

SAFETY DATA SHEET

IMMULITE® 2000 Osteocalcin

SDS no.:

L2KON2

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

1.1 Product identifier

Product name : IMMULITE® 2000 Osteocalcin
Product code : L2KON2, 10381477

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

Identified uses Osteocalcin Reagent Wedge Diagnostic agents.
 Osteocalcin 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 : Osteocalcin Reagent Wedge Mixture
 Osteocalcin Adjustors Mixture

Classification according to UK CLP/GHS

Osteocalcin Reagent Wedge

Skin Sens. 1, H317

Osteocalcin 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 : Osteocalcin Reagent Wedge Warning
 Osteocalcin Adjustors Danger

SECTION 2: Hazards identification

Hazard statements	: Osteocalcin Reagent Wedge Osteocalcin Adjustors	H317 - May cause an allergic skin reaction. H302 - Harmful if swallowed. H311 - Toxic in contact with skin. H411 - Toxic to aquatic life with long lasting effects.
 <u>Precautionary statements</u>		
Prevention	: Osteocalcin Reagent Wedge Osteocalcin Adjustors	P280 - Wear protective gloves/protective clothing/eye protection/face protection. P264 - Wash hands thoroughly after handling. P280 - Wear protective gloves/protective clothing/eye protection/face protection. P273 - Avoid release to the environment.
Response	: Osteocalcin Reagent Wedge Osteocalcin Adjustors	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. 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.
Storage	: Osteocalcin Reagent Wedge Osteocalcin Adjustors	Not applicable. Not applicable.
Disposal	: Osteocalcin Reagent Wedge Osteocalcin Adjustors	Not applicable. P501 - Dispose of contents and container in accordance with all local, regional, and national regulations.
Supplemental label elements	: Osteocalcin Reagent Wedge Osteocalcin Adjustors	Not applicable. 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	: Osteocalcin Reagent Wedge Osteocalcin 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	: Osteocalcin Reagent Wedge Osteocalcin 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	: Osteocalcin Reagent Wedge Osteocalcin Adjustors	None known. None known.
Additional information	: Not available. Not available.	

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SECTION 3: Composition/information on ingredients

3.1 Substances : Osteocalcin Reagent Wedge Mixture
Osteocalcin Adjustors Mixture

Product/ingredient name	Identifiers	%	Classification	Type
Osteocalcin Reagent Wedge aminocaproic acid	EC: 200-469-3 CAS: 60-32-2	≤3	Eye Irrit. 2, H319	[1]
zinc chloride	EC: 231-592-0 CAS: 7646-85-7 Index: 030-003-00-2	<0.1	Acute Tox. 4, H302 Skin Corr. 1B, H314 Eye Dam. 1, H318 STOT SE 3, H335 Aquatic Acute 1, H400 (M=10) Aquatic Chronic 1, H410 (M=1)	[1] [2]
3(2H)-Isothiazolone, 2-methyl-	EC: 220-239-6 CAS: 2682-20-4	<0.1	Acute Tox. 3, H301 Acute Tox. 2, H330 Skin Corr. 1B, H314 Eye Dam. 1, H318 Skin Sens. 1A, H317 Aquatic Acute 1, H400 (M=10) Aquatic Chronic 1, H410 (M=1) EUH071	[1]
Osteocalcin Adjustors sodium azide	EC: 247-852-1 CAS: 26628-22-8 Index: 011-004-00-7	≤9	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	<1	Resp. Sens. 1, H334 Skin Sens. 1, H317 Repr. 2, H361 See Section 16 for the full text of the H statements declared above.	[1]

Type

[1] Substance classified with a health or environmental hazard

[2] Substance with a workplace exposure limit

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

SECTION 4: First aid measures

4.1 Description of first aid measures

Eye contact : Osteocalcin Reagent Wedge

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.

Osteocalcin 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.

