

SAFETY DATA SHEET

IMMULITE® 2000 CEA

SIEMENS
Healthineers

SDS no.:

L2KCE2_6

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

1.1 Product identifier

Product name : IMMULITE® 2000 CEA
Product code : L2KCE2/6, 10380994, 10380995

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

Identified uses	CEA Reagent Wedge A	Diagnostic agents.
	CEA Reagent Wedge B	Diagnostic agents.
	CEA 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	: CEA Reagent Wedge A	Mixture
	CEA Reagent Wedge B	Mixture
	CEA Adjustors	Mixture

Classification according to UK CLP/GHS

CEA Reagent Wedge A

Eye Dam. 1, H318

CEA Adjustors

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

Hazard pictograms

:



Signal word

: CEA Reagent Wedge A	Danger
CEA Reagent Wedge B	No signal word.
CEA Adjustors	No signal word.

SECTION 2: Hazards identification

Hazard statements	: CEA Reagent Wedge A CEA Reagent Wedge B CEA Adjustors	H318 - Causes serious eye damage. No known significant effects or critical hazards. H412 - Harmful to aquatic life with long lasting effects.
<u>Precautionary statements</u>		
Prevention	: CEA Reagent Wedge A CEA Reagent Wedge B CEA Adjustors	P280 - Wear protective gloves/protective clothing/eye protection/face protection. Not applicable. P273 - Avoid release to the environment.
Response	: CEA Reagent Wedge A CEA Reagent Wedge B CEA Adjustors	P305 - IF IN EYES: P351 - Rinse cautiously with water for several minutes. P338 - Remove contact lenses, if present and easy to do. Continue rinsing. P310 - Immediately call a POISON CENTER or doctor/physician. Not applicable. Not applicable.
Storage	: CEA Reagent Wedge A CEA Reagent Wedge B CEA Adjustors	Not applicable. Not applicable. Not applicable.
Disposal	: CEA Reagent Wedge A CEA Reagent Wedge B CEA Adjustors	Not applicable. Not applicable. P501 - Dispose of contents and container in accordance with all local, regional, national and international regulations.
Supplemental label elements	: CEA Reagent Wedge A CEA Reagent Wedge B CEA Adjustors	Not applicable. 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	: CEA Reagent Wedge A CEA Reagent Wedge B CEA Adjustors	Not applicable. 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	: CEA Reagent Wedge A CEA Reagent Wedge B CEA 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. 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	: CEA Reagent Wedge A CEA Reagent Wedge B CEA Adjustors	None known. None known. 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 : CEA Reagent Wedge A Mixture
 CEA Reagent Wedge B Mixture
 CEA Adjustors Mixture

Product/ingredient name	Identifiers	%	Classification	Type
CEA Reagent Wedge A tetrasodium ethylene diamine tetraacetate	EC: 200-573-9 CAS: 64-02-8 Index: 607-428-00-2	≤10	Acute Tox. 4, H302 Eye Dam. 1, H318	[1]
sodium azide	EC: 247-852-1 CAS: 26628-22-8 Index: 011-004-00-7	<0.1	Acute Tox. 2, H300 Acute Tox. 1, H310 Aquatic Acute 1, H400 (M=1) Aquatic Chronic 1, H410 (M=1) EUH032	[1] [2]
CEA Reagent Wedge B aminocaproic acid	EC: 200-469-3 CAS: 60-32-2	≤3	Eye Irrit. 2, H319	[1]
CEA Adjustors 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 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** : CEA Reagent Wedge A

Get medical attention immediately. Call a poison center or physician.

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. Chemical burns must be treated promptly by a physician. 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.

