

SAFETY DATA SHEET

IMMULITE® 2000 Intact PTH

SIEMENS
Healthineers 

SDS no.:

L2KPP2_6

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

1.1 Product identifier

Product name : IMMULITE® 2000 Intact PTH
Product code : L2KPP2/6, 10381441, 10381442

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

Identified uses Intact PTH Reagent Wedge Diagnostic agents.
 Intact PTH 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 : Intact PTH Reagent Wedge Mixture
 Intact PTH Adjustors Mixture

Classification according to UK CLP/GHS

Intact PTH Adjustors

Acute Tox. 4, H302

Acute Tox. 3, H311

Aquatic Chronic 2, H411

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

: Intact PTH Reagent Wedge No signal word.
 Intact PTH Adjustors Danger

SECTION 2: Hazards identification

Hazard statements	: Intact PTH Reagent Wedge Intact PTH Adjustors	No known significant effects or critical hazards. H302 - Harmful if swallowed. H311 - Toxic in contact with skin. H411 - Toxic to aquatic life with long lasting effects.
<u>Precautionary statements</u>		
Prevention	: Intact PTH Reagent Wedge Intact PTH Adjustors	Not applicable. P264 - Wash hands thoroughly after handling. P280 - Wear protective gloves/protective clothing/eye protection/face protection. P273 - Avoid release to the environment.
Response	: Intact PTH Reagent Wedge Intact PTH Adjustors	Not applicable. P312 - Call a POISON CENTER or doctor/physician if you feel unwell. P361 + P364 - Take off immediately all contaminated clothing and wash it before reuse. P391 - Collect spillage.
Storage	: Intact PTH Reagent Wedge Intact PTH Adjustors	Not applicable. Not applicable.
Disposal	: Intact PTH Reagent Wedge Intact PTH Adjustors	Not applicable. P501 - Dispose of contents and container in accordance with all local, regional, and national regulations.
Supplemental label elements	: Intact PTH Reagent Wedge Intact PTH 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	: Intact PTH Reagent Wedge Intact PTH 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	: Intact PTH Reagent Wedge Intact PTH 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	: Intact PTH Reagent Wedge Intact PTH Adjustors	None known. None known.
Additional information	: Potentially biohazardous material. Not available.	

SECTION 3: Composition/information on ingredients

3.1 Substances	: Intact PTH Reagent Wedge Intact PTH Adjustors	Mixture Mixture
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SECTION 3: Composition/information on ingredients

Product/ingredient name	Identifiers	%	Classification	Type
Intact PTH Reagent Wedge aminocaproic acid	EC: 200-469-3 CAS: 60-32-2	≤3	Eye Irrit. 2, H319	[1]
Intact PTH Adjustors sodium azide	EC: 247-852-1 CAS: 26628-22-8 Index: 011-004-00-7	≤5	Acute Tox. 2, H300 Acute Tox. 1, H310 Aquatic Acute 1, H400 (M=1) Aquatic Chronic 1, H410 (M=1) EUH032 See Section 16 for the full text of the H statements declared above.	[1] [2]

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** : Intact PTH 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.

Intact PTH 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.

Inhalation : Intact PTH 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. 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 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.

Intact PTH Adjustors

SECTION 4: First aid measures

Skin contact	: Intact PTH Reagent Wedge	Flush contaminated skin with plenty of water. Remove contaminated clothing and shoes. Get medical attention if symptoms occur.
	Intact PTH 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 necessary, call a poison center or physician. Wash clothing before reuse. Clean shoes thoroughly before reuse.
Ingestion	: Intact PTH 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.
	Intact PTH 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 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	: Intact PTH Reagent Wedge	No action shall be taken involving any personal risk or without suitable training.
	Intact PTH 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	: Intact PTH Reagent Wedge	No specific data.
	Intact PTH Adjustors	No specific data.
Inhalation	: Intact PTH Reagent Wedge	No specific data.
	Intact PTH Adjustors	No specific data.
Skin contact	: Intact PTH Reagent Wedge	No specific data.
	Intact PTH Adjustors	No specific data.
Ingestion	: Intact PTH Reagent Wedge	No specific data.
	Intact PTH Adjustors	No specific data.

