# **SAFETY DATA SHEET**

MSDS no.: L2KCVG2\_6

SIEMENS

IMMULITE® 2000 CMV IgG

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

1.1 Product identifier		
Product name	: IMMULITE® 2000 CMV IgG	
Product code	: L2KCVG2/6, 10381308, 10381309	
<b>Product description</b>	: Not available.	
Product type	: Liquid.	
Other means of identification	: CMV IgG Reagent Wedge A CMV IgG Reagent Wedge B IgG/IgM Sample Diluent CMV IgG Controls CMV IgG Adjustor	L2CVGA2-A L2CVGA2-B L2IGZ1/2 LCVGC1, LCVGC2, LCVGCM, 10469595 LCVGR

**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)

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

2.1 Classification of the su	bstance or mixture	
Product definition	: CMV IgG Reagent Wedge A CMV IgG Reagent Wedge B IgG/IgM Sample Diluent CMV IgG Controls CMV IgG Adjustor	Mixture Mixture Mixture Mixture Mixture
Classification according to	o Directive 1999/45/EC [DPD]	
	CMV IgG Reagent Wedge A	The product is not classified as dangerous according to Directive 1999/45/EC and its amendments.
	CMV IgG Reagent Wedge B	The product is not classified as dangerous according to Directive 1999/45/EC and its amendments.
	IgG/IgM Sample Diluent	The product is not classified as dangerous according to Directive 1999/45/EC and its amendments.
	CMV IgG Controls	The product is not classified as dangerous according to Directive 1999/45/EC and its amendments.
	CMV IgG Adjustor	The product is not classified as dangerous according to Directive 1999/45/EC and its amendments.
Classification	: CMV IgG Reagent Wedge A CMV IgG Reagent Wedge B IgG/IgM Sample Diluent CMV IgG Controls CMV IgG Adjustor	Not classified. Not classified. Not classified. Not classified. Not classified.
Physical/chemical hazards	: CMV IgG Reagent Wedge A CMV IgG Reagent Wedge B IgG/IgM Sample Diluent CMV IgG Controls CMV IgG Adjustor	Not applicable. Not applicable. Not applicable. Not applicable. Not applicable.
Human health hazards	: CMV IgG Reagent Wedge A CMV IgG Reagent Wedge B IgG/IgM Sample Diluent CMV IgG Controls CMV IgG Adjustor	Not applicable. Not applicable. Not applicable. Not applicable. Not applicable.
Environmental hazards	: CMV IgG Reagent Wedge A CMV IgG Reagent Wedge B IgG/IgM Sample Diluent CMV IgG Controls CMV IgG Adjustor	Not applicable. Not applicable. Not applicable. Not applicable. Not applicable.
See Section 16 for the full te	ext of the R phrases or H statements declar	red above.

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 <u>Precautionary statements</u> Indication of danger	:	
Risk phrases	: CMV IgG Reagent Wedge A	This product is not classified as dangerous according to EU legislation.
	CMV IgG Reagent Wedge B	This product is not classified as dangerous according to EU legislation.
	IgG/IgM Sample Diluent	This product is not classified as dangerous according to EU legislation.
	CMV IgG Controls	This product is not classified as dangerous according to EU legislation.
	CMV IgG Adjustor	This product is not classified as dangerous according to EU legislation.

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

: CMV IgG Reagent Wedge A	Not applicable.
	Not applicable.
	Not applicable.
	Not applicable.
CMV IgG Adjustor	Not applicable.
: Not applicable.	
: CMV IgG Reagent Wedge A	Not applicable.
CMV IgG Reagent Wedge B	Not applicable.
IgG/IgM Sample Diluent	Not applicable.
CMV IgG Controls	Not applicable.
CMV IgG Adjustor	Not applicable.
	<ul> <li>CMV IgG Reagent Wedge B IgG/IgM Sample Diluent CMV IgG Controls CMV IgG Adjustor</li> <li>Not applicable.</li> <li>CMV IgG Reagent Wedge A CMV IgG Reagent Wedge B IgG/IgM Sample Diluent CMV IgG Controls</li> </ul>

Other hazards which do	1	None known.
not result in classification		

Not available.

