

SAFETY DATA SHEET

(REACH regulation (EC) n° 1907/2006 - n° 2015/830)

SECTION 1 : IDENTIFICATION OF THE SUBSTANCE/MIXTURE AND OF THE COMPANY/UNDERTAKING

1.1. Product identifier

Product name : ANIOSYME XL3 Product code : 2381000.

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

Cleaning and pre-disinfection of medical devices For further information on product indication, please see the label.

1.3. Details of the supplier of the safety data sheet

Registered company name : Laboratoires ANIOS. Address : PAVE DU MOULIN .59260.LILLE - HELLEMMES.FRANCE. Telephone : + 33 (0)3 20 67 67 67. Fax : + 33 (0)3 20 67 67 68. e:mail : fds@anios.com www.anios.com

1.4. Emergency telephone number : + 33(0)1 45 42 59 59. Association/Organisation : INRS.

SECTION 2 : HAZARDS IDENTIFICATION

2.1. Classification of the substance or mixture

In compliance with EC regulation No. 1272/2008 and its amendments.

Skin irritation, Category 2 (Skin Irrit. 2, H315).

Serious eye damage, Category 1 (Eye Dam. 1, H318).

Specific target organ toxicity (repeated exposure), Category 2 (STOT RE 2, H373).

Hazardous to the aquatic environment - Acute hazard, Category 1 (Aquatic Acute 1, H400).

Hazardous to the aquatic environment - Chronic hazard, Category 2 (Aquatic Chronic 2, H411).

This mixture does not present a physical hazard. Refer to the recommendations regarding the other products present on the site.

2.2. Label elements

Detergent mixture (see section 15).

This mixture being intended for professional use only, the labelling for contents under detergent regulation does not appear on the label but is resumed in section 15

In compliance with EC regulation No. 1272/2008 and its amendments.

Hazard pictograms :



Signal Word : DANGER Product identifiers : EC 292-562-0 AMINES, N-C12-14-ALKYLTRIMETHYLENEDI-CAS 71060-57-6 ALCOHOLS, C8-10, ETHOXYLATED CAS 894406-76-9 N,N-DIDECYL-N,N-DIMETHYLAMMONIUM CARBONATE Hazard statements : H315 Causes skin irritation. H318 Causes serious eye damage. H373 May cause damage to organs through prolonged or repeated exposure (if swallowed).

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H410	Very toxic to aquatic life with long lasting effects.
Precautionary statements - 0	General :
P102	Keep out of reach of children.
Precautionary statements - I	Prevention :
P273	Avoid release to the environment.
P280	Wear protective gloves and eye protection/face protection.
Precautionary statements - I	Response :
P302 + P352	IF ON SKIN: Wash with plenty of water.
P305 + P351 + P338	IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if
	present and easy to do. Continue rinsing.
P310	Immediately call a POISON CENTER or doctor/physician.
Precautionary statements - I	Disposal :
P501	Dispose of product and its container as hazardous waste.

2.3. Other hazards

The mixture does not contain substances classified as 'Substances of Very High Concern' (SVHC) >= 0.1% published by the European CHemicals Agency (ECHA) under article 57 of REACH: http://echa.europa.eu/fr/candidate-list-table No other hazard identified in the current state of knowledge.

SECTION 3 : COMPOSITION/INFORMATION ON INGREDIENTS

Title for H and EUH statements: see § 16.

3.2. Mixtures

lentification	(EC) 1272/2008	Note	%
JDEX: 016-026-00-0	GHS07		2.5 <= x % < 10
AS: 5329-14-6	Wng		
C: 226-218-8	Eye Irrit. 2, H319		
EACH: 01-2119488633-28	Skin Irrit. 2, H315		
	Aquatic Chronic 3, H412		
ULPHAMIDIC ACID			
AS: 90640-43-0	GHS06, GHS05, GHS09, GHS08		2.5 <= x % < 10
C: 292-562-0	Dgr		
EACH: 01-2119957843-25	Acute Tox. 3, H301		
	Skin Corr. 1B, H314		
MINES,	STOT RE 1, H372		
-C12-14-ALKYLTRIMETHYLENEDI-	Aquatic Acute 1, H400		
	M Acute = 100		
	Aquatic Chronic 1, H410		
	M Chronic = 1		
AS: 71060-57-6	GHS07, GHS05		2.5 <= x % < 10
	Dgr		
LCOHOLS, C8-10, ETHOXYLATED	Acute Tox. 4, H302		
	Eye Dam. 1, H318		
AS: 894406-76-9	GHS06, GHS05, GHS09		0 <= x % < 2.5
EACH: 01-0000019102-83	Dgr		
	Acute Tox. 3, H301		
,N-DIDECYL-N,N-DIMETHYLAMMONIU	Skin Corr. 1B, H314		
I CARBONATE	Aquatic Chronic 2, H411		
	Aquatic Acute 1, H400		
	M Acute = 10		
ATTY ALCOHOL ALKOXYLATE 8	GHS07		0 <= x % < 2.5
	Wng		
	Skin Irrit. 2, H315		

