



## 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 PLA II  
Product code : 1307000.

#### 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).  
Hazardous to the aquatic environment - Acute hazard, Category 1 (Aquatic Acute 1, H400).  
Hazardous to the aquatic environment - Chronic hazard, Category 3 (Aquatic Chronic 3, H412).  
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 :



GHS05



GHS09

Signal Word :

DANGER

Product identifiers :

EC 200-573-9

TETRASODIUM ETHYLENE DIAMINE TETRAACETATE

EC 230-525-2

DIDECYLDIMETHYLAMMONIUM CHLORIDE

Hazard statements :

H315

Causes skin irritation.

H318

Causes serious eye damage.

H410

Very toxic to aquatic life with long lasting effects.

Precautionary statements - General :

P102

Keep out of reach of children.

Precautionary statements - Prevention :

P261	Avoid breathing dust.
P273	Avoid release to the environment.
P280	Wear protective gloves and eye protection/face protection.
Precautionary statements - Response :	
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 - Disposal :	
P501	Dispose of unused 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)  $\geq 0.1\%$  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****3.2. Mixtures****Composition :**

Identification	(EC) 1272/2008	Note	%
INDEX: 011-005-00-2 CAS: 497-19-8 EC: 207-838-8 REACH: 01-2119485498-19  SODIUM CARBONATE	GHS07 Wng Eye Irrit. 2, H319		25 $\leq$ x % < 50
CAS: 64-02-8 EC: 200-573-9 REACH: 01-2119486762-27  TETRASODIUM ETHYLENE DIAMINE TETRAACETATE	GHS07, GHS05 Dgr Acute Tox. 4, H302 Eye Dam. 1, H318 Acute Tox. 4, H332		10 $\leq$ x % < 25
CAS: 7173-51-5 EC: 230-525-2  DIDECYLDIMETHYLAMMONIUM CHLORIDE	GHS06, GHS05, GHS09 Dgr Acute Tox. 3, H301 Skin Corr. 1B, H314 Aquatic Chronic 2, H411 Aquatic Acute 1, H400 M Acute = 10		2.5 $\leq$ x % < 10
INDEX: 607-620-00-6 CAS: 5064-31-3 EC: 225-768-6 REACH: 01-2119519239-36  TRISODIUM NITRILOTRIACETATE	GHS08, GHS07 Wng Carc. 2, H351 Acute Tox. 4, H302 Eye Irrit. 2, H319	[2]	0 $\leq$ x % < 2.5

(Full text of H-phrases: see section 16)

**Information on ingredients :**

[2] Carcinogenic, mutagenic or reprotoxic (CMR) substance.

**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 immediately 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.  
Take care not to skid.  
Avoid all contact with skin or eyes.

**6.2. Environmental precautions**

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

**6.3. Methods and material for containment and cleaning up**

Collect up dry  
Collect up and dispose of in drums. Wash the contaminated surface thoroughly with water.  
Do not collect the product for re-use.

**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 – Do not breathe in the dust.  
Close the container carefully after use.  
Avoid all contact with skin or eyes.  
Handle in accordance with user instructions on label  
To be used diluted in water.

**Fire prevention :**

Prevent access by unauthorised personnel.

**Recommended equipment and procedures :**

For personal protection, see section 8.  
Observe precautions stated on label and also industrial safety regulations.  
Avoid inhaling dust.  
Avoid eye contact with this mixture at all times.  
Eye bath and water point nearby.

**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 and away from dampness  
Store ONLY in the original package.

Store between +5°C. and +35°C. in a dry place, away from dampness.

Do not use after the expiry date mentioned on the packaging.

Keep out of the reach of children

Close the container carefully after use.

Store away from incompatible materials (see section 10)

### 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 contact with eyes.

Before handling powders or dust emission, wear mask goggles in accordance with standard EN166.

Prescription glasses are not considered as protection.

Provide eye washes in workshops.

If necessary, the nearest water supply

#### - Hand protection

Use suitable protective gloves that are resistant to chemical agents in accordance with standard EN374.

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.

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

Do not breathe in the dust.

## SECTION 9 : PHYSICAL AND CHEMICAL PROPERTIES

### 9.1. Information on basic physical and chemical properties

#### General information :

Physical state :	Powder or dust.
Odour:	sweet-smelling
Colour:	white

#### Important health, safety and environmental information

pH :	Not relevant.
Boiling point/boiling range :	Not specified.
Flash point interval :	Not relevant.
Vapour pressure (50°C) :	Not relevant.
Density :	< 1
Water solubility :	Soluble.
Melting point/melting range :	Not specified.
Self-ignition temperature :	Not specified.
Decomposition point/decomposition range :	Not specified.

