SAFETY DATA SHEET



Immulite® 2000 and Immulite® 2500 Chemiluminescent Substrate Module

SDS no.:

L2SUBM

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

1.1 Product identifier

Product name : Immulite® 2000 and Immulite® 2500 Chemiluminescent Substrate Module

Product code : L2SUBM, 10385232

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

Identified uses Diagnostic agents.

Restrictions on use For professional users only.

1.3 Details of the supplier of the safety data sheet

Manufactured/supplied : Siemens Healthcare Diagnostics Limited

Sir William Siemens Square

Newton House Camberley Frimley Surrey GU16 8QD UK

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

e-mail address of person responsible for this SDS

: dx.msds.healthcare@siemens.com

1.4 Emergency telephone number

Poison Control:

In England and Wales:

NHS Direct - 0845 4647 or 111

In Scotland: NHS 24 – 08454 24 24 24 In the Republic of Ireland: 01 809 2166

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

SECTION 2: Hazards identification

2.1 Classification of the substance or mixture

Product definition : Immulite® Chemiluminescent Substrate Mixture

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

Not classified.

Immulite® Chemiluminescent Substrate

The product is not classified as hazardous according to

Regulation (EC) 1272/2008 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

Immulite® 2000 and Immulite® 2500 Chemiluminescent Substrate Module

SECTION 2: Hazards identification

Signal word : Immulite® Chemiluminescent Substrate No signal word.

Hazard statements : Immulite® Chemiluminescent Substrate Not applicable.

Precautionary statements

Prevention: Immulite® Chemiluminescent SubstrateNot applicable.Response: Immulite® Chemiluminescent SubstrateNot applicable.Storage: Immulite® Chemiluminescent SubstrateNot applicable.Disposal: Immulite® Chemiluminescent SubstrateNot applicable.

Supplemental label : Immulite® Chemiluminescent Substrate

Safety data sheet available on request.

Annex XVII - Restrictions on the manufacture, placing on the market and use of certain dangerous substances, mixtures and articles : Immulite® Chemiluminescent Substrate Not applicable.

2.3 Other hazards

elements

Substance meets the criteria for PBT according to Regulation (EC) No.

1907/2006, Annex XIII

: Immulite® Chemiluminescent Substrate Immulite® Chemiluminescent Substrate

Not applicable.
P: Not available. B: Not available. T: Not

available.

Substance meets the criteria for vPvB according to Regulation (EC) No. 1907/2006, Annex XIII

: Immulite® Chemiluminescent Substrate Immulite® Chemiluminescent Substrate

vP: Not available. vB: Not available.

Other hazards which do not result in classification

: Immulite® Chemiluminescent Substrate

None known.

Not applicable.

Additional information: Not available.

SECTION 3: Composition/information on ingredients

3.2 Mixtures : Immulite® Chemiluminescent Substrate Mixture

Product/ingredient name	Identifiers	%	Classification Regulation (EC) No. 1272/2008 [CLP]	Туре
Immulite® Chemiluminescent Substrate 2-amino- 2-methylpropanol	EC: 204-709-8 CAS: 124-68-5 Index: 603-070-00-6	≤3	Skin Irrit. 2, H315 Eye Irrit. 2, H319 Aquatic Chronic 3, H412 See Section 16 for the full text of the H statements declared above.	[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, vPvBs or Substances of equivalent concern, or have been assigned a workplace exposure limit and hence require reporting in this section.

<u>Type</u>

Immulite® 2000 and Immulite® 2500 Chemiluminescent Substrate Module

SECTION 3: Composition/information on ingredients

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

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

SECTION 4: First aid measures

4.1 Description of first aid measures

Eye contact: Immulite® Chemiluminescent Substrate 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 : Immulite® Chemiluminescent Substrate 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.

Skin contact : Immulite® Chemiluminescent Substrate Flush contaminated skin with plenty of

water. Remove contaminated clothing and shoes. Get medical attention if

symptoms occur.

Ingestion : Immulite® Chemiluminescent Substrate Wash out mouth with water. Remove

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

attention if symptoms occur.

Protection of first-aiders : Immulite® Chemiluminescent Substrate No action shall be taken involving any

personal risk or without suitable training.

