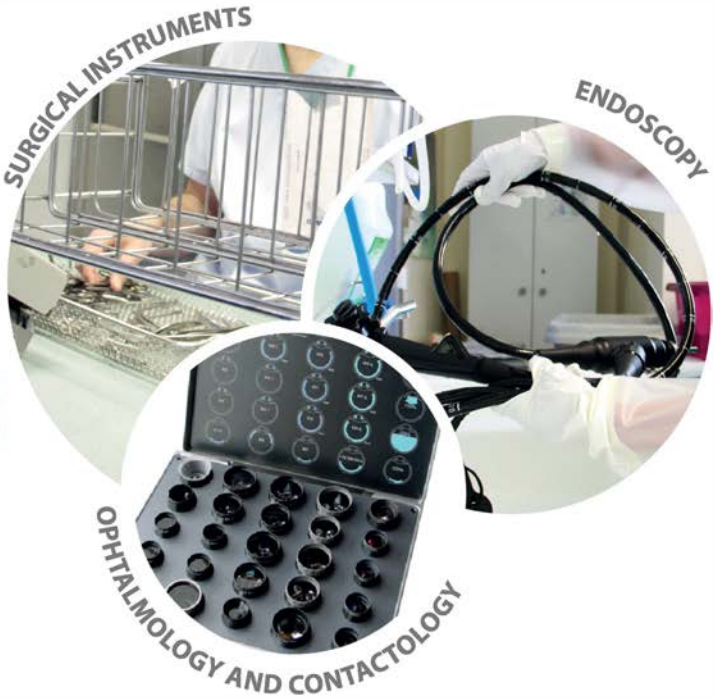
ENZYMEX L9

DETERGENT DEZINFECTANT ENZIMATIC PENTRU PRE-DEZINFECTAREA DISPOZITIVELOR MEDICALE



APLICARE

- Sala de operatie, endoscopie, oftalmologie si lentile de contact

BENEFICIILE PRODUSULUI

- Complex tri-enzimatic (lipază, amilază și protează) combinat cu surfactanți eficienți
- Integritatea instrumentatiei garantata timp de 72 de ore in baia de imersie
- Poate fi folosita in cuva cu ultrasunete
- Activitate tuberculocida
- Eficiență dovedită pe biofilm

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ENZYMEX L9

DETERGENT DEZINFECTANT ENZIMATIC PENTRU PRE-DEZINFECTAREA DISPOZITIVELOR MEDICALE

Instrucțiuni de utilizare

Pregătirea soluției de lucru

- Purtați echipament de protecție conform Fișei de Date de Securitate
- Diluați cantitatea necesară pentru a obține concentrația dorită (conform tabelului de mai jos)

	Concentrația soluției de lucru		
	0.5%	2%	5%
Dozarea în 5L	25 ml	100 ml	250 ml

Mod de utilizare

1- Se imersează integral instrumentele murdare
2- Periați dispozitivele medicale și folosiți o lavetă la necesitate
3- Timp de contact: conform activității antimicrobiale dorite (vedeți proprietăți de dezinfectare)
4- Clătiți intens

Renew the bath for each use

Proprietăți de dezinfectare

Activitate	Norma	Diluția	Timp de contact
Bactericid	EN 13727 +A1	0.5%	5 minutes
	EN 14561	0.5%	10 minutes
Levuricid	EN 13624	0.5%	5 minutes
	EN 14562	0.5%	10 minutes
Virucid	EN 14476 + A2 *(Herpes Virus)*	0.5%	5 minutes
	EN 14476 + A1 *(DBV Virus Hepatitis C model, HIV Virus)*	0.5%	10 minutes
	EN 17111 *(Vaccinia Virus)*	0.5%	10 minutes
Tuberculocid	EN 14348	2%	60 minutes
		5%	10 minutes
	EN 14563	2%	60 minutes
		5%	10 minutes

Precauții de utilizare

Vezi fișa de data de securitate

Proprietăți

- Forma: Lichid
- Culoare: Verde
- PH la 0.5%: 7
- Termen de valabilitate: 2 ani

Compoziție

- Surfactanți non-ionici
- Săruri cuaternare de amoniu
- Enzime: lipază, amilază și protează
- Sechestranți