CEA Reagent Wedge B

CEA Adjustors

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	: CEA Reagent Wedge A	Get medical attention immediately. Call a poison center or physician. Remove victim to fresh air and keep at rest in a position comfortable for breathing. If it is suspected that fumes are still present, the rescuer should wear an appropriate mask or self-contained breathing apparatus. 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. 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.
	CEA Reagent Wedge B	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.
	CEA Adjustors	Remove victim to fresh air and keep at rest in a position comfortable for breathing.
Skin contact	: CEA Reagent Wedge A	Get medical attention immediately. Call a poison center or physician. Flush contaminated skin with plenty of 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. Chemical burns must be treated promptly by a physician. Wash clothing before reuse. Clean shoes thoroughly before reuse.
	CEA Reagent Wedge B	Flush contaminated skin with plenty of water. Remove contaminated clothing and shoes. Get medical attention if symptoms occur.
	CEA Adjustors	Flush contaminated skin with plenty of water. Remove contaminated clothing and shoes. Get medical attention if symptoms occur.
Ingestion	: CEA Reagent Wedge A	Get medical attention immediately. Call a poison center or physician. 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

SECTION 4: First aid measures

CEA Reagent Wedge B

CEA Adjustors

Protection of first-aiders : CEA Reagent Wedge A

CEA Reagent Wedge B

CEA Adjustors

vomit does not enter the lungs.
Chemical burns must be treated promptly by a 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.
Wash out mouth with water. If material has been swallowed and the exposed person is conscious, give small quantities of water to drink. Do not induce vomiting unless directed to do so by medical personnel. Get medical attention if symptoms occur.
Wash out mouth with water. 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.

No action shall be taken involving any personal risk or without suitable training. If it is suspected that fumes are still present, the rescuer should wear an appropriate mask or self-contained breathing apparatus. 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.
No action shall be taken involving any personal risk or without suitable training. No action shall be taken involving any personal risk or without suitable training.

4.2 Most important symptoms and effects, both acute and delayed**Over-exposure signs/symptoms****Eye contact** : CEA Reagent Wedge A

Adverse symptoms may include the following:

pain
watering
redness

No specific data.

No specific data.

Inhalation : CEA Reagent Wedge A
CEA Reagent Wedge B
CEA Adjustors

No specific data.

No specific data.

No specific data.

Skin contact : CEA Reagent Wedge A

Adverse symptoms may include the following:

pain or irritation
redness
blistering may occur

No specific data.

No specific data.

CEA Reagent Wedge B
CEA Adjustors

SECTION 4: First aid measures

Ingestion	: CEA Reagent Wedge A	Adverse symptoms may include the following:
	CEA Reagent Wedge B	stomach pains
	CEA Adjustors	No specific data.
		No specific data.

4.3 Indication of any immediate medical attention and special treatment needed

Notes to physician	: CEA Reagent Wedge A	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.
	CEA Reagent Wedge B	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.
	CEA Adjustors	Treat symptomatically. Contact poison treatment specialist immediately if large quantities have been ingested or inhaled.
Specific treatments	: CEA Reagent Wedge A	No specific treatment.
	CEA Reagent Wedge B	No specific treatment.
	CEA Adjustors	No specific treatment.
	CEA Reagent Wedge A	Not available.
	CEA Reagent Wedge B	Not available.
	CEA Adjustors	Not available.

SECTION 5: Firefighting measures**5.1 Extinguishing media**

Suitable extinguishing media	: Use an extinguishing agent suitable for the surrounding fire.
Unsuitable extinguishing media	: None known.

5.2 Special hazards arising from the substance or mixture

Hazards from the substance or mixture	: In a fire or if heated, a pressure increase will occur and the container may burst.
Hazardous combustion products	: Decomposition products may include the following materials: carbon dioxide carbon monoxide nitrogen oxides sulfur oxides 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. Avoid breathing vapour or mist. Provide adequate ventilation. Wear appropriate respirator when ventilation is inadequate. Put on appropriate personal protective equipment.
- For emergency responders** : If specialised clothing is required to deal with the spillage, take note of any information in Section 8 on suitable and unsuitable materials. See also the information in "For non-emergency personnel".

- 6.2 Environmental precautions** : Avoid dispersal of spilt material and runoff and contact with soil, waterways, drains and sewers. Inform the relevant authorities if the product has caused environmental pollution (sewers, waterways, soil or air).