4.2 Most important symptoms and effects, both acute and delayed

Potential acute health effects

Eye contact

: Immulite® Chemiluminescent Substrate

No known significant effects or critical

hazards.

Inhalation : Immulite® Chemiluminescent Substrate

No known significant effects or critical

hazards.

Skin contact : Immulite® Chemiluminescent Substrate

No known significant effects or critical

hazards.

Ingestion : Immulite® Chemiluminescent Substrate

No known significant effects or critical

hazards.

Over-exposure signs/symptoms

Eye contact: Immulite® Chemiluminescent SubstrateNo specific data.Inhalation: Immulite® Chemiluminescent SubstrateNo specific data.Skin contact: Immulite® Chemiluminescent SubstrateNo specific data.Ingestion: Immulite® Chemiluminescent SubstrateNo specific data.

Immulite® 2000 and Immulite® 2500 Chemiluminescent Substrate Module

SECTION 4: First aid measures

4.3 Indication of any immediate medical attention and special treatment needed

Notes to physician : Immulite® Chemiluminescent Substrate 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: Immulite® Chemiluminescent Substrate: No specific treatment.

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 thermal decomposition products

: Decomposition products may include the following materials: carbon dioxide

carbon monoxide nitrogen 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.

SECTION 6: Accidental release measures

6.1 Personal precautions, protective equipment and emergency procedures

For non-emergency personnel

: No action shall be taken involving any personal risk or without suitable training. Evacuate surrounding areas. Keep unnecessary and unprotected personnel from entering. Do not touch or walk through spilt material. Put on appropriate personal protective equipment.

For emergency responders:

: If specialised clothing is required to deal with the spillage, take note of any information in Section 8 on suitable and unsuitable materials. See also 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

Immulite® 2000 and Immulite® 2500 Chemiluminescent Substrate Module

SECTION 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.

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 noncombustible, 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

7.1 Precautions for safe handling

Protective measures Advice on general occupational hygiene

- : 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. 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** : Not available. solutions

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 exposure or environmental releases.

8.1 Control parameters

Occupational exposure limits

No exposure limit value known.

procedures

Recommended monitoring : 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

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Immulite® 2000 and Immulite® 2500 Chemiluminescent Substrate Module

SECTION 8: Exposure controls/personal protection

(Workplace atmospheres - General requirements for the performance of procedures for the measurement of chemical agents) Reference to national guidance documents for methods for the determination of hazardous substances will also be required.

DNELs/DMELs

No DNELs/DMELs available.

PNECs

No PNECs available

8.2 Exposure controls

Appropriate engineering controls

: Good general ventilation should be sufficient to control worker exposure to airborne contaminants.

Individual protection measures

Hygiene measures

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

Eye/face protection

: Safety eyewear complying with an approved standard should be used when a risk assessment indicates this is necessary to avoid exposure to liquid splashes, mists, 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.

Impervious gloves (e.g. butyl, nitrile, etc.) are recommended if skin contact is possible and for processing operations. Protective gloves must meet the standards in accordance with CEN EN374, ASTM F1001 or international equivalent.

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.

Immulite® 2000 and Immulite® 2500 Chemiluminescent Substrate Module

SECTION 9: Physical and chemical properties

9.1 Information on basic physical and chemical properties

Appearance

Physical state : Immulite® Chemiluminescent Substrate Liquid. Colour Immulite® Chemiluminescent Substrate Colourless. Odour Immulite® Chemiluminescent Substrate Odourless.

Immulite® Chemiluminescent Substrate Not relevant/applicable due to nature **Odour threshold**

of the product.

рH Immulite® Chemiluminescent Substrate 10 to 10.2 Melting point/freezing point : Immulite® Chemiluminescent Substrate Not available. Initial boiling point and boiling : Immulite® Chemiluminescent Substrate Not available.

range

: Immulite® Chemiluminescent Substrate Not available. Flash point

Evaporation rate : Immulite® Chemiluminescent Substrate Not relevant/applicable due to nature

of the product.

Flammability (solid, gas) Immulite® Chemiluminescent Substrate Not relevant/applicable due to nature

of the product.

Upper/lower flammability or

explosive limits

: Immulite® Chemiluminescent Substrate Not relevant/applicable due to nature

of the product.

