

SAFETY DATA SHEET

IMMULITE® 2000 Total IgE

SDS no.:

L2KIE2_6

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

1.1 Product identifier

Product name : IMMULITE® 2000 Total IgE
Product code : L2KIE2/6, 10380873, 10380872

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

Identified uses Total IgE Reagent Wedge Diagnostic agents.
 Total IgE 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 : Total IgE Reagent Wedge Mixture
 Total IgE Adjustors Mixture

Classification according to UK CLP/GHS

Total IgE Adjustors

Skin Sens. 1, H317

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

Hazard pictograms :



Signal word : Total IgE Reagent Wedge No signal word.
 Total IgE Adjustors Warning

Hazard statements : Total IgE Reagent Wedge No known significant effects or critical hazards.
 Total IgE Adjustors H317 - May cause an allergic skin reaction.

Precautionary statements

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SECTION 2: Hazards identification

Prevention	: Total IgE Reagent Wedge Total IgE Adjustors	Not applicable. P280 - Wear protective gloves/protective clothing/eye protection/face protection.
Response	: Total IgE Reagent Wedge Total IgE Adjustors	Not applicable. P302 + P352 - IF ON SKIN: Wash with plenty of soap and water. P333 + P313 - If skin irritation or rash occurs: Get medical advice/attention. P362 + P364 - Take off contaminated clothing and wash it before reuse.
Storage	: Total IgE Reagent Wedge Total IgE Adjustors	Not applicable. Not applicable.
Disposal	: Total IgE Reagent Wedge Total IgE Adjustors	Not applicable. Not applicable.
Supplemental label elements	: Total IgE Reagent Wedge Total IgE Adjustors	Safety data sheet available on request. Not applicable.
Annex XVII - Restrictions on the manufacture, placing on the market and use of certain dangerous substances, mixtures and articles	: Total IgE Reagent Wedge Total IgE Adjustors	Not applicable. Not applicable.

2.3 Other hazards

Product meets the criteria for PBT or vPvB according to Regulation (EC) No. 1907/2006, Annex XIII	: Total IgE Reagent Wedge Total IgE Adjustors	This mixture does not contain any substances that are assessed to be a PBT or a vPvB. 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	: Total IgE Reagent Wedge Total IgE Adjustors	None known. None known.
Additional information	: Potentially biohazardous material. Not available.	

SECTION 3: Composition/information on ingredients

3.1 Substances : Total IgE Reagent Wedge Mixture
Total IgE Adjustors Mixture

Product/ingredient name	Identifiers	%	Classification	Type
Total IgE Reagent Wedge aminocaproic acid	EC: 200-469-3 CAS: 60-32-2	≤3	Eye Irrit. 2, H319	[1]
Total IgE Adjustors sodium azide	EC: 247-852-1 CAS: 26628-22-8 Index: 011-004-00-7	<0.1	Acute Tox. 2, H300 Acute Tox. 1, H310 Aquatic Acute 1, H400 (M=1) Aquatic Chronic 1, H410 (M=1) EUH032	[1] [2]
3(2H)-Isothiazolone, 2-methyl-	EC: 220-239-6 CAS: 2682-20-4	<0.1	Acute Tox. 3, H301 Acute Tox. 3, H311 Acute Tox. 2, H330 Skin Corr. 1B, H314 Eye Dam. 1, H318	[1]

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SECTION 3: Composition/information on ingredients

			Skin Sens. 1A, H317 Aquatic Acute 1, H400 (M=10) Aquatic Chronic 1, H410 (M=1) EUH071 See Section 16 for the full text of the H statements declared above.
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Type

[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.

