SAFETY DATA SHEET

IMMULITE® 2000 Insulin

SIEMENS Healthineers

SDS no.: L2KIN2_6

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

1.1 Product identifier

Product name : IMMULITE® 2000 Insulin

Product code : L2KIN2/6, 10381455, 10381456

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

Identified uses	Insulin Reagent Wedge	Diagnostic agents.
	IMMULITE® Insulin Controls	Diagnostic agents.
	Insulin Adjustors	Diagnostic agents.
Restrictions on use	For professional users only.	

Supplier : Siemens Healthcare Diagnostics Limited
Park View,
Watchmoor Park,
Camberley,
Surrey,
GU15 3YL
United Kingdom

Phone: +44 (0) 345 600 1955

e-mail address of person responsible for this SDS : dx.msds.healthcare@siemens-healthineers.com

1.4 Emergency telephone number

CHEMTREC: +44 20 3807 3798

SECTION 2: Hazards identification

2.1 Classification of the substance or mixture

Product definition :	Insulin Reagent Wedge	Mixture
	IMMULITE® Insulin Controls	Mixture
	Insulin Adjustors	Mixture

Classification according to UK CLP/GHS

IMMULITE® Insulin Controls

Acute Tox. 4, H302
Acute Tox. 4, H312
Aquatic Chronic 3, H412

Insulin Adjustors

Acute Tox. 4, H302
Acute Tox. 4, H312
Aquatic Chronic 3, H412

The product is classified as hazardous according to UK CLP Regulation SI 2019/720 as amended.

See Section 16 for the full text of the H statements declared above.

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

2.2 Label elements

SECTION 2: Hazards identification

Hazard pictograms :

Signal word	:	Insulin Reagent Wedge	No signal word.
		IMMULITE® Insulin Controls	Warning
		Insulin Adjustors	Warning
Hazard statements	:	Insulin Reagent Wedge	No known significant effects or critical hazards.
		IMMULITE® Insulin Controls	H302 + H312 - Harmful if swallowed or in contact with skin. H412 - Harmful to aquatic life with long lasting effects.
		Insulin Adjustors	H302 + H312 - Harmful if swallowed or in contact with skin. H412 - Harmful to aquatic life with long lasting effects.

Precautionary statements

Prevention	:	Insulin Reagent Wedge	Not applicable.
		IMMULITE® Insulin Controls	P264 - Wash hands thoroughly after handling. P280 - Wear protective gloves/protective clothing/eye protection/face protection. P273 - Avoid release to the environment.
		Insulin Adjustors	P264 - Wash hands thoroughly after handling. P280 - Wear protective gloves/protective clothing/eye protection/face protection. P273 - Avoid release to the environment.
Response	:	Insulin Reagent Wedge	Not applicable.
		IMMULITE® Insulin Controls	P312 - Call a POISON CENTER or doctor/physician if you feel unwell.
		Insulin Adjustors	P312 - Call a POISON CENTER or doctor/physician if you feel unwell.
Storage	:	Insulin Reagent Wedge	Not applicable.
		IMMULITE® Insulin Controls	Not applicable.
		Insulin Adjustors	Not applicable.
Disposal	:	Insulin Reagent Wedge	Not applicable.
		IMMULITE® Insulin Controls	P501 - Dispose of contents and container in accordance with all local, regional, and national regulations.
		Insulin Adjustors	P501 - Dispose of contents and container in accordance with all local, regional, and national regulations.
Supplemental label elements	:	Insulin Reagent Wedge	Safety data sheet available on request.
		IMMULITE® Insulin Controls	Contains N-ethylmaleimide. May produce an allergic reaction.
		Insulin Adjustors	Contains N-ethylmaleimide. May produce an allergic reaction.
Annex XVII - Restrictions on the manufacture, placing on the market and use of certain dangerous substances, mixtures and articles	:	Insulin Reagent Wedge	Not applicable.
		IMMULITE® Insulin Controls	Not applicable.
		Insulin Adjustors	Not applicable.

2.3 Other hazards

SECTION 2: Hazards identification

Product meets the criteria for PBT or vPvB according to Regulation (EC) No. 1907/2006, Annex XIII	:	Insulin Reagent Wedge	This mixture does not contain any substances that are assessed to be a PBT or a vPvB.
		IMMULITE® Insulin Controls	This mixture does not contain any substances that are assessed to be a PBT or a vPvB.
		Insulin Adjustors	This mixture does not contain any substances that are assessed to be a PBT or a vPvB.
Other hazards which do not result in classification	:	Insulin Reagent Wedge	None known.
		IMMULITE® Insulin Controls	None known.
		Insulin Adjustors	None known.
Additional information	:	Not available.	
		Sodium azide may react with lead or copper plumbing to form highly explosive metal azides.	

