

SAFETY DATA SHEET

SIEMENS

IMMULITE® 2000 BR-MA (CA15-3)

MSDS no.

L2KBR2

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

Identification of the substance or mixture

Product name : IMMULITE® 2000 BR-MA (CA15-3)
Product code : L2KBR2, 10380983
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 (with hours of operation) : +49 6131 - 19240; [24x7x365]

2. Hazards identification

The product is classified as dangerous according to Directive 1999/45/EC and its amendments.

Classification : Xn; R22
 R52/53

Physical/chemical hazards : BR-MA Reagent Wedge A Not applicable.
 BR-MA Reagent Wedge B Not applicable.
 BR-MA Adjustors Not applicable.

Human health hazards : BR-MA Reagent Wedge A Not applicable.
 BR-MA Reagent Wedge B Toxic by inhalation.
 BR-MA Adjustors Harmful if swallowed.

Environmental hazards : BR-MA Reagent Wedge A Not applicable.
 BR-MA Reagent Wedge B Not applicable.
 BR-MA Adjustors Harmful to aquatic organisms, may cause long-term adverse effects in the aquatic environment.

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

Date of issue/Date of revision : 1/22/2013.

1/12

3. Composition/information on ingredients

Substance/preparation :

Ingredient name	CAS number	%	EC number	Classification
BR-MA Reagent Wedge B Oxirane, 2-methyl-, polymer with oxirane glycerol	9003-11-6 56-81-5	0.1 - 1 0.1 - 1	200-289-5	T+; R26 [1] Not classified. [2]
BR-MA Adjustors sodium azide	26628-22-8	0.1 - 1	247-852-1	T+; R28 [1] [2] R32 N; R50/53
See section 16 for the full text of the R-phrases declared above				

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.

[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.

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. 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.

Ingestion

: Wash out mouth with water. Remove dentures if any. 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. 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. 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.

Skin contact

: Flush contaminated skin with plenty of water. Remove contaminated clothing and shoes. Get medical attention if symptoms occur. Wash clothing before reuse. Clean shoes thoroughly before reuse.

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, CO₂, 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. This material is harmful to aquatic organisms. Fire water contaminated with this material must be contained and prevented from being discharged to any waterway, sewer or drain.
- Hazardous combustion products** : Decomposition products may include the following materials:
carbon dioxide
carbon monoxide
nitrogen oxides
sulfur oxides
halogenated compounds
metal oxide/oxides
- 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. Avoid breathing vapour or mist. Provide adequate ventilation. Wear appropriate respirator when ventilation is inadequate. 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). Water polluting material.
- 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. Do not ingest. Avoid contact with eyes, skin and clothing. 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.
- 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

<u>Ingredient name</u>	<u>Occupational exposure limits</u>
BR-MA Reagent Wedge B glycerol	EH40/2005 WELs (United Kingdom (UK), 1/2012). TWA: 10 mg/m ³ 8 hour(s). Form: Mist
BR-MA Adjustors sodium azide	EH40/2005 WELs (United Kingdom (UK), 1/2012). Absorbed through skin. Notes: as NaN₃ STEL: 0.3 mg/m ³ , (as NaN ₃) 15 minute(s). TWA: 0.1 mg/m ³ , (as NaN ₃) 8 hour(s).

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.

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	:	BR-MA Reagent Wedge A	Liquid.
	:	BR-MA Reagent Wedge B	Liquid.
	:	BR-MA Adjustors	Solid.
Colour	:	BR-MA Reagent Wedge A	Colourless.
	:	BR-MA Reagent Wedge B	Colourless.
	:	BR-MA Adjustors	Off White.

