SAFETY DATA SHEET

SIEMENS : Healthineers :

IMMULITE® 2000 FSH

SDS no.: L2KFS2 6

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

1.1 Product identifier

Product name : IMMULITE® 2000 FSH

Product code : L2KFS2/6, 10381201, 10381180, 10901852, 10901859

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

Identified usesFSH Reagent WedgeDiagnostic agents.

FSH 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 : FSH Reagent Wedge Mixture

FSH Adjustors Mixture

Classification according to UK CLP/GHS

Not classified.

The product is not classified as hazardous according to UK CLP Regulation SI 2019/720 as amended.

See Section 11 for more detailed information on health effects and symptoms.

2.2 Label elements

Storage

Signal word : FSH Reagent Wedge No signal word.

FSH Adjustors No signal word.

Hazard statements : FSH Reagent Wedge No known significant effects or critical

hazards.

FSH Adjustors No known significant effects or critical

hazards.

Precautionary statements

Prevention: FSH Reagent Wedge Not applicable.

FSH Adjustors Not applicable.

Response : FSH Reagent Wedge Not applicable. FSH Adjustors Not applicable.

: FSH Reagent Wedge Not applicable.
FSH Adjustors Not applicable.

SECTION 2: Hazards identification

Disposal : FSH Reagent Wedge Not applicable.

FSH Adjustors Not applicable.

Supplemental label : FSH Reagent Wedge

elements FSH Adjustors Not applicable.

Annex XVII - Restrictions : FSH Reagent Wedge Not applicable. on the manufacture, placing on the market and

2.3 Other hazards

articles

use of certain dangerous substances, mixtures and

Product meets the criteria : FSH Reagent Wedge This mixture does not contain any substances that are assessed to be a

to Regulation (EC) No.

PBT or a vPvB.

1907/2006, Annex XIII FSH Adjustors This mixture does not contain any

substances that are assessed to be a

Safety data sheet available on request.

PBT or a vPvB.

None known.

None known.

Other hazards which do : FSH Reagent Wedge not result in classification FSH Adjustors

Additional information: Not available.

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

azides.

SECTION 3: Composition/information on ingredients

3.1 Substances : FSH Reagent Wedge Mixture FSH Adjustors Mixture

Product/ingredient name	Identifiers	%	Classification	Туре
FSH Reagent Wedge aminocaproic acid	EC: 200-469-3 CAS: 60-32-2	≤3	Eye Irrit. 2, H319	[1]
			See Section 16 for the full text of the H statements declared above.	

Type

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

SECTION 4: First aid measures

4.1 Description of first aid measures

Eye contact : FSH 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.

FSH 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 : FSH 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.

FSH Adjustors Remove victim to fresh air and keep at

rest in a position comfortable for breathing. Get medical attention if

symptoms occur.

Skin contact : FSH Reagent Wedge Flush contaminated skin with plenty of

water. Remove contaminated clothing and shoes. Get medical attention if

symptoms occur.

FSH Adjustors Flush contaminated skin with plenty of

water. Remove contaminated clothing and shoes. Get medical attention if

symptoms occur.

Ingestion: FSH 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.

FSH Adjustors 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.

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

FSH Adjustors

Over-exposure signs/symptoms

Skin contact

Eye contact: FSH Reagent Wedge No specific data.

FSH Adjustors No specific data.

Inhalation: FSH Reagent WedgeNo specific data.FSH AdjustorsNo specific data.

: FSH Reagent Wedge No specific data.
FSH Adjustors No specific data.

Ingestion: FSH Reagent Wedge No specific data.

FSH Adjustors No specific data.

4.3 Indication of any immediate medical attention and special treatment needed

Notes to physician : FSH 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.

FSH Adjustors Treat symptomatically. Contact poison

treatment specialist immediately if large quantities have been ingested or inhaled.

SECTION 4: First aid measures

Specific treatments

: FSH Reagent Wedge No specific treatment. FSH Adjustors No specific treatment.

FSH Reagent Wedge Not available. FSH 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

SECTION 6: Accidental release measures

6.1 Personal precautions, protective equipment and emergency procedures

For non-emergency personnel

: No action shall be taken involving any personal risk or without suitable training. Evacuate surrounding areas. Keep unnecessary and unprotected personnel from entering. Do not touch or walk through spilt material. Put on appropriate personal protective equipment.

For emergency responders

: If specialised clothing is required to deal with the spillage, take note of any information in Section 8 on suitable and unsuitable materials. See also the information in "For non-emergency personnel".

6.2 Environmental precautions

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

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.

SECTION 6: Accidental release measures

Large spill

: Stop leak if without risk. Move containers from spill area. 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 noncombustible, 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. 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).

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

No exposure limit value known.

procedures

Recommended monitoring: 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

No DNELs/DMELs available.

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

SECTION 8: Exposure controls/personal protection

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.

: Personal protective equipment for the body should be selected based on the task **Body protection** 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.

Based on the hazard and potential for exposure, select a respirator that meets the Respiratory protection

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 : FSH Reagent Wedge Liquid.

> **FSH Adjustors** Liquid.