Immulite® Chemiluminescent Substrate Not relevant/applicable due to nature Vapour pressure

of the product.

Immulite® Chemiluminescent Substrate Not relevant/applicable due to nature Vapour density

of the product.

Relative density Immulite® Chemiluminescent Substrate 1

Solubility(ies) Immulite® Chemiluminescent Substrate Not relevant/applicable due to nature

of the product.

Solubility in water Immulite® Chemiluminescent Substrate Not relevant/applicable due to nature

of the product.

Auto-ignition temperature

water

Partition coefficient: n-octanol/ : Not relevant/applicable due to nature of the product.

: Immulite® Chemiluminescent Substrate Not relevant/applicable due to nature of the product.

Decomposition temperature : Immulite® Chemiluminescent Substrate Not relevant/applicable due to nature

of the product.

Viscosity : Not relevant/applicable due to nature of the product.

Immulite® Chemiluminescent Substrate Not relevant/applicable due to nature **Explosive properties**

of the product.

Oxidising properties : Not relevant/applicable due to nature of the product.

9.2 Other information

Not relevant/applicable due to nature of the product.

SECTION 10: Stability and reactivity

10.1 Reactivity : Immulite® Chemiluminescent Substrate No specific test data related to reactivity

available for this product or its

ingredients.

10.2 Chemical stability : Immulite® Chemiluminescent Substrate The product is stable.

Immulite® 2000 and Immulite® 2500 Chemiluminescent Substrate Module

SECTION 10: Stability and reactivity

10.3 Possibility of hazardous reactions

: Immulite® Chemiluminescent Substrate

Under normal conditions of storage and use, hazardous reactions will not occur.

10.4 Conditions to avoid : Immulite® Chemiluminescent Substrate No specific data.

10.5 Incompatible materials : Immulite® Chemiluminescent Substrate No specific data.

10.6 Hazardous decomposition products

: Immulite® Chemiluminescent Substrate

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
Immulite®				
Chemiluminescent				
Substrate				
2-amino-2-methylpropanol	LD50 Oral	Rat	2900 mg/kg	-

Conclusion/Summary :

: Immulite® Chemiluminescent Substrate

Not available.

Acute toxicity estimates

Not available.

Irritation/Corrosion

Conclusion/Summary

Skin: Immulite® Chemiluminescent SubstrateNot available.Eyes: Immulite® Chemiluminescent SubstrateNot available.Respiratory: Immulite® Chemiluminescent SubstrateNot available.

Sensitisation

Conclusion/Summary

Skin: Immulite® Chemiluminescent SubstrateNot available.Respiratory: Immulite® Chemiluminescent SubstrateNot available.

Mutagenicity

Conclusion/Summary: Immulite® Chemiluminescent Substrate Not available.

Carcinogenicity

Conclusion/Summary : Immulite® Chemiluminescent Substrate Not available.

Reproductive toxicity

Conclusion/Summary: Immulite® Chemiluminescent Substrate Not available.

Teratogenicity

Conclusion/Summary : Immulite® Chemiluminescent Substrate Not available.

Specific target organ toxicity (single exposure)

Not available.

Specific target organ toxicity (repeated exposure)

Not available.

Aspiration hazard

Not available.

Immulite® 2000 and Immulite® 2500 Chemiluminescent Substrate Module

SECTION 11: Toxicological information

Information on likely routes of exposure

: Immulite® Chemiluminescent Substrate Not available.

Potential acute health effects

Eye contact : Immulite® Chemiluminescent Substrate No known significant effects or critical

hazards.

Inhalation : Immulite® Chemiluminescent Substrate No known significant effects or critical

hazards.

Skin contact : Immulite® Chemiluminescent Substrate No known significant effects or critical

hazards.

Ingestion : Immulite® Chemiluminescent Substrate No known significant effects or critical

hazards.

Symptoms related to the physical, chemical and toxicological characteristics

Eye contact: Immulite® Chemiluminescent SubstrateNo specific data.Inhalation: Immulite® Chemiluminescent SubstrateNo specific data.Skin contact: Immulite® Chemiluminescent SubstrateNo specific data.Ingestion: Immulite® Chemiluminescent SubstrateNo specific data.