SECTION 4: First aid measures

Inhalation	: Osteocalcin Reagent Wedge	<p>Remove victim to fresh air and keep at rest in a position comfortable for breathing. If not breathing, if breathing is irregular or if respiratory arrest occurs, provide artificial respiration or oxygen by trained personnel. It may be dangerous to the person providing aid to give mouth-to-mouth resuscitation. Get medical attention if adverse health effects persist or are severe. If unconscious, place in recovery position and get medical attention immediately. Maintain an open airway. Loosen tight clothing such as a collar, tie, belt or waistband. In case of inhalation of decomposition products in a fire, symptoms may be delayed. The exposed person may need to be kept under medical surveillance for 48 hours.</p> <p>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.</p>
	Osteocalcin Adjustors	
Skin contact	: Osteocalcin Reagent Wedge	<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 symptoms, avoid further exposure. Wash clothing before reuse. Clean shoes thoroughly before reuse.</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. If necessary, call a poison center or physician. Wash clothing before reuse. Clean shoes thoroughly before reuse.</p>
	Osteocalcin Adjustors	
Ingestion	: Osteocalcin Reagent Wedge	<p>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</p>

SECTION 4: First aid measures

Osteocalcin Adjustors

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. 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 : Osteocalcin Reagent Wedge

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.

Osteocalcin 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	: Osteocalcin Reagent Wedge Osteocalcin Adjustors	No specific data. No specific data.
Inhalation	: Osteocalcin Reagent Wedge Osteocalcin Adjustors	No specific data. No specific data.
Skin contact	: Osteocalcin Reagent Wedge Osteocalcin Adjustors	Adverse symptoms may include the following: irritation redness No specific data.
Ingestion	: Osteocalcin Reagent Wedge Osteocalcin Adjustors	No specific data. No specific data.

4.3 Indication of any immediate medical attention and special treatment needed

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SECTION 4: First aid measures

Notes to physician	: Osteocalcin Reagent Wedge Osteocalcin 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. 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	: Osteocalcin Reagent Wedge Osteocalcin Adjustors Osteocalcin Reagent Wedge Osteocalcin Adjustors	No specific treatment. No specific treatment. Not available. 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 toxic 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. Collect spillage.

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). 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 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
Osteocalcin 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
Osteocalcin Reagent Wedge zinc chloride	EH40/2005 WELs (United Kingdom (UK), 1/2020). STEL: 2 mg/m ³ 15 minutes. Form: Fume TWA: 1 mg/m ³ 8 hours. Form: Fume
Osteocalcin 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	
Osteocalcin Reagent Wedge zinc chloride	DNEL	Long term Oral	0.83 mg/kg bw/day	General population	Systemic	
	DNEL	Long term Inhalation	1 mg/m ³	Workers	Systemic	
	DNEL	Long term Dermal	8.3 mg/kg bw/day	General population	Systemic	
	DNEL	Long term Dermal	8.3 mg/kg bw/day	Workers	Systemic	
	3(2H)-Isothiazolone, 2-methyl-	DNEL	Long term Inhalation	1.25 mg/m ³	General population	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
	Osteocalcin Adjustors sodium azide	DNEL	Short term Oral	0.053 mg/kg bw/day	General population	Systemic
		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

SECTION 8: Exposure controls/personal protection

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.

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	: Osteocalcin Reagent Wedge	Liquid.
	: Osteocalcin Adjustors	Solid.
Colour	: Osteocalcin Reagent Wedge	Clear.
	: Osteocalcin Adjustors	Amber.
Odour	: Osteocalcin Reagent Wedge	Odourless.
	: Osteocalcin Adjustors	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	: Osteocalcin Reagent Wedge	Not available.
	: Osteocalcin Adjustors	Not available.

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SECTION 9: Physical and chemical properties

Flammability (solid, gas)	: Osteocalcin Reagent Wedge Osteocalcin Adjustors	Not relevant/applicable due to nature of the product. Not relevant/applicable due to nature of the product.
Upper/lower flammability or explosive limits	: Osteocalcin Reagent Wedge Osteocalcin Adjustors	Not available. Not applicable.
Flash point	: Osteocalcin Reagent Wedge Osteocalcin Adjustors	[Product does not sustain combustion.] [Product does not sustain combustion.]