Ambalaj

❶ Box of 250 dosis of 25ml.....ref. **1043547**
❷ Box of 12 x1L.....ref. **1043516**
❸ Box of 4 x 5L.....ref. **1043520**

MADE IN FRANCE

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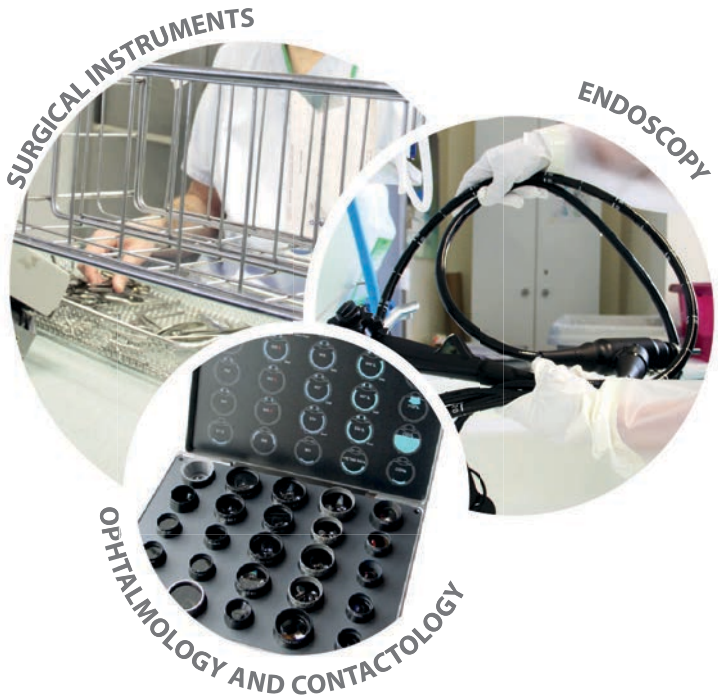
FT 770
v14_02.2022

ENZYMEX L9

ENZYMATIC DISINFECTANT DETERGENT FOR THE PRE-DISINFECTION OF MEDICAL DEVICES



APPLICATION

- Operating room, endoscopy, ophtalmology and contact lens

PRODUCT BENEFITS

- Tri-enzymatic complex (lipase, amylase and protease) combined with effective surfactants
- Instrumentation integrity guaranteed for 72 hours in immersion-bath
- Can be used in ultrasonic vat
- Activity tuberculocidal
- Proven efficiency on biofilm

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ENZYMATIC DISINFECTANT DETERGENT FOR THE PRE-DISINFECTION OF MEDICAL DEVICES

INSTRUCTIONS FOR USE

Preparation of the pre-cleaning bath:

- Wear suitable personal protective equipment (see Safety Data sheet)
- Dilute the appropriate volume of **ENZYMEX L9**in 5L of water and homogenize the solution (see dilution table)

	Solution concentration		
	0.5%	2%	5%
dose for 5L	25 ml	100 ml	250 ml

Use:

1- Soiled instruments have to be fully immersed
2- Scrub medical devices and use a swab if necessary
3- Contact time: according to the antimicrobial activity desired (see disinfecting properties)
4- Rinse thoroughly
Renew the bath for each use

DISINFECTING PROPERTIES

Activity	Norms	Concentration	Contact time
Bactericidal	EN 13727 +A1	0.5%	5 minutes
	EN 14561	0.5%	10 minutes
Yeasticidal	EN 13624	0.5%	5 minutes
	EN 14562	0.5%	10 minutes
Virucidal	EN 14476 + A2 *(Herpes Virus)*	0.5%	5 minutes
	EN 14476 + A1 *(DBV Virus Hepatitis C model, HIV Virus)*	0.5%	10 minutes
	EN 17111 *(Vaccinia Virus)*	0.5%	10 minutes
Tuberculocidal	EN 14348	2%	60 minutes
		5%	10 minutes
	EN 14563	2%	60 minutes
		5%	10 minutes

PRECAUTIONS OF USE

See Safety Data Sheet

FEATURES

- Form : **Liquid**
- Color: **Green**
- pH at 0.5%: **7.5**
- Expiration date: **2 years**

COMPOSITION

- Non-ionic surfactants
- Quaternary ammonium
- Enzymes: lipase, amylase and protease
- Sequestrants

PACKAGING

❶ Box of 250 dosis of 25ml .....ref. **1043547**
❷ Box of 12 x1L .....ref. **1043516**
❸ Box of 4 x 5L.....ref. **1043520**

Hazardous product - Follow precautions of use. Read label and product information before use. Medical device Class IIb.