Important health, safety and environmental information

pH	:	BR-MA Reagent Wedge A	7.95 to 8.05
	:	BR-MA Reagent Wedge B	7.95 to 8.05
	:	BR-MA Adjustors	Not applicable.
Boiling point	:	BR-MA Reagent Wedge A	Not available.
	:	BR-MA Reagent Wedge B	Not available.
	:	BR-MA Adjustors	Not available.
Melting point	:	BR-MA Reagent Wedge A	Not available.
	:	BR-MA Reagent Wedge B	Not available.
	:	BR-MA Adjustors	Not available.
Flash point	:	BR-MA Reagent Wedge A	Not available.
	:	BR-MA Reagent Wedge B	Not available.
	:	BR-MA Adjustors	Not available.
Explosion limits	:	BR-MA Reagent Wedge A	Not available.
	:	BR-MA Reagent Wedge B	Not available.
	:	BR-MA Adjustors	Not available.
Vapour pressure	:	BR-MA Reagent Wedge A	Not available.
	:	BR-MA Reagent Wedge B	Not available.
	:	BR-MA Adjustors	Not available.
Relative density	:	BR-MA Reagent Wedge A	1
	:	BR-MA Reagent Wedge B	1
	:	BR-MA Adjustors	Not available.
Octanol/water partition coefficient	:	BR-MA Reagent Wedge A	Not available.
	:	BR-MA Reagent Wedge B	Not available.
	:	BR-MA Adjustors	Not available.

9. Physical and chemical properties

- Viscosity** : BR-MA Reagent Wedge Not available.
 A
 BR-MA Reagent Wedge Not available.
 B
 BR-MA Adjustors Not available.
- Evaporation rate (butyl acetate = 1)** : BR-MA Reagent Wedge Not available.
 A
 BR-MA Reagent Wedge Not available.
 B
 BR-MA Adjustors Not available.

Other information

- Auto-ignition temperature** : BR-MA Reagent Wedge Not available.
 A
 BR-MA Reagent Wedge Not available.
 B
 BR-MA 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** : Harmful if swallowed.
- 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
BR-MA Reagent Wedge B Oxirane, 2-methyl-, polymer with oxirane	LD50 Oral	Rat	5700 mg/kg	-
	LDLo	Rat	10 g/kg	-
	Intraperitoneal			
	LDLo Oral	Rat	16 g/kg	-
	LC50 Inhalation	Rat	320 mg/m3	4 hours
glycerol	Vapour			
	LD50	Rat	4420 mg/kg	-
	Intraperitoneal			
	LD50	Rat	5566 mg/kg	-
	Intravenous			
	LD50 Oral	Rat	12600 mg/kg	-
	LD50	Rat	100 mg/kg	-
	Subcutaneous			
	LDLo	Rat	10 mL/kg	-
	Intramuscular			
LDLo	Rat	10 mg/kg	-	
Intramuscular				
TDLo	Rat	8 mL/kg	-	
Intramuscular				

11. Toxicological information

TDL0 Intramuscular	Rat	4 mL/kg	-
TDL0 Intramuscular	Rat	>5000 mg/kg	-
TDL0 Intramuscular	Rat	4000 mg/kg	-

BR-MA Adjustors

sodium azide	LD50 Dermal	Rat	50 mg/kg	-
	LD50 Dermal	Rabbit	20 mg/kg	-
	LD50 Intratracheal	Rat	47.5 mg/kg	-
	LD50 Intratracheal	Rat	47500 ug/kg	-
	LD50 Oral	Rat	27 mg/kg	-
	LD50 Subcutaneous	Rat	45 mg/kg	-
	LD50 Subcutaneous	Rat	45100 ug/kg	-
	LDLo Intraperitoneal	Rat	30 mg/kg	-
	LDLo Intraperitoneal	Rat	3 mg/kg	-

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.

11. Toxicological information

Skin	: No specific data.	
Eyes	: No specific data.	
Other adverse effects	: BR-MA Reagent Wedge A BR-MA Reagent Wedge B BR-MA Adjustors	Not available. Not available. Not available.

12. Ecological information

Environmental effects : Harmful to aquatic organisms, may cause long-term adverse effects in the aquatic environment.