SECTION 3: Composition/information on ingredients

3.1 Substances	:	Insulin Reagent Wedge	Mixture
		IMMULITE® Insulin Controls	Mixture
		Insulin Adjustors	Mixture

Product/ingredient name	Identifiers	%	Classification	Type
Insulin Reagent Wedge				
aminocaproic acid	EC: 200-469-3 CAS: 60-32-2	≤3	Eye Irrit. 2, H319	[1]
IMMULITE® Insulin Controls				
sodium azide	EC: 247-852-1 CAS: 26628-22-8 Index: 011-004-00-7	≤1.9	Acute Tox. 2, H300 Acute Tox. 1, H310 Aquatic Acute 1, H400 (M=1) Aquatic Chronic 1, H410 (M=1) EUH032	[1] [2]
N-ethylmaleimide	EC: 204-892-4 CAS: 128-53-0	≤0.3	Acute Tox. 2, H300 Acute Tox. 3, H311 Skin Corr. 1B, H314 Eye Dam. 1, H318 Skin Sens. 1, H317	[1]
Insulin Adjustors				
sodium azide	EC: 247-852-1 CAS: 26628-22-8 Index: 011-004-00-7	≤1.9	Acute Tox. 2, H300 Acute Tox. 1, H310 Aquatic Acute 1, H400 (M=1) Aquatic Chronic 1, H410 (M=1) EUH032	[1] [2]
N-ethylmaleimide	EC: 204-892-4 CAS: 128-53-0	≤0.3	Acute Tox. 2, H300 Acute Tox. 3, H311 Skin Corr. 1B, H314 Eye Dam. 1, H318 Skin Sens. 1, H317 **See Section 16 for the full text of the H statements declared above.**	[1]

Type

[1] Substance classified with a health or environmental hazard
[2] Substance with a workplace exposure limit

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	:	Insulin Reagent Wedge	Immediately flush eyes with plenty of water, occasionally lifting the upper and lower eyelids. Check for and remove any contact lenses. Get medical attention if irritation occurs.
		IMMULITE® Insulin Controls	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.
		Insulin Adjustors	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.
Inhalation	:	Insulin Reagent Wedge	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.
		IMMULITE® Insulin Controls	Remove victim to fresh air and keep at rest in a position comfortable for breathing. If not breathing, if breathing is irregular or if respiratory arrest occurs, provide artificial respiration or oxygen by trained personnel. It may be dangerous to the person providing aid to give mouth-to-mouth resuscitation. Get medical attention if adverse health effects persist or are severe. If unconscious, place in recovery position and get medical attention immediately. Maintain an open airway. Loosen tight clothing such as a collar, tie, belt or waistband. In case of inhalation of decomposition products in a fire, symptoms may be delayed. The exposed person may need to be kept under medical surveillance for 48 hours.
		Insulin Adjustors	Remove victim to fresh air and keep at rest in a position comfortable for breathing. If not breathing, if breathing is irregular or if respiratory arrest occurs, provide artificial respiration or oxygen by trained personnel. It may be dangerous to the person providing aid to give mouth-to-mouth resuscitation. Get medical attention if adverse health effects persist or are severe. If unconscious, place in recovery position and get medical attention immediately. Maintain an open airway. Loosen tight clothing such as a collar, tie, belt or waistband. In case of inhalation of decomposition products in a fire, symptoms may be delayed. The

SECTION 4: First aid measures

			exposed person may need to be kept under medical surveillance for 48 hours.
Skin contact	:	Insulin Reagent Wedge	Flush contaminated skin with plenty of water. Remove contaminated clothing and shoes. Get medical attention if symptoms occur.
		IMMULITE® Insulin Controls	Wash with plenty of soap and water. Remove contaminated clothing and shoes. Wash contaminated clothing thoroughly with water before removing it, or wear gloves. Continue to rinse for at least 10 minutes. Get medical attention if adverse health effects persist or are severe. If necessary, call a poison center or physician. Wash clothing before reuse. Clean shoes thoroughly before reuse.
		Insulin Adjustors	Wash with plenty of soap and water. Remove contaminated clothing and shoes. Wash contaminated clothing thoroughly with water before removing it, or wear gloves. Continue to rinse for at least 10 minutes. Get medical attention if adverse health effects persist or are severe. If necessary, call a poison center or physician. Wash clothing before reuse. Clean shoes thoroughly before reuse.
Ingestion	:	Insulin Reagent Wedge	Wash out mouth with water. If material has been swallowed and the exposed person is conscious, give small quantities of water to drink. Do not induce vomiting unless directed to do so by medical personnel. Get medical attention if symptoms occur.
		IMMULITE® Insulin Controls	Wash out mouth with water. Remove dentures if any. If material has been swallowed and the exposed person is conscious, give small quantities of water to drink. Stop if the exposed person feels sick as vomiting may be dangerous. Do not induce vomiting unless directed to do so by medical personnel. If vomiting occurs, the head should be kept low so that vomit does not enter the lungs. Get medical attention. If necessary, call a poison center or physician. 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.
		Insulin Adjustors	Wash out mouth with water. Remove dentures if any. If material has been swallowed and the exposed person is conscious, give small quantities of water to drink. Stop if the exposed person feels sick as vomiting may be dangerous. Do not induce vomiting unless directed to do so by medical personnel. If vomiting occurs, the head should be

SECTION 4: First aid measures

kept low so that vomit does not enter the lungs. Get medical attention. If necessary, call a poison center or physician. 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.

Protection of first-aiders	:	Insulin Reagent Wedge	No action shall be taken involving any personal risk or without suitable training.
		IMMULITE® Insulin Controls	No action shall be taken involving any personal risk or without suitable training. It may be dangerous to the person providing aid to give mouth-to-mouth resuscitation. Wash contaminated clothing thoroughly with water before removing it, or wear gloves.
		Insulin Adjustors	No action shall be taken involving any personal risk or without suitable training. It may be dangerous to the person providing aid to give mouth-to-mouth resuscitation. Wash contaminated clothing thoroughly with water before removing it, or wear gloves.

