reagent Wedge A	Not available.
	H. pylori IgG Reagent Wedge B.	Not available.
	H. Pylori IgG Adjustors	Not available.
	IMMULITE® H. Pylori IgG Control Module	Not available.
	H. pylori IgG Sample Diluent	Not available.
<b>Elimination</b>	: H. Pylori IgG Reagent Wedge A	Not available.
	H. pylori IgG Reagent Wedge B.	Not available.
	H. Pylori IgG Adjustors	Not available.
	IMMULITE® H. Pylori IgG Control Module	Not available.
	H. pylori IgG Sample Diluent	Not available.
<b>Other information</b>	: H. Pylori IgG Reagent Wedge A	Not available.
	H. pylori IgG Reagent Wedge B.	Not available.
	H. Pylori IgG Adjustors	Not available.
	IMMULITE® H. Pylori IgG Control Module	Not available.
	H. pylori IgG Sample Diluent	Not available.

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

Product/ingredient name	Result	Species	Exposure
<b>H. Pylori IgG Reagent Wedge A</b> 3(2H)-Isothiazolone, 2-methyl-	Acute EC50 0.18 ppm Fresh water	Daphnia - Water flea - Daphnia magna	48 hours
	Acute LC50 0.07 ppm Fresh water	Fish - Rainbow trout,donaldson trout - Oncorhynchus mykiss	96 hours
<b>H. pylori IgG Reagent Wedge B.</b> 3(2H)-Isothiazolone, 2-methyl-  zinc chloride	Acute EC50 0.18 ppm Fresh water	Daphnia - Water flea - Daphnia magna	48 hours
	Acute LC50 0.07 ppm Fresh water	Fish - Rainbow trout,donaldson trout - Oncorhynchus mykiss	96 hours
	Acute EC50 34 µg/l Fresh water	Algae - Green algae - Chlorella vulgaris - Exponential growth phase	72 hours
	Acute EC50 26 µg/l Marine water	Algae - Diatom - Navicula incerta	96 hours
	Acute EC50 1.8 mg/l Fresh water	Aquatic plants - Lesser Duckweed - Lemna aequinoctialis	96 hours
	Acute EC50 100 µg/l Fresh water	Daphnia - Water flea - Daphnia magna	48 hours
	Acute LC50 49.99 µg/l Fresh water	Crustaceans - Water flea - Moina irrasa - Neonate	48 hours
	Acute LC50 0.027 mg/l Marine water	Fish - Sand Flounder - Limanda punctatissima - Pre-larvae	96 hours
	Chronic NOEC 20 µg/l Marine water	Algae - Green algae - Chlorella sp. - Exponential growth phase	72 hours
	Chronic NOEC 1000 µg/l Fresh water	Crustaceans - Red swamp crayfish - Procambarus clarkii - Intermolt	21 days
	Chronic NOEC 80 µg/l Fresh water	Daphnia - Water flea - Daphnia magna - Juvenile (Fledgling, Hatchling, Weanling)	21 days
	Chronic NOEC 31.5 µg/l Fresh water	Fish - Rainbow trout,donaldson trout - Oncorhynchus mykiss	30 days

**SECTION 12: Ecological information**

<b>Conclusion/Summary</b>	: H. Pylori IgG Reagent Wedge A	Not available.
	H. pylori IgG Reagent Wedge B.	Not available.
	H. Pylori IgG Adjustors	Not available.
	IMMULITE® H. Pylori IgG Control Module	Not available.
	H. pylori IgG Sample Diluent	Not available.

**12.2 Persistence and degradability**

<b>Conclusion/Summary</b>	: H. Pylori IgG Reagent Wedge A	Not available.
	H. pylori IgG Reagent Wedge B.	Not available.
	H. Pylori IgG Adjustors	Not available.
	IMMULITE® H. Pylori IgG Control Module	Not available.
	H. pylori IgG Sample Diluent	Not available.