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

Substance/mixture	: CMV IgG Reag CMV IgG Reag IgG/IgM Sample CMV IgG Contr CMV IgG Adjus	ent Wedge e Diluent ols		ure ure	
Product/ingredient name	Identifiers	%	<u>Clas</u> 67/548/EEC	<u>ssification</u> Regulation (EC) No. 1272/2008 [CLP]	Туре
CMV IgG Reagent Wedge A aminocaproic acid	EC: 200-469-3 CAS: 60-32-2	>=1, <5	Not classified.	Eye Irrit. 2, H319	[1]
CMV IgG Reagent Wedge B aminocaproic acid	EC: 200-469-3 CAS: 60-32-2	>=1, <5	Not classified.	Eye Irrit. 2, H319	[1]
IgG/IgM Sample Diluent aminocaproic acid	EC: 200-469-3 CAS: 60-32-2	>=1, <5	Not classified.	Eye Irrit. 2, H319 See Section 16 for the full text of the H statements declared	[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.

<u>Type</u>

[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

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

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

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

4.1 Description of first aid	measures	
Eye contact	: CMV 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. Get medical attention if irritation occurs.
	CMV 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. Get medical attention if irritation occurs.
	IgG/IgM Sample Diluent	Immediately flush eyes with plenty of water, occasionally lifting the upper and lower eyelids. Check for and remove any contact lenses. Get medical attention if irritation occurs.
	CMV IgG Controls	Immediately flush eyes with plenty of water, occasionally lifting the upper and lower eyelids. Check for and remove any contact lenses. Get medical attention if irritation occurs.
	CMV IgG 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.
Inhalation	: CMV IgG 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.
	CMV IgG 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.
	IgG/IgM Sample Diluent	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
	CMV IgG Controls	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
Date of issue/Date of revision	CMV IgG Adjustor : 2/17/2015. Date of previous issue	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
Date OF ISSUE/Date OF FEVISION	: 2/17/2015. Date of previous issue	: No previous validation. Version : 1 4/21

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# **SECTION 4: First aid measures**

		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.
Skin contact :	CMV IgG Reagent Wedge A	Flush contaminated skin with plenty of water. Remove contaminated clothing and shoes. Get medical attention if symptoms occur.
	CMV IgG Reagent Wedge B	Flush contaminated skin with plenty of water. Remove contaminated clothing and shoes. Get medical attention if
	IgG/IgM Sample Diluent	symptoms occur. Flush contaminated skin with plenty of water. Remove contaminated clothing and shoes. Get medical attention if
	CMV IgG Controls	symptoms occur. Flush contaminated skin with plenty of water. Remove contaminated clothing and shoes. Get medical attention if
	CMV IgG Adjustor	symptoms occur. Flush contaminated skin with plenty of water. Remove contaminated clothing and shoes. Get medical attention if symptoms occur.
Ingestion :	CMV IgG 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.
	CMV IgG 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 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
	IgG/IgM Sample Diluent	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.
	CMV IgG Controls	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
	CMV IgG Adjustor	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

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# Conforms to Regulation (EC) No. 1907/2006 (REACH), Annex II - United Kingdom (UK)

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

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 healt	<u>h effects</u>	-
Eye contact	: CMV IgG Reagent Wedge A	No known significant effects or critical hazards.
	CMV IgG Reagent Wedge B	No known significant effects or critical hazards.
	IgG/IgM Sample Diluent	No known significant effects or critical hazards.
	CMV IgG Controls	No known significant effects or critical hazards.
	CMV IgG Adjustor	No known significant effects or critical hazards.
Inhalation	: CMV IgG Reagent Wedge A	Exposure to decomposition products may cause a health hazard. Serious effects may be delayed following exposure.
	CMV IgG Reagent Wedge B	Exposure to decomposition products may cause a health hazard. Serious effects may be delayed following exposure.
	IgG/IgM Sample Diluent	Exposure to decomposition products may cause a health hazard. Serious effects may be delayed following exposure.
	CMV IgG Controls	Exposure to decomposition products may cause a health hazard. Serious effects may be delayed following exposure.
	CMV IgG Adjustor	Exposure to decomposition products may cause a health hazard. Serious effects may be delayed following exposure.
Skin contact	: CMV IgG Reagent Wedge A	No known significant effects or critical hazards.
	CMV IgG Reagent Wedge B	No known significant effects or critical hazards.
	IgG/IgM Sample Diluent	No known significant effects or critical hazards.
	CMV IgG Controls	No known significant effects or critical hazards.
	CMV IgG Adjustor	No known significant effects or critical hazards.
Ingestion	: CMV IgG Reagent Wedge A	No known significant effects or critical hazards.
	CMV IgG Reagent Wedge B	No known significant effects or critical hazards.
	IgG/IgM Sample Diluent	No known significant effects or critical hazards.
	CMV IgG Controls	No known significant effects or critical hazards.
	CMV IgG Adjustor	No known significant effects or critical hazards.