4.3 Indication of any immediate medical attention and special treatment needed

SECTION 4: First aid measures

Notes to physician	: Intact PTH 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.
	Intact PTH 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.
Specific treatments	: Intact PTH Reagent Wedge	No specific treatment.
	Intact PTH Adjustors	No specific treatment.
	Intact PTH Reagent Wedge	Not available.
	Intact PTH 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: carbon dioxide carbon monoxide nitrogen oxides sulfur oxides phosphorus oxides 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. Do not breathe 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".

SECTION 6: Accidental release measures

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 get in eyes or on skin or clothing. Do not breathe vapour or mist. Do not ingest. 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. Store locked up. 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.

Seveso Directive - Reporting thresholds

Danger criteria

Category	Notification and MAPP threshold	Safety report threshold
Intact PTH Adjustors E2	200 tonne	500 tonne

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
Intact PTH 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

Product/ingredient name	Type	Exposure	Value	Population	Effects
Intact PTH 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/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

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.

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.

SECTION 8: Exposure controls/personal protection

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

Ingredient name	Closed cup			Open cup		
	°C	°F	Method	°C	°F	Method
Intact PTH Reagent Wedge toluene	4.4	39.9		4	39.2	

Auto-ignition temperature :

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

- Decomposition temperature** : Not relevant/applicable due to nature of the product.
- pH** : Intact PTH Reagent Wedge 7.35 to 7.45
Intact PTH Adjustors Not applicable.
- Viscosity** : Intact PTH Reagent Wedge Not available.
Intact PTH Adjustors Not applicable.
- Solubility(ies)** :
Not available.
- Solubility in water** : Not relevant/applicable due to nature of the product.

SECTION 9: Physical and chemical properties**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** :

Ingredient name	Vapour Pressure at 20°C			Vapour pressure at 50°C		
	mm Hg	kPa	Method	mm Hg	kPa	Method
Intact PTH Reagent Wedge						
water	23.8	3.2				

Evaporation rate : Not relevant/applicable due to nature of the product.**Relative density** : Intact PTH Reagent Wedge 1
Intact PTH Adjustors Not available.**Density** : Intact PTH Reagent Wedge Not available.
Intact PTH Adjustors Not available.**Vapour density** : Intact PTH Reagent Wedge Not available.
Intact PTH Adjustors Not applicable.**Explosive properties** : Intact PTH Reagent Wedge Not available.
Intact PTH Adjustors Not available.**Oxidising properties** : Intact PTH Reagent Wedge Not available.
Intact PTH Adjustors Not available.**Particle characteristics****Median particle size** : Not applicable.**9.2 Other information****Fire point** : Intact PTH Reagent Wedge Not available.
Intact PTH 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
Intact PTH Adjustors sodium azide	LD50 Dermal LD50 Dermal LD50 Oral	Rabbit Rat Rat	20 mg/kg 50 mg/kg 27 mg/kg	- - -

Conclusion/Summary : Intact PTH Reagent Wedge Not available.
Intact PTH 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)
Intact PTH Adjustors Intact PTH Adjustors sodium azide	571.3 27	423.2 20	N/A N/A	N/A N/A	N/A N/A

Irritation/Corrosion

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

Conclusion/Summary

Skin : Intact PTH Reagent Wedge Not available.
Intact PTH Adjustors Not available.

Eyes : Intact PTH Reagent Wedge Not available.
Intact PTH Adjustors Not available.

Respiratory : Intact PTH Reagent Wedge Not available.
Intact PTH Adjustors Not available.

Sensitisation**Conclusion/Summary**

Skin : Intact PTH Reagent Wedge Not available.
Intact PTH Adjustors Not available.

Respiratory : Intact PTH Reagent Wedge Not available.
Intact PTH Adjustors Not available.