Ingredient name	Closed cup			Open cup		
	°C	°F	Method	°C	°F	Method
Osteocalcin Reagent Wedge Oxirane, 2-methyl-, polymer with oxirane	252	485.6				

Auto-ignition temperature :

Ingredient name	°C	°F	Method
Osteocalcin Reagent Wedge 4-(2-hydroxyethyl)piperazin-1-ylethanesulphonic acid	>400	>752	EU A.16

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

pH : Osteocalcin Reagent Wedge 7.15 to 7.25
Osteocalcin Adjustors Not applicable.

Viscosity : Osteocalcin Reagent Wedge Not available.
Osteocalcin Adjustors Not applicable.

Solubility(ies) :
Not available.

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

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

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

Vapour pressure :

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

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

Relative density : Osteocalcin Reagent Wedge 1
Osteocalcin Adjustors >1

Density : Osteocalcin Reagent Wedge Not available.
Osteocalcin Adjustors Not available.

Vapour density : Osteocalcin Reagent Wedge Not available.
Osteocalcin Adjustors Not applicable.

Explosive properties : Osteocalcin Reagent Wedge Not available.
Osteocalcin Adjustors Not available.

Oxidising properties : Osteocalcin Reagent Wedge Not available.
Osteocalcin Adjustors Not available.

Particle characteristics

Median particle size : Not applicable.

9.2 Other information

Fire point : Osteocalcin Reagent Wedge Not available.
Osteocalcin Adjustors Not available.

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

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SECTION 9: Physical and chemical properties

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
Osteocalcin Reagent Wedge zinc chloride	LD50 Oral	Rat	350 mg/kg	-
Osteocalcin Adjustors sodium azide	LD50 Dermal LD50 Dermal	Rabbit Rat	20 mg/kg 50 mg/kg	- -
Gentamicin, sulfate (salt)	LD50 Oral LD50 Oral	Rat Rat	27 mg/kg >5 g/kg	- -

Conclusion/Summary : Osteocalcin Reagent Wedge Not available.
Osteocalcin 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)
Osteocalcin Reagent Wedge zinc chloride	350	N/A	N/A	N/A	N/A
3(2H)-Isothiazolone, 2-methyl-	100	300	N/A	0.5	N/A
Osteocalcin Adjustors Osteocalcin Adjustors	397.7	294.6	N/A	N/A	N/A
sodium azide	27	20	N/A	N/A	N/A

Irritation/Corrosion

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SECTION 11: Toxicological information

Product/ingredient name	Result	Species	Score	Exposure	Observation
Osteocalcin Reagent Wedge aminocaproic acid	Eyes - Mild irritant	Rabbit	-	24 hours 500 mg	-
zinc chloride	Skin - Severe irritant	Rabbit	-	120 hours 1 %	-

Conclusion/Summary

Skin : Osteocalcin Reagent Wedge Not available.
Osteocalcin Adjustors Not available.

Eyes : Osteocalcin Reagent Wedge Not available.
Osteocalcin Adjustors Not available.

Respiratory : Osteocalcin Reagent Wedge Not available.
Osteocalcin Adjustors Not available.

Sensitisation

Conclusion/Summary

Skin : Osteocalcin Reagent Wedge Not available.
Osteocalcin Adjustors Not available.

Respiratory : Osteocalcin Reagent Wedge Not available.
Osteocalcin Adjustors Not available.

Mutagenicity

Conclusion/Summary

: Osteocalcin Reagent Wedge Not available.
Osteocalcin Adjustors Not available.

Carcinogenicity

Conclusion/Summary

: Osteocalcin Reagent Wedge Not available.
Osteocalcin Adjustors Not available.

Reproductive toxicity

Conclusion/Summary

: Osteocalcin Reagent Wedge Not available.
Osteocalcin Adjustors Not available.

Teratogenicity

Conclusion/Summary

: Osteocalcin Reagent Wedge Not available.
Osteocalcin Adjustors Not available.