4.2 Most important symptoms and effects, both acute and delayed

Over-exposure signs/symptoms

Eye contact	:	Insulin Reagent Wedge	No specific data.
		IMMULITE® Insulin Controls	No specific data.
		Insulin Adjustors	No specific data.
Inhalation	:	Insulin Reagent Wedge	No specific data.
		IMMULITE® Insulin Controls	No specific data.
		Insulin Adjustors	No specific data.
Skin contact	:	Insulin Reagent Wedge	No specific data.
		IMMULITE® Insulin Controls	No specific data.
		Insulin Adjustors	No specific data.
Ingestion	:	Insulin Reagent Wedge	No specific data.
		IMMULITE® Insulin Controls	No specific data.
		Insulin Adjustors	No specific data.

4.3 Indication of any immediate medical attention and special treatment needed

Notes to physician	:	Insulin Reagent Wedge	In case of inhalation of decomposition products in a fire, symptoms may be delayed. The exposed person may need to be kept under medical surveillance for 48 hours.
		IMMULITE® Insulin Controls	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.
		Insulin Adjustors	In case of inhalation of decomposition products in a fire, symptoms may be delayed. The exposed person may need to be kept under medical surveillance for 48 hours.

SECTION 4: First aid measures

Specific treatments	:	Insulin Reagent Wedge	No specific treatment.
		IMMULITE® Insulin Controls	No specific treatment.
		Insulin Adjustors	No specific treatment.
		Insulin Reagent Wedge	Not available.
		IMMULITE® Insulin Controls	Not available.
		Insulin Adjustors	Not available.

SECTION 5: Firefighting measures

5.1 Extinguishing media

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

Unsuitable extinguishing media : None known.

5.2 Special hazards arising from the substance or mixture

Hazards from the substance or mixture : In a fire or if heated, a pressure increase will occur and the container may burst. This material is harmful to aquatic life with long lasting effects. 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:
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.

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). Water polluting material. May be harmful to the environment if released in large quantities.

6.3 Methods and material for containment and cleaning up

Small spill : Stop leak if without risk. Move containers from spill area. Dilute with water and mop up if water-soluble. Alternatively, or if water-insoluble, absorb with an inert dry material and place in an appropriate waste disposal container. Dispose of via a licensed waste disposal contractor.

SECTION 6: Accidental release measures

Large spill : Stop leak if without risk. Move containers from spill area. Approach the release from upwind. Prevent entry into sewers, water courses, basements or confined areas. Wash spillages into an effluent treatment plant or proceed as follows. Contain and collect spillage with non-combustible, absorbent material e.g. sand, earth, vermiculite or diatomaceous earth and place in container for disposal according to local regulations (see Section 13). Dispose of via a licensed waste disposal contractor. Contaminated absorbent material may pose the same hazard as the spilt product. Note: see Section 1 for emergency contact information and Section 13 for waste disposal.

6.4 Reference to other sections : See Section 1 for emergency contact information.
See Section 8 for information on appropriate personal protective equipment.
See Section 13 for additional waste treatment information.

SECTION 7: Handling and storage

7.1 Precautions for safe handling

Protective measures : Put on appropriate personal protective equipment (see Section 8). Do not ingest. Avoid contact with eyes, skin and clothing. Avoid breathing vapour or mist. Avoid release to the environment. Keep in the original container or an approved alternative made from a compatible material, kept tightly closed when not in use. Empty containers retain product residue and can be hazardous. Do not reuse container.

Advice on general occupational hygiene : Eating, drinking and smoking should be prohibited in areas where this material is handled, stored and processed. Workers should wash hands and face before eating, drinking and smoking. Remove contaminated clothing and protective equipment before entering eating areas. See also Section 8 for additional information on hygiene measures.

7.2 Conditions for safe storage, including any incompatibilities

Store in accordance with local regulations. Store in original container protected from direct sunlight in a dry, cool and well-ventilated area, away from incompatible materials (see Section 10) and food and drink. Keep container tightly closed and sealed until ready for use. Containers that have been opened must be carefully resealed and kept upright to prevent leakage. Do not store in unlabelled containers. Use appropriate containment to avoid environmental contamination. See Section 10 for incompatible materials before handling or use.

7.3 Specific end use(s)

Recommendations : Not available.

Industrial sector specific solutions : Not available.

SECTION 8: Exposure controls/personal protection

8.1 Control parameters

Occupational exposure limits

Product/ingredient name	Exposure limit values
IMMULITE® Insulin Controls sodium azide	**EH40/2005 WELs (United Kingdom (UK), 1/2020). Absorbed through skin.** STEL: 0.3 mg/m³, (as NaN3) 15 minutes. TWA: 0.1 mg/m³, (as NaN3) 8 hours.
Insulin Adjustors sodium azide	**EH40/2005 WELs (United Kingdom (UK), 1/2020). Absorbed through skin.** STEL: 0.3 mg/m³, (as NaN3) 15 minutes. TWA: 0.1 mg/m³, (as NaN3) 8 hours.

SECTION 8: Exposure controls/personal protection

Recommended monitoring procedures : If this product contains ingredients with exposure limits, personal, workplace atmosphere or biological monitoring may be required to determine the effectiveness of the ventilation or other control measures and/or the necessity to use respiratory protective equipment. Reference should be made to appropriate monitoring standards. Reference to national guidance documents for methods for the determination of hazardous substances will also be required.

