



ANIOSYME XL3



CLEANING AND PRE-DISINFECTANT OF INSTRUMENTS

Aniosyme XL3

XL ENZYMATIC PRE-DISINFECTANT CLEANING POWER FOR ADVANCED MANUAL REPROCESSING

Aniosyme XL3 is the neutral enzymatic pre-disinfectant for manual instrument reprocessing. Providing strong cleaning performance, its specially developed tri-enzymatic formula, offers excellent material compatibility by lowest concentrations in the shortest contact times.

- **UNIQUE** - Patented formula
- **STRONG** - Very high performing detergency
- **FAST** - Optimised antimicrobial efficacy from 5 minutes
- **BALANCED** - Not corrosive on materials



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Aniosyme XL3

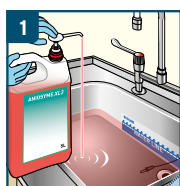
XL enzymatic pre-disinfectant cleaning power for advanced manual reprocessing

PRODUCT CHARACTERISTICS

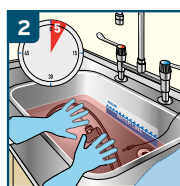
- Clear orange solution
- Density 20°C 1,18g/ml
- pH value* (concentrate) 20°C: 7.84
- pH diluted 0.5%: 8.06
- pH diluted 1%: 7.96
- pH diluted 2%: 7.97
- Conductivity at 0.5%, 1% and 2%: 0.72 - 1.30 - 2.33 mS/cm

*pH value measurements under operating conditions always by means of a pH meter with temperature compensation.

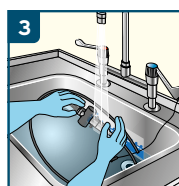
INSTRUCTIONS FOR USE



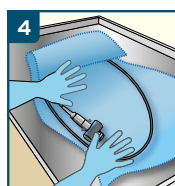
Concentrated solution for professional use. Use for soaking at a required solution, respecting the contact time.



Totally immerse the medical device. Cover the basin. Brush if visible soiling is present.



Thoroughly rinse treated medical devices with tap water to remove all traces of product and organic soiling.



Replace the solution as soon as it is visibly soiled and at least once per day to maintain the effectiveness of the product. Prime the associated pump before first use.

MICROBIOLOGICAL PROPERTIES

CLAIM/CONDITIONS	CONCENTRATION	CONTACT TIME
Disinfections of Instruments According to VAH (bactericidal and yeasticidal), dirty conditions	0,5%	15 min
Bactericidal According to EN 13727 and EN 14561, dirty conditions	0,5%	5 min
Yeasticidal According to EN 13624 and EN 14562, dirty conditions	0,5%	5 min
Tuberculocidal According to EN 14348 and EN 14563, dirty conditions	1,0%	30 min
Effective against enveloped viruses According to EN 14476 / EN 17111, dirty conditions	0,5%	15 min

PACKAGING AND ORDERING INFORMATION

PRODUCT	PACKAGING UNIT	ORDER CODE
Aniosyme XL3 Dosing Bottle	12 x 1 L	XXXXXX
Aniosyme XL3 Cans	2 x 5 L	XXXXXX



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Distributed by:
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APPLICATION AREA

Cleaning and disinfection of medical devices: surgical and medical instruments, heat-sensitive instruments and endoscopy equipment, before sterilization.

INSTRUCTIONS FOR USE

Concentrated solution for professional use. Use for soaking at a required solution, respecting the contact time.

Totally immerse the medical device. Cover the basin. Brush if visible soiling is present.

Thoroughly rinse treated medical devices with tap water to remove all traces of product and organic soiling. Replace the solution as soon as it is visibly soiled and at least once per day to maintain the effectiveness of the product. Prime the associated pump before first use.

INGREDIENTS

Quaternary ammonium carbonate, non ionic surfactants, enzyme complex (protease, amylase and mannanase), sequestering agent, fragrance, coloring, excipients.

STORAGE

Dangerous. Respect the precautions for use (drawn up according to the European rules in force regarding the classification and labelling of chemical products). Storage: between +5°C and +25°C.

CERTIFICATES

Medical device. Full antimicrobial activity for Aniosyme XL3 is included in the scientific dossier, available on request.

MEDICAL DEVICE USE SAFELY

Please read label and product information.



FOR PROFESSIONAL USE ONLY.

