SAFETY DATA SHEET

IMMULITE® ACTH Control Module

SIEMENS Healthineers

SDS no.: LACCM

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

1.1 Product identifier

Product name : IMMULITE® ACTH Control Module

Product code : LACCM, 10385382

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

Identified uses	IMMULITE® ACTH Controls	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 : IMMULITE® ACTH Controls Mixture

Classification according to UK CLP/GHS

IMMULITE® ACTH Controls

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

Signal word	: IMMULITE® ACTH Controls	No signal word.
Hazard statements	: IMMULITE® ACTH Controls	H412 - Harmful to aquatic life with long lasting effects.

Precautionary statements

Prevention	: IMMULITE® ACTH Controls	P273 - Avoid release to the environment.
Response	: IMMULITE® ACTH Controls	Not applicable.
Storage	: IMMULITE® ACTH Controls	Not applicable.
Disposal	: IMMULITE® ACTH Controls	P501 - Dispose of contents and container in accordance with all local, regional, national and international regulations.

SECTION 2: Hazards identification

Supplemental label elements : IMMULITE® ACTH Controls — Contains Gentamicin, sulfate (salt). May produce an allergic reaction.

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

2.3 Other hazards

Product meets the criteria for PBT or vPvB according to Regulation (EC) No. 1907/2006, Annex XIII : IMMULITE® ACTH Controls — 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 : IMMULITE® ACTH Controls — None known.

Additional information : Potentially biohazardous material.

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

SECTION 3: Composition/information on ingredients

3.1 Substances : IMMULITE® ACTH Controls — Mixture

Product/ingredient name	Identifiers	%	Classification	Type
IMMULITE® ACTH Controls				
disodium dihydrogen ethylenediaminetetraacetate	EC: 205-358-3 CAS: 139-33-3	≤3	Acute Tox. 4, H332 STOT RE 2, H373 (respiratory tract) (inhalation)	[1]
sodium azide	EC: 247-852-1 CAS: 26628-22-8 Index: 011-004-00-7	<1	Acute Tox. 2, H300 Acute Tox. 1, H310 Aquatic Acute 1, H400 (M=1) Aquatic Chronic 1, H410 (M=1) EUH032	[1] [2]
Gentamicin, sulfate (salt)	EC: 215-778-9 CAS: 1405-41-0	≤0.3	Resp. Sens. 1, H334 Skin Sens. 1, H317 Repr. 2, H361	[1]
			See Section 16 for the full text of the H statements declared above.	

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

Eye contact : IMMULITE® ACTH Controls — 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.

SECTION 4: First aid measures

Inhalation	:	IMMULITE® ACTH Controls	Remove victim to fresh air and keep at rest in a position comfortable for breathing. 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® ACTH Controls	Flush contaminated skin with plenty of water. Remove contaminated clothing and shoes. Get medical attention if symptoms occur.
Ingestion	:	IMMULITE® ACTH Controls	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.
Protection of first-aiders	:	IMMULITE® ACTH Controls	No action shall be taken involving any personal risk or without suitable training.

4.2 Most important symptoms and effects, both acute and delayed

Over-exposure signs/symptoms

Eye contact	:	IMMULITE® ACTH Controls	No specific data.
Inhalation	:	IMMULITE® ACTH Controls	No specific data.
Skin contact	:	IMMULITE® ACTH Controls	No specific data.
Ingestion	:	IMMULITE® ACTH Controls	No specific data.

4.3 Indication of any immediate medical attention and special treatment needed

Notes to physician	:	IMMULITE® ACTH 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.
Specific treatments	:	IMMULITE® ACTH Controls	No specific treatment.
		IMMULITE® ACTH Controls	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:
carbon dioxide
carbon monoxide
nitrogen oxides
sulfur oxides
phosphorus oxides
halogenated compounds
metal oxide/oxides

SECTION 5: Firefighting measures

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.

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

SECTION 7: Handling and storage

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

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® ACTH Controls					
disodium dihydrogen ethylenediaminetetraacetate	DNEL	Long term Inhalation	0.6 mg/m³	General population	Local
	DNEL	Short term Inhalation	1.2 mg/m³	General population	Local
	DNEL	Long term Inhalation	1.5 mg/m³	Workers	Local
	DNEL	Short term Inhalation	3 mg/m³	Workers	Local
	DNEL	Long term Oral	25 mg/kg bw/day	General population	Systemic
	DNEL	Long term Inhalation	1.5 mg/m³	Workers	Systemic
	DNEL	Short term Inhalation	3 mg/m³	Workers	Systemic
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

SECTION 8: Exposure controls/personal protection

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.