Delayed and immediate effects as well as chronic effects from short and long-term exposure

Short term exposure

Potential immediate : Immulite® Chemiluminescent Substrate Not available.

effects

Potential delayed effects : Immulite® Chemiluminescent Substrate Not available.

Long term exposure

Potential immediate : Immulite® Chemiluminescent Substrate Not available.

effects

Potential delayed effects : Immulite® Chemiluminescent Substrate Not available.

Potential chronic health effects

Not available.

Conclusion/Summary: Immulite® Chemiluminescent Substrate Not available.

General : Immulite® Chemiluminescent Substrate No known significant effects or critical

hazards.

Carcinogenicity : Immulite® Chemiluminescent Substrate No known significant effects or critical

hazards.

Mutagenicity : Immulite® Chemiluminescent Substrate No known significant effects or critical

hazards.

Teratogenicity: Immulite® Chemiluminescent Substrate No known significant effects or critical

hazards.

Developmental effects : Immulite® Chemiluminescent Substrate No known significant effects or critical

hazards.

Fertility effects : Immulite® Chemiluminescent Substrate No known significant effects or critical

hazards.

Interactive effects : Immulite® Chemiluminescent Substrate Not available.

Toxicokinetics

Absorption: Immulite® Chemiluminescent SubstrateNot available.Distribution: Immulite® Chemiluminescent SubstrateNot available.Metabolism: Immulite® Chemiluminescent SubstrateNot available.

Immulite® 2000 and Immulite® 2500 Chemiluminescent Substrate Module

SECTION 11: Toxicological information

Elimination : Immulite® Chemiluminescent Substrate Not available.

: Immulite® Chemiluminescent Substrate Other information Not available.

SECTION 12: Ecological information

12.1 Toxicity

Conclusion/Summary : Immulite® Chemiluminescent Substrate Not available.

12.2 Persistence and degradability

Conclusion/Summary : Immulite® Chemiluminescent Substrate Not available.

12.3 Bioaccumulative potential

Product/ingredient name	LogPow	BCF	Potential
Immulite® Chemiluminescent Substrate			
2-amino-2-methylpropanol	-0.63	320	low

12.4 Mobility in soil

Soil/water partition coefficient (Koc)

: Immulite® Chemiluminescent Substrate

Not available.

Mobility

: Immulite® Chemiluminescent Substrate Not available.

12.5 Results of PBT and vPvB assessment

PBT : Immulite® Chemiluminescent Substrate Not applicable. **vPvB** : Immulite® Chemiluminescent Substrate Not applicable.

12.6 Other adverse effects

: Immulite® Chemiluminescent Substrate

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

: Immulite® Chemiluminescent Substrate

Within the present knowledge of the supplier, this product is not regarded as hazardous waste, as defined by EU

Directive 2008/98/EC.

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.

: 12/13/2016 Date of issue/Date of revision 10/14 Date of previous issue : No previous validation Version

Immulite® 2000 and Immulite® 2500 Chemiluminescent Substrate Module

SECTION 13: Disposal considerations

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	Immulite® Chemiluminescent Substrate	Not regulated.
14.1 ON Hamber	inmunice Onemiuminescent Substrate	Not regulated.
14.2 UN proper shipping name	Immulite® Chemiluminescent Substrate	-
14.3 Transport hazard class(es)	Immulite® Chemiluminescent Substrate	-
14.4 Packing group	Immulite® Chemiluminescent Substrate	-
14.5 Environmental hazards	Immulite® Chemiluminescent Substrate	No.
Additional information	Immulite® Chemiluminescent Substrate	-
<u>ADN</u>		
14.1 UN number	Immulite® Chemiluminescent Substrate	Not regulated.
14.2 UN proper shipping name	Immulite® Chemiluminescent Substrate	-
14.3 Transport hazard class(es)	Immulite® Chemiluminescent Substrate	-
14.4 Packing group	Immulite® Chemiluminescent Substrate	-
14.5 Environmental hazards	Immulite® Chemiluminescent Substrate	No.
Additional information	Immulite® Chemiluminescent Substrate	-
<u>IMDG</u>		
14.1 UN number	Immulite® Chemiluminescent Substrate	Not regulated.
14.2 UN proper shipping name	Immulite® Chemiluminescent Substrate	-
14.3 Transport hazard class(es)	Immulite® Chemiluminescent Substrate	-
14.4 Packing group	Immulite® Chemiluminescent Substrate	-