SECTION 4 : FIRST AID MEASURES

As a general rule, in case of doubt or if symptoms persist, always call a doctor. NEVER induce swallowing by an unconscious person.

4.1. Description of first aid measures

In the event of exposure by inhalation :

Move the person away from the place of exposure and take him/her outside.

In the event of splashes or contact with eyes :

If applicable, remove contact lenses.

Wash thoroughly with soft clean water for 15 minutes, holding the eyelids open.

Take care not to introduce rinsing water in the undamaged eye.

Additional treatment to be provided immediately in an eye clinic or by an ophthalmologist.

Continue rinsing until medical advice is obtained.

In the event of splashes or contact with skin :

Remove all contaminated or stained clothing immediately. Do not use them again until they have been decontaminated.

Rinse immediately and thoroughly with water.

In the event of skin irritation, seek medical advice. Show this container or label.

In the event of swallowing :

Rinse out the mouth, do not allow to drink, do not induce vomiting. Calm the person down and transfer immediatly to hospital or doctor. Show the label to the doctor.

4.2. Most important symptoms and effects, both acute and delayed

Cf. § 11

4.3. Indication of any immediate medical attention and special treatment needed

Refer to the recommendation of the doctor.

SECTION 5 : FIREFIGHTING MEASURES

5.1. Extinguishing media

Suitable methods of extinction

Any extinguishing agents are authorized: foam, sand, carbon dioxide, water, powder.

5.2. Special hazards arising from the substance or mixture

A fire will often produce a thick black smoke. Exposure to decomposition products may be hazardous to health.

Do not breathe in smoke.

5.3. Advice for firefighters

Use autonomous insulating breathing apparatus and a full protective suit.

SECTION 6 : ACCIDENTAL RELEASE MEASURES

6.1. Personal precautions, protective equipment and emergency procedures

Consult the safety measures listed under headings 7 and 8. Avoid all contact with skin or eves.

6.2. Environmental precautions

Contain and control the leaks or spills with non-combustible absorbent materials such as sand, earth, vermiculite, diatomaceous earth in drums for waste disposal.

Do not get rid in natural spaces (waterways, ground and vegetations...)

6.3. Methods and material for containment and cleaning up

Absorb any spilled product with absorbent non-combustible materials, and sweep away or remove with a shovel. Put any waste in drums for disposal. Do not mix with any other waste. Wash the contaminated surface thoroughly with water.

Do not collect the product for re-use. Do not get rid in natural spaces.

6.4. Reference to other sections

Disposal considerations: see section 13.

SECTION 7 : HANDLING AND STORAGE

7.1. Precautions for safe handling

Product for external use - do not swallow. Avoid all contact with skin, eyes and clothes. Handle in accordance with user instructions on label Handle at a temperature not exceeding 60° C.

Recommended equipment and procedures :

For personal protection, see section 8.

Observe precautions stated on label and also industrial safety regulations.

Avoid eye contact with this mixture at all times.

Safety shower, eye bath and water point nearby.

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Prohibited equipment and procedures :

No smoking, eating or drinking in areas where the mixture is used.

7.2. Conditions for safe storage, including any incompatibilities

Keep the container tightly closed

Keep ONLY in the original container

Store between + 5 °C and + 35 °C in a dry, well ventilated place Do not use after the expiry date mentioned on the packaging. Keep out of the reach of children

7.3. Specific end use(s)

For professional use only Refer to paragraph 1 for product indication

SECTION 8 : EXPOSURE CONTROLS/PERSONAL PROTECTION

The information in this chapter refers to the product specifically described in this document. If the product is handled and/or exposed simultaneously with other chemical agents, these must be taken into consideration when choosing personal safety equipment.