6.3 Methods and material for containment and cleaning up

- Small spill** : Stop leak if without risk. Move containers from spill area. Dilute with water and mop up if water-soluble. Alternatively, or if water-insoluble, absorb with an inert dry material and place in an appropriate waste disposal container. Dispose of via a licensed waste disposal contractor.
- Large spill** : Stop leak if without risk. Move containers from spill area. Approach the release from upwind. Prevent entry into sewers, water courses, basements or confined areas. Wash spillages into an effluent treatment plant or proceed as follows. Contain and collect spillage with non-combustible, absorbent material e.g. sand, earth, vermiculite or diatomaceous earth and place in container for disposal according to local regulations (see Section 13). Dispose of via a licensed waste disposal contractor. Contaminated absorbent material may pose the same hazard 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. Keep in the original container or an approved alternative made from a compatible material, kept tightly closed when not in use. Empty containers retain product residue and can be hazardous. Do not reuse container.
- Advice on general occupational hygiene** : Eating, drinking and smoking should be prohibited in areas where this material is handled, stored and processed. Workers should wash hands and face before eating, drinking and smoking. Remove contaminated clothing and protective equipment before entering eating areas. See also Section 8 for additional information on hygiene measures.

7.2 Conditions for safe storage, including any incompatibilities

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

7.3 Specific end use(s)

- Recommendations** : Not available.
- Industrial sector specific solutions** : Not available.

SECTION 8: Exposure controls/personal protection**8.1 Control parameters****Occupational exposure limits**

Product/ingredient name	Exposure limit values
CEA Reagent Wedge A 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.
CEA 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
CEA Reagent Wedge A tetrasodium ethylene diamine tetraacetate	DNEL	Long term Inhalation	0.6 mg/m ³	General population	Local
	DNEL	Short term Inhalation	1.2 mg/m ³	General population	Local
	DNEL	Long term Inhalation	1.5 mg/m ³	Workers	Local
	DNEL	Short term Inhalation	3 mg/m ³	Workers	Local
	DNEL	Long term Oral	25 mg/kg bw/day	General population	Systemic
	DNEL	Long term Inhalation	1.5 mg/m ³	Workers	Systemic
	DNEL	Short term Inhalation	3 mg/m ³	Workers	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
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
CEA 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

SECTION 8: Exposure controls/personal protection**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: chemical splash goggles.

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	: CEA Reagent Wedge A CEA Reagent Wedge B CEA Adjustors	Liquid. Liquid. Solid.
Colour	: CEA Reagent Wedge A CEA Reagent Wedge B CEA Adjustors	Colourless. Colourless. Off-white.
Odour	: CEA Reagent Wedge A CEA Reagent Wedge B CEA Adjustors	Odourless. Odourless. 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.	

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SECTION 9: Physical and chemical properties

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

Ingredient name	Closed cup			Open cup		
	°C	°F	Method	°C	°F	Method
CEA Reagent Wedge A Sorbitan monolaurate, ethoxylated	275	527		>149	>300.2	
CEA Reagent Wedge B Sorbitan monolaurate, ethoxylated	275	527		>149	>300.2	

Auto-ignition temperature :

Ingredient name	°C	°F	Method
CEA Reagent Wedge A tetrasodium ethylene diamine tetraacetate	>200	>392	
CEA Reagent Wedge B sodium azide	309	588.2	EU A.16

Decomposition temperature	:	Not relevant/applicable due to nature of the product.	
pH	:	CEA Reagent Wedge A	6.45 to 6.55
		CEA Reagent Wedge B	7.55 to 7.65
		CEA Adjustors	Not applicable.
Viscosity	:	CEA Reagent Wedge A	Not available.
		CEA Reagent Wedge B	Not available.
		CEA 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	:		

SECTION 9: Physical and chemical properties

Ingredient name	Vapour Pressure at 20°C			Vapour pressure at 50°C		
	mm Hg	kPa	Method	mm Hg	kPa	Method
CEA Reagent Wedge A Sorbitan monolaurate, ethoxylated	<0.9998	<0.13				
CEA Reagent Wedge B Sorbitan monolaurate, ethoxylated	<0.9998	<0.13				

Evaporation rate	: Not relevant/applicable due to nature of the product.	
Relative density	: CEA Reagent Wedge A	1
	CEA Reagent Wedge B	1
	CEA Adjustors	Not available.
Density	: CEA Reagent Wedge A	Not available.
	CEA Reagent Wedge B	Not available.
	CEA Adjustors	Not available.
Vapour density	: CEA Reagent Wedge A	Not available.
	CEA Reagent Wedge B	Not available.
	CEA Adjustors	Not applicable.
Explosive properties	: CEA Reagent Wedge A	Not available.
	CEA Reagent Wedge B	Not available.
	CEA Adjustors	Not available.
Oxidising properties	: CEA Reagent Wedge A	Not available.
	CEA Reagent Wedge B	Not available.
	CEA Adjustors	Not available.