SECTION 4: First aid measures

4.1 Description of first aid measures

<p>Eye contact</p> <p style="padding-left: 100px;">Total IgE Reagent Wedge</p> <p style="padding-left: 100px;">Total IgE Adjustors</p>	<p>: Total IgE Reagent Wedge</p>	<p>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.</p> <p>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.</p>
<p>Inhalation</p> <p style="padding-left: 100px;">Total IgE Reagent Wedge</p> <p style="padding-left: 100px;">Total IgE Adjustors</p>	<p>: Total IgE Reagent Wedge</p>	<p>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. 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.</p>
<p>Skin contact</p> <p style="padding-left: 100px;">Total IgE Reagent Wedge</p> <p style="padding-left: 100px;">Total IgE Adjustors</p>	<p>: Total IgE Reagent Wedge</p>	<p>Flush contaminated skin with plenty of water. Remove contaminated clothing and shoes. Get medical attention if symptoms occur.</p> <p>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. In the event of any complaints or</p>

SECTION 4: First aid measures

Ingestion : Total IgE Reagent Wedge

Total IgE Adjustors

symptoms, avoid further exposure. Wash clothing before reuse. Clean shoes thoroughly before reuse.

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.

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 adverse health effects persist or are severe. 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.

No action shall be taken involving any personal risk or without suitable training. 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.

Protection of first-aiders : Total IgE Reagent Wedge

Total IgE Adjustors

4.2 Most important symptoms and effects, both acute and delayed

Over-exposure signs/symptoms

Eye contact : Total IgE Reagent Wedge
Total IgE Adjustors

No specific data.
No specific data.

Inhalation : Total IgE Reagent Wedge
Total IgE Adjustors

No specific data.
No specific data.

Skin contact : Total IgE Reagent Wedge
Total IgE Adjustors

No specific data.
Adverse symptoms may include the following:
irritation
redness

Ingestion : Total IgE Reagent Wedge
Total IgE Adjustors

No specific data.
No specific data.

4.3 Indication of any immediate medical attention and special treatment needed

Notes to physician : Total IgE Reagent Wedge

Total IgE 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.

Treat symptomatically. Contact poison treatment specialist immediately if large quantities have been ingested or inhaled.

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SECTION 4: First aid measures

Specific treatments	: Total IgE Reagent Wedge	No specific treatment.
	Total IgE Adjustors	No specific treatment.
	Total IgE Reagent Wedge	Not available.
	Total IgE 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.
Hazardous combustion products	: Decomposition products may include the following materials: carbon dioxide carbon monoxide nitrogen oxides sulfur 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. Avoid breathing vapour or mist. Provide adequate ventilation. Wear appropriate respirator when ventilation is inadequate. 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

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. 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

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SECTION 6: Accidental release measures

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). Persons with a history of skin sensitization problems should not be employed in any process in which this product is used. Do not get in eyes or on skin or clothing. Do not ingest. 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.
- 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
Total IgE Adjustors sodium azide	EH40/2005 WELs (United Kingdom (UK), 1/2020). Absorbed through skin. STEL: 0.3 mg/m ³ , (as NaN ₃) 15 minutes. TWA: 0.1 mg/m ³ , (as NaN ₃) 8 hours.

- 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

SECTION 8: Exposure controls/personal protection

Product/ingredient name	Type	Exposure	Value	Population	Effects
Total IgE Adjustors sodium azide 3(2H)-Isothiazolone, 2-methyl-	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/m ³	General population	Systemic
	DNEL	Long term Dermal	46.7 µg/kg bw/day	Workers	Systemic
	DNEL	Long term Inhalation	0.164 mg/ m ³	Workers	Systemic
	DNEL	Long term Inhalation	0.021 mg/ m ³	General population	Local
	DNEL	Long term Inhalation	0.021 mg/ m ³	Workers	Local
	DNEL	Long term Oral	0.027 mg/ kg bw/day	General population	Systemic
	DNEL	Short term Inhalation	0.043 mg/ m ³	General population	Local
	DNEL	Short term Inhalation	0.043 mg/ m ³	Workers	Local
	DNEL	Short term Oral	0.053 mg/ kg bw/day	General population	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. Contaminated work clothing should not be allowed out of the workplace. 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.

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.