### 9.2. Other information

pH in aqueous solution:	9,5 - 11 (0,5%)
-------------------------	-----------------

## 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 any exposure to dampness.

Do not mix with other products.

### 10.5. Incompatible materials

Aluminium and galvanized light alloys.

Copper, brass, iron, galvanized steels.

### 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

#### 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.

Ingestion may lead to irritation of the digestive system, abdominal pain, headaches and nausea.

#### 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.

#### Other information

The preparation contains sensitizing enzymes by inhalation without inducing the classification of the preparation.

## SECTION 12 : ECOLOGICAL INFORMATION

### 12.1. Toxicity

#### 12.1.1. Substances

Not specified

#### 12.1.2. Mixtures

Acute toxicity:

Very toxic to aquatic organisms.

Chronic toxicity:

Harmful 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 2014/955/EC, Directive 2008/98/EEC on hazardous waste) :

18 01 06 \* chemicals consisting of or containing dangerous substances

20 01 29 \* detergents containing dangerous substances

For information :

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

The following waste codes are given as guidelines only.

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

20 = Municipal wastes and similar commercial, industrial and institutional wastes including separately collected fractions

### SECTION 14 : TRANSPORT INFORMATION

Transport product in compliance with provisions of the ADR for road, RID for rail, IMDG for sea and ICAO/IATA for air transport (ADR 2017 - IMDG 2016 - ICAO/IATA 2017).

#### 14.1. UN number

3077

#### 14.2. UN proper shipping name

UN3077=ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID, N.O.S.

(didecyldimethylammonium chloride)

#### 14.3. Transport hazard class(es)

- Classification :



9

#### 14.4. Packing group

III

**14.5. Environmental hazards**

- Environmentally hazardous material :

**14.6. Special precautions for user**

ADR/RID	Class	Code	Pack gr.	Label	Ident.	LQ	Provis.	EQ	Cat.	Tunnel
	9	M7	III	9	90	5 kg	274 335 375 601	E1	3	-

\*Not subject to this regulation if Q ≤ 5 l / 5 kg (ADR 3.3.1 - DS 375)

IMDG	Class	2°Label	Pack gr.	LQ	EMS	Provis.	EQ
	9	-	III	5 kg	F-A,S-F	274 335 969	E1

\*Not subject to this regulation if Q ≤ 5 l / 5 kg (IMDG 3.3.1 - 2.10.2.7)

IATA	Class	2°Label	Pack gr.	Passager	Passager	Cargo	Cargo	note	EQ
	9	-	III	956	400 kg	956	400 kg	A97 A158 A179 A197	E1
	9	-	III	Y956	30 kg G	-	-	A97 A158 A179 A197	E1

\*Not subject to this regulation if Q ≤ 5 l / 5 kg (IATA 4.4.4 - DS A197)

For limited quantities, see part 2.7 of the OACI/IATA and chapter 3.4 of the ADR and IMDG.

For excepted quantities, see part 2.6 of the OACI/IATA and chapter 3.5 of the ADR and IMDG.

**14.7. Transport in bulk according to Annex II of Marpol and the IBC Code**

Not applicable

**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) :**

- 15 % or over but less than 30 % : phosphates
- 15 % or over but less than 30 % : nonionic surfactants
- 5 % or over but less than 15 % : EDTA and salts thereof
- 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**

- § 2
- § 3
- § 9
- § 12
- § 13

**Wording of the phrases mentioned in section 3 :**

H301	Toxic if swallowed.
H302	Harmful if swallowed.
H302 + H332	Harmful if swallowed or if inhaled.
H314	Causes severe skin burns and eye damage.
H318	Causes serious eye damage.
H319	Causes serious eye irritation.
H332	Harmful if inhaled.
H351	Suspected of causing cancer .
H400	Very toxic to aquatic life.
H411	Toxic to aquatic life with long lasting effects.

**Abbreviations :**

CMR: Carcinogenic, mutagenic or reprotoxic.

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

GHS09 : Environment

PBT: Persistent, bioaccumulable and toxic.

vPvB : Very persistent, very bioaccumulable.

SVHC : Substances of very high concern.