Summary

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Aniosyme XL3

Regulation and General Information

Aniosyme XL3 is designed, produced and controlled by the Laboratoires ANIOS, certified by the AFAQ Organism under the number 34199 in accordance with the Quality System ISO 9001 : 2015

Aniosyme XL3 has the CE mark for medical devices in the category class IIb

Aniosyme XL3 formulation fulfils the requirements of Regulation (EC) No 648/2004 on detergents and its amendments

Aniosyme XL3 is labelled in accordance with the European regulation related to the classification and labelling of chemical products

Aniosyme XL3 meets our voluntary eco-design commitment included in our ANIOSAFE charter

2381_RGI sheet_EN_08/04/2020v2

Aniosyme XL3

Composition

Antimicrobial active ingredient (indicative w/w %)

N,N-didecyl-N,N-dimethylammonium carbonate	1.25%
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Other ingredients

Surfactants

Enzymatic complex (protease, amylase, mannanase)

Chelating agent

Colouring agent

Fragrance

Excipients

2381_Composition_EN_08/28/2013

Aniosyme XL3

Stability and storage conditions

Pure product:

- Storage between +5°C and +25°C.
- Stability:
 - Bottle not opened: 24 months from the production date indicated on the label.
 - Bottle opened: maintains the 24-month shelf life provided the bottle is resealed after use.

Product diluted:

- Dilution: 0.5% - 5mL per liter of water.
- Storage of the diluted solution in a closed bottle: 7 days.
- Storage of the diluted solution in open container: 24 hours.
- Any prepared solution should be discarded after use.

2381_Stability & Storage_EN_09/09/2020

Aniosyme XL3

Antimicrobial efficacy

Studies	Results		
	ANIOSYME XL3 is used at 0,5%		
	Active concentration	Contact time	Specific conditions
BACTERICIDAL activity			
EN 13727+A2 (December 2015) Enterococcus hirae Pseudomonas aeruginosa Staphylococcus aureus	0.25 % 0.50 % 0.25 %	5 min.	Dirty conditions
EN 14561 (March 2007) Enterococcus hirae Pseudomonas aeruginosa Staphylococcus aureus	0.40 % 0.40 % 0.40 %	5 min.	Dirty conditions
TUBERCULOCIDAL activity			
EN 14348 (June 2005) - Mycobacterium terrae	0.50 % 1.00 % 2.00 %	60 min. 30 min. 15 min.	Dirty conditions
EN 14563 (February 2009) - Mycobacterium terrae	1.00 % 1.00 % 1.00 %	60 min. 30 min. 15 min.	Dirty conditions
YEASTICIDAL activity			
EN 13624 (November 2013) - Candida albicans	0.50 %	5 min.	Dirty conditions
EN 14562 (September 2006) - Candida albicans	0.50 %	5 min.	Dirty conditions
VIRUCIDAL activity			
Vaccinia virus - according to EN 14476+ A2 (July 2019) - according to EN 17111 (October 2018)	0.50 % 0.50 %	5 min. 15 min.	Dirty conditions Dirty conditions

EN 13727, EN 14561, EN 14348, EN 14563, EN 13624, EN 14562, EN 14476, EN 17111
Dirty conditions: bovin albumine 3g/L + erythrocytes 3ml/L

2381_Antimicrobial Efficacy_EN_08/31/2020

Aniosyme XL3

Biofilm

Aniosyme XL3 antimicrobial efficacy is tested against monobacterial biofilm with *Pseudomonas aeruginosa*, artificially developed inside a Tygon ®tube, according to the ISO/TC 15883 – 5 : 2006 standard.

After the passing of the 0.5% **Aniosyme XL3** diluted solution during 5 minutes, followed by rinsing with distilled water during 2 minutes, number of viable bacteria fixed by cm² of carrier and concentration of proteins are determined inside the Tygon ®tube.

Viable bacteria fixed in biofilm

	Number of viable cells (CFU/cm ²) for the test concentration (B)
Aniosyme XL3 (0.5%)	0
Reduction of viable cell count / cm ² - R = [Log (A) – log (B)]	
Aniosyme XL3 (0.5%)	<u>8.20 log</u>

Concentration in proteins determined in biofilm

	Concentration in proteins µg/cm ²	Reduction %
Control tube	60.38	
Aniosyme XL3 (0.5%)	8.68	<u>85.62%</u>