Specific target organ toxicity (single exposure)

Product/ingredient name	Category	Route of exposure	Target organs
Osteocalcin Reagent Wedge zinc chloride	Category 3	-	Respiratory tract irritation

Specific target organ toxicity (repeated exposure)

Not available.

Aspiration hazard

Not available.

Information on likely routes of exposure

: Osteocalcin Reagent Wedge Not available.
Osteocalcin Adjustors Not available.

Potential acute health effects

Eye contact

: Osteocalcin Reagent Wedge No known significant effects or critical hazards.
Osteocalcin Adjustors No known significant effects or critical hazards.

SECTION 11: Toxicological information

Inhalation	: Osteocalcin Reagent Wedge Osteocalcin Adjustors	No known significant effects or critical hazards. No known significant effects or critical hazards.
Skin contact	: Osteocalcin Reagent Wedge Osteocalcin Adjustors	May cause an allergic skin reaction. Toxic in contact with skin.
Ingestion	: Osteocalcin Reagent Wedge Osteocalcin Adjustors	No known significant effects or critical hazards. Harmful if swallowed.

Symptoms related to the physical, chemical and toxicological characteristics

Eye contact	: Osteocalcin Reagent Wedge Osteocalcin Adjustors	No specific data. No specific data.
Inhalation	: Osteocalcin Reagent Wedge Osteocalcin Adjustors	No specific data. No specific data.
Skin contact	: Osteocalcin Reagent Wedge Osteocalcin Adjustors	Adverse symptoms may include the following: irritation redness No specific data.
Ingestion	: Osteocalcin Reagent Wedge Osteocalcin Adjustors	No specific data. No specific data.

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

Short term exposure

Potential immediate effects	: Osteocalcin Reagent Wedge Osteocalcin Adjustors	Not available. Not available.
Potential delayed effects	: Osteocalcin Reagent Wedge Osteocalcin Adjustors	Not available. Not available.

Long term exposure

Potential immediate effects	: Osteocalcin Reagent Wedge Osteocalcin Adjustors	Not available. Not available.
Potential delayed effects	: Osteocalcin Reagent Wedge Osteocalcin Adjustors	Not available. Not available.

Potential chronic health effects

Not available.

Conclusion/Summary	: Osteocalcin Reagent Wedge Osteocalcin Adjustors	Not available. Not available.
General	: Osteocalcin Reagent Wedge Osteocalcin Adjustors	Once sensitized, a severe allergic reaction may occur when subsequently exposed to very low levels. No known significant effects or critical hazards.
Carcinogenicity	: Osteocalcin Reagent Wedge Osteocalcin Adjustors	No known significant effects or critical hazards. No known significant effects or critical hazards.
Mutagenicity	: Osteocalcin Reagent Wedge Osteocalcin Adjustors	No known significant effects or critical hazards. No known significant effects or critical hazards.
Reproductive toxicity	: Osteocalcin Reagent Wedge Osteocalcin Adjustors	No known significant effects or critical hazards. No known significant effects or critical hazards.

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Interactive effects	: Osteocalcin Reagent Wedge Osteocalcin Adjustors	Not available. Not available.
Toxicokinetics		
Absorption	: Osteocalcin Reagent Wedge Osteocalcin Adjustors	Not available. Not available.
Distribution	: Osteocalcin Reagent Wedge Osteocalcin Adjustors	Not available. Not available.
Metabolism	: Osteocalcin Reagent Wedge Osteocalcin Adjustors	Not available. Not available.
Elimination	: Osteocalcin Reagent Wedge Osteocalcin Adjustors	Not available. Not available.
Other information	: Osteocalcin Reagent Wedge Osteocalcin Adjustors	Not available. Not available.