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ENZYMEX L9

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: ENZYMEX L9

Product code: 10435

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

Enzymatic disinfectant detergent for soaking medical devices.

1.3.Details of the supplier of the safety data sheet

Registered company name: FRANKLAB.

Address: 3 avenue des Frênes.78180.MONTIGNY LE BRETONNEUX.FRANCE.

Telephone: +33 1 39 44 93 40. Fax : +33 1 39 44 93 41.

contact@sterifrance.com

www.sterifrance.com

1.4. Emergency telephone number: +33 1 40 44 30 00

Association/Organization: INRS Paris

SECTION 2: HAZARDS IDENTIFICATION

2.1.Classification of the substance or mixture

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

Skin corrosion, Category 1B (Skin Corr. 1B, H314).

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

Hazardous to the aquatic environment, 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).

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

Hazard pictograms:

GHS05

GHS09

Signal word

DANGER

Product identifiers:

CAS 94667-33-1	N,N-DIDECYL-N-METHYLPOLY(OXYETHLY)AMMONIUM PROPIONATE
EC 230-525-2	DIDECYLDIMETHYLAMMONIUM CHLORIDE

Hazard statements-:

H314	Causes severe skin burns and eye damage.
H410	Very toxic to aquatic life with long lasting effects.

Precautionary statements - Prevention:

P264	Wash yourself thoroughly after handling.
P273	Avoid release to the environment
P280	Wear protective gloves/protective clothing/eye protection/face protection.

Precautionary statements - Response:

P303 + P361 + P353	IF ON SKIN (or hair): Take off immediately all contaminated clothing. Rinse skin with water [or shower].
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/doctor.
P321	Specific treatment (see on this label)

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. Refer to Section 3 to identify the substances concerned.
The mixture satisfies neither the PBT nor the vPvB criteria for mixtures in accordance with annex XIII of the REACH regulations EC 1907/2006.
The mixture does not contain substances >= 0.1% with endocrine disrupting properties according to the criteria set out in Commission Delegated Regulation (EU) 2017/2100 or Commission Regulation (EU) 2018/605.

SECTION 3: COMPOSITION/INFORMATION ON INGREDIENTS

3.2. Mixtures:

Composition:

Identification	(CE) 1272/2008	Nota	%
CAS: 120313-48-6 ALCOHOLS, C12-15-LINEAR AND BRANCHED, ETHOXYLATED, PROPOXYLATED	GHS07 Wng Skin Irrit. 2, H315 Eye Irrit. 2 H319		10<= x % < 25
CAS : 94667-33-1 REACH : 01-2119950327-36-000 N,N-DIDECYL-N-METHYLPOLY(OXYETHLY)AMMONIUM PROPIONATE	GHS07, GHS05, GHS09 Dgr Acute Tox. 4, H302 Skin Corr. 1B, H314 Aquatic Acute 1, H400 M Acute = 10 Aquatic Chronic 1, H410 M Chronic = 10		2.5<= x % < 10
CAS : 7173-51-5 EC : 230-525-2 DIDECYLDIMETHYLAMMONIUM CHLORIDE	GHS07, GHS05, GHS09 Dgr Acute Tox. 4, H302 Skin Corr. 1B, H314 Eye Dam. 1, H318 Aquatic Chronic 2, H411 Aquatic Acute 1, H400 M Acute = 10		2.5 <= x % < 10
CAS : 107-21-1 EC : 203-473-3 ÉTHANE-1,2-DIOL	GHS07, GHS08 Wng Acute Tox. 4, H302 STOT RE 2, H373	[1]	0 <= x % < 2.5
CAS : 64-17-5 EC : 200-578-6 REACH : 01-2119457610-43-xxxx ETHYL ALCOHOL	GHS02, GHS07 Dgr Eye Irrit. 2, H319 Flam. Liq 2, H225	[1]	0 <= x % < 2.5