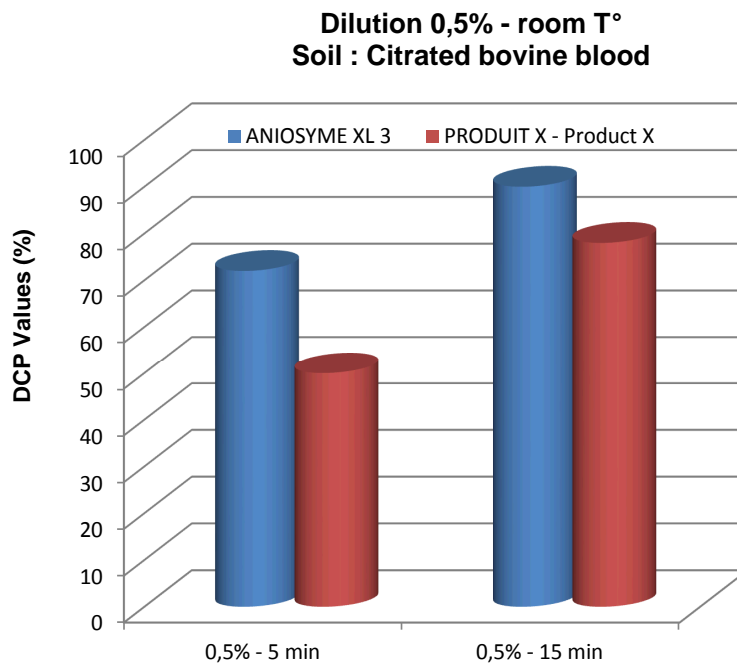
2381_Biofilm_EN_30715_09/29/2014

Aniosyme XL3

Degreasing Cleaning Power (DCP)

Present surfactants distinguish themselves by hydrophilic and hydrophobic properties, which ensures performances against proteic and glucidic soilings on one hand, and greasy soiling (lipidic) on another hand, by solubilisation and/or emulsification.

The tri-enzyme pre-disinfectant detergent **Aniosyme XL3**, diluted at 0.5 % in tap water, presents a good Degreasing Cleaning Power versus a blood based stain fixed on brass surfaces.



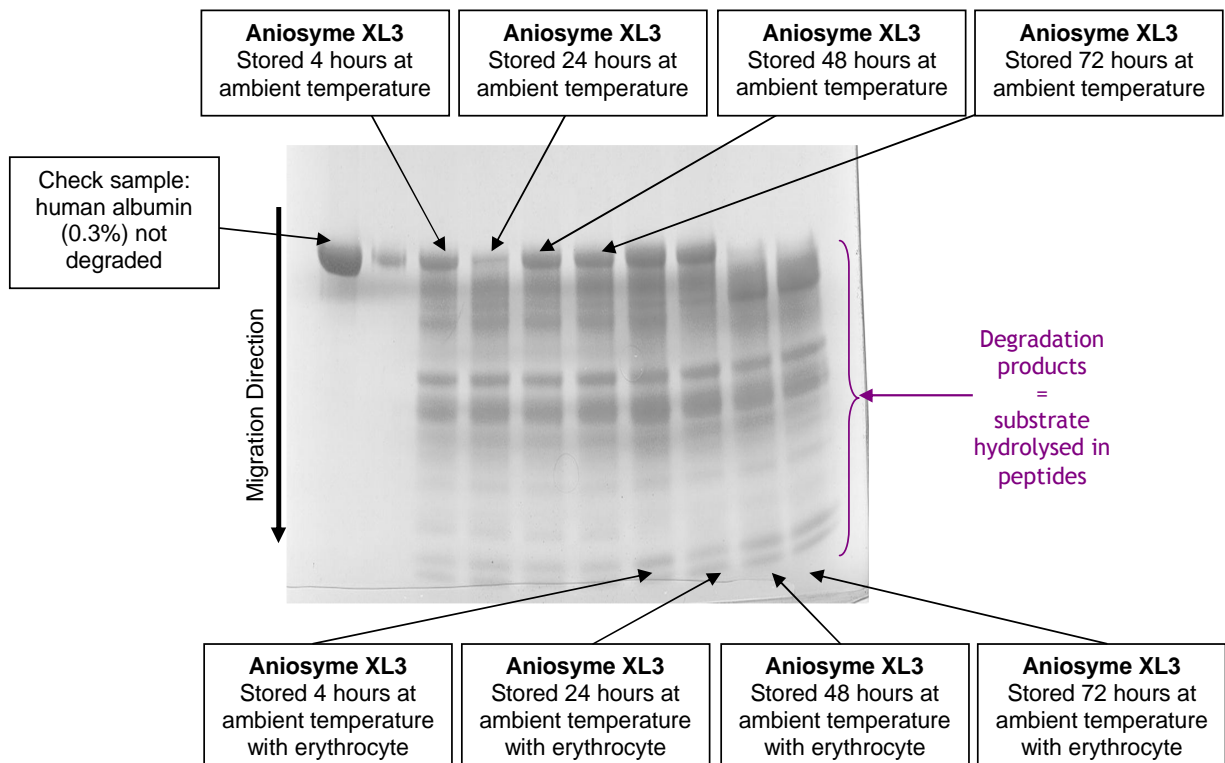
2381_DCP_EN_F14 024 01_01/24/2014

Aniosyme XL3

Enzymatic properties (1)

