

SAFETY DATA SHEET

SIEMENS

IMMULITE® 2000 PAPP-A

MSDS no.

L2KPC2_6

1. Identification of the substance/preparation and company/undertaking

Identification of the substance or mixture

Product name : IMMULITE® 2000 PAPP-A
Product code : L2KPC2/6, 10381213, 10381215
Product type : Liquid.
Use of the substance/mixture : Diagnostic Agents

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 : dx.msds.healthcare@siemens.com

Emergency telephone number : +49 6131 - 19240; [24x7x365]
(with hours of operation)

2. Hazards identification

The product is not classified as dangerous according to Directive 1999/45/EC and its amendments.

Classification : Not classified.

Physical/chemical hazards : PAPP-A Reagent Wedge Not applicable.
PAPP-A Adjustors Not applicable.

Human health hazards : PAPP-A Reagent Wedge Not applicable.
PAPP-A Adjustors Not applicable.

Environmental hazards : PAPP-A Reagent Wedge Not applicable.
PAPP-A Adjustors Not applicable.
Potentially biohazardous material.

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

3. Composition/information on ingredients

Substance/preparation :

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 and hence require reporting in this section.

4. First-aid measures

First-aid measures

- | | |
|---------------------|--|
| Inhalation | : Move exposed person to fresh air. Keep person warm and at rest. If not breathing, if breathing is irregular or if respiratory arrest occurs, provide artificial respiration or oxygen by trained personnel. 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. |
| Ingestion | : Wash out mouth with water. Move exposed person to fresh air. Keep person warm and at rest. 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. |
| Skin contact | : Flush contaminated skin with plenty of water. Remove contaminated clothing and shoes. Get medical attention if symptoms occur. |
| Eye contact | : 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. |

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

5. Fire-fighting measures

Extinguishing media

- | | |
|---|---|
| Suitable | : Use dry chemical, CO ₂ , water spray (fog) or foam. |
| Not suitable | : None known. |
| Special exposure hazards | : In a fire or if heated, a pressure increase will occur and the container may burst. 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. |
| Hazardous combustion products | : Decomposition products may include the following materials:
carbon dioxide
carbon monoxide
nitrogen oxides
sulfur oxides
halogenated compounds
metal oxide/oxides |
| 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. |

6. Accidental release measures

- | | |
|----------------------------------|---|
| Personal precautions | : 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 (see section 8). |
| 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. Accidental release measures

- 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.

7. Handling and storage

- Handling** : Put on appropriate personal protective equipment (see section 8). 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.
- Storage** : 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.

Packaging materials

- Recommended** : Use original container.

8. Exposure controls/personal protection

Exposure limit values

<u>Ingredient name</u>	<u>Occupational exposure limits</u>
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 European Standard EN 689 for methods for the assessment of exposure by inhalation to chemical agents and national guidance documents for methods for the determination of hazardous substances.

Exposure controls

- Occupational exposure controls** : No special ventilation requirements. Good general ventilation should be sufficient to control worker exposure to airborne contaminants. If this product contains ingredients with exposure limits, use process enclosures, local exhaust ventilation or other engineering controls to keep worker exposure below any recommended or statutory limits.
- Hygiene measures** : Wash hands, forearms and face thoroughly after handling chemical products, before eating, smoking and using the lavatory and at the end of the working period. Appropriate techniques should be used to remove potentially contaminated clothing. Wash contaminated clothing before reusing. Ensure that eyewash stations and safety showers are close to the workstation location.
- 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.
- 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.
- Eye protection** : Safety eyewear complying with an approved standard should be used when a risk assessment indicates this is necessary to avoid exposure to liquid splashes, mists or dusts.

8. Exposure controls/personal protection

- Skin 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.
- 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.

9. Physical and chemical properties

General information

Appearance

- Physical state** : PAPP-A Reagent Wedge Liquid.
PAPP-A Adjustors Solid.
- Colour** : PAPP-A Reagent Wedge Colourless.
PAPP-A Adjustors Off-white.

Important health, safety and environmental information

- pH** : PAPP-A Reagent Wedge 7.55 to 7.65
PAPP-A Adjustors Not applicable.
- Boiling point** : PAPP-A Reagent Wedge Not available.
PAPP-A Adjustors Not available.
- Melting point** : PAPP-A Reagent Wedge Not available.
PAPP-A Adjustors Not available.
- Flash point** : PAPP-A Reagent Wedge Not available.
PAPP-A Adjustors Not available.
- Explosion limits** : PAPP-A Reagent Wedge Not available.
PAPP-A Adjustors Not available.
- Vapour pressure** : PAPP-A Reagent Wedge Not available.
PAPP-A Adjustors Not available.
- Relative density** : PAPP-A Reagent Wedge 1
PAPP-A Adjustors >1
- Octanol/water partition coefficient** : PAPP-A Reagent Wedge Not available.
PAPP-A Adjustors Not available.
- Viscosity** : PAPP-A Reagent Wedge Not available.
PAPP-A Adjustors Not available.
- Evaporation rate (butyl acetate = 1)** : PAPP-A Reagent Wedge Not available.
PAPP-A Adjustors Not available.

Other information

- Auto-ignition temperature** : PAPP-A Reagent Wedge Not available.
PAPP-A Adjustors Not available.