DNELs/DMELs

Product/ingredient name	Type	Exposure	Value	Population	Effects
IMMULITE® Insulin Controls					
sodium azide	DNEL	Long term Oral	16.7 µg/kg bw/day	General population	Systemic
	DNEL	Long term Dermal	16.7 µg/kg bw/day	General population	Systemic
	DNEL	Long term Inhalation	29 µg/m³	General population	Systemic
	DNEL	Long term Dermal	46.7 µg/kg bw/day	Workers	Systemic
	DNEL	Long term Inhalation	0.164 mg/m³	Workers	Systemic
Insulin Adjustors					
sodium azide	DNEL	Long term Oral	16.7 µg/kg bw/day	General population	Systemic
	DNEL	Long term Dermal	16.7 µg/kg bw/day	General population	Systemic
	DNEL	Long term Inhalation	29 µg/m³	General population	Systemic
	DNEL	Long term Dermal	46.7 µg/kg bw/day	Workers	Systemic
	DNEL	Long term Inhalation	0.164 mg/m³	Workers	Systemic

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. Considering the parameters specified by the glove manufacturer, check during use that the gloves are still retaining their protective properties. It should be noted that the time to breakthrough for any glove material may be different for different glove manufacturers. In the case of mixtures, consisting of several substances, the protection time of the gloves cannot be accurately estimated.

SECTION 8: Exposure controls/personal protection

Body protection : Personal protective equipment for the body should be selected based on the task being performed and the risks involved and should be approved by a specialist before handling this product.

Other skin protection : Appropriate footwear and any additional skin protection measures should be selected based on the task being performed and the risks involved and should be approved by a specialist before handling this product.

Respiratory protection : Based on the hazard and potential for exposure, select a respirator that meets the appropriate standard or certification. Respirators must be used according to a respiratory protection program to ensure proper fitting, training, and other important aspects of use.

Environmental exposure controls : Emissions from ventilation or work process equipment should be checked to ensure they comply with the requirements of environmental protection legislation. In some cases, fume scrubbers, filters or engineering modifications to the process equipment will be necessary to reduce emissions to acceptable levels.

SECTION 9: Physical and chemical properties

The conditions of measurement of all properties are at standard temperature and pressure unless otherwise indicated.

9.1 Information on basic physical and chemical properties

Appearance

Physical state :
- Insulin Reagent Wedge: Liquid.
- IMMULITE® Insulin Controls: Solid.
- Insulin Adjustors: Solid.

Colour :
- Insulin Reagent Wedge: Colourless.
- IMMULITE® Insulin Controls: Off-white.
- Insulin Adjustors: Pale colour.

Odour :
- Insulin Reagent Wedge: Odourless.
- IMMULITE® Insulin Controls: Bland.
- Insulin Adjustors: Bland.

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

Melting point/freezing point : Not relevant/applicable due to nature of the product.

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

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

Initial boiling point and boiling range :
- Insulin Reagent Wedge: Not available.
- IMMULITE® Insulin Controls: Not available.
- Insulin Adjustors: Not available.

Flammability (solid, gas) :
- Insulin Reagent Wedge: Not relevant/applicable due to nature of the product.
- IMMULITE® Insulin Controls: Not relevant/applicable due to nature of the product.
- Insulin Adjustors: Not relevant/applicable due to nature of the product.

Upper/lower flammability or explosive limits :
- Insulin Reagent Wedge: Not available.
- IMMULITE® Insulin Controls: Not applicable.
- Insulin Adjustors: Not applicable.

Flash point :
- Insulin Reagent Wedge: [Product does not sustain combustion.]
- IMMULITE® Insulin Controls: [Product does not sustain combustion.]
- Insulin Adjustors: [Product does not sustain combustion.]

Auto-ignition temperature :

Ingredient name	°C	°F	Method
Insulin Reagent Wedge			
sodium azide	309	588.2	EU A.16

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

pH :
- Insulin Reagent Wedge: 5.85 to 5.95
- IMMULITE® Insulin Controls: Not applicable.
- Insulin Adjustors: Not applicable.

SECTION 9: Physical and chemical properties

Viscosity : Insulin Reagent Wedge — Not available.
IMMULITE® Insulin Controls — Not applicable.
Insulin Adjustors — Not applicable.

Solubility(ies) :

Not available.

Solubility in water : Not relevant/applicable due to nature of the product.

Miscible with water : Not relevant/applicable due to nature of the product.

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

Vapour pressure :

	Vapour Pressure at 20˚C			Vapour pressure at 50˚C		
Ingredient name	**mm Hg**	**kPa**	**Method**	**mm Hg**	**kPa**	**Method**
Insulin Reagent Wedge						
water	23.8	3.2				

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

Relative density : Insulin Reagent Wedge — 1
IMMULITE® Insulin Controls — >1
Insulin Adjustors — >1

Density : Insulin Reagent Wedge — Not available.
IMMULITE® Insulin Controls — Not available.
Insulin Adjustors — Not available.

Vapour density : Insulin Reagent Wedge — Not available.
IMMULITE® Insulin Controls — Not applicable.
Insulin Adjustors — Not applicable.

Explosive properties : Insulin Reagent Wedge — Not available.
IMMULITE® Insulin Controls — Not available.
Insulin Adjustors — Not available.

Oxidising properties : Insulin Reagent Wedge — Not available.
IMMULITE® Insulin Controls — Not available.
Insulin Adjustors — Not available.

Particle characteristics

Median particle size : Not applicable.

9.2 Other information

Fire point : Insulin Reagent Wedge — Not available.
IMMULITE® Insulin Controls — Not available.
Insulin Adjustors — Not available.

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

Fundamental burning velocity : Not relevant/applicable due to nature of the product.

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

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

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

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

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

Flow time (ISO 2431) : Not relevant/applicable due to nature of the product.