Colour : FSH Reagent Wedge Colourless.

FSH Adjustors Colourless. FSH Reagent Wedge Odourless.

Odour

FSH 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.

: Not relevant/applicable due to nature of the product. Softening point

Sublimation temperature : Not relevant/applicable due to nature of the product. Initial boiling point and : FSH Reagent Wedge Not available.

boiling range FSH Adjustors Not available.

Flammability (solid, gas) : FSH Reagent Wedge Not relevant/applicable due to nature

of the product.

FSH Adjustors Not relevant/applicable due to nature

of the product.

Upper/lower flammability or

explosive limits

: FSH Reagent Wedge **FSH Adjustors**

Not available. Not available.

FSH Reagent Wedge Flash point **FSH Adjustors**

[Product does not sustain combustion.] [Product does not sustain combustion.]

Auto-ignition temperature

SECTION 9: Physical and chemical properties

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

Decomposition temperature

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

pН

: FSH Reagent Wedge 7.95 to 8.05 **FSH Adjustors** Not applicable.

Viscosity FSH Reagent Wedge

Not available. Not available.

Solubility(ies)

Not available.

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

FSH Adjustors

water

Vapour pressure

	V	Vapour Pressure at 20°C		V	Vapour pressure at 50°C	
Ingredient name	mm Hg	kPa	Method	mm Hg	kPa	Method
FSH Reagent Wedge						
sodium azide	0.0075	0.001				
FSH Adjustors						
water	23.8	3.2				

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

Relative density

: FSH Reagent Wedge

FSH Adjustors

Not available.

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1

Density

: FSH Reagent Wedge Not available. **FSH Adjustors** Not available.

Vapour density

: FSH Reagent Wedge **FSH Adjustors** Not available.

Explosive properties

: FSH Reagent Wedge Not available. **FSH Adjustors** Not available.

Oxidising properties

Not available. : FSH Reagent Wedge Not available. **FSH Adjustors**

Particle characteristics

Median particle size : Not applicable.

9.2 Other information

Not available. Fire point : FSH Reagent Wedge

> **FSH Adjustors** Not available.

Burning time Fundamental burning velocity

: 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.

Burning rate 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.

SECTION 9: Physical and chemical properties

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

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

Acute toxicity estimates

N/A

Irritation/Corrosion

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

Conclusion/Summary

Skin : FSH Reagent Wedge Not available.

FSH Adjustors Not available.

: FSH Reagent Wedge Not available.

FSH Adjustors Not available.

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

Sensitisation

Eyes

Conclusion/Summary

Skin : FSH Reagent Wedge Not available.

FSH Adjustors Not available.

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

Mutagenicity

Conclusion/Summary: FSH Reagent Wedge Not available.

FSH Adjustors Not available.

Carcinogenicity

Conclusion/Summary: FSH Reagent Wedge Not available.

FSH Adjustors Not available.

Reproductive toxicity

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

Teratogenicity

SECTION 11: Toxicological information

Conclusion/Summary : FSH Reagent Wedge

FSH Reagent Wedge Not available. FSH 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

: FSH Reagent Wedge

FSH Adjustors

Not available.

Potential acute health effects

Eye contact : FSH Reagent Wedge

hazards.

FSH Adjustors

No known significant effects or critical

No known significant effects or critical

No known significant effects or critical

hazards.

Inhalation : FSH Reagent Wedge

nazards

FSH Adjustors

No known significant effects or critical

hazards.

Skin contact: FSH Reagent Wedge

No known significant effects or critical

hazards.

No known significant effects or critical hazards.

Ingestion : FSH Reagent Wedge

No known significant effects or critical

hazards.

FSH Adjustors

FSH Adjustors

No known significant effects or critical

hazards.

Symptoms related to the physical, chemical and toxicological characteristics

Eye contact : FSH Reagent Wedge

FSH Adjustors No specific data.

Inhalation : FSH Reagent Wedge FSH Adjustors

No specific data. No specific data.

No specific data.

No specific data.

Skin contact : FSH Reagent Wedge

FSH Reagent Wedge No specific data. FSH Adjustors No specific data.

Ingestion : FSH Reagent Wedge

FSH 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: FSH Reagent Wedge
FSH AdjustorsNot available.Potential delayed effects: FSH Reagent Wedge
FSH AdjustorsNot available.Potential delayed effects: FSH Reagent Wedge
FSH AdjustorsNot available.

Long term exposure

Potential immediate
effects: FSH Reagent Wedge
FSH AdjustorsNot available.Potential delayed effects: FSH Reagent Wedge
FSH AdjustorsNot available.Potential delayed effects: FSH Reagent Wedge
FSH AdjustorsNot available.

Potential chronic health effects

Not available.

SECTION 11: Toxicological information

Conclusion/Summary : FSH Reagent Wedge Not available.

FSH Adjustors Not available.

General: FSH Reagent Wedge No known significant effects or critical

hazards.

FSH Adjustors No known significant effects or critical

hazards.

Carcinogenicity: FSH Reagent Wedge No known significant effects or critical

hazards.

FSH Adjustors No known significant effects or critical

hazards.