#### **Over-exposure signs/symptoms**

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Eye contact	: CMV IgG Reagent Wedge A	No specific data.
	CMV IgG Reagent Wedge B	No specific data.
	IgG/IgM Sample Diluent	No specific data.
	CMV IgG Controls CMV IgG Adjustor	No specific data. No specific data.
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nhalation	: CMV IgG Reagent Wedge A CMV IgG Reagent Wedge B	No specific data. No specific data.
	IgG/IgM Sample Diluent	No specific data.
	CMV IgG Controls	No specific data.
	CMV IgG Adjustor	No specific data.
Skin contact	: CMV IgG Reagent Wedge A	No specific data.
	CMV IgG Reagent Wedge B	No specific data.
	IgG/IgM Sample Diluent	No specific data.
	CMV IgG Controls	No specific data.
	CMV IgG Adjustor	No specific data.
Ingestion	: CMV IgG Reagent Wedge A	No specific data.
	CMV IgG Reagent Wedge B	No specific data.
	IgG/IgM Sample Diluent	No specific data.
	CMV IgG Controls	No specific data.
	CMV IgG Adjustor	No specific data.

4.3 Indication of any immediate medical attention and special treatment needed

Notes to physician	: 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.
Specific treatments	: No specific treatment.

# **SECTION 5: Firefighting measures**

5.1 Extinguishing media Suitable extinguishing media	:	Use dry chemical, CO <sub>2</sub> , water spray (fog) or foam.			
Unsuitable extinguishing media	:	None known.			
5.2 Special hazards arising f	ron	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 thermal decomposition products	:	Decomposition products may include the following materials: carbon dioxide carbon monoxide nitrogen oxides sulfur oxides halogenated compounds metal oxide/oxides			
5.3 Advice for firefighters					
Special protective actions for fire-fighters	:	Promptly isolate the scene by removing all persons from the vicinity of the incident if there is a fire. No action shall be taken involving any personal risk or without suitable training.			
Special protective equipment for fire-fighters	:	Fire-fighters should wear appropriate protective equipment and self-contained breathing apparatus (SCBA) with a full face-piece operated in positive pressure mode. 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.			

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### **SECTION 6: Accidental release measures**

6.1 Personal precautions, pro	ote	ctive 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 fo	or c	ontainment 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.					

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### **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.
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#### **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 measured	ures					
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 perio Appropriate techniques should be used to remove potentially contaminated clothin 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 ris assessment indicates this is necessary to avoid exposure to liquid splashes, mis 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.				

Date of issue/Date of revision

: No previous validation.