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

SECTION 10: Stability and reactivity

10.1 Reactivity : No specific test data related to reactivity available for this product or its ingredients.

10.2 Chemical stability : The product is stable.

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

10.4 Conditions to avoid : No specific data.

10.5 Incompatible materials : No specific data.

10.6 Hazardous decomposition products : Under normal conditions of storage and use, hazardous decomposition products should not be produced.

SECTION 11: Toxicological information

11.1 Information on toxicological effects

Acute toxicity

Product/ingredient name	Result	Species	Dose	Exposure
IMMULITE® Insulin Controls				
sodium azide	LD50 Dermal	Rabbit	20 mg/kg	-
	LD50 Dermal	Rat	50 mg/kg	-
	LD50 Oral	Rat	27 mg/kg	-
N-ethylmaleimide	LD50 Oral	Rat	25 mg/kg	-
Insulin Adjustors				
sodium azide	LD50 Dermal	Rabbit	20 mg/kg	-
	LD50 Dermal	Rat	50 mg/kg	-
	LD50 Oral	Rat	27 mg/kg	-
N-ethylmaleimide	LD50 Oral	Rat	25 mg/kg	-

Conclusion/Summary : Insulin Reagent Wedge — Not available.
IMMULITE® Insulin Controls — Not available.
Insulin Adjustors — Not available.

Acute toxicity estimates

Product/ingredient name	Oral (mg/kg)	Dermal (mg/kg)	Inhalation (gases) (ppm)	Inhalation (vapours) (mg/l)	Inhalation (dusts and mists) (mg/l)
IMMULITE® Insulin Controls					
IMMULITE® Insulin Controls	1614.4	1440.2	N/A	N/A	N/A
sodium azide	27	20	N/A	N/A	N/A
N-ethylmaleimide	25	300	N/A	N/A	N/A
Insulin Adjustors					
Insulin Adjustors	1614.4	1440.2	N/A	N/A	N/A
sodium azide	27	20	N/A	N/A	N/A
N-ethylmaleimide	25	300	N/A	N/A	N/A

Irritation/Corrosion

Product/ingredient name	Result	Species	Score	Exposure	Observation
Insulin Reagent Wedge					
aminocaproic acid	Eyes - Mild irritant	Rabbit	-	24 hours 500 mg	-

Conclusion/Summary

SECTION 11: Toxicological information

Skin	:	Insulin Reagent Wedge	Not available.
		IMMULITE® Insulin Controls	Not available.
		Insulin Adjustors	Not available.
Eyes	:	Insulin Reagent Wedge	Not available.
		IMMULITE® Insulin Controls	Not available.
		Insulin Adjustors	Not available.
Respiratory	:	Insulin Reagent Wedge	Not available.
		IMMULITE® Insulin Controls	Not available.
		Insulin Adjustors	Not available.

Sensitisation

Conclusion/Summary

Skin	:	Insulin Reagent Wedge	Not available.
		IMMULITE® Insulin Controls	Not available.
		Insulin Adjustors	Not available.
Respiratory	:	Insulin Reagent Wedge	Not available.
		IMMULITE® Insulin Controls	Not available.
		Insulin Adjustors	Not available.

Mutagenicity

Conclusion/Summary	:	Insulin Reagent Wedge	Not available.
		IMMULITE® Insulin Controls	Not available.
		Insulin Adjustors	Not available.

Carcinogenicity

Conclusion/Summary	:	Insulin Reagent Wedge	Not available.
		IMMULITE® Insulin Controls	Not available.
		Insulin Adjustors	Not available.

Reproductive toxicity

Conclusion/Summary	:	Insulin Reagent Wedge	Not available.
		IMMULITE® Insulin Controls	Not available.
		Insulin Adjustors	Not available.

Teratogenicity

Conclusion/Summary	:	Insulin Reagent Wedge	Not available.
		IMMULITE® Insulin Controls	Not available.
		Insulin Adjustors	Not available.

Specific target organ toxicity (single exposure)

Not available.

Specific target organ toxicity (repeated exposure)

Not available.

Aspiration hazard

Not available.

Information on likely routes of exposure	:	Insulin Reagent Wedge	Not available.
		IMMULITE® Insulin Controls	Not available.
		Insulin Adjustors	Not available.

Potential acute health effects

Eye contact	:	Insulin Reagent Wedge	No known significant effects or critical hazards.
		IMMULITE® Insulin Controls	No known significant effects or critical hazards.
		Insulin Adjustors	No known significant effects or critical hazards.

SECTION 11: Toxicological information

Inhalation	:	Insulin Reagent Wedge	No known significant effects or critical hazards.
		IMMULITE® Insulin Controls	No known significant effects or critical hazards.
		Insulin Adjustors	No known significant effects or critical hazards.
Skin contact	:	Insulin Reagent Wedge	No known significant effects or critical hazards.
		IMMULITE® Insulin Controls	Harmful in contact with skin.
		Insulin Adjustors	Harmful in contact with skin.
Ingestion	:	Insulin Reagent Wedge	No known significant effects or critical hazards.
		IMMULITE® Insulin Controls	Harmful if swallowed.
		Insulin Adjustors	Harmful if swallowed.