Limites de concentration spécifiques et estimation de la toxicité aiguë

Identification	Limites de concentration spécifiques	ETA
CAS: 94667-33-1 REACH: 01-2119950327-36-000 N,N-DIDECYL-N-METHYLPOLY(OXYETHLY)AMMONIUM PROPIONATE		orale: ETA = 1157 mg/kg PC

Information on components:
(Full H-phrases text: see Section 16)
[1] Substance having occupational exposure limit values.

SECTION 4: FIRST AID MESURES

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 splashes or contact with eyes:

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

Regardless of the initial state, refer the patient to an ophthalmologist and show him the label.

In the event of splashes or contact with skin:

Remove any soiled or splashed clothing immediately.

Watch out for any remaining product between skin and clothing, watches, shoes, etc.

If allergic manifestation, consult a doctor.

If the contaminated area is widespread and/or there is damage to the skin, a doctor must be consulted, or the patient transferred to hospital.

In the event of swallowing:

Do not give the patient anything orally.

Seek medical attention immediately, showing the label.

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

No data available.

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

No data available.

SECTION 5: FIREFIGHTING MEASURES

Non -flammable.

5.1. Extinguishing media

Suitable methods of extinction:

Use extinguishing measures that are appropriate to local circumstances and the surrounding environment.

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.

In the event of a fire, the following may be formed:

- carbon monoxide (CO)
- carbon dioxide (CO_2)

5.3. Firefighter advice

Use self-contained breathing apparatus and full protective gear.

SECTION 6: ACCIDENTAL RELEASE MEASURES

6.1. Personal precautions, protective equipment and emergency procedures

Consult the safety measures listed under headings 7 and 8.

For non-first aid worker:

Avoid any contact with the skin and eyes.

For first aid worker:

First aid workers will be equipped with suitable personal protective equipment (See section 8).

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.

Prevent any material from entering drains or waterways.

6.3. Methods and material for containment and cleaning up

If the ground is contaminated, once the product has been recovered by sponging with an inert and non-combustible absorbent material, wash the contaminated area in plenty of water.

6.4. Reference to other sections

No data available.

SECTION 7: HANDLING AND STORAGE

Requirements relating to storage premises apply to all facilities where the mixture is handled.

7.1. Precautions for safe handling

Always wash hands after handling.

Remove and wash contaminated clothing before re-using.

Emergency showers and eye wash stations will be required in facilities where the mixture is handled constantly.

Fire prevention:

Prevent access by unauthorized personnel.

Recommended equipment and procedures:

For personal protection, see section 8.

Observe precautions stated on label and also industrial safety regulations.

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

No data available.

Packaging:

Always keep in packaging made of an identical material to the original.

7.3. Specific end use(s)

Professional use only.

Consult section 1 for the product use.

SECTION 8: EXPOSURE CONTROLS/PERSONAL PROTECTION

8.1. Control parameters

Occupational exposure limit values:

- European Union (2019/1831, 2017/2398, 2017/164, 2009/161, 2006/15/CE, 2000/39/CE, 98/24/CE)

CAS	VME-mg/m3	VME-ppm :	VLE-mg/m3	VLE-ppm :	Notes :
107-21-1	52	20	104	40	Skin

- ACGIH TLV (American Conference of Governmental Industrial Hygienists, Threshold Limit Values, 2010) :

CAS	TWA :	STEL	Ceiling	Definition:	Criteria:
107-21-1	-	-	100	-	-
64-17-5		1000 ppm		A3	

- France (INRS – ED984 / 2020-1546) :

CAS	VME-ppm:	VME-mg/m3 :	VLE-ppm	VLE-mg/m3 :	Notes:	TMP N° :	
107-21-1	20	52	40	104	*	84	-
64-17-5	1000	1900	5000	9500	-	84	

- Mexico:

CAS	TWA	STEL	Ceiling	Definition:	Criteria:
107-21-1	-	-	100 mg/m3	-	-
64-17-5	1000 ppm	-	-	-	-

8.2. Exposure controls

Personal protection measures, such as personal protective equipment

Pictogram(s) indicating the obligation to wear personal protective equipment (PPE):



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, wear safety goggles with protective sides in accordance with standard NF EN166

In case of increased danger, use a face shield to protect the face.