**12.3 Bioaccumulative potential**

Product/ingredient name	LogP <sub>ow</sub>	BCF	Potential
<b>H. Pylori IgG Reagent Wedge A</b> aminocaproic acid	-2.95	-	low
<b>H. pylori IgG Reagent Wedge B.</b> aminocaproic acid	-2.95	-	low

**12.4 Mobility in soil**

<b>Soil/water partition coefficient (K<sub>oc</sub>)</b>	: H. Pylori IgG Reagent Wedge A	Not available.
	H. pylori IgG Reagent Wedge B.	Not available.
	H. Pylori IgG Adjustors	Not available.
	IMMULITE® H. Pylori IgG Control Module	Not available.
	H. pylori IgG Sample Diluent	Not available.
<b>Mobility</b>	: H. Pylori IgG Reagent Wedge A	Not available.
	H. pylori IgG Reagent Wedge B.	Not available.
	H. Pylori IgG Adjustors	Not available.
	IMMULITE® H. Pylori IgG Control Module	Not available.
	H. pylori IgG 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**

IMMULITE® 2000 H. pylori IgG

**SECTION 13: Disposal considerations**

- 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>	H. Pylori IgG Reagent Wedge A	Not regulated.
	H. pylori IgG Reagent Wedge B.	Not regulated.
	H. Pylori IgG Adjustors	Not regulated.
	IMMULITE® H. Pylori IgG Control Module	Not regulated.
	H. pylori IgG Sample Diluent	Not regulated.
<b>14.2 UN proper shipping name</b>	H. Pylori IgG Reagent Wedge A	-
	H. pylori IgG Reagent Wedge B.	-
	H. Pylori IgG Adjustors	-
	IMMULITE® H. Pylori IgG Control Module	-
	H. pylori IgG Sample Diluent	-
<b>14.3 Transport hazard class(es)</b>	H. Pylori IgG Reagent Wedge A	-
	H. pylori IgG Reagent Wedge B.	-
	H. Pylori IgG Adjustors	-
	IMMULITE® H. Pylori IgG Control Module	-
	H. pylori IgG Sample Diluent	-
<b>14.4 Packing group</b>	H. Pylori IgG Reagent Wedge A	-
	H. pylori IgG Reagent Wedge B.	-
	H. Pylori IgG Adjustors	-
	IMMULITE® H. Pylori IgG Control Module	-
	H. pylori IgG Sample Diluent	-
<b>14.5 Environmental hazards</b>	H. Pylori IgG Reagent Wedge A	No.
	H. pylori IgG Reagent Wedge B.	No.
	H. Pylori IgG Adjustors	No.
	IMMULITE® H. Pylori IgG Control Module	No.
	H. pylori IgG Sample Diluent	No.
<b>Additional information</b>	H. Pylori IgG Reagent Wedge A	-
	H. pylori IgG Reagent Wedge B.	-
	H. Pylori IgG Adjustors	-
	IMMULITE® H. Pylori IgG Control Module	-
	H. pylori IgG Sample Diluent	-

**ADN**

<b>14.1 UN number</b>	H. Pylori IgG Reagent Wedge A	Not regulated.
	H. pylori IgG Reagent Wedge B.	Not regulated.
	H. Pylori IgG Adjustors	Not regulated.
	IMMULITE® H. Pylori IgG Control Module	Not regulated.
	H. pylori IgG Sample Diluent	Not regulated.
<b>14.2 UN proper shipping name</b>	H. Pylori IgG Reagent Wedge A	-
	H. pylori IgG Reagent Wedge B.	-
	H. Pylori IgG Adjustors	-
	IMMULITE® H. Pylori IgG Control Module	-
	H. pylori IgG Sample Diluent	-

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<b>14.3 Transport hazard class(es)</b>	H. Pylori IgG Reagent Wedge A	-
	H. pylori IgG Reagent Wedge B.	-
	H. Pylori IgG Adjustors	-
	IMMULITE® H. Pylori IgG Control Module	-
	H. pylori IgG Sample Diluent	-
<b>14.4 Packing group</b>	H. Pylori IgG Reagent Wedge A	-
	H. pylori IgG Reagent Wedge B.	-
	H. Pylori IgG Adjustors	-
	IMMULITE® H. Pylori IgG Control Module	-
	H. pylori IgG Sample Diluent	-
<b>14.5 Environmental hazards</b>	H. Pylori IgG Reagent Wedge A	No.
	H. pylori IgG Reagent Wedge B.	No.
	H. Pylori IgG Adjustors	No.
	IMMULITE® H. Pylori IgG Control Module	No.
	H. pylori IgG Sample Diluent	No.
<b>Additional information</b>	H. Pylori IgG Reagent Wedge A	-
	H. pylori IgG Reagent Wedge B.	-
	H. Pylori IgG Adjustors	-
	IMMULITE® H. Pylori IgG Control Module	-
	H. pylori IgG Sample Diluent	-