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	:	IMMULITE® ACTH Controls	Solid.
Colour	:	IMMULITE® ACTH Controls	Off-white.
Odour	:	IMMULITE® ACTH Controls	Odourless.
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	:	IMMULITE® ACTH Controls	Not available.
Flammability (solid, gas)	:	IMMULITE® ACTH Controls	Not relevant/applicable due to nature of the product.
Upper/lower flammability or explosive limits	:	IMMULITE® ACTH Controls	Not applicable.
Flash point	:	IMMULITE® ACTH Controls	[Product does not sustain combustion.]

SECTION 9: Physical and chemical properties

Decomposition temperature	:	Not relevant/applicable due to nature of the product.	
pH	:	IMMULITE® ACTH Controls	Not applicable.
Viscosity	:	IMMULITE® ACTH Controls	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	:	Not available.	
Evaporation rate	:	Not relevant/applicable due to nature of the product.	
Relative density	:	IMMULITE® ACTH Controls	1
Density	:	IMMULITE® ACTH Controls	Not available.
Vapour density	:	IMMULITE® ACTH Controls	Not applicable.
Explosive properties	:	IMMULITE® ACTH Controls	Not available.
Oxidising properties	:	IMMULITE® ACTH Controls	Not available.

Particle characteristics

Median particle size	:	Not applicable.

9.2 Other information

Fire point	:	IMMULITE® ACTH Controls	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® ACTH Controls				
disodium dihydrogen ethylenediaminetetraacetate	LD50 Oral	Rat	2 g/kg	-
sodium azide	LD50 Dermal	Rabbit	20 mg/kg	-
	LD50 Dermal	Rat	50 mg/kg	-
	LD50 Oral	Rat	27 mg/kg	-
Gentamicin, sulfate (salt)	LD50 Oral	Rat	>5 g/kg	-

Conclusion/Summary : IMMULITE® ACTH Controls 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® ACTH Controls					
IMMULITE® ACTH Controls	3000	2222.2	N/A	N/A	83.3
disodium dihydrogen ethylenediaminetetraacetate	N/A	N/A	N/A	N/A	1.5
sodium azide	27	20	N/A	N/A	N/A

Irritation/Corrosion

Conclusion/Summary

Skin : IMMULITE® ACTH Controls Not available.

Eyes : IMMULITE® ACTH Controls Not available.

Respiratory : IMMULITE® ACTH Controls Not available.

Sensitisation

Conclusion/Summary

Skin : IMMULITE® ACTH Controls Not available.

Respiratory : IMMULITE® ACTH Controls Not available.

Mutagenicity

Conclusion/Summary : IMMULITE® ACTH Controls Not available.

Carcinogenicity

Conclusion/Summary : IMMULITE® ACTH Controls Not available.

Reproductive toxicity

Conclusion/Summary : IMMULITE® ACTH Controls Not available.

Teratogenicity

Conclusion/Summary : IMMULITE® ACTH Controls Not available.

Specific target organ toxicity (single exposure)

Not available.

Specific target organ toxicity (repeated exposure)

Product/ingredient name	Category	Route of exposure	Target organs
IMMULITE® ACTH Controls			
disodium dihydrogen ethylenediaminetetraacetate	Category 2	inhalation	respiratory tract

Aspiration hazard

Not available.

Information on likely routes of exposure : IMMULITE® ACTH Controls Not available.

SECTION 11: Toxicological information

Potential acute health effects

Eye contact	:	IMMULITE® ACTH Controls	No known significant effects or critical hazards.
Inhalation	:	IMMULITE® ACTH Controls	No known significant effects or critical hazards.
Skin contact	:	IMMULITE® ACTH Controls	No known significant effects or critical hazards.
Ingestion	:	IMMULITE® ACTH Controls	No known significant effects or critical hazards.

Symptoms related to the physical, chemical and toxicological characteristics

Eye contact	:	IMMULITE® ACTH Controls	No specific data.
Inhalation	:	IMMULITE® ACTH Controls	No specific data.
Skin contact	:	IMMULITE® ACTH Controls	No specific data.
Ingestion	:	IMMULITE® ACTH Controls	No specific data.