Immulite® 2000 and Immulite® 2500 Chemiluminescent Substrate Module

SECTION 14: Transport information

		•	
E	14.5 Environmental nazards	Immulite® Chemiluminescent Substrate	No.
_	Additional nformation	Immulite® Chemiluminescent Substrate	-
<u>IAT</u>	<u> </u>		
1	14.1 UN number	Immulite® Chemiluminescent Substrate	Not regulated.
	14.2 UN proper shipping name	Immulite® Chemiluminescent Substrate	-
	4.3 Transport nazard class(es)	Immulite® Chemiluminescent Substrate	-
	14.4 Packing group	Immulite® Chemiluminescent Substrate	-
E	14.5 Environmental nazards	Immulite® Chemiluminescent Substrate	No.

Immulite® Chemiluminescent Substrate

14.6 Special precautions for : Immulite® Chemiluminescent Substrate **user**

Transport within user's premises: always transport in closed containers that are upright and secure. Ensure that persons transporting the product know what to do in the event of an accident or spillage.

14.7 Transport in bulk according to Annex II of Marpol and the IBC Code

Additional

information

Notes : A "-" = not applicable.

SECTION 15: Regulatory information

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

Annex XIV - List of substances subject to authorisation

Annex XIV

None of the components are listed.

Substances of very high concern

None of the components are listed.

Annex XVII - Restrictions on the manufacture, placing on the market and use of certain dangerous substances, mixtures and articles

: Immulite® Chemiluminescent Substrate

Not applicable.

Other EU regulations

Immulite® 2000 and Immulite® 2500 Chemiluminescent Substrate Module

SECTION 15: Regulatory information

Europe inventory: Immulite® Chemiluminescent Substrate Not determined.

Black List Chemicals (76/464/EEC)

: Immulite® Chemiluminescent Substrate Not listed

Industrial emissions (integrated pollution prevention and control) - : Immulite® Chemiluminescent Substrate Not listed

. Air

Industrial emissions (integrated pollution prevention and control) - : Immulite® Chemiluminescent Substrate Not listed

. Water

Ozone depleting substances (1005/2009/EU)

Not listed.

Prior Informed Consent (PIC) (649/2012/EU)

Not listed.

Seveso Directive

Immulite® Chemiluminescent Substrate

This product is not controlled under the Seveso Directive.

International regulations

Chemical Weapon Convention List Schedules I, II & III Chemicals

Not listed.

15.2 Chemical safety

assessment

: Not applicable.

SECTION 16: Other information

Abbreviations and acronyms: ATE = Acute Toxicity Estimate

CLP = Classification, Labelling and Packaging Regulation [Regulation (EC) No.

1272/2008]

DMEL = Derived Minimal Effect Level
DNEL = Derived No Effect Level

EUH statement = CLP-specific Hazard statement PBT = Persistent, Bioaccumulative and Toxic PNEC = Predicted No Effect Concentration RRN = REACH Registration Number

vPvB = Very Persistent and Very Bioaccumulative ASTM = American Society of Testing Materials CEN = European Committee on Standardization

ECHA = European Chemicals Agency

RTECS = Registry of Toxic Effects of Chemical Substances

Key literature references and sources for data

: This SDS was prepared on the basis of sheets of individual components, literature data, online databases (e.g. ECHA, RTECS) as well as our knowledge and experience, taking into account current legislation.

Procedure used to derive the classification according to Regulation (EC) No. 1272/2008 [CLP/GHS]

Classification	Justification
Not classified.	

Full text of abbreviated H statements

Immulite® 2000 and Immulite® 2500 Chemiluminescent Substrate Module

SECTION 16: Other information

Immulite® Chemiluminescent Substrate	
H315	Causes skin irritation.
H319	Causes serious eye irritation.
H412	Harmful to aquatic life with long lasting effects.

Full text of classifications [CLP/GHS]

egory 2
е

Training advice : Provide workers with adequate training to assure that chemicals are handled safely

in accordance with national and community legislation.

Date of printing : 12/13/2016

Date of issue/ Date of : 12/13/2016

revision

Date of previous issue : No previous validation

Version : 1

Indicates information that has changed from previously issued version.

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.