SECTION 8: Exposure controls/personal protection

- 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** : Total IgE Reagent Wedge Liquid.
Total IgE Adjustors Liquid.
- Colour** : Total IgE Reagent Wedge Colourless.
Total IgE Adjustors Colourless.
- Odour** : Total IgE Reagent Wedge Odourless.
Total IgE 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** : Total IgE Reagent Wedge Not available.
Total IgE Adjustors Not available.
- Flammability (solid, gas)** : Total IgE Reagent Wedge Not relevant/applicable due to nature of the product.
Total IgE Adjustors Not relevant/applicable due to nature of the product.
- Upper/lower flammability or explosive limits** : Total IgE Reagent Wedge Not available.
Total IgE Adjustors Not available.
- Flash point** : Total IgE Reagent Wedge [Product does not sustain combustion.]
Total IgE Adjustors [Product does not sustain combustion.]
- Auto-ignition temperature** :

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

- Decomposition temperature** : Not relevant/applicable due to nature of the product.
- pH** : Total IgE Reagent Wedge 7.95 to 8.05
Total IgE Adjustors Not applicable.
- Viscosity** : Total IgE Reagent Wedge Not available.
Total IgE Adjustors Not available.
- 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** :

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SECTION 9: Physical and chemical properties

Ingredient name	Vapour Pressure at 20°C			Vapour pressure at 50°C		
	mm Hg	kPa	Method	mm Hg	kPa	Method
Total IgE Reagent Wedge						
sodium azide	0.0075	0.001				
Total IgE Adjustors						
sodium azide	0.0075	0.001				

Evaporation rate	: Not relevant/applicable due to nature of the product.
Relative density	: Total IgE Reagent Wedge Total IgE Adjustors
Density	: Total IgE Reagent Wedge Total IgE Adjustors
Vapour density	: Total IgE Reagent Wedge Total IgE Adjustors
Explosive properties	: Total IgE Reagent Wedge Total IgE Adjustors
Oxidising properties	: Total IgE Reagent Wedge Total IgE Adjustors
Particle characteristics	
Median particle size	: Not applicable.

9.2 Other information

Fire point	: Total IgE Reagent Wedge Total IgE Adjustors
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.

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SECTION 11: Toxicological information

11.1 Information on toxicological effects

Acute toxicity

Product/ingredient name	Result	Species	Dose	Exposure
Total IgE Adjustors sodium azide	LD50 Dermal	Rabbit	20 mg/kg	-
	LD50 Dermal	Rat	50 mg/kg	-
	LD50 Oral	Rat	27 mg/kg	-

Conclusion/Summary : Total IgE Reagent Wedge : Not available.
Total IgE 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)
Total IgE Adjustors sodium azide	27	20	N/A	N/A	N/A
3(2H)-Isothiazolone, 2-methyl-	100	300	N/A	0.5	N/A

Irritation/Corrosion

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

Conclusion/Summary

Skin : Total IgE Reagent Wedge : Not available.
Total IgE Adjustors : Not available.

Eyes : Total IgE Reagent Wedge : Not available.
Total IgE Adjustors : Not available.

Respiratory : Total IgE Reagent Wedge : Not available.
Total IgE Adjustors : Not available.

Sensitisation

Conclusion/Summary

Skin : Total IgE Reagent Wedge : Not available.
Total IgE Adjustors : Not available.

Respiratory : Total IgE Reagent Wedge : Not available.
Total IgE Adjustors : Not available.

Mutagenicity

Conclusion/Summary : Total IgE Reagent Wedge : Not available.
Total IgE Adjustors : Not available.

Carcinogenicity

Conclusion/Summary : Total IgE Reagent Wedge : Not available.
Total IgE Adjustors : Not available.

Reproductive toxicity

Conclusion/Summary : Total IgE Reagent Wedge : Not available.
Total IgE Adjustors : Not available.

Teratogenicity

Conclusion/Summary : Total IgE Reagent Wedge : Not available.
Total IgE Adjustors : Not available.