Wearing prescription glasses is not protective.

It is recommended that contact lens wearers use prescription lenses when working with irritating vapours.

Provide eyewash fountains in workshops where the product is handled on a constant basis.

- **Hand protection**

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

Use suitable chemical-resistant protective gloves in accordance with the standard EN ISO 374-1.

The selection of gloves should be made according to the application and the duration of use at the workstation.

Protective gloves should be chosen according to the workstation: other chemicals that may be handled, physical protection required (cut, puncture, thermal protection), dexterity required.

- **Body protection**

Avoid skin contact.

Wear suitable protective clothing.

In case of strong splashes, wear liquid-tight chemical protective clothing (type 3) in accordance with NF

EN14605/A1 standard to avoid contact with the skin.

If there is a risk of splashing, wear chemical protective clothing (type 6) in accordance with standard NF EN13034/A1 to avoid contact with the skin.

Wear appropriate protective clothing, in particular an apron and boots. These items should be kept in good condition and cleaned after use.

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.

SECTION 9: PHYSICAL AND CHEMICAL PROPERTIES

9.1. Information on basic physical and chemical properties

General information:

Aspect:	
Aspect:	Fluid liquid.
Colour	
No data available	
Odour:	
Odour threshold:	No data available
Freezing point:	
Freezing point/range:	No data available
Initial boiling point and boiling range:	
Boiling point/range:	Not applicable
Flammability:	
Flammability (solid, gas):	No data available
Upper and lower explosive limits:	
Explosive danger, lower explosive limit (%):	No data available
Explosive danger, upper explosive limit (%):	No data available
Flash point:	
Flash point range	Not applicable
Auto-ignition temperature:	
Auto-ignition point/range	Not applicable
Decomposition temperature:	
Decomposition point/range	Not applicable

pH

pH in aqueous solution:	No data available
pH:	Not applicable

Kinematic viscosity

Viscosity:	No data available

Solubility

Water solubility:	Soluble in water
Fat solubility:	No data available

n-Octanol/water partition coefficient

n-Octanol/water partition coefficient:	No data available

Vapour pressure

Vapour pressure (50°C):	Lower than 110 kPa (1.10 bar).

Density and/or relative density

Density:	>1

Relative vapour density

Vapour density	No data available

9.2. Other information

No data available.

9.2.1. Information on physical hazard classes

No data available.

9.2.2. Other security features

No data available.

SECTION 10: STABILITY AND REACTIVITY

10.1. Reactivity

No dangerous reactions if handling and storage conditions 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

No data available.

10.4. Conditions to avoid

Avoid:

- frost

10.5. Incompatible materials

10.6. Hazardous decomposition products

The thermal decomposition may release/form:

- carbon monoxide (CO)
- carbon dioxide (CO_2)

SECTION 11: TOXICOLOGICAL INFORMATION

11.1. Information on toxicological effects

May cause irreversible skin damage, such as visible necrosis through the epidermis and into the dermis, following exposure for three minutes to one hour.

Corrosive reactions are characterised by ulcerations, bleeding, bloody bedsores and, at the end of a 14-day observation period, discolouration due to whitening of the skin, areas of alopecia and scars

11.1.1. Substances

Acute toxicity:

N-DIDECYL-N-METHYLPOLY(OXYETHLY)AMMONIUM PROPIONATE (CAS: 94667-33-1)

Oral route:	LD50 = 1157/ mg/kg Species: Rat

Skin corrosion/skin irritation:

N-DIDECYL-N-METHYLPOLY(OXYETHLY)AMMONIUM PROPIONATE (CAS: 94667-33-1)

Corrosivity: Causes severe skin burns.
Species: Rabbit

11.1.2.Mixture

No toxicological information is available on the mixture.
Substance(s) described in an INRS (Institut National de Recherche et de Sécurité) toxicological data sheet:
- Ethylene glycol (CAS 107-21-1): See toxicological data sheet n° 25
- Ethanol (CAS 64-17-5): See the toxicological sheet n°48.