10. Stability and reactivity

- Stability** : The product is stable.
- Conditions to avoid** : No specific data.
- Materials to avoid** : No specific data.
- Hazardous decomposition products** : Under normal conditions of storage and use, hazardous decomposition products should not be produced.

11. Toxicological information

Potential acute health effects

- Inhalation** : Exposure to decomposition products may cause a health hazard. Serious effects may be delayed following exposure.
- Ingestion** : No known significant effects or critical hazards.
- Skin contact** : No known significant effects or critical hazards.
- Eye contact** : No known significant effects or critical hazards.

Acute toxicity

Product/ingredient name	Result	Species	Dose	Exposure
Not available.				

Potential chronic health effects

Chronic toxicity

Product/ingredient name	Result	Species	Dose	Exposure
Not available.				

Carcinogenicity

Product/ingredient name	Result	Species	Dose	Exposure
Not available.				

Mutagenicity

Product/ingredient name	Test	Experiment	Result
Not available.			

Teratogenicity

Product/ingredient name	Result	Species	Dose	Exposure
Not available.				

Reproductive toxicity

Product/ingredient name	Maternal toxicity	Fertility	Developmental toxin	Species	Dose	Exposure
Not available.						

- Chronic effects** : No known significant effects or critical hazards.
- Carcinogenicity** : No known significant effects or critical hazards.
- Mutagenicity** : No known significant effects or critical hazards.
- Teratogenicity** : No known significant effects or critical hazards.
- Developmental effects** : No known significant effects or critical hazards.
- Fertility effects** : No known significant effects or critical hazards.

Over-exposure signs/symptoms

- Inhalation** : No specific data.
- Ingestion** : No specific data.
- Skin** : No specific data.
- Eyes** : No specific data.
- Other adverse effects** : PAPP-A Reagent Wedge Not available.
PAPP-A Adjustors Not available.

12. Ecological information

Environmental effects : No known significant effects or critical hazards.

Aquatic ecotoxicity

Conclusion/Summary : Not available.

Biodegradability

Conclusion/Summary : Not available.

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

13. Disposal considerations

Methods of disposal : The generation of waste should be avoided or minimised wherever possible. Empty containers or liners may retain some product residues. This material and its container must be disposed of in a safe way. Dispose of surplus and non-recyclable products via a licensed waste disposal contractor. 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. Avoid dispersal of spilt material and runoff and contact with soil, waterways, drains and sewers.

Hazardous waste : Within the present knowledge of the supplier, this product is not regarded as hazardous waste, as defined by EU Directive 91/689/EEC.

European waste catalogue (EWC) : Hazardous waste
18 01 06* chemicals consisting of or containing dangerous substances
Non-hazardous waste
18 01 07 chemicals other than those mentioned in 18 01 06

14. Transport information

International transport regulations

ADR/RID Class

UN number	PAPP-A Reagent Wedge	Not regulated.
	PAPP-A Adjustors	Not regulated.
Proper shipping name	PAPP-A Reagent Wedge	-
	PAPP-A Adjustors	-
Classes	PAPP-A Reagent Wedge	-
	PAPP-A Adjustors	-
PG*	PAPP-A Reagent Wedge	-
	PAPP-A Adjustors	-
Label		
Additional information	PAPP-A Reagent Wedge	-
	PAPP-A Adjustors	-

ADN/ADNR Class

UN number	PAPP-A Reagent Wedge	Not regulated.
	PAPP-A Adjustors	Not regulated.
Proper shipping name	PAPP-A Reagent Wedge	-
	PAPP-A Adjustors	-
Classes	PAPP-A Reagent Wedge	-
	PAPP-A Adjustors	-
PG*	PAPP-A Reagent Wedge	-
	PAPP-A Adjustors	-
Label		

14. Transport information

Additional information	PAPP-A Reagent Wedge	-
	PAPP-A Adjustors	-
IMDG Class		
UN number	PAPP-A Reagent Wedge	Not regulated.
	PAPP-A Adjustors	Not regulated.
Proper shipping name	PAPP-A Reagent Wedge	-
	PAPP-A Adjustors	-
Classes	PAPP-A Reagent Wedge	-
	PAPP-A Adjustors	-
PG*	PAPP-A Reagent Wedge	-
	PAPP-A Adjustors	-
Label		
Additional information	PAPP-A Reagent Wedge	-
	PAPP-A Adjustors	-
IATA Class		
UN number	PAPP-A Reagent Wedge	Not regulated.
	PAPP-A Adjustors	Not regulated.
Proper shipping name	PAPP-A Reagent Wedge	-
	PAPP-A Adjustors	-
Classes	PAPP-A Reagent Wedge	-
	PAPP-A Adjustors	-
PG*	PAPP-A Reagent Wedge	-
	PAPP-A Adjustors	-
Label		
Additional information	PAPP-A Reagent Wedge	-
	PAPP-A Adjustors	-

PG* : Packing group

15. Regulatory information

EU regulations

Classification and labeling have been determined according to EU Directives 67/548/EEC and 1999/45/EC (including amendments) and take into account the intended product use.

Risk phrases	: This product is not classified as dangerous according to EU legislation.
Product use	: Industrial applications.
Europe inventory	: Not determined.

16. Other information

History

Date of issue/Date of revision	: 1/23/2013.
Version	: 1.01
Prepared by	: Siemens Healthcare Diagnostics EHS Product Stewardship

Notice to reader

16. Other information

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

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