SECTION 12: Ecological information

12.1 Toxicity

Product/ingredient name	Result	Species	Exposure
Osteocalcin Reagent Wedge zinc chloride	Acute EC50 34 µg/l Fresh water	Algae - Green algae - Chlorella vulgaris - Exponential growth phase	72 hours
	Acute EC50 26 µg/l Marine water	Algae - Diatom - Navicula incerta	96 hours
	Acute EC50 1.8 mg/l Fresh water	Aquatic plants - Lesser Duckweed - Lemna aequinoctialis	96 hours
	Acute EC50 100 µg/l Fresh water	Daphnia - Water flea - Daphnia magna	48 hours
	Acute LC50 49.99 µg/l Fresh water	Crustaceans - Water flea - Moina irrasa - Neonate	48 hours
	Acute LC50 0.027 mg/l Marine water	Fish - Sand Flounder - Limanda punctatissima - Pre-larvae	96 hours
	Chronic NOEC 20 µg/l Marine water	Algae - Green algae - Chlorella sp. - Exponential growth phase	72 hours
	Chronic NOEC 1000 µg/l Fresh water	Crustaceans - Red swamp crayfish - Procambarus clarkii - Intermolt	21 days
	Chronic NOEC 80 µg/l Fresh water	Daphnia - Water flea - Daphnia magna - Juvenile (Fledgling, Hatchling, Weanling)	21 days
	Chronic NOEC 31.5 µg/l Fresh water	Fish - Rainbow trout, donaldson trout - Oncorhynchus mykiss	30 days
3(2H)-Isothiazolone, 2-methyl-	Acute EC50 0.18 ppm Fresh water	Daphnia - Water flea - Daphnia magna	48 hours
	Acute LC50 0.07 ppm Fresh water	Fish - Rainbow trout, donaldson trout - Oncorhynchus mykiss	96 hours
Osteocalcin 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	96 hours

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SECTION 12: Ecological information

Gentamicin, sulfate (salt)	Acute EC50 21.2 ppm Fresh water	pyrifera Daphnia - Water flea - Daphnia magna	48 hours
	Acute LC50 >955 ppm Fresh water	Fish - Rainbow trout, donaldson trout - Oncorhynchus mykiss	96 hours

Conclusion/Summary : Osteocalcin Reagent Wedge Not available.
Osteocalcin Adjustors Not available.

12.2 Persistence and degradability

Conclusion/Summary : Osteocalcin Reagent Wedge Not available.
Osteocalcin Adjustors Not available.

12.3 Bioaccumulative potential

Product/ingredient name	LogP _{ow}	BCF	Potential
Osteocalcin Reagent Wedge			
aminocaproic acid	-2.95	-	low
zinc chloride	-	60960	high

12.4 Mobility in soil

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

Mobility : Osteocalcin Reagent Wedge Not available.
Osteocalcin Adjustors Not available.

12.5 Results of PBT and vPvB assessment

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

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

SECTION 13: Disposal considerations

13.1 Waste treatment methods

Product

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

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


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 spill material and runoff and contact with soil, waterways, drains and sewers.

SECTION 14: Transport information


ADR/RID

14.1 UN number	Osteocalcin Reagent Wedge Osteocalcin Adjustors	Not regulated. UN3288
14.2 UN proper shipping name	Osteocalcin Reagent Wedge Osteocalcin Adjustors	- Toxic solid, inorganic, n.o.s. (sodium azide)
14.3 Transport hazard class(es)	Osteocalcin Reagent Wedge Osteocalcin Adjustors	- 6.1
		
14.4 Packing group	Osteocalcin Reagent Wedge Osteocalcin Adjustors	- III
14.5 Environmental hazards	Osteocalcin Reagent Wedge Osteocalcin Adjustors	No. No.
Additional information	Osteocalcin Reagent Wedge Osteocalcin Adjustors	- <u>Tunnel code</u> (E)

ADN

14.1 UN number	Osteocalcin Reagent Wedge Osteocalcin Adjustors	Not regulated. UN3288
14.2 UN proper shipping name	Osteocalcin Reagent Wedge Osteocalcin Adjustors	- Toxic solid, inorganic, n.o.s. (sodium azide)
14.3 Transport hazard class(es)	Osteocalcin Reagent Wedge Osteocalcin Adjustors	- 6.1
		