Aquatic ecotoxicity

Product/ingredient name	Test	Result	Species	Exposure
BR-MA Reagent Wedge B glycerol	-	Acute LC50 54 to 57 ml/L Fresh water	Fish - Rainbow trout, donaldson trout - Oncorhynchus mykiss - 0.9 g	96 hours
BR-MA Adjustors sodium azide	-	Acute EC50 6.4 to 8.9 mg/L Fresh water	Crustaceans - Water flea - Simocephalus serrulatus - Larvae - es7:k56s:7pt	48 hours
	-	Acute EC50 4.2 to 6.2 mg/L Fresh water	Daphnia - Water flea - Daphnia pulex - Larvae - es7:k56s:7pt	48 hours
	-	Acute EC50 0.348 mg/L Fresh water	Algae - Green algae - Pseudokirchneriella subcapitata	96 hours
	-	Acute EC50 9200 ug/L Marine water	Algae - Giant kelp - Macrocystis pyrifera	96 hours
	-	Acute LC50 0.8 mg/L Fresh water	Fish - Rainbow trout, donaldson trout - Oncorhynchus mykiss - 1.4 g	96 hours
	-	Acute LC50 0.68 mg/L Fresh water	Fish - Bluegill - Lepomis macrochirus - 0.6 g	96 hours
	-	Acute LC50 9000 ug/L Fresh water	Crustaceans - Scud - Gammarus lacustris - 2 months	48 hours
	-	Acute LC50 3920 ug/L Fresh water	Fish - Rainbow trout, donaldson trout - Oncorhynchus mykiss - 8.57 cm	96 hours

12. Ecological information

- 7.84 g

-	Acute LC50 2840 ug/L Fresh water	Fish - Rainbow trout, donaldson trout - Oncorhynchus mykiss - 7.87 cm - 6.07 g	96 hours
-	Acute LC50 2750 ug/L Fresh water	Fish - Rainbow trout, donaldson trout - Oncorhynchus mykiss - 7.32 cm - 4.76 g	96 hours
-	Chronic NOEC 5600 ug/L Marine water	Algae - Giant kelp - Macrocystis pyrifera	96 hours

Conclusion/Summary : Not available.

Other ecological information

Biodegradability

Conclusion/Summary : Not available.

Bioaccumulative potential

Product/ingredient name

BR-MA Reagent Wedge B

glycerol

LogP_{ow}

-1.76

BCF

-

Potential

low

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 : The classification of the product may meet the criteria for a hazardous waste.

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

Sodium azide may react with lead or copper plumbing to form highly explosive metal azides.

14. Transport information

International transport regulations

ADR/RID Class

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

ADN/ADNR Class

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

IMDG Class

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

14. Transport information

BR-MA Reagent Wedge A	-
BR-MA Reagent Wedge B	-
BR-MA Adjustors	-

IATA Class

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

Hazard symbol or symbols :



Harmful

Risk phrases

: R22- Harmful if swallowed.
R52/53- Harmful to aquatic organisms, may cause long-term adverse effects in the aquatic environment.

Safety phrases

: S28- After contact with skin, wash immediately with plenty of water.
S35- This material and its container must be disposed of in a safe way.

Contains

: **BR-MA Reagent Wedge B**
Oxirane, 2-methyl-, polymer with oxirane

BR-MA Adjustors

sodium azide

247-852-1

Product use

: Industrial applications.

Europe inventory

: Not determined.

16. Other information

Full text of R-phrases referred to in sections 2 and 3 - United Kingdom (UK) : R28- Very toxic if swallowed.
R26- Very toxic by inhalation.
R22- Harmful if swallowed.
R32- Contact with acids liberates very toxic gas.
R50/53- Very toxic to aquatic organisms, may cause long-term adverse effects in the aquatic environment.
R52/53- Harmful to aquatic organisms, may cause long-term adverse effects in the aquatic environment.

Full text of classifications referred to in sections 2 and 3 - United Kingdom (UK) : T+ - Very toxic
Xn - Harmful
N - Dangerous for the environment

History

Date of issue/Date of revision : 1/22/2013.

Version : 2

Prepared by : Siemens Healthcare Diagnostics EHS Product Stewardship

Notice to reader

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

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