8.1. Control parameters

Not applicable

8.2. Exposure controls

Personal protection measures, such as personal protective equipment

Use personal protective equipment that is clean and has been properly maintained.

Store personal protective equipment in a clean place, away from the work area.

Never eat, drink or smoke during use. Remove and wash contaminated clothing before re-using. Ensure that there is adequate ventilation, especially in confined areas.

- Eye / face protection

Avoid all contact with skin or eyes.

Make safety goggles with side protection available to the personnel.

Provide eye washes in workshops.

If necessary, the nearest water supply

Hand protection

Gloves must be selected according to the application and duration of use at the workstation.

Protective gloves need to be selected according to their suitability for the workstation in question : other chemical products that may be handled, necessary physical protections (cutting, pricking, heat protection), level of dexterity required.

When handling this product, wear suitable gloves.

Nitrile, latex or vinyl gloves.

Gloves must be replaced immediately if they show signs of wear and tear.

- Body protection

Avoid skin contact.

Work clothing worn by personnel shall be laundered regularly.

After contact with the product, all parts of the body that have been soiled must be washed.

Respiratory protection

Not applicable in normal conditions of use.

SECTION 9 : PHYSICAL AND CHEMICAL PROPERTIES

9.1. Information on basic physical and chemical properties

General	information	:
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Physical state :	Fluid liquid.	
Odour:	sweet-smelling	
Important health, safety and environmental information		
pH :	8.00 .	
	Slightly basic.	
Boiling point/boiling range :	Not specified.	
Flash point interval :	Not relevant.	
Vapour pressure (50°C) :	Not relevant.	
Density :	+/- 1.2	
Water solubility :	Soluble.	
Melting point/melting range :	Not specified.	
Self-ignition temperature :	Not specified.	
Decomposition point/decomposition range :	Not specified.	

9.2. Other information

The pH stated in section 9.1 is an indicative value. Below the minimum and maximum product pH:

pH pure product:

7,0 - 9,5

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SECTION 10 : STABILITY AND REACTIVITY

10.1. Reactivity

No hazardous reaction if the instructions/indications for storage and handling are respected.

10.2. Chemical stability

This mixture is stable under the recommended handling and storage conditions in section 7.

10.3. Possibility of hazardous reactions

Cf. § 10.1 and 10.2

10.4. Conditions to avoid

Avoid :

- frost

10.5. Incompatible materials

Do not mix with other products.

Refer to the scientific folder*: product/material compatibility table

* available on request

10.6. Hazardous decomposition products

At high temperatures, dangerous decomposition products may be produced, such as fumes, carbon dioxide and carbon monoxide, nitrogen oxide.

SECTION 11 : TOXICOLOGICAL INFORMATION

11.1. Information on toxicological effects

11.1.1. Substances

Not specified

11.1.2. Mixture

The toxicological data of the mixture (resulting from studies or in accordance with conventional methods) are outlined below.

Acute toxicity :

Acute toxicity estimate (ATE)* :

Oral ATE :

> 2000 mg/kg

* according to the method of calculation describe in the CLP regulation (Classification, Labelling, Packaging) Part 3 Chapter 3.1 based on the data of the different components present in the product.

If swallowed: burns to upper digestive and respiratory tract, abdominal pain, vomiting blood, serious lesions to mucous membranes and risk of perforation.

Skin corrosion/skin irritation :

Skin irritation: itching, light to moderate local redness, burning sensation...

Serious damage to eyes/eye irritation :

Serious eyes damage.

Burns, characterized by discomfort or pain, excessive blinking, lacrimation and redness, swelling of the conjunctiva.

Respiratory or skin sensitisation :

Product not classified in this hazard category.

Germ cell mutagenicity :

Product not classified in this hazard category.

Carcinogenicity :

Product not classified in this hazard category.

Reproductive toxicant :

Product not classified in this hazard category.

Specific target organ systemic toxicity - single exposure :

Product not classified in this hazard category.

Specific target organ systemic toxicity - repeated exposure :

Product not classified in this hazard category.

Aspiration hazard :

Product not classified in this hazard category.

SECTION 12 : ECOLOGICAL INFORMATION

Following information is based on data from the compounds.

Avoid any product release into waterways.