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

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9.1 Information on basic physic	cal and chemical properties	
<u>Appearance</u>		
Physical state	: CMV IgG Reagent Wedge A CMV IgG Reagent Wedge B IgG/IgM Sample Diluent CMV IgG Controls CMV IgG Adjustor	Liquid. Liquid. Liquid. Liquid. Liquid.
Colour	: CMV IgG Reagent Wedge A CMV IgG Reagent Wedge B IgG/IgM Sample Diluent CMV IgG Controls CMV IgG Adjustor	Colourless. Colourless. Colourless. Colourless. Colourless.
Odour	: CMV IgG Reagent Wedge A CMV IgG Reagent Wedge B IgG/IgM Sample Diluent CMV IgG Controls CMV IgG Adjustor	Odorless. Odorless. Bland. Odorless. Odorless.
рН	<ul> <li>CMV IgG Reagent Wedge A CMV IgG Reagent Wedge B IgG/IgM Sample Diluent CMV IgG Controls CMV IgG Adjustor</li> </ul>	7.95 to 8.05 7.95 to 8.05 Not applicable. 7.95 to 8.05 7.95 to 8.05
Melting point/freezing point	: CMV IgG Reagent Wedge A CMV IgG Reagent Wedge B IgG/IgM Sample Diluent CMV IgG Controls CMV IgG Adjustor	Not available. Not available. Not available. Not available. Not available.
Initial boiling point and boiling range	: CMV IgG Reagent Wedge A CMV IgG Reagent Wedge B IgG/IgM Sample Diluent CMV IgG Controls CMV IgG Adjustor	Not available. Not available. Not available. Not available. Not available.
Flash point	: CMV IgG Reagent Wedge A CMV IgG Reagent Wedge B IgG/IgM Sample Diluent CMV IgG Controls CMV IgG Adjustor	Not available. Not available. Not available. Not available. Not available.
Evaporation rate	: CMV IgG Reagent Wedge A CMV IgG Reagent Wedge B IgG/IgM Sample Diluent CMV IgG Controls CMV IgG Adjustor	Not available. Not available. Not available. Not available. Not available.
Flammability (solid, gas)	: CMV IgG Reagent Wedge A CMV IgG Reagent Wedge B IgG/IgM Sample Diluent CMV IgG Controls CMV IgG Adjustor	Not available. Not available. Not available. Not available. Not available.
Burning time	: CMV IgG Reagent Wedge A CMV IgG Reagent Wedge B IgG/IgM Sample Diluent CMV IgG Controls CMV IgG Adjustor	Not applicable. Not applicable. Not applicable. Not applicable. Not applicable.
Burning rate	: CMV IgG Reagent Wedge A CMV IgG Reagent Wedge B IgG/IgM Sample Diluent CMV IgG Controls CMV IgG Adjustor	Not applicable. Not applicable. Not applicable. Not applicable. Not applicable.

# SECTION 9: Physical and chemical properties

SECTION 9: Physical an	la	chemical properties	
Upper/lower flammability or explosive limits		CMV IgG Reagent Wedge A CMV IgG Reagent Wedge B IgG/IgM Sample Diluent CMV IgG Controls CMV IgG Adjustor	Not available. Not available. Not available. Not available. Not available.
Vapour pressure	:	CMV IgG Reagent Wedge A CMV IgG Reagent Wedge B IgG/IgM Sample Diluent CMV IgG Controls CMV IgG Adjustor	Not available. Not available. Not available. Not available. Not available.
Solubility in water	:	CMV IgG Reagent Wedge A CMV IgG Reagent Wedge B IgG/IgM Sample Diluent CMV IgG Controls CMV IgG Adjustor	Not available. Not available. Not available. Not available. Not available.
Partition coefficient: n-octanol/ water	:	CMV IgG Reagent Wedge A CMV IgG Reagent Wedge B IgG/IgM Sample Diluent CMV IgG Controls CMV IgG Adjustor	Not available. Not available. Not available. Not available. Not available.
Auto-ignition temperature	:	CMV IgG Reagent Wedge A CMV IgG Reagent Wedge B IgG/IgM Sample Diluent CMV IgG Controls CMV IgG Adjustor	Not available. Not available. Not available. Not available. Not available.
Decomposition temperature	:	CMV IgG Reagent Wedge A CMV IgG Reagent Wedge B IgG/IgM Sample Diluent CMV IgG Controls CMV IgG Adjustor	Not available. Not available. Not available. Not available. Not available.
Viscosity	•	CMV IgG Reagent Wedge A CMV IgG Reagent Wedge B IgG/IgM Sample Diluent CMV IgG Controls CMV IgG Adjustor	Not available. Not available. Not available. Not available. Not available.
Explosive properties	:	CMV IgG Reagent Wedge A CMV IgG Reagent Wedge B IgG/IgM Sample Diluent CMV IgG Controls CMV IgG Adjustor	Not available. Not available. Not available. Not available. Not available.
Oxidising properties	:	CMV IgG Reagent Wedge A CMV IgG Reagent Wedge B IgG/IgM Sample Diluent CMV IgG Controls CMV IgG Adjustor	Not available. Not available. Not available. Not available. Not available.
9.2 Other information			
SADT	:	Not available.	
Aerosol product			
Type of aerosol	:	Not applicable.	
Heat of combustion		Not available.	
Ignition distance		Not applicable.	
Enclosed space ignition - Time equivalent		Not applicable.	
Enclosed space ignition - Deflagration density		Not applicable.	
Flame height		Not applicable.	
Flame duration	÷	Not applicable.	