Proteases, mannanases and amylases act in the same way as surfactants, degrading, by hydrolysis, organic compounds not much or not soluble in soluble components with lowest molecular weight.

The proteasic activity of a 0.5% **Aniosyme XL3** solution is demonstrated after storage up to 72 hours at room temperature with or without erythrocytes, by putting it into contact during 15 minutes with the human albumin substrate.



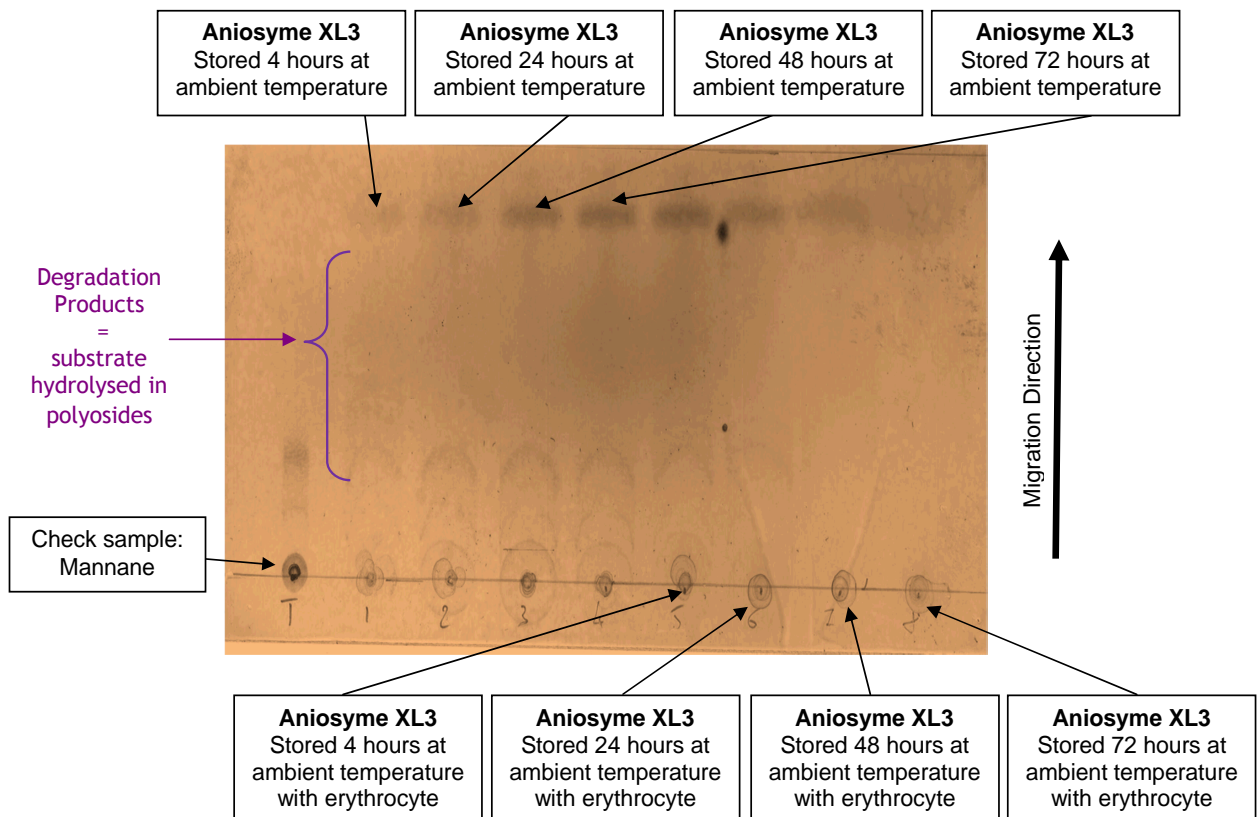
2381_enzymes_EN_F13 329 02_11/22/2013_Page 1/3

Aniosyme XL3

Enzymatic properties (2)

Mannanasic and amylasic activities of **Aniosyme XL3** are demonstrated identically by thin layer chromatography method.