14.4 Packing group	Osteocalcin Reagent Wedge Osteocalcin Adjustors	- III
14.5 Environmental hazards	Osteocalcin Reagent Wedge Osteocalcin Adjustors	No. No.
Additional information	Osteocalcin Reagent Wedge Osteocalcin Adjustors	- -

IMDG

14.1 UN number	Osteocalcin Reagent Wedge Osteocalcin Adjustors	Not regulated. UN3288
14.2 UN proper shipping name	Osteocalcin Reagent Wedge Osteocalcin Adjustors	- Toxic solid, inorganic, n.o.s. (sodium azide)
14.3 Transport hazard class(es)	Osteocalcin Reagent Wedge Osteocalcin Adjustors	- 6.1
		
14.4 Packing group	Osteocalcin Reagent Wedge Osteocalcin Adjustors	- III
14.5 Environmental hazards	Osteocalcin Reagent Wedge Osteocalcin Adjustors	No. No.

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SECTION 14: Transport information

Additional information	Osteocalcin Reagent Wedge	-
	Osteocalcin Adjustors	-

IATA

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



14.4 Packing group	Osteocalcin Reagent Wedge Osteocalcin Adjustors	- III
14.5 Environmental hazards	Osteocalcin Reagent Wedge Osteocalcin Adjustors	No. No.
Additional information	Osteocalcin Reagent Wedge Osteocalcin Adjustors	- -

14.6 Special precautions for user : Osteocalcin Reagent Wedge

Osteocalcin 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

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SECTION 15: Regulatory information

Not listed.

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

Seveso Directive

This product is controlled under the Seveso Directive.

Danger criteria

Category

Osteocalcin Adjustors

E2

National regulations

EU regulations

Industrial emissions (integrated pollution prevention and control) - Air : Osteocalcin Reagent Wedge : Not listed
Osteocalcin Adjustors : Not listed

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

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SECTION 16: Other information

Procedure used to derive the classification

Classification	Justification
Osteocalcin Reagent Wedge Skin Sens. 1, H317	Calculation method
Osteocalcin 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

Osteocalcin Reagent Wedge	
H301	Toxic if swallowed.
H302	Harmful if swallowed.
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.
H319	Causes serious eye irritation.
H330	Fatal if inhaled.
H335	May cause respiratory irritation.
H400	Very toxic to aquatic life.
H410	Very toxic to aquatic life with long lasting effects.
EUH071	Corrosive to the respiratory tract.
Osteocalcin Adjustors	
H300	Fatal if swallowed.
H302	Harmful if swallowed.
H310	Fatal in contact with skin.
H311	Toxic in contact with skin.
H317	May cause an allergic skin reaction.
H334	May cause allergy or asthma symptoms or breathing difficulties if inhaled.
H361	Suspected of damaging fertility or the unborn child.
H400	Very toxic to aquatic life.
H410	Very toxic to aquatic life with long lasting effects.
H411	Toxic to aquatic life with long lasting effects.
EUH032	Contact with acids liberates very toxic gas.

Full text of classifications

Osteocalcin Reagent Wedge	
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
Eye Dam. 1	SERIOUS EYE DAMAGE/EYE IRRITATION - Category 1
Eye Irrit. 2	SERIOUS EYE DAMAGE/EYE IRRITATION - Category 2
Skin Corr. 1B	SKIN CORROSION/IRRITATION - Category 1B
Skin Sens. 1	SKIN SENSITISATION - Category 1
Skin Sens. 1A	SKIN SENSITISATION - Category 1A
STOT SE 3	SPECIFIC TARGET ORGAN TOXICITY - SINGLE EXPOSURE - Category 3
Osteocalcin 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

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SECTION 16: Other information

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
Repr. 2	REPRODUCTIVE TOXICITY - Category 2
Resp. Sens. 1	RESPIRATORY SENSITISATION - Category 1
Skin Sens. 1	SKIN SENSITISATION - Category 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.