Date of issue/Date of revision

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.

11.1 Information on toxicolo	gica	al effects
Acute toxicity		
<b>Conclusion/Summary</b>	:	Not available.
Acute toxicity estimates		
Not available.		

### Irritation/Corrosion

Product/ingredient name	Result	Species	Score	Exposure	Observation
CMV IgG Reagent Wedge A aminocaproic acid	Eyes - Mild irritant	Rabbit	-	24 hours 500 milligrams	-
CMV IgG Reagent Wedge B aminocaproic acid	Eyes - Mild irritant	Rabbit	-	24 hours 500 milligrams	-
IgG/IgM Sample Diluent aminocaproic acid	Eyes - Mild irritant	Rabbit	-	24 hours 500 milligrams	-
Conclusion/Summary	: Not available.				
Sensitisation					
Conclusion/Summary <u>Mutagenicity</u>	: Not available.				
Conclusion/Summary Carcinogenicity	: Not available.				
Conclusion/Summary Reproductive toxicity	: Not available.				
Conclusion/Summary Teratogenicity	: Not available.				
Conclusion/Summary	: Not available.				
nformation on the likely routes of exposure	: Not available.				
Potential acute health effects					

Eye contact	: CMV IgG Reagent Wedge A	No known significant effects or critical hazards.
	CMV IgG Reagent Wedge B	No known significant effects or critical hazards.
	IgG/IgM Sample Diluent	No known significant effects or critical hazards.
	CMV IgG Controls	No known significant effects or critical hazards.
	CMV IgG Adjustor	No known significant effects or critical hazards.
Inhalation	: CMV IgG Reagent Wedge A	Exposure to decomposition products may cause a health hazard. Serious effects may be delayed following exposure.
	CMV IgG Reagent Wedge B	Exposure to decomposition products may cause a health hazard. Serious effects may be delayed following exposure.
	IgG/IgM Sample Diluent	Exposure to decomposition products may cause a health hazard. Serious effects may be delayed following exposure.
	CMV IgG Controls	Exposure to decomposition products may cause a health hazard. Serious effects may be delayed following
	CMV IgG Adjustor	exposure. Exposure to decomposition products may cause a health hazard. Serious effects may be delayed following exposure.
Skin contact	: CMV IgG Reagent Wedge A	No known significant effects or critical hazards.
	CMV IgG Reagent Wedge B	No known significant effects or critical hazards.
	IgG/IgM Sample Diluent	No known significant effects or critical hazards.
	CMV IgG Controls	No known significant effects or critical hazards.
	CMV IgG Adjustor	No known significant effects or critical hazards.
Ingestion	: CMV IgG Reagent Wedge A	No known significant effects or critical hazards.
	CMV IgG Reagent Wedge B	No known significant effects or critical hazards.
	IgG/IgM Sample Diluent	No known significant effects or critical hazards.
	CMV IgG Controls	No known significant effects or critical hazards.
	CMV IgG Adjustor	No known significant effects or critical hazards.

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

Eye contact	: CMV IgG Reagent Wedge A CMV IgG Reagent Wedge B IgG/IgM Sample Diluent CMV IgG Controls CMV IgG Adjustor	No specific data. No specific data. No specific data. No specific data. No specific data.
Inhalation	: CMV IgG Reagent Wedge A CMV IgG Reagent Wedge B IgG/IgM Sample Diluent CMV IgG Controls CMV IgG Adjustor	No specific data. No specific data. No specific data. No specific data. No specific data.