### IMDG

<b>14.1 UN number</b>	H. Pylori IgG Reagent Wedge A	Not regulated.
	H. pylori IgG Reagent Wedge B.	Not regulated.
	H. Pylori IgG Adjustors	Not regulated.
	IMMULITE® H. Pylori IgG Control Module	Not regulated.
	H. pylori IgG Sample Diluent	Not regulated.
<b>14.2 UN proper shipping name</b>	H. Pylori IgG Reagent Wedge A	-
	H. pylori IgG Reagent Wedge B.	-
	H. Pylori IgG Adjustors	-
	IMMULITE® H. Pylori IgG Control Module	-
	H. pylori IgG Sample Diluent	-
<b>14.3 Transport hazard class(es)</b>	H. Pylori IgG Reagent Wedge A	-
	H. pylori IgG Reagent Wedge B.	-
	H. Pylori IgG Adjustors	-
	IMMULITE® H. Pylori IgG Control Module	-
	H. pylori IgG Sample Diluent	-
<b>14.4 Packing group</b>	H. Pylori IgG Reagent Wedge A	-
	H. pylori IgG Reagent Wedge B.	-
	H. Pylori IgG Adjustors	-
	IMMULITE® H. Pylori IgG Control Module	-
	H. pylori IgG Sample Diluent	-
<b>14.5 Environmental hazards</b>	H. Pylori IgG Reagent Wedge A	No.
	H. pylori IgG Reagent Wedge B.	No.
	H. Pylori IgG Adjustors	No.
	IMMULITE® H. Pylori IgG Control Module	No.
	H. pylori IgG Sample Diluent	No.
<b>Additional information</b>	H. Pylori IgG Reagent Wedge A	-
	H. pylori IgG Reagent Wedge B.	-
	H. Pylori IgG Adjustors	-
	IMMULITE® H. Pylori IgG Control Module	-
	H. pylori IgG Sample Diluent	-

### IATA

**SECTION 14: Transport information**

<b>14.1 UN number</b>	H. Pylori IgG Reagent Wedge A	Not regulated.
	H. pylori IgG Reagent Wedge B.	Not regulated.
	H. Pylori IgG Adjustors	Not regulated.
	IMMULITE® H. Pylori IgG Control Module	Not regulated.
	H. pylori IgG Sample Diluent	Not regulated.
<b>14.2 UN proper shipping name</b>	H. Pylori IgG Reagent Wedge A	-
	H. pylori IgG Reagent Wedge B.	-
	H. Pylori IgG Adjustors	-
	IMMULITE® H. Pylori IgG Control Module	-
	H. pylori IgG Sample Diluent	-
<b>14.3 Transport hazard class(es)</b>	H. Pylori IgG Reagent Wedge A	-
	H. pylori IgG Reagent Wedge B.	-
	H. Pylori IgG Adjustors	-
	IMMULITE® H. Pylori IgG Control Module	-
	H. pylori IgG Sample Diluent	-
<b>14.4 Packing group</b>	H. Pylori IgG Reagent Wedge A	-
	H. pylori IgG Reagent Wedge B.	-
	H. Pylori IgG Adjustors	-
	IMMULITE® H. Pylori IgG Control Module	-
	H. pylori IgG Sample Diluent	-
<b>14.5 Environmental hazards</b>	H. Pylori IgG Reagent Wedge A	No.
	H. pylori IgG Reagent Wedge B.	No.
	H. Pylori IgG Adjustors	No.
	IMMULITE® H. Pylori IgG Control Module	No.
	H. pylori IgG Sample Diluent	No.
<b>Additional information</b>	H. Pylori IgG Reagent Wedge A	-
	H. pylori IgG Reagent Wedge B.	-
	H. Pylori IgG Adjustors	-
	IMMULITE® H. Pylori IgG Control Module	-
	H. pylori IgG Sample Diluent	-
<b>14.6 Special precautions for user</b>	<p>H. Pylori IgG Reagent Wedge A</p> <p>H. pylori IgG Reagent Wedge B.</p> <p>H. Pylori IgG Adjustors</p> <p>IMMULITE® H. Pylori IgG Control Module</p> <p>H. pylori IgG Sample Diluent</p>	
	<p><b>Transport within user's premises:</b> 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.</p> <p><b>Transport within user's premises:</b> 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.</p> <p><b>Transport within user's premises:</b> 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.</p> <p><b>Transport within user's premises:</b> 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.</p> <p><b>Transport within user's premises:</b> 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.</p>	



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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.