Symptoms related to the physical, chemical and toxicological characteristics

Eye contact	:	Insulin Reagent Wedge	No specific data.
		IMMULITE® Insulin Controls	No specific data.
		Insulin Adjustors	No specific data.
Inhalation	:	Insulin Reagent Wedge	No specific data.
		IMMULITE® Insulin Controls	No specific data.
		Insulin Adjustors	No specific data.
Skin contact	:	Insulin Reagent Wedge	No specific data.
		IMMULITE® Insulin Controls	No specific data.
		Insulin Adjustors	No specific data.
Ingestion	:	Insulin Reagent Wedge	No specific data.
		IMMULITE® Insulin Controls	No specific data.
		Insulin Adjustors	No specific data.

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

Short term exposure

Potential immediate effects	:	Insulin Reagent Wedge	Not available.
		IMMULITE® Insulin Controls	Not available.
		Insulin Adjustors	Not available.
Potential delayed effects	:	Insulin Reagent Wedge	Not available.
		IMMULITE® Insulin Controls	Not available.
		Insulin Adjustors	Not available.

Long term exposure

Potential immediate effects	:	Insulin Reagent Wedge	Not available.
		IMMULITE® Insulin Controls	Not available.
		Insulin Adjustors	Not available.
Potential delayed effects	:	Insulin Reagent Wedge	Not available.
		IMMULITE® Insulin Controls	Not available.
		Insulin Adjustors	Not available.

Potential chronic health effects

Not available.

Conclusion/Summary	:	Insulin Reagent Wedge	Not available.
		IMMULITE® Insulin Controls	Not available.
		Insulin Adjustors	Not available.
General	:	Insulin Reagent Wedge	No known significant effects or critical hazards.
		IMMULITE® Insulin Controls	No known significant effects or critical hazards.
		Insulin Adjustors	No known significant effects or critical hazards.

SECTION 11: Toxicological information

Carcinogenicity	:	Insulin Reagent Wedge	No known significant effects or critical hazards.
		IMMULITE® Insulin Controls	No known significant effects or critical hazards.
		Insulin Adjustors	No known significant effects or critical hazards.
Mutagenicity	:	Insulin Reagent Wedge	No known significant effects or critical hazards.
		IMMULITE® Insulin Controls	No known significant effects or critical hazards.
		Insulin Adjustors	No known significant effects or critical hazards.
Reproductive toxicity	:	Insulin Reagent Wedge	No known significant effects or critical hazards.
		IMMULITE® Insulin Controls	No known significant effects or critical hazards.
		Insulin Adjustors	No known significant effects or critical hazards.
Interactive effects	:	Insulin Reagent Wedge	Not available.
		IMMULITE® Insulin Controls	Not available.
		Insulin Adjustors	Not available.

Toxicokinetics

Absorption	:	Insulin Reagent Wedge	Not available.
		IMMULITE® Insulin Controls	Not available.
		Insulin Adjustors	Not available.
Distribution	:	Insulin Reagent Wedge	Not available.
		IMMULITE® Insulin Controls	Not available.
		Insulin Adjustors	Not available.
Metabolism	:	Insulin Reagent Wedge	Not available.
		IMMULITE® Insulin Controls	Not available.
		Insulin Adjustors	Not available.
Elimination	:	Insulin Reagent Wedge	Not available.
		IMMULITE® Insulin Controls	Not available.
		Insulin Adjustors	Not available.
Other information	:	Insulin Reagent Wedge	Not available.
		IMMULITE® Insulin Controls	Not available.
		Insulin Adjustors	Not available.

SECTION 12: Ecological information

12.1 Toxicity

Product/ingredient name	Result	Species	Exposure
IMMULITE® Insulin Controls			
sodium azide	Acute EC50 9200 µg/l Marine water	Algae - Giant kelp - Macrocystis pyrifera	96 hours
	Acute EC50 6.4 mg/l Fresh water	Crustaceans - Water flea - Simocephalus serrulatus - Larvae	48 hours
	Acute EC50 4.2 mg/l Fresh water	Daphnia - Water flea - Daphnia pulex - Larvae	48 hours
	Acute LC50 0.68 mg/l Fresh water	Fish - Bluegill - Lepomis macrochirus	96 hours
	Chronic NOEC 5600 µg/l Marine water	Algae - Giant kelp - Macrocystis pyrifera	96 hours
Insulin Adjustors			
sodium azide	Acute EC50 9200 µg/l Marine water	Algae - Giant kelp - Macrocystis pyrifera	96 hours

SECTION 12: Ecological information

	Acute EC50 6.4 mg/l Fresh water	Crustaceans - Water flea - Simocephalus serrulatus - Larvae	48 hours
	Acute EC50 4.2 mg/l Fresh water	Daphnia - Water flea - Daphnia pulex - Larvae	48 hours
	Acute LC50 0.68 mg/l Fresh water	Fish - Bluegill - Lepomis macrochirus	96 hours
	Chronic NOEC 5600 µg/l Marine water	Algae - Giant kelp - Macrocystis pyrifera	96 hours

Conclusion/Summary : Insulin Reagent Wedge — Not available.
IMMULITE® Insulin Controls — Not available.
Insulin Adjustors — Not available.

12.2 Persistence and degradability

Conclusion/Summary : Insulin Reagent Wedge — Not available.
IMMULITE® Insulin Controls — Not available.
Insulin Adjustors — Not available.

12.3 Bioaccumulative potential

Product/ingredient name	$LogP_{ow}$	BCF	Potential
Insulin Reagent Wedge aminocaproic acid	-2.95	-	low

12.4 Mobility in soil

Soil/water partition coefficient (K_{OC}) : Insulin Reagent Wedge — Not available.
IMMULITE® Insulin Controls — Not available.
Insulin Adjustors — Not available.