Mutagenicity

Conclusion/Summary : Intact PTH Reagent Wedge Not available.
Intact PTH Adjustors Not available.

Carcinogenicity

Conclusion/Summary : Intact PTH Reagent Wedge Not available.
Intact PTH Adjustors Not available.

Reproductive toxicity

Conclusion/Summary : Intact PTH Reagent Wedge Not available.
Intact PTH Adjustors Not available.

Teratogenicity

Conclusion/Summary : Intact PTH Reagent Wedge Not available.
Intact PTH 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 : Intact PTH Reagent Wedge Not available.
Intact PTH Adjustors Not available.

Potential acute health effects

Eye contact : Intact PTH Reagent Wedge No known significant effects or critical hazards.
Intact PTH Adjustors No known significant effects or critical hazards.

Inhalation : Intact PTH Reagent Wedge No known significant effects or critical hazards.
Intact PTH Adjustors No known significant effects or critical hazards.

Skin contact : Intact PTH Reagent Wedge No known significant effects or critical hazards.
Intact PTH Adjustors Toxic in contact with skin.

Ingestion : Intact PTH Reagent Wedge No known significant effects or critical hazards.
Intact PTH Adjustors Harmful if swallowed.

Symptoms related to the physical, chemical and toxicological characteristics

Eye contact : Intact PTH Reagent Wedge No specific data.
Intact PTH Adjustors No specific data.

Inhalation : Intact PTH Reagent Wedge No specific data.
Intact PTH Adjustors No specific data.

Skin contact : Intact PTH Reagent Wedge No specific data.
Intact PTH Adjustors No specific data.

Ingestion : Intact PTH Reagent Wedge No specific data.
Intact PTH 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 : Intact PTH Reagent Wedge Not available.
Intact PTH Adjustors Not available.

Potential delayed effects : Intact PTH Reagent Wedge Not available.
Intact PTH Adjustors Not available.

Long term exposure

Potential immediate effects : Intact PTH Reagent Wedge Not available.
Intact PTH Adjustors Not available.

Potential delayed effects : Intact PTH Reagent Wedge Not available.
Intact PTH Adjustors Not available.

Potential chronic health effects

Not available.

Conclusion/Summary : Intact PTH Reagent Wedge Not available.
Intact PTH Adjustors Not available.

General : Intact PTH Reagent Wedge No known significant effects or critical hazards.
Intact PTH Adjustors No known significant effects or critical hazards.

Carcinogenicity : Intact PTH Reagent Wedge No known significant effects or critical hazards.
Intact PTH Adjustors No known significant effects or critical hazards.

SECTION 11: Toxicological information

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

SECTION 12: Ecological information**12.1 Toxicity**

Product/ingredient name	Result	Species	Exposure
Intact PTH 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

Conclusion/Summary : Intact PTH Reagent Wedge Not available.
Intact PTH Adjustors Not available.

12.2 Persistence and degradability

Conclusion/Summary : Intact PTH Reagent Wedge Not available.
Intact PTH Adjustors Not available.

12.3 Bioaccumulative potential

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

12.4 Mobility in soil

Soil/water partition coefficient (K_{oc}) : Intact PTH Reagent Wedge Not available.
Intact PTH Adjustors Not available.

Mobility : Intact PTH Reagent Wedge Not available.
Intact PTH Adjustors Not available.

SECTION 12: Ecological information**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	Intact PTH Reagent Wedge Intact PTH Adjustors	Not regulated. UN3288
14.2 UN proper shipping name	Intact PTH Reagent Wedge Intact PTH Adjustors	- Toxic solid, inorganic, n.o.s. (sodium azide)
14.3 Transport hazard class(es)	Intact PTH Reagent Wedge Intact PTH Adjustors	- 6.1



14.4 Packing group	Intact PTH Reagent Wedge Intact PTH Adjustors	- III
14.5 Environmental hazards	Intact PTH Reagent Wedge Intact PTH Adjustors	No. No.
Additional information	Intact PTH Reagent Wedge Intact PTH Adjustors	- <u>Tunnel code</u> (E)