Mannanasic Activity

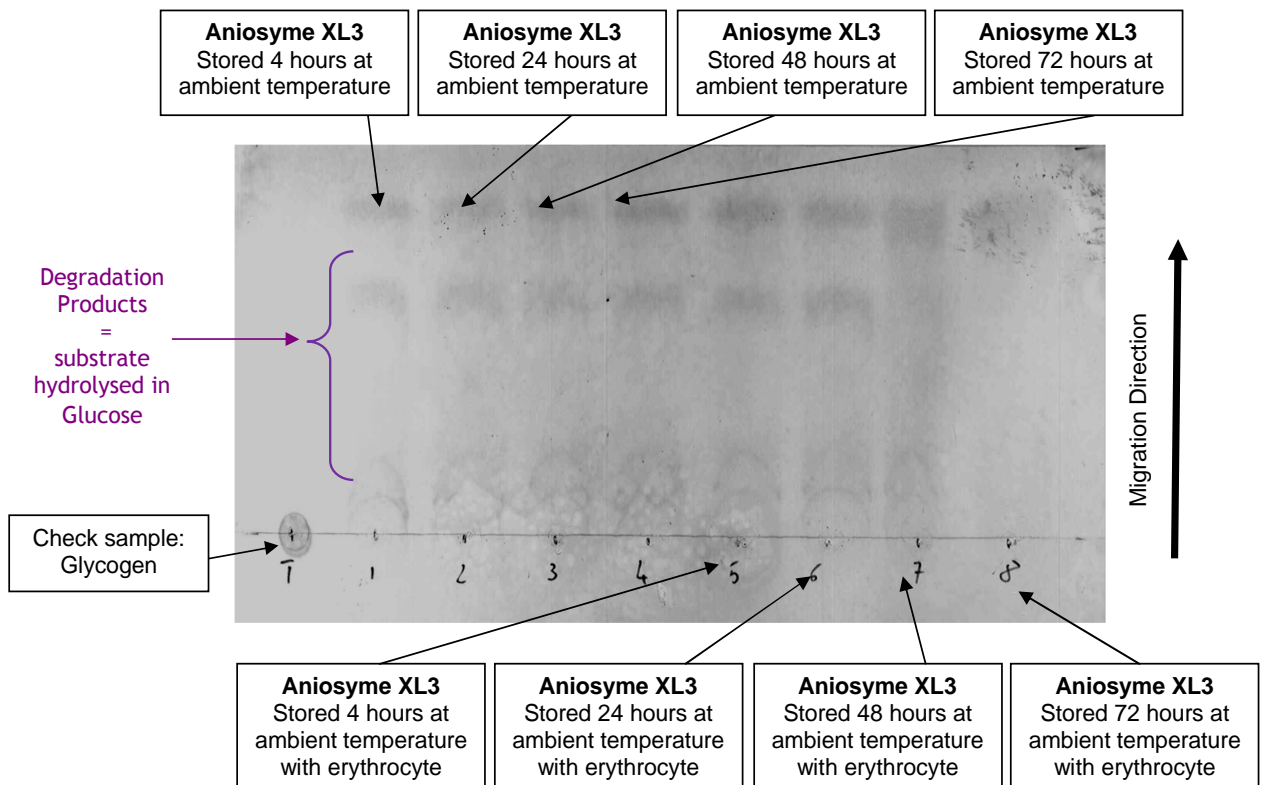


2381_enzymes_EN_F13 329 02_11/22/2013_Page 2/3

Aniosyme XL3

Enzymatic properties (3)

Amylasic Activity



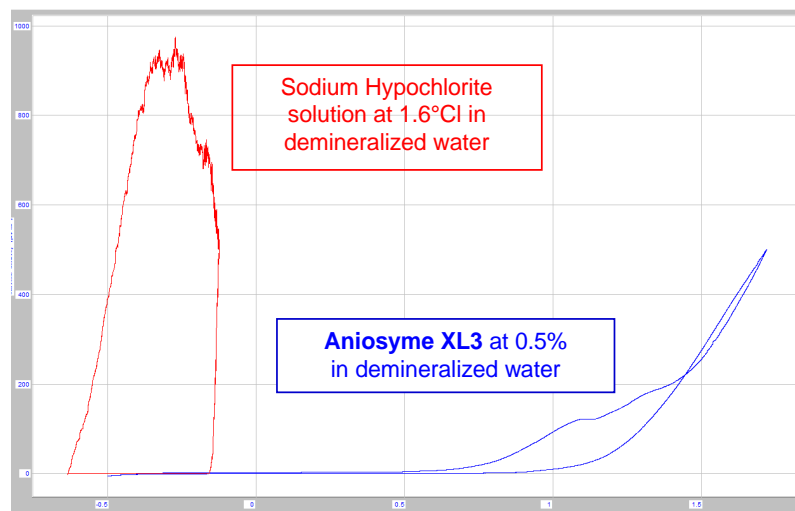
2381_enzymes_EN_F13 329 02_11/22/2013_Page 3/3