SECTION 12: ECOLOGICAL INFORMATION

Very toxic to aquatic life with long lasting effects.

The product must not be allowed to run into drains or waterways.

12.1.Toxicity

12.1.1. Substances

DIDECYLDIMETHYLAMMONIUM CHLORIDE (CAS: 7173-51-5)

Fish toxicity: 0,01 < NOEC <= 0,1 mg/l

Crustacean toxicity: 0,01 < EC50 <= 0,1 mg/l
Factor M = 10
Species: Daphnia magna
Duration of exposure: 48 h

N,N-DIDECYL-N-METHYLPOLY(OXYETHLY)AMMONIUM PROPIONATE (CAS: 94667-33-1)

Fish toxicity: 0.01 < EC50 < = 0.1 mg/l
Factor M = 10

12.1.2. Mixtures

No aquatic toxicity data available for the mixture.

12.2.Persistence and degradability

12.2.1. Substances

DIDECYLDIMETHYLAMMONIUM CHLORIDE (CAS: 7173-51-5)

Biodegradability: Rapidly degradable.

N,N-DIDECYL-N-METHYLPOLY(OXYETHLY)AMMONIUM PROPIONATE (CAS: 94667-33-1)

Biodegradability: no degradability data is available; the substance is considered as not degrading quickly.

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.Endocrine-disrupting properties

No data available.

12.7.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.

13.1. Waste treatment methods

Do not pour into drains or waterways.

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.

Do not contaminate the ground or water with waste, do not dispose of waste into the environment.

Soiled packaging:

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

Give to a certified disposal contractor.

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 2021 - IMDG 2020 - OACI/IATA 2021).

14.1. UN Number

3082

14.2. UN proper shipping name

UN3082= ENVIRONMENTALLY HAZARDOUS SUBSTANCE, LIQUID, N.O.S.
(N,N-DIDECYL-N-METHYLPOLY(OXYETHLY)AMMONIUM PROPIONATE)

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	Groupe	Etiquette	Ident.	QL	Dispo.	EQ	Cat.	Tunnel
	9	M6	III	9	90	5 L	274 335 375 601	E1	3	-

Not subject to this regulation if Q <= 5L/5kg (ADR 3.3.1- DS 375)

IMDG	Class	2°Etiq	Groupe	QL	FS	Dispo.	EQ	Stowage handling	Separation
	9	-	III	5 L	F-A,S-F	274 335 969	E1	Category A	-

Not subject to this regulation if Q <= 5L/5kg (IMDG 3.3.1 - 2.10.2.7)

IATA	Class	2°Etiq.	Groupe	Passenger	Passenger	Cargo	Cargo	note	EQ
	9	-	III	964	450 L	964	450 L	A97 A158 A197 A215	E1
	9	-	III	Y964	30 kg G	-	-	A97 A158 A197 A215	E1

Not subject to this regulation if Q <= 5L/5kg (IATA 4.4.4 - DS A197)

For limited quantities of dangerous goods, see part 2.7 of the OACI/IATA and chapter 3.4 of the ADR and IMDG
For excepted quantities of dangerous goods, see part 2.6 of the OACI/IATA and chapter 3.5 of the ADR and IMDG.
Marine Pollutant (IMDG 3.1.2.9): (n,n-didecyl-n-methyl-poly(oxyethyl)ammonium propionate)

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

No data available.

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 (CE) No. 1272/2008 amended by EU Regulation No. 2021/643 (ATP 16).
- -Regulation (CE) No. 1272/2008 amended by EU Regulation No. 2021/849 (ATP 17).

- Container information:

No data available.

- Particular provisions:

No data available.