Particle characteristics

Median particle size	: Not applicable.
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9.2 Other information

Fire point	: CEA Reagent Wedge A CEA Reagent Wedge B CEA Adjustors	Not available. Not available. 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.

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SECTION 10: Stability and reactivity

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
CEA Reagent Wedge A tetrasodium ethylene diamine tetraacetate sodium azide	LD50 Oral	Rat	10 g/kg	-
	LD50 Dermal	Rabbit	20 mg/kg	-
	LD50 Dermal	Rat	50 mg/kg	-
	LD50 Oral	Rat	27 mg/kg	-
CEA Adjustors sodium azide	LD50 Dermal	Rabbit	20 mg/kg	-
	LD50 Dermal	Rat	50 mg/kg	-
	LD50 Oral	Rat	27 mg/kg	-

Conclusion/Summary : CEA Reagent Wedge A Not available.
CEA Reagent Wedge B Not available.
CEA 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)
CEA Reagent Wedge A CEA Reagent Wedge A tetrasodium ethylene diamine tetraacetate sodium azide	8009	N/A	N/A	N/A	N/A
	500	N/A	N/A	N/A	N/A
	27	20	N/A	N/A	N/A
CEA Adjustors CEA Adjustors sodium azide	8185.7	6063.5	N/A	N/A	N/A
	27	20	N/A	N/A	N/A

Irritation/Corrosion

Product/ingredient name	Result	Species	Score	Exposure	Observation
CEA Reagent Wedge A tetrasodium ethylene diamine tetraacetate	Eyes - Moderate irritant	Rabbit	-	24 hours 100 mg	-
	Skin - Moderate irritant	Rabbit	-	24 hours 500 mg	-
CEA Reagent Wedge B aminocaproic acid	Eyes - Mild irritant	Rabbit	-	24 hours 500 mg	-

Conclusion/Summary

Skin : CEA Reagent Wedge A Not available.
CEA Reagent Wedge B Not available.
CEA Adjustors Not available.

Eyes : CEA Reagent Wedge A Not available.
CEA Reagent Wedge B Not available.
CEA Adjustors Not available.

Respiratory : CEA Reagent Wedge A Not available.
CEA Reagent Wedge B Not available.
CEA Adjustors Not available.

Sensitisation

SECTION 11: Toxicological information**Conclusion/Summary**

Skin	: CEA Reagent Wedge A	Not available.
	CEA Reagent Wedge B	Not available.
	CEA Adjustors	Not available.
Respiratory	: CEA Reagent Wedge A	Not available.
	CEA Reagent Wedge B	Not available.
	CEA Adjustors	Not available.

Mutagenicity

Conclusion/Summary	: CEA Reagent Wedge A	Not available.
	CEA Reagent Wedge B	Not available.
	CEA Adjustors	Not available.

Carcinogenicity

Conclusion/Summary	: CEA Reagent Wedge A	Not available.
	CEA Reagent Wedge B	Not available.
	CEA Adjustors	Not available.

Reproductive toxicity

Conclusion/Summary	: CEA Reagent Wedge A	Not available.
	CEA Reagent Wedge B	Not available.
	CEA Adjustors	Not available.

Teratogenicity

Conclusion/Summary	: CEA Reagent Wedge A	Not available.
	CEA Reagent Wedge B	Not available.
	CEA Adjustors	Not available.

Specific target organ toxicity (single exposure)

Not available.

Specific target organ toxicity (repeated exposure)

Not available.

Aspiration hazard

Not available.

Information on likely routes of exposure	: CEA Reagent Wedge A	Not available.
	CEA Reagent Wedge B	Not available.
	CEA Adjustors	Not available.