12.1. Toxicity

12.1.1. Substances

Not specified

12.1.2. Mixtures

Very toxic to aquatic life with long lasting effects.

12.2. Persistence and degradability

The surfactant(s) contained in this preparation complies(comply) with the biodegradability criteria as laid down in Regulation (EC) No.648/2004 on detergents.

Data to support this assertion are held at the disposal of the competent authorities of the Member States and will be made available to them, at their direct request or at the request of a detergent manufacturer.

12.3. Bioaccumulative potential

No data available.

12.4. Mobility in soil

No data available.

12.5. Results of PBT and vPvB assessment

No data available.

12.6. Other adverse effects

No data available.

SECTION 13 : DISPOSAL CONSIDERATIONS

Proper waste management of the mixture and/or its container must be determined in accordance with Directive 2008/98/EC. The packages must not be reused.

Do not pour into waterways.

13.1. Waste treatment methods

Waste :

Waste management is carried out without endangering human health, without harming the environment and, in particular without risk to water, air, soil, plants or animals.

Recycle or dispose of waste in compliance with current legislation, preferably via a certified collector or company.

Soiled packaging :

Empty container completely. Keep label(s) on container.

Give to a certified disposal contractor. Codes of wastes (Decision 2001/573/EC, Directive 2006/12/EEC, Directive 94/31/EEC on hazardous waste) :

18 01 06 * chemicals consisting of or containing dangerous substances

For information :

The waste code is given for indicative purposes.

The waste code must be determined by the user, according to the application of the product.

18 = Wastes from human or animal health care and/or related research (except kitchen and restaurant wastes not arising from immediate health care)

SECTION 14 : TRANSPORT INFORMATION

Exempt from transport classification and labelling.

UN3082, special provisions (375): these substances, when transported in single or combination packagings containing a net quantity per single or inner packaging of 5 L or less for liquids or having a net mass per single or inner packaging of 5 kg or less for solids, are not subject to any other provisions of these transport regulations provided that the packagings meet the general provisions of 4.1.1.1, 4.1.1.2 and 4.1.1.4 to 4.1.1.8.

14.1. UN number

- 14.2. UN proper shipping name
- 14.3. Transport hazard class(es)
- -
- 14.4. Packing group
- 14.5. Environmental hazards
- -
- 14.6. Special precautions for user

SECTION 15 : REGULATORY INFORMATION

15.1. Safety, health and environmental regulations/legislation specific for the substance or mixture

- Classification and labelling information included in section 2:

- The following regulations have been used: Regulation (EC) No. 1272/2008 and its amendments.
- Labelling for detergents (EC Regulation No. 648/2004,907/2006) :
- 5 % or over but less than 15 % : nonionic surfactants
- enzymes
- disinfectants
- perfumes

15.2. Chemical safety assessment

Information from the chemical safety assessment of substances present in the product is included in the appropriate sections of this safety data sheet, whenever necessary.

SECTION 16 : OTHER INFORMATION

Since the user's working conditions are not known by us, the information supplied on this safety data sheet is based on our current level of knowledge and on national and community regulations.

It is at all times the responsibility of the user to take all necessary measures to comply with legal requirements and local regulations. The information in this safety data sheet must be regarded as a description of the safety requirements relating to the mixture. It is recommended that the information contained in this safety data sheet is provided to the users, if necessary in an appropriate form. This information relates to the specifically designated product and may not be valid in combination with any another product. The product must not be used for applications other than those specified in heading 1 without having first obtained written handling instructions.

- UPDATES SINCE PREVIOUS VERSION
- § 14

Wording of the phrases mentioned in section 3 :

H301	Toxic if swallowed.
H302	Harmful if swallowed.
H314	Causes severe skin burns and eye damage.
H315	Causes skin irritation.
H318	Causes serious eye damage.
H319	Causes serious eye irritation.
H372	Causes damage to organs through prolonged or repeated exposure .
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.
H412	Harmful to aquatic life with long lasting effects.

Abbreviations :

ADR : European agreement concerning the international carriage of dangerous goods by Road.

IMDG : International Maritime Dangerous Goods.

IATA : International Air Transport Association.

ICAO : International Civil Aviation Organisation

RID : Regulations concerning the International carriage of Dangerous goods by rail.

GHS05 : Corrosion

GHS08 : Health hazard

GHS09 : Environment