- Labelling for detergents (EC Regulation No. 648/2004,907/2006):

- - 5 % or over but less than 15 %: cationic surfactants
- - less than 5 %: amphoteric surfactants
- - 5 % or over but less than 15 %: non-ionic surfactants
- - enzymes
- - disinfectants

- Tables of occupational diseases according to the French Labour Code:

N°TMP	Label
84	Conditions caused by liquid organic solvents for professional use:
84	Aliphatic or cyclic saturated or unsaturated liquid hydrocarbons and their mixtures; halogenated liquid hydrocarbons; nitro derivatives of aliphatic hydrocarbons; alcohols, glycols, glycol ethers; ketones; aldehydes; aliphatic and cyclic ethers, including tetrahydrofuran; esters; dimethylformamide and dimethylacetamine; acetonitrile and propionitrile; pyridine; dimethylsulfone, dimethylsulfoxide.

15.2. Chemical safety assessment

No data available.

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.

The mixture must not be used for other uses than those specified in section 1 without having first obtained written handling instructions.

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 and not as a guarantee of the properties thereof.

Wording of the phrases mentioned in section 3:

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.
H373	May cause 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.

Abbreviations:

LD50: The dose of a test substance resulting in 50% lethality over a given period.

LC50: The concentration of a test substance causing 50% lethality over a given period of time.

EC50: The effective concentration of substance that causes 50% maximum response.

NOEC: The no observed effect concentration.

REACH: Registration, Evaluation, Authorisation and Restriction of Chemicals.

ETA: Acute Toxicity Estimate

CP: Body weight

STEL: Short-term exposure limit

TWA: Time Weighted Averages

TMP: Tableaux des Maladies Professionnelles (France)

VLE: Valeur Limite d'Exposition (Exposure Limit Value).

VME: Valeur Moyenne d'Exposition (Average Exposure Value).

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, bioaccumulative et toxic
vPvB: very Persistent and very Bioaccumulative.
SVHC: Substance of Very High Concern.

AGENȚIA MEDICAMENTULUI ȘI DISPOZITIVELOR MEDICALE

REGISTRUL DE STAT AL DISPOZITIVELOR MEDICALE

Введите текст для поиска...

Nr	Denumire	Den.comerc.	Model	Nr. catalog	Tara	Producatorul	Reprezentant	Ordin	Data
						frank	sofra		
DM000388371	DETERGENT	FRANKLAB®	PHOSPHAX, 200L, DRUM WITH DRUMTAINER	10317128	Franta	FRANKLAB	SOFRAGRUP S.R.L.	Rg04-000271	15-11-2022
DM000388404	DEZINFECTANT ȘI DETERGENT PENTRU DISPOZITIVE MEDICALE	FRANKLAB®	ENZYMEX L9, 25ML	1031721	Franta	FRANKLAB	SOFRAGRUP S.R.L.	Rg04-000271	15-11-2022
DM000388365	DETERGENT	FRANKLAB®	ENZYMEX LD, 10L, CAN	1027111	Franta	FRANKLAB	SOFRAGRUP S.R.L.	Rg04-000271	15-11-2022
DM000388382	DETERGENT	FRANKLAB®	TFD7, 200L, DRUM	1020889	Franta	FRANKLAB	SOFRAGRUP S.R.L.	Rg04-000271	15-11-2022
DM000388402	DEZINFECTANT ȘI DETERGENT PENTRU DISPOZITIVE MEDICALE	FRANKLAB®	ENZYMEX L9, 1L	1031705B	Franta	FRANKLAB	SOFRAGRUP S.R.L.	Rg04-000271	15-11-2022
DM000388383	DETERGENT	FRANKLAB®	TFD7, 200L, DRUM WITH DRUMTAINER	10208128	Franta	FRANKLAB	SOFRAGRUP S.R.L.	Rg04-000271	15-11-2022
DM000388400	DEZINFECTANT ȘI DETERGENT PENTRU DISPOZITIVE MEDICALE	FRANKLAB®	DDN 9, 25 ML	1027111	Franta	FRANKLAB	SOFRAGRUP S.R.L.	Rg04-000271	15-11-2022
DM000388380	DETERGENT	FRANKLAB®	TFD7, 10L, CAN	1020811	Franta	FRANKLAB	SOFRAGRUP S.R.L.	