Potential acute health effects

Eye contact	: CEA Reagent Wedge A	Causes serious eye damage.
	CEA Reagent Wedge B	No known significant effects or critical hazards.
	CEA Adjustors	No known significant effects or critical hazards.
Inhalation	: CEA Reagent Wedge A	No known significant effects or critical hazards.
	CEA Reagent Wedge B	No known significant effects or critical hazards.
	CEA Adjustors	No known significant effects or critical hazards.
Skin contact	: CEA Reagent Wedge A	No known significant effects or critical hazards.
	CEA Reagent Wedge B	No known significant effects or critical hazards.
	CEA Adjustors	No known significant effects or critical hazards.

SECTION 11: Toxicological information

Ingestion	: CEA Reagent Wedge A	No known significant effects or critical hazards.
	CEA Reagent Wedge B	No known significant effects or critical hazards.
	CEA Adjustors	No known significant effects or critical hazards.

Symptoms related to the physical, chemical and toxicological characteristics

Eye contact	: CEA Reagent Wedge A	Adverse symptoms may include the following: pain watering redness
	CEA Reagent Wedge B	No specific data.
	CEA Adjustors	No specific data.
Inhalation	: CEA Reagent Wedge A	No specific data.
	CEA Reagent Wedge B	No specific data.
	CEA Adjustors	No specific data.
Skin contact	: CEA Reagent Wedge A	Adverse symptoms may include the following: pain or irritation redness blistering may occur
	CEA Reagent Wedge B	No specific data.
	CEA Adjustors	No specific data.
Ingestion	: CEA Reagent Wedge A	Adverse symptoms may include the following: stomach pains
	CEA Reagent Wedge B	No specific data.
	CEA 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	: CEA Reagent Wedge A	Not available.
	CEA Reagent Wedge B	Not available.
	CEA Adjustors	Not available.
Potential delayed effects	: CEA Reagent Wedge A	Not available.
	CEA Reagent Wedge B	Not available.
	CEA Adjustors	Not available.

Long term exposure

Potential immediate effects	: CEA Reagent Wedge A	Not available.
	CEA Reagent Wedge B	Not available.
	CEA Adjustors	Not available.
Potential delayed effects	: CEA Reagent Wedge A	Not available.
	CEA Reagent Wedge B	Not available.
	CEA Adjustors	Not available.

Potential chronic health effects

Not available.

Conclusion/Summary	: CEA Reagent Wedge A	Not available.
	CEA Reagent Wedge B	Not available.
	CEA Adjustors	Not available.
General	: CEA Reagent Wedge A	No known significant effects or critical hazards.
	CEA Reagent Wedge B	No known significant effects or critical hazards.
	CEA Adjustors	No known significant effects or critical hazards.

SECTION 11: Toxicological information

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

SECTION 12: Ecological information**12.1 Toxicity**

Product/ingredient name	Result	Species	Exposure
CEA Reagent Wedge A tetrasodium ethylene diamine tetraacetate sodium azide	Acute LC50 486000 µg/l Fresh water	Fish - Bluegill - Lepomis macrochirus	96 hours
	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
CEA Adjustors sodium azide	Acute EC50 9200 µg/l Marine water	Algae - Giant kelp - Macrocystis	96 hours

SECTION 12: Ecological information

	Acute EC50 6.4 mg/l Fresh water	pyrifer 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 pyrifer	96 hours

Conclusion/Summary : CEA Reagent Wedge A Not available.
CEA Reagent Wedge B Not available.
CEA Adjustors Not available.

12.2 Persistence and degradability

Conclusion/Summary : CEA Reagent Wedge A Not available.
CEA Reagent Wedge B Not available.
CEA Adjustors Not available.

12.3 Bioaccumulative potential

Product/ingredient name	LogP _{ow}	BCF	Potential
CEA Reagent Wedge A tetrasodium ethylene diamine tetraacetate	5.01	1.8	low
CEA Reagent Wedge B aminocaproic acid	-2.95	-	low

12.4 Mobility in soil

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

Mobility : CEA Reagent Wedge A Not available.
CEA Reagent Wedge B Not available.
CEA Adjustors Not available.