Mutagenicity : FSH Reagent Wedge No known significant effects or critical

hazards.

FSH Adjustors No known significant effects or critical

hazards.

Reproductive toxicity : FSH Reagent Wedge No known significant effects or critical

hazards.

FSH Adjustors No known significant effects or critical

hazards.

Interactive effects : FSH Reagent Wedge Not available.

FSH Adjustors Not available.

Toxicokinetics

Absorption: FSH Reagent Wedge Not available.

FSH Adjustors Not available.

Distribution : FSH Reagent Wedge Not available.

FSH Adjustors Not available.

: FSH Reagent Wedge Not available.

Metabolism: FSH Reagent WedgeNot available.FSH AdjustorsNot available.

: FSH Reagent Wedge Not available. FSH Adjustors Not available.

Other information : FSH Reagent Wedge Not available.

FSH Adjustors Not available.

SECTION 12: Ecological information

12.1 Toxicity

Elimination

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

12.2 Persistence and degradability

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

12.3 Bioaccumulative potential

Product/ingredient name	LogPow	BCF	Potential
FSH Reagent Wedge			
aminocaproic acid	-2.95	-	low

12.4 Mobility in soil

Soil/water partition
coefficient (Koc): FSH Reagent Wedge
FSH AdjustorsNot available.Mobility: FSH Reagent Wedge
FSH AdjustorsNot available.MotionNot available.

12.5 Results of PBT and vPvB assessment

SECTION 12: Ecological information

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: Within the present knowledge of the supplier, this product is not regarded as

hazardous waste, as defined by EU Directive 2008/98/EC.

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

azides.

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. 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	FSH Reagent Wedge	Not regulated.	
	FSH Adjustors	Not regulated.	

14.2 UN proper FSH Reagent Wedge - **shipping name** FSH Adjustors -

14.3 Transport FSH Reagent Wedge - hazard class(es) FSH Adjustors -

14.4 Packing
groupFSH Reagent Wedge
FSH Adjustors-

14.5FSH Reagent WedgeNo.EnvironmentalFSH AdjustorsNo.

Additional FSH Reagent Wedge - information FSH Adjustors -

<u>ADN</u>

hazards

14.1 UN number FSH Reagent Wedge Not regulated. FSH Adjustors Not regulated.

14.2 UN proper
shipping nameFSH Reagent Wedge
FSH Adjustors-14.3 TransportFSH Reagent Wedge-

hazard class(es) FSH Adjustors -

SECTION 14: Transport information

32311311 14. T		
14.4 Packing group	FSH Reagent Wedge FSH Adjustors	- -
14.5 Environmental hazards	FSH Reagent Wedge FSH Adjustors	No. No.
Additional information	FSH Reagent Wedge FSH Adjustors	- -
<u>IMDG</u>		
14.1 UN number	FSH Reagent Wedge FSH Adjustors	Not regulated. Not regulated.
14.2 UN proper shipping name	FSH Reagent Wedge FSH Adjustors	- -
14.3 Transport hazard class(es)	FSH Reagent Wedge FSH Adjustors	-
14.4 Packing group	FSH Reagent Wedge FSH Adjustors	- -
14.5 Environmental hazards	FSH Reagent Wedge FSH Adjustors	No. No.
Additional information	FSH Reagent Wedge FSH Adjustors	- -
<u>IATA</u>		
14.1 UN number	FSH Reagent Wedge FSH Adjustors	Not regulated. Not regulated.
14.2 UN proper shipping name	FSH Reagent Wedge FSH Adjustors	- -
14.3 Transport hazard class(es)	FSH Reagent Wedge FSH Adjustors	-
14.4 Packing group	FSH Reagent Wedge FSH Adjustors	-
14.5 Environmental hazards	FSH Reagent Wedge FSH Adjustors	No. No.
Additional information	FSH Reagent Wedge FSH Adjustors	- -

14.6 Special precautions for : FSH Reagent Wedge

user

FSH 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.

SECTION 14: Transport information

14.7 Transport in bulk

Not applicable.

according to IMO instruments

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

: FSH Reagent Wedge **FSH Adjustors**

Not applicable. Not applicable.

Seveso Directive

This product is not controlled under the Seveso Directive.

National regulations

EU regulations

Industrial emissions (integrated pollution : FSH Reagent Wedge **FSH Adjustors**

Not listed Not listed

prevention and control) -

Industrial emissions (integrated pollution : FSH Reagent Wedge **FSH Adjustors**

Not listed Not listed

prevention and control) -Water

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 : ATE = Acute Toxicity Estimate

acronyms 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

Not classified.

Full text of abbreviated H statements

FSH Reagent

Wedge

H319 Causes serious eye irritation.

Full text of classifications

FSH Reagent Wedge

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

Date of printing : 12/13/2022 Date of issue/ Date of : 12/13/2022

revision

Date of previous issue : No previous validation

Version : 1

Notice to reader

To the best of our knowledge, the information contained herein is accurate. However, neither the abovenamed supplier, nor any of its subsidiaries, assumes any liability whatsoever for the accuracy or completeness of the information contained herein.

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.