Specific target organ toxicity (single exposure)

Not available.

Specific target organ toxicity (repeated exposure)

Not available.

SECTION 11: Toxicological information

Aspiration hazard

Not available.

Information on likely routes of exposure : Total IgE Reagent Wedge : Not available.
 Total IgE Adjustors : Not available.

Potential acute health effects

Eye contact : Total IgE Reagent Wedge : No known significant effects or critical hazards.
 Total IgE Adjustors : No known significant effects or critical hazards.

Inhalation : Total IgE Reagent Wedge : No known significant effects or critical hazards.
 Total IgE Adjustors : No known significant effects or critical hazards.

Skin contact : Total IgE Reagent Wedge : No known significant effects or critical hazards.
 Total IgE Adjustors : May cause an allergic skin reaction.

Ingestion : Total IgE Reagent Wedge : No known significant effects or critical hazards.
 Total IgE Adjustors : No known significant effects or critical hazards.

Symptoms related to the physical, chemical and toxicological characteristics

Eye contact : Total IgE Reagent Wedge : No specific data.
 Total IgE Adjustors : No specific data.

Inhalation : Total IgE Reagent Wedge : No specific data.
 Total IgE Adjustors : No specific data.

Skin contact : Total IgE Reagent Wedge : No specific data.
 Total IgE Adjustors : Adverse symptoms may include the following:
 irritation
 redness

Ingestion : Total IgE Reagent Wedge : No specific data.
 Total IgE 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 : Total IgE Reagent Wedge : Not available.
 Total IgE Adjustors : Not available.

Potential delayed effects : Total IgE Reagent Wedge : Not available.
 Total IgE Adjustors : Not available.

Long term exposure

Potential immediate effects : Total IgE Reagent Wedge : Not available.
 Total IgE Adjustors : Not available.

Potential delayed effects : Total IgE Reagent Wedge : Not available.
 Total IgE Adjustors : Not available.

Potential chronic health effects

Not available.

Conclusion/Summary : Total IgE Reagent Wedge : Not available.
 Total IgE Adjustors : Not available.

General : Total IgE Reagent Wedge : No known significant effects or critical hazards.
 Total IgE Adjustors : Once sensitized, a severe allergic reaction may occur when subsequently exposed to very low levels.

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SECTION 11: Toxicological information

Carcinogenicity	: Total IgE Reagent Wedge Total IgE Adjustors	No known significant effects or critical hazards. No known significant effects or critical hazards.
Mutagenicity	: Total IgE Reagent Wedge Total IgE Adjustors	No known significant effects or critical hazards. No known significant effects or critical hazards.
Reproductive toxicity	: Total IgE Reagent Wedge Total IgE Adjustors	No known significant effects or critical hazards. No known significant effects or critical hazards.
Interactive effects	: Total IgE Reagent Wedge Total IgE Adjustors	Not available. Not available.
<u>Toxicokinetics</u>		
Absorption	: Total IgE Reagent Wedge Total IgE Adjustors	Not available. Not available.
Distribution	: Total IgE Reagent Wedge Total IgE Adjustors	Not available. Not available.
Metabolism	: Total IgE Reagent Wedge Total IgE Adjustors	Not available. Not available.
Elimination	: Total IgE Reagent Wedge Total IgE Adjustors	Not available. Not available.
Other information	: Total IgE Reagent Wedge Total IgE Adjustors	Not available. Not available.

SECTION 12: Ecological information

12.1 Toxicity

Product/ingredient name	Result	Species	Exposure
Total IgE Adjustors 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
	3(2H)-Isothiazolone, 2-methyl-	Acute EC50 0.18 ppm Fresh water	Daphnia - Water flea - Daphnia magna
Acute LC50 0.07 ppm Fresh water		Fish - Rainbow trout, donaldson trout - Oncorhynchus mykiss	96 hours

Conclusion/Summary : Total IgE Reagent Wedge
Total IgE Adjustors Not available.
Not available.