Mobility : Insulin Reagent Wedge — Not available.
IMMULITE® Insulin Controls — Not available.
Insulin Adjustors — Not available.

12.5 Results of PBT and vPvB assessment

This mixture does not contain any substances that are assessed to be a PBT or a vPvB.

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

SECTION 13: Disposal considerations

13.1 Waste treatment methods

Product

Methods of disposal : The generation of waste should be avoided or minimised wherever possible. Disposal of this product, solutions and any by-products should at all times comply with the requirements of environmental protection and waste disposal legislation and any regional local authority requirements. Dispose of surplus and non-recyclable products via a licensed waste disposal contractor. Waste should not be disposed of untreated to the sewer unless fully compliant with the requirements of all authorities with jurisdiction.

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

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

Packaging

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.

SECTION 13: Disposal considerations

Special precautions : This material and its container must be disposed of in a safe way. Care should be taken when handling emptied containers that have not been cleaned or rinsed out. Empty containers or liners may retain some product residues. Avoid dispersal of spilt material and runoff and contact with soil, waterways, drains and sewers.

SECTION 14: Transport information

ADR/RID

14.1 UN number	Insulin Reagent Wedge	Not regulated.
	IMMULITE® Insulin Controls	Not regulated.
	Insulin Adjustors	Not regulated.
14.2 UN proper shipping name	Insulin Reagent Wedge	-
	IMMULITE® Insulin Controls	-
	Insulin Adjustors	-
14.3 Transport hazard class(es)	Insulin Reagent Wedge	-
	IMMULITE® Insulin Controls	-
	Insulin Adjustors	-
14.4 Packing group	Insulin Reagent Wedge	-
	IMMULITE® Insulin Controls	-
	Insulin Adjustors	-
14.5 Environmental hazards	Insulin Reagent Wedge	No.
	IMMULITE® Insulin Controls	No.
	Insulin Adjustors	No.
Additional information	Insulin Reagent Wedge	-
	IMMULITE® Insulin Controls	-
	Insulin Adjustors	-

ADN

14.1 UN number	Insulin Reagent Wedge	Not regulated.
	IMMULITE® Insulin Controls	Not regulated.
	Insulin Adjustors	Not regulated.
14.2 UN proper shipping name	Insulin Reagent Wedge	-
	IMMULITE® Insulin Controls	-
	Insulin Adjustors	-
14.3 Transport hazard class(es)	Insulin Reagent Wedge	-
	IMMULITE® Insulin Controls	-
	Insulin Adjustors	-
14.4 Packing group	Insulin Reagent Wedge	-
	IMMULITE® Insulin Controls	-
	Insulin Adjustors	-
14.5 Environmental hazards	Insulin Reagent Wedge	No.
	IMMULITE® Insulin Controls	No.
	Insulin Adjustors	No.
Additional information	Insulin Reagent Wedge	-
	IMMULITE® Insulin Controls	-
	Insulin Adjustors	-

IMDG

14.1 UN number	Insulin Reagent Wedge	Not regulated.
	IMMULITE® Insulin Controls	Not regulated.
	Insulin Adjustors	Not regulated.

SECTION 14: Transport information

14.2 UN proper shipping name	Insulin Reagent Wedge	-
	IMMULITE® Insulin Controls	-
	Insulin Adjustors	-
14.3 Transport hazard class(es)	Insulin Reagent Wedge	-
	IMMULITE® Insulin Controls	-
	Insulin Adjustors	-
14.4 Packing group	Insulin Reagent Wedge	-
	IMMULITE® Insulin Controls	-
	Insulin Adjustors	-
14.5 Environmental hazards	Insulin Reagent Wedge	No.
	IMMULITE® Insulin Controls	No.
	Insulin Adjustors	No.
Additional information	Insulin Reagent Wedge	-
	IMMULITE® Insulin Controls	-
	Insulin Adjustors	-

IATA

14.1 UN number	Insulin Reagent Wedge	Not regulated.
	IMMULITE® Insulin Controls	Not regulated.
	Insulin Adjustors	Not regulated.
14.2 UN proper shipping name	Insulin Reagent Wedge	-
	IMMULITE® Insulin Controls	-
	Insulin Adjustors	-
14.3 Transport hazard class(es)	Insulin Reagent Wedge	-
	IMMULITE® Insulin Controls	-
	Insulin Adjustors	-
14.4 Packing group	Insulin Reagent Wedge	-
	IMMULITE® Insulin Controls	-
	Insulin Adjustors	-
14.5 Environmental hazards	Insulin Reagent Wedge	No.
	IMMULITE® Insulin Controls	No.
	Insulin Adjustors	No.
Additional information	Insulin Reagent Wedge	-
	IMMULITE® Insulin Controls	-
	Insulin Adjustors	-

14.6 Special precautions for user

Insulin Reagent Wedge	**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.
IMMULITE® Insulin Controls	**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.
Insulin Adjustors	**Transport within user's premises:** always transport in closed containers that are upright and secure. Ensure that persons transporting the product know

SECTION 14: Transport information

what to do in the event of an accident or spillage.

14.7 Transport in bulk according to IMO instruments Not applicable.

SECTION 15: Regulatory information

15.1 Safety, health and environmental regulations/legislation specific for the substance or mixture

UK (GB) /REACH

Annex XIV - List of substances subject to authorisation

Annex XIV

None of the components are listed.

Substances of very high concern

None of the components are listed.

Ozone depleting substances

Not listed.

Prior Informed Consent (PIC)

Not listed.