Aniosyme XL3

Anticorrosive properties

It is demonstrated, by electrochemical study of pitting corrosion according to the NF S 94-402-1 standard (May 2004), that **Aniosyme XL3** does not present pitting corrosive character with stainless steel Z30 Cr13 in the conditions of use recommended by Laboratoires ANIOS.

Parameters studied	Aniosyme XL3 at 0.5%	Sodium hypochlorite solution at 1.6°C1
Rest Potential	-500mV	-620mV
Pitting Potential	489mV	-158mV
Protecting Potential (intensity 100µA)	769mV	-620mV



2381_corrosion_EN_F13 172 02_07/30/2013

Aniosyme XL3

Compatibility with materials

A panel of materials representative of the field of application of **Aniosyme XL3** have been tested at the maximum concentration of 1% as well as at the recommended application rate of 0.5%.

Compatibility

- ◆ Polyvinyl chloride (PVC)
- ◆ Poly (methyl methacrylate) (PMMA)
- ◆ Low density polyethylene (LDPE)
- ◆ Polyoxymethylene Acetal-Copolymer (POM-C)
- ◆ Polyoxymethylene Acetal-Homopolymer (POM-H)
- ◆ Silicone
- ◆ EPDM
- ◆ Synthetic rubber
- ◆ Neoprene
- ◆ Acrylonitrilebutadiene Styrene (ABS)
- ◆ Polypropylene (PP)
- ◆ Polycarbonate (PC)
- ◆ TEFLON®
- ◆ Polysulfone (PSU)
- ◆ Polyphenylsulfone (PPSU)
- ◆ CORIAN®
- ◆ Aluminium AG3
- ◆ Aluminium AU4G
- ◆ Raw aluminium
- ◆ Shiny stainless steel
- ◆ Brushed stainless steel
- ◆ Copper
- ◆ Brass

2381_Compatibility_EN_2381/FR/EN/18A & 19A_09/10/2018 & 19/04/2019

Aniosyme XL3

Biodegradability data

Inorganic material 55.5 %¹

Not concerned by biodegradability notion

Biodegradable organic material² 44.1 %¹

Readily biodegradable substances and/or inherently biodegradable³

Non-biodegradable organic material
or material without any biodegradability² 0.4 %¹

Substances which not fulfil the biodegradability criteria,
or substances without any biodegradability data.

Conclusion

Aniosyme XL3 contains 99.6 % of inorganic material and of biodegradable organic material.

¹ Indicative w/w %

² Biodegradability data on raw material used for product formulation, provided by our suppliers and available at the date of this document

³ According to 301 and 302 OCDE guidelines

Aniosyme XL3

TOXICOLOGICAL AND ECOTOXICOLOGICAL INFORMATION AT DILUTION OF USE

Hazards identification and Personal protection at maximum
dilution of use (2%)

HAZARDS IDENTIFICATION AT DILUTION OF USE*

Health

Not classified at dilution of use in terms of health hazards.

Environment

Not classified at dilution of use in terms of environmental hazards.

** Classification drawn up in accordance with European regulation related to the classification and labelling of chemical products.*

PERSONAL PROTECTION AT THE APPLICATION RATE UNDER THE CONDITIONS OF THE INTENDED USE

Refers exclusively to this product. If the product is handled and/or exposed simultaneously with other chemical agents, these must be taken into consideration when choosing personal safety equipment.

Respiratory protection

Not applicable in normal conditions of use.

Hand protection

When handling, wear suitable gloves (nitrile, latex or vinyl)

Eye and face protection

Avoid all contact with eyes.

Water source nearby.

2381_Tox Ecotox Info dilution_EN_01/24/2014

Safety Data Sheet

The Safety Data Sheet (SDS) of this product is available on our Web site www.ecolab.com/sds. In addition to visualization and/or impression, it is possible for you to download it.

In the absence of an Internet access, the SDS remains available on request near our laboratories.

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