SECTION 11: Toxico	-	
Skin contact	: CMV IgG Reagent Wedge A CMV IgG Reagent Wedge B IgG/IgM Sample Diluent CMV IgG Controls CMV IgG Adjustor	No specific data. No specific data. No specific data. No specific data. No specific data.
Ingestion	: CMV IgG Reagent Wedge A CMV IgG Reagent Wedge B IgG/IgM Sample Diluent CMV IgG Controls CMV IgG Adjustor	No specific data. No specific data. No specific data. No specific data. No specific data.
Delayed and immediate effect	cts and also chronic effects from sho	ort and long term exposure
Short term exposure		
Potential immediate	: CMV IgG Reagent Wedge A	Not available.
effects	CMV IgG Reagent Wedge B IgG/IgM Sample Diluent CMV IgG Controls CMV IgG Adjustor	Not available. Not available. Not available. Not available.
Potential delayed effects	: CMV IgG Reagent Wedge A CMV IgG Reagent Wedge B IgG/IgM Sample Diluent CMV IgG Controls CMV IgG Adjustor	Not available. Not available. Not available. Not available. Not available.
Long term exposure		
Potential immediate effects	: CMV IgG Reagent Wedge A CMV IgG Reagent Wedge B IgG/IgM Sample Diluent CMV IgG Controls CMV IgG Adjustor	Not available. Not available. Not available. Not available. Not available.
Potential delayed effects	: CMV IgG Reagent Wedge A CMV IgG Reagent Wedge B IgG/IgM Sample Diluent CMV IgG Controls CMV IgG Adjustor	Not available. Not available. Not available. Not available. Not available.
Potential chronic health eff Not available.	ects	
Conclusion/Summary	: Not available.	
General	: CMV IgG Reagent Wedge A	No known significant effects or critical hazards.
	CMV IgG Reagent Wedge B	No known significant effects or critical hazards.
	IgG/IgM Sample Diluent	No known significant effects or critical hazards.
	CMV IgG Controls CMV IgG Adjustor	No known significant effects or critical hazards. No known significant effects or critical
Carcinogenicity	: CMV IgG Reagent Wedge A	hazards. No known significant effects or critical
Garcinogenicity	CMV IgG Reagent Wedge B	hazards. No known significant effects or critical
	IgG/IgM Sample Diluent	hazards. No known significant effects or critical
	CMV IgG Controls	hazards. No known significant effects or critical
	CMV IgG Adjustor	hazards. No known significant effects or critical hazards.

	ological information	
Mutagenicity	: CMV IgG Reagent Wedge A	No known significant effects or critical hazards.
	CMV IgG Reagent Wedge B	No known significant effects or critical hazards.
	IgG/IgM Sample Diluent	No known significant effects or critical hazards.
	CMV IgG Controls	No known significant effects or critical hazards.
	CMV IgG Adjustor	No known significant effects or critical hazards.
Teratogenicity	: CMV IgG Reagent Wedge A	No known significant effects or critical hazards.
	CMV IgG Reagent Wedge B	No known significant effects or critical hazards.
	IgG/IgM Sample Diluent	No known significant effects or critical hazards.
	CMV IgG Controls	No known significant effects or critical hazards.
	CMV IgG Adjustor	No known significant effects or critical hazards.
<b>Developmental effects</b>	: CMV IgG Reagent Wedge A	No known significant effects or critical hazards.
	CMV IgG Reagent Wedge B	No known significant effects or critical hazards.
	IgG/IgM Sample Diluent	No known significant effects or critical hazards.
	CMV IgG Controls	No known significant effects or critical hazards.
	CMV IgG Adjustor	No known significant effects or critical hazards.
Fertility effects	: CMV IgG Reagent Wedge A	No known significant effects or critical hazards.
	CMV IgG Reagent Wedge B	No known significant effects or critical hazards.
	IgG/IgM Sample Diluent	No known significant effects or critical hazards.
	CMV IgG Controls	No known significant effects or critical hazards.
	CMV IgG Adjustor	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

Product/ingredient name	LogPow	BCF	Potential
CMV IgG Reagent Wedge A aminocaproic acid	-2.95	-	low
CMV IgG Reagent Wedge B aminocaproic acid	-2.95	-	low
Date of issue/Date of revision	: 2/17/2015.	Date of previous issue : No pr	evious validation. Version : 1 15/21

 $\textit{IMMULITE} \verb"® 2000 CMV lgG"$ 

# SECTION 12: Ecological information

5			
IgG/IgM Sample Diluent aminocaproic acid	-2.95	-	low
	-2:00		1011

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

РВТ	: CMV IgG Reagent Wedge A CMV IgG Reagent Wedge B IgG/IgM Sample Diluent CMV IgG Controls CMV IgG Adjustor	Not applicable. Not applicable. Not applicable. Not applicable. Not applicable.
vPvB	: CMV IgG Reagent Wedge A CMV IgG Reagent Wedge B IgG/IgM Sample Diluent CMV IgG Controls CMV IgG Adjustor	Not applicable. Not applicable. Not applicable. Not applicable. 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	<ul> <li>Within the present knowledge of the supplier, this product is not regarded as hazardous waste, as defined by EU Directive 91/689/EEC.</li> <li>Not available.</li> </ul>
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 spilt material and runoff and contact with soil, waterways, drains and sewers.