ADN

14.1 UN number	Intact PTH Reagent Wedge Intact PTH Adjustors	Not regulated. UN3288
14.2 UN proper shipping name	Intact PTH Reagent Wedge Intact PTH Adjustors	- Toxic solid, inorganic, n.o.s. (sodium azide)

SECTION 14: Transport information

14.3 Transport hazard class(es)	Intact PTH Reagent Wedge	-
	Intact PTH Adjustors	6.1



14.4 Packing group	Intact PTH Reagent Wedge	-
	Intact PTH Adjustors	III

14.5 Environmental hazards	Intact PTH Reagent Wedge	No.
	Intact PTH Adjustors	No.

Additional information	Intact PTH Reagent Wedge	-
	Intact PTH Adjustors	-

IMDG

14.1 UN number	Intact PTH Reagent Wedge	Not regulated.
	Intact PTH Adjustors	UN3288
14.2 UN proper shipping name	Intact PTH Reagent Wedge	-
	Intact PTH Adjustors	Toxic solid, inorganic, n.o.s. (sodium azide)
14.3 Transport hazard class(es)	Intact PTH Reagent Wedge	-
	Intact PTH Adjustors	6.1



14.4 Packing group	Intact PTH Reagent Wedge	-
	Intact PTH Adjustors	III

14.5 Environmental hazards	Intact PTH Reagent Wedge	No.
	Intact PTH Adjustors	No.

Additional information	Intact PTH Reagent Wedge	-
	Intact PTH Adjustors	-

IATA

14.1 UN number	Intact PTH Reagent Wedge	Not regulated.
	Intact PTH Adjustors	UN3288
14.2 UN proper shipping name	Intact PTH Reagent Wedge	-
	Intact PTH Adjustors	Toxic solid, inorganic, n.o.s. (sodium azide)
14.3 Transport hazard class(es)	Intact PTH Reagent Wedge	-
	Intact PTH Adjustors	6.1



14.4 Packing group	Intact PTH Reagent Wedge	-
	Intact PTH Adjustors	III

14.5 Environmental hazards	Intact PTH Reagent Wedge	No.
	Intact PTH Adjustors	No.

Additional information	Intact PTH Reagent Wedge	-
	Intact PTH Adjustors	-

IMMULITE® 2000 Intact PTH

SECTION 14: Transport information

14.6 Special precautions for user : Intact PTH Reagent Wedge

Intact PTH 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 : Intact PTH Reagent Wedge
Intact PTH Adjustors

Not applicable.

Not applicable.

Seveso Directive

This product is not controlled under the Seveso Directive.

Danger criteria

Category

Intact PTH Adjustors
E2

National regulations

EU regulations

Industrial emissions (integrated pollution prevention and control) - Air : Intact PTH Reagent Wedge
Intact PTH Adjustors

Not listed

Not listed

IMMULITE® 2000 Intact PTH

SECTION 15: Regulatory information

Industrial emissions (integrated pollution prevention and control) - Water : Intact PTH Reagent Wedge Not listed
Intact PTH 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.

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
Intact PTH Adjustors Acute Tox. 4, H302 Acute Tox. 3, H311 Aquatic Chronic 2, H411	Calculation method Calculation method Calculation method

Full text of abbreviated H statements

Intact PTH Reagent Wedge H319	Causes serious eye irritation.
Intact PTH Adjustors H300 H302 H310 H311 H400 H410 H411	Fatal if swallowed. Harmful if swallowed. Fatal in contact with skin. Toxic in contact with skin. Very toxic to aquatic life. Very toxic to aquatic life with long lasting effects. Toxic to aquatic life with long lasting effects.

IMMULITE® 2000 Intact PTH

SECTION 16: Other information

EUH032 Contact with acids liberates very toxic gas.

Full text of classifications

Intact PTH Reagent

Wedge

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

Intact PTH 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 2	LONG-TERM (CHRONIC) AQUATIC HAZARD - Category 2

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Version : 1

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