12.2 Persistence and degradability

Conclusion/Summary : Total IgE Reagent Wedge
Total IgE Adjustors Not available.
Not available.

12.3 Bioaccumulative potential

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SECTION 12: Ecological information

Product/ingredient name	LogP _{ow}	BCF	Potential
Total IgE Reagent Wedge aminocaproic acid	-2.95	-	low

12.4 Mobility in soil

Soil/water partition coefficient (K_{oc})	: Total IgE Reagent Wedge Total IgE Adjustors	Not available. Not available.
Mobility	: Total IgE Reagent Wedge Total IgE Adjustors	Not available. 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.

Packaging

Methods of disposal : The generation of waste should be avoided or minimised wherever possible. Waste packaging should be recycled. Incineration or landfill should only be considered when recycling is not feasible.

Special precautions : This material and its container must be disposed of in a safe way. 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 Total IgE Reagent Wedge Not regulated.
Total IgE Adjustors Not regulated.

14.2 UN proper shipping name Total IgE Reagent Wedge -
Total IgE Adjustors -

14.3 Transport hazard class(es) Total IgE Reagent Wedge -
Total IgE Adjustors -

14.4 Packing group Total IgE Reagent Wedge -
Total IgE Adjustors -

14.5 Environmental hazards Total IgE Reagent Wedge No.
Total IgE Adjustors No.

Additional information Total IgE Reagent Wedge -
Total IgE Adjustors -

IMMULITE® 2000 Total IgE

SECTION 14: Transport information

ADN

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

IMDG

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

IATA

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

IMMULITE® 2000 Total IgE

SECTION 14: Transport information

14.6 Special precautions for user : Total IgE Reagent Wedge user

Total IgE Adjustors

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.

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 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 : Total IgE Reagent Wedge
Total IgE Adjustors

Not applicable.
Not applicable.

Seveso Directive

This product is not controlled under the Seveso Directive.

EU regulations

Industrial emissions (integrated pollution prevention and control) - Air : Total IgE Reagent Wedge
Total IgE Adjustors

Not listed
Not listed

Industrial emissions (integrated pollution prevention and control) - Water : Total IgE Reagent Wedge
Total IgE Adjustors

Not listed
Not listed

International regulations

Montreal Protocol

Not listed.

Stockholm Convention on Persistent Organic Pollutants

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SECTION 15: Regulatory information

Not listed.

Rotterdam Convention on Prior Informed Consent (PIC)

Not listed.

UNECE Aarhus Protocol on POPs and Heavy Metals

Not listed.

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
Total IgE Adjustors Skin Sens. 1, H317	Calculation method

Full text of abbreviated H statements

Total IgE Reagent Wedge H319	Causes serious eye irritation.
Total IgE Adjustors H300	Fatal if swallowed.
H301	Toxic if swallowed.
H310	Fatal in contact with skin.
H311	Toxic in contact with skin.
H314	Causes severe skin burns and eye damage.
H317	May cause an allergic skin reaction.
H318	Causes serious eye damage.
H330	Fatal if inhaled.
H400	Very toxic to aquatic life.
H410	Very toxic to aquatic life with long lasting effects.
EUH032	Contact with acids liberates very toxic gas.
EUH071	Corrosive to the respiratory tract.

Full text of classifications

IMMULITE® 2000 Total IgE

SECTION 16: Other information

Total IgE Reagent Wedge

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

Total IgE Adjustors

Acute Tox. 1 ACUTE TOXICITY - Category 1
 Acute Tox. 2 ACUTE TOXICITY - Category 2
 Acute Tox. 3 ACUTE TOXICITY - Category 3
 Aquatic Acute 1 SHORT-TERM (ACUTE) AQUATIC HAZARD - Category 1
 Aquatic Chronic 1 LONG-TERM (CHRONIC) AQUATIC HAZARD - Category 1
 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
 Skin Sens. 1A SKIN SENSITISATION - Category 1A

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