<b>Annex XVII - Restrictions on the manufacture, placing on the market and use of certain dangerous substances, mixtures and articles</b>	: H. Pylori IgG Reagent Wedge A	Not applicable.
	H. pylori IgG Reagent Wedge B.	Not applicable.
	H. Pylori IgG Adjustors	Not applicable.
	IMMULITE® H. Pylori IgG Control Module	Not applicable.
	H. pylori IgG Sample Diluent	Not applicable.

### Seveso Directive

This product is not controlled under the Seveso Directive.

### EU regulations

<b>Industrial emissions (integrated pollution prevention and control) - Air</b>	: H. Pylori IgG Reagent Wedge A	Not listed
	H. pylori IgG Reagent Wedge B.	Not listed
	H. Pylori IgG Adjustors	Not listed
	IMMULITE® H. Pylori IgG Control Module	Not listed
	H. pylori IgG Sample Diluent	Not listed
<b>Industrial emissions (integrated pollution prevention and control) - Water</b>	: H. Pylori IgG Reagent Wedge A	Not listed
	H. pylori IgG Reagent Wedge B.	Not listed
	H. Pylori IgG Adjustors	Not listed
	IMMULITE® H. Pylori IgG Control Module	Not listed
	H. pylori IgG 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

IMMULITE® 2000 *H. pylori* IgG**SECTION 15: Regulatory information**

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>H. Pylori IgG Reagent Wedge A</b> Skin Sens. 1, H317	Calculation method
<b>H. pylori IgG Reagent Wedge B.</b> Skin Sens. 1, H317	Calculation method

**Full text of abbreviated H statements**

<b>H. Pylori IgG Reagent Wedge A</b>	
H301	Toxic if swallowed.
H311	Toxic in contact with skin.
H314	Causes severe skin burns and eye damage.
H317	May cause an allergic skin reaction.
H318	Causes serious eye damage.
H319	Causes serious eye irritation.
H330	Fatal if inhaled.
H400	Very toxic to aquatic life.
H410	Very toxic to aquatic life with long lasting effects.
EUH071	Corrosive to the respiratory tract.
<b>H. pylori IgG Reagent Wedge B.</b>	
H301	Toxic if swallowed.
H302	Harmful if swallowed.
H311	Toxic in contact with skin.
H314	Causes severe skin burns and eye damage.
H317	May cause an allergic skin reaction.
H318	Causes serious eye damage.
H319	Causes serious eye irritation.
H330	Fatal if inhaled.
H335	May cause respiratory irritation.
H400	Very toxic to aquatic life.
H410	Very toxic to aquatic life with long lasting effects.
EUH071	Corrosive to the respiratory tract.

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**SECTION 16: Other information****Full text of classifications****H. Pylori IgG****Reagent Wedge A**

Acute Tox. 2	ACUTE TOXICITY - Category 2
Acute Tox. 3	ACUTE TOXICITY - Category 3
Aquatic Acute 1	SHORT-TERM (ACUTE) AQUATIC HAZARD - Category 1
Aquatic Chronic 1	LONG-TERM (CHRONIC) AQUATIC HAZARD - Category 1
Eye Dam. 1	SERIOUS EYE DAMAGE/EYE IRRITATION - Category 1
Eye Irrit. 2	SERIOUS EYE DAMAGE/EYE IRRITATION - Category 2
Skin Corr. 1B	SKIN CORROSION/IRRITATION - Category 1B
Skin Sens. 1	SKIN SENSITISATION - Category 1
Skin Sens. 1A	SKIN SENSITISATION - Category 1A

**H. pylori IgG****Reagent Wedge B.**

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
Eye Dam. 1	SERIOUS EYE DAMAGE/EYE IRRITATION - Category 1
Eye Irrit. 2	SERIOUS EYE DAMAGE/EYE IRRITATION - Category 2
Skin Corr. 1B	SKIN CORROSION/IRRITATION - Category 1B
Skin Sens. 1	SKIN SENSITISATION - Category 1
Skin Sens. 1A	SKIN SENSITISATION - Category 1A
STOT SE 3	SPECIFIC TARGET ORGAN TOXICITY - SINGLE EXPOSURE - Category 3

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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.