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

#### ADR/RID

14.1 UN number

CMV IgG Reagent Wedge A CMV IgG Reagent Wedge B IgG/IgM Sample Diluent CMV IgG Controls CMV IgG Adjustor

Not regulated. Not regulated. Not regulated. Not regulated. Not regulated.

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

SECTION 14: Transport information			
CMV IgG Reagent Wedge A	_		
IgG/IgM Sample Diluent	-		
	-		
<b>o</b> ,	-		
	-		
IgG/IgM Sample Diluent	-		
	-		
CIVIN IGG AUJUSION			
CMV IgG Reagent Wedge A	-		
	-		
CMV IgG Controls	-		
• •	-		
<b>a a a</b>	No. No.		
IgG/IgM Sample Diluent	No.		
CMV IgG Controls	No.		
	No.		
	-		
	_		
CMV IgG Controls	-		
CIVIV IGG Adjustor	-		
	Not regulated. Not regulated.		
IgG/IgM Sample Diluent	Not regulated.		
CMV IgG Controls	Not regulated.		
- /	Not regulated.		
	-		
IgG/IgM Sample Diluent	-		
	-		
<b>U</b> <i>J</i>	-		
	-		
IgG/IgM Sample Diluent	-		
	-		
	-		
IgG/IgM Sample Diluent	-		
CMV IgG Controls	-		
<b>o</b> <i>y</i>	-		
	No. No.		
IgG/IgM Sample Diluent	No.		
CMV IgG Controls	No.		
CIVIN 196 AUJUSION	No.		
	CMV IgG Reagent Wedge A CMV IgG Reagent Wedge B IgG/IgM Sample Diluent CMV IgG Adjustor CMV IgG Reagent Wedge A CMV IgG Reagent Wedge B IgG/IgM Sample Diluent CMV IgG Controls CMV IgG Adjustor CMV IgG Reagent Wedge A CMV IgG Reagent Wedge B IgG/IgM Sample Diluent CMV IgG Reagent Wedge A CMV IgG Reagent Wedge B IgG/IgM Sample Diluent CMV IgG Reagent Wedge A CMV IgG Reagent Wedge B IgG/IgM Sample Diluent CMV IgG Controls CMV IgG Reagent Wedge A CMV IgG Reagent Wedge B IgG/IgM Sample Diluent CMV IgG Reagent Wedge B		

# **SECTION 14: Transport information**

3ECTION 14. 1	ransport mormation	
Additional information	CMV IgG Reagent Wedge A CMV IgG Reagent Wedge B IgG/IgM Sample Diluent CMV IgG Controls CMV IgG Adjustor	- - - - -
IMDG		
14.1 UN number	CMV IgG Reagent Wedge A CMV IgG Reagent Wedge B IgG/IgM Sample Diluent CMV IgG Controls CMV IgG Adjustor	Not regulated. Not regulated. Not regulated. Not regulated. Not regulated.
14.2 UN proper shipping name	CMV IgG Reagent Wedge A CMV IgG Reagent Wedge B IgG/IgM Sample Diluent CMV IgG Controls CMV IgG Adjustor	- - - -
14.3 Transport hazard class(es)	CMV IgG Reagent Wedge A CMV IgG Reagent Wedge B IgG/IgM Sample Diluent CMV IgG Controls CMV IgG Adjustor	- - - -
14.4 Packing group	CMV IgG Reagent Wedge A CMV IgG Reagent Wedge B IgG/IgM Sample Diluent CMV IgG Controls CMV IgG Adjustor	- - - -
14.5 Environmental hazards	CMV IgG Reagent Wedge A CMV IgG Reagent Wedge B IgG/IgM Sample Diluent CMV IgG Controls CMV IgG Adjustor	No. No. No. No. No.
Additional information	CMV IgG Reagent Wedge A CMV IgG Reagent Wedge B IgG/IgM Sample Diluent CMV IgG Controls CMV IgG Adjustor	- - - - -
<u>IATA</u>		
14.1 UN number	CMV IgG Reagent Wedge A CMV IgG Reagent Wedge B IgG/IgM Sample Diluent CMV IgG Controls CMV IgG Adjustor	Not regulated. Not regulated. Not regulated. Not regulated. Not regulated.
14.2 UN proper shipping name	CMV IgG Reagent Wedge A CMV IgG Reagent Wedge B IgG/IgM Sample Diluent CMV IgG Controls CMV IgG Adjustor	- - - -
14.3 Transport hazard class(es)	CMV IgG Reagent Wedge A CMV IgG Reagent Wedge B IgG/IgM Sample Diluent CMV IgG Controls CMV IgG Adjustor	- - - -