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

Short term exposure

Potential immediate effects	:	IMMULITE® ACTH Controls	Not available.
Potential delayed effects	:	IMMULITE® ACTH Controls	Not available.

Long term exposure

Potential immediate effects	:	IMMULITE® ACTH Controls	Not available.
Potential delayed effects	:	IMMULITE® ACTH Controls	Not available.

Potential chronic health effects

Not available.

Conclusion/Summary	:	IMMULITE® ACTH Controls	Not available.
General	:	IMMULITE® ACTH Controls	No known significant effects or critical hazards.
Carcinogenicity	:	IMMULITE® ACTH Controls	No known significant effects or critical hazards.
Mutagenicity	:	IMMULITE® ACTH Controls	No known significant effects or critical hazards.
Reproductive toxicity	:	IMMULITE® ACTH Controls	No known significant effects or critical hazards.
Interactive effects	:	IMMULITE® ACTH Controls	Not available.

Toxicokinetics

Absorption	:	IMMULITE® ACTH Controls	Not available.
Distribution	:	IMMULITE® ACTH Controls	Not available.
Metabolism	:	IMMULITE® ACTH Controls	Not available.
Elimination	:	IMMULITE® ACTH Controls	Not available.
Other information	:	IMMULITE® ACTH Controls	Not available.

SECTION 12: Ecological information

12.1 Toxicity

Product/ingredient name	Result	Species	Exposure
IMMULITE® ACTH 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
Gentamicin, sulfate (salt)	Acute EC50 21.2 ppm Fresh water	Daphnia - Water flea - Daphnia magna	48 hours
	Acute LC50 >955 ppm Fresh water	Fish - Rainbow trout,donaldson trout - Oncorhynchus mykiss	96 hours

Conclusion/Summary : IMMULITE® ACTH Controls Not available.

12.2 Persistence and degradability

Conclusion/Summary : IMMULITE® ACTH Controls Not available.

12.3 Bioaccumulative potential

Product/ingredient name	$LogP_{ow}$	BCF	Potential
IMMULITE® ACTH Controls			
disodium dihydrogen ethylenediaminetetraacetate	-4.3	1.8	low

12.4 Mobility in soil

Soil/water partition coefficient (K_{OC}) : IMMULITE® ACTH Controls Not available.

Mobility : IMMULITE® ACTH Controls 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.

SECTION 13: Disposal considerations

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

ADN

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

IMDG

14.1 UN number	IMMULITE® ACTH Controls	Not regulated.
14.2 UN proper shipping name	IMMULITE® ACTH Controls	-
14.3 Transport hazard class(es)	IMMULITE® ACTH Controls	-

SECTION 14: Transport information

14.4 Packing group	IMMULITE® ACTH Controls	-
14.5 Environmental hazards	IMMULITE® ACTH Controls	No.
Additional information	IMMULITE® ACTH Controls	-

IATA

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

14.6 Special precautions for user : IMMULITE® ACTH 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.

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.

SECTION 15: Regulatory information

Annex XVII - Restrictions on the manufacture, placing on the market and use of certain dangerous substances, mixtures and articles	: IMMULITE® ACTH Controls	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	: IMMULITE® ACTH Controls	Not listed
Industrial emissions (integrated pollution prevention and control) - Water	: IMMULITE® ACTH Controls	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.

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® ACTH Controls Aquatic Chronic 3, H412	Calculation method

Full text of abbreviated H statements

SECTION 16: Other information

IMMULITE®
ACTH Controls

H300	Fatal if swallowed.
H310	Fatal in contact with skin.
H317	May cause an allergic skin reaction.
H332	Harmful if inhaled.
H334	May cause allergy or asthma symptoms or breathing difficulties if inhaled.
H361	Suspected of damaging fertility or the unborn child.
H373	May cause damage to organs through prolonged or repeated exposure.
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

IMMULITE® ACTH Controls

Acute Tox. 1	ACUTE TOXICITY - Category 1
Acute Tox. 2	ACUTE TOXICITY - Category 2
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
Repr. 2	REPRODUCTIVE TOXICITY - Category 2
Resp. Sens. 1	RESPIRATORY SENSITISATION - Category 1
Skin Sens. 1	SKIN SENSITISATION - Category 1
STOT RE 2	SPECIFIC TARGET ORGAN TOXICITY - REPEATED EXPOSURE - Category 2

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Notice to reader

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