Persistent Organic Pollutants

Not listed.

Annex XVII - Restrictions on the manufacture, placing on the market and use of certain dangerous substances, mixtures and articles	:	Insulin Reagent Wedge	Not applicable.
		IMMULITE® Insulin Controls	Not applicable.
		Insulin Adjustors	Not applicable.

Seveso Directive

This product is not controlled under the Seveso Directive.

National regulations

EU regulations

Industrial emissions (integrated pollution prevention and control) - Air	:	Insulin Reagent Wedge	Listed
		IMMULITE® Insulin Controls	Not listed
		Insulin Adjustors	Not listed
Industrial emissions (integrated pollution prevention and control) - Water	:	Insulin Reagent Wedge	Not listed
		IMMULITE® Insulin Controls	Not listed
		Insulin Adjustors	Not listed

International regulations

Montreal Protocol

Not listed.

Stockholm Convention on Persistent Organic Pollutants

Not listed.

Rotterdam Convention on Prior Informed Consent (PIC)

Not listed.

UNECE Aarhus Protocol on POPs and Heavy Metals

Not listed.

SECTION 15: Regulatory information

15.2 Chemical safety assessment : Not applicable.

SECTION 16: Other information

Indicates information that has changed from previously issued version.

Abbreviations and acronyms : ATE = Acute Toxicity Estimate
GB CLP = UK CLP (EC No 1272/2008) on the Classification, Labelling and Packaging of Substances and Mixtures as amended by (EU Exit) Regulations 2019 No. 720 and amendments
DMEL = Derived Minimal Effect Level
DNEL = Derived No Effect Level
EUH statement = GB CLP-specific Hazard statement
N/A = Not available
PBT = Persistent, Bioaccumulative and Toxic
PNEC = Predicted No Effect Concentration
RRN = REACH Registration Number
SGG = Segregation Group
vPvB = Very Persistent and Very Bioaccumulative

Procedure used to derive the classification

Classification	Justification
IMMULITE® Insulin Controls	
Acute Tox. 4, H302	Calculation method
Acute Tox. 4, H312	Calculation method
Aquatic Chronic 3, H412	Calculation method
Insulin Adjustors	
Acute Tox. 4, H302	Calculation method
Acute Tox. 4, H312	Calculation method
Aquatic Chronic 3, H412	Calculation method

Full text of abbreviated H statements

Insulin Reagent Wedge

H319	Causes serious eye irritation.

IMMULITE® Insulin Controls

H300	Fatal if swallowed.
H302	Harmful if swallowed.
H310	Fatal in contact with skin.
H311	Toxic in contact with skin.
H312	Harmful in contact with skin.
H314	Causes severe skin burns and eye damage.
H317	May cause an allergic skin reaction.
H318	Causes serious eye damage.
H400	Very toxic to aquatic life.
H410	Very toxic to aquatic life with long lasting effects.
H412	Harmful to aquatic life with long lasting effects.
EUH032	Contact with acids liberates very toxic gas.

Insulin Adjustors

H300	Fatal if swallowed.
H302	Harmful if swallowed.
H310	Fatal in contact with skin.

SECTION 16: Other information

H311	Toxic in contact with skin.
H312	Harmful in contact with skin.
H314	Causes severe skin burns and eye damage.
H317	May cause an allergic skin reaction.
H318	Causes serious eye damage.
H400	Very toxic to aquatic life.
H410	Very toxic to aquatic life with long lasting effects.
H412	Harmful to aquatic life with long lasting effects.
EUH032	Contact with acids liberates very toxic gas.

Full text of classifications

Insulin Reagent Wedge

Eye Irrit. 2	SERIOUS EYE DAMAGE/EYE IRRITATION - Category 2

IMMULITE® Insulin Controls

Acute Tox. 1	ACUTE TOXICITY - Category 1
Acute Tox. 2	ACUTE TOXICITY - Category 2
Acute Tox. 3	ACUTE TOXICITY - Category 3
Acute Tox. 4	ACUTE TOXICITY - Category 4
Aquatic Acute 1	SHORT-TERM (ACUTE) AQUATIC HAZARD - Category 1
Aquatic Chronic 1	LONG-TERM (CHRONIC) AQUATIC HAZARD - Category 1
Aquatic Chronic 3	LONG-TERM (CHRONIC) AQUATIC HAZARD - Category 3
Eye Dam. 1	SERIOUS EYE DAMAGE/EYE IRRITATION - Category 1
Skin Corr. 1B	SKIN CORROSION/IRRITATION - Category 1B
Skin Sens. 1	SKIN SENSITISATION - Category 1

Insulin Adjustors

Acute Tox. 1	ACUTE TOXICITY - Category 1
Acute Tox. 2	ACUTE TOXICITY - Category 2
Acute Tox. 3	ACUTE TOXICITY - Category 3
Acute Tox. 4	ACUTE TOXICITY - Category 4
Aquatic Acute 1	SHORT-TERM (ACUTE) AQUATIC HAZARD - Category 1
Aquatic Chronic 1	LONG-TERM (CHRONIC) AQUATIC HAZARD - Category 1
Aquatic Chronic 3	LONG-TERM (CHRONIC) AQUATIC HAZARD - Category 3
Eye Dam. 1	SERIOUS EYE DAMAGE/EYE IRRITATION - Category 1
Skin Corr. 1B	SKIN CORROSION/IRRITATION - Category 1B
Skin Sens. 1	SKIN SENSITISATION - Category 1

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Date of previous issue : No previous validation

Version : 1

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