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

JECHON 14. 1	ransport information	
14.4 Packing group	CMV IgG Reagent Wedge A CMV IgG Reagent Wedge B IgG/IgM Sample Diluent CMV IgG Controls CMV IgG Adjustor	- - - -
14.5 Environmental hazards	CMV IgG Reagent Wedge A CMV IgG Reagent Wedge B IgG/IgM Sample Diluent CMV IgG Controls CMV IgG Adjustor	No. No. No. No. No.
Additional information	CMV IgG Reagent Wedge A CMV IgG Reagent Wedge B IgG/IgM Sample Diluent CMV IgG Controls CMV IgG Adjustor	- - - -
14.6 Special precau user	tions for : CMV IgG Reagent Wedge A	<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.
	CMV IgG Reagent Wedge B	<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.
	IgG/IgM Sample Diluent	<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.
	CMV IgG Controls	<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.
	CMV IgG Adjustor	<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.

14.7 Transport in bulk: Not available.according to Annex II ofMARPOL 73/78 and the IBCCode

# **SECTION 15: Regulatory information**

15.1 Safety, health and environmental regulations/legislation specific for the substance or mixture <u>EU Regulation (EC) No. 1907/2006 (REACH)</u> <u>Annex XIV - List of substances subject to authorisation</u> <u>Annex XIV</u> None of the components are listed. <u>Substances of very high concern</u>

Date of issue/Date of revision

# **SECTION 15: Regulatory information**

o _ o o o gala		.,			
None of the components an	e l	isted.			
Annex XVII - Restrictions on the manufacture, placing on the market and use of certain dangerous substances, mixtures and articles	:	CMV IgG Reagent Wedge A CMV IgG Reagent Wedge B IgG/IgM Sample Diluent CMV IgG Controls CMV IgG Adjustor	Not applicable. Not applicable. Not applicable. Not applicable. Not applicable.		
Other EU regulations					
Europe inventory	1	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 whic required.	ch Chemical Safety Assessments are still		

# **SECTION 16: Other information**

Indicates information that	has changed from previously	<i>issued version.</i>	
Abbreviations and acronyms	<ul> <li>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 vPvB = Very Persistent and Very Bioaccumulative</li> </ul>		
Classification according to Not classified.	Regulation (EC) No. 1272/2	2008 [CLP/GHS]	
Not classified.			
Full text of abbreviated H statements	: CMV IgG Reagent Wedge A H319	Causes serious eye irritation.	
	CMV IgG Reagent Wedge B H319 IgG/IgM Sample Diluent H319	Causes serious eye irritation. Causes serious eye irritation.	
Full text of classifications [CLP/GHS]	: CMV IgG Reagent Wedge A Eye Irrit. 2, H319	SERIOUS EYE DAMAGE/ EYE IRRITATION - Category 2	
	CMV IgG Reagent Wedge B Eye Irrit. 2, H319 IgG/IgM Sample Dilue Eye Irrit. 2, H319	SERIOUS EYE DAMAGE/ EYE IRRITATION - Category 2 nt SERIOUS EYE DAMAGE/ EYE IRRITATION - Category 2	
Full text of abbreviated R phrases	: Not applicable.		
Full text of classifications [DSD/DPD]	: Not applicable.		
Date of printing	: 2/17/2015.		
Date of issue/Date of revision	: 2/17/2015. Date of prev	vious issue : No previous validation. Version : 1 20/21	

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

Date of issue/ Date of revision	: 2/17/2015.
Date of previous issue	: No previous validation.
Version	: 1

#### Notice to reader

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

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