12.5 Results of PBT and vPvB assessment

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

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

SECTION 13: Disposal considerations**13.1 Waste treatment methods****Product**

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

Hazardous waste : The classification of the product may meet the criteria for a hazardous waste. Sodium azide may react with lead or copper plumbing to form highly explosive metal azides.

Packaging

SECTION 13: Disposal considerations

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

ADN

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

IMDG

SECTION 14: Transport information

14.1 UN number	CEA Reagent Wedge A	Not regulated.
	CEA Reagent Wedge B	Not regulated.
	CEA Adjustors	Not regulated.

14.2 UN proper shipping name	CEA Reagent Wedge A	-
	CEA Reagent Wedge B	-
	CEA Adjustors	-

14.3 Transport hazard class(es)	CEA Reagent Wedge A	-
	CEA Reagent Wedge B	-
	CEA Adjustors	-

14.4 Packing group	CEA Reagent Wedge A	-
	CEA Reagent Wedge B	-
	CEA Adjustors	-

14.5 Environmental hazards	CEA Reagent Wedge A	No.
	CEA Reagent Wedge B	No.
	CEA Adjustors	No.

Additional information	CEA Reagent Wedge A	-
	CEA Reagent Wedge B	-
	CEA Adjustors	-

IATA

14.1 UN number	CEA Reagent Wedge A	Not regulated.
	CEA Reagent Wedge B	Not regulated.
	CEA Adjustors	Not regulated.

14.2 UN proper shipping name	CEA Reagent Wedge A	-
	CEA Reagent Wedge B	-
	CEA Adjustors	-

14.3 Transport hazard class(es)	CEA Reagent Wedge A	-
	CEA Reagent Wedge B	-
	CEA Adjustors	-

14.4 Packing group	CEA Reagent Wedge A	-
	CEA Reagent Wedge B	-
	CEA Adjustors	-

14.5 Environmental hazards	CEA Reagent Wedge A	No.
	CEA Reagent Wedge B	No.
	CEA Adjustors	No.

Additional information	CEA Reagent Wedge A	-
	CEA Reagent Wedge B	-
	CEA Adjustors	-

14.6 Special precautions for user : CEA Reagent Wedge A

CEA Reagent Wedge B

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.

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SECTION 14: Transport information

CEA 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.

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

: CEA Reagent Wedge A
CEA Reagent Wedge B
CEA Adjustors

Not applicable.
Not applicable.
Not applicable.

Seveso Directive

This product is not controlled under the Seveso Directive.

EU regulations

Industrial emissions (integrated pollution prevention and control) - Air

: CEA Reagent Wedge A
CEA Reagent Wedge B
CEA Adjustors

Not listed
Not listed
Not listed

Industrial emissions (integrated pollution prevention and control) - Water

: CEA Reagent Wedge A
CEA Reagent Wedge B
CEA Adjustors

Not listed
Not listed
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

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SECTION 15: Regulatory information

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
CEA Reagent Wedge A Eye Dam. 1, H318	Calculation method
CEA Adjustors Aquatic Chronic 3, H412	Calculation method

Full text of abbreviated H statements

CEA Reagent Wedge A	
H300	Fatal if swallowed.
H302	Harmful if swallowed.
H310	Fatal in contact with skin.
H318	Causes serious eye damage.
H400	Very toxic to aquatic life.
H410	Very toxic to aquatic life with long lasting effects.
EUH032	Contact with acids liberates very toxic gas.
CEA Reagent Wedge B	
H319	Causes serious eye irritation.
CEA Adjustors	
H300	Fatal if swallowed.
H310	Fatal in contact with skin.
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

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SECTION 16: Other information

CEA Reagent Wedge A

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
Eye Dam. 1	SERIOUS EYE DAMAGE/EYE IRRITATION - Category 1

CEA Reagent Wedge B

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

Acute Tox. 1	ACUTE TOXICITY - Category 1
Acute Tox. 2	ACUTE TOXICITY - Category 2
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

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Date of previous issue	: No previous validation
Version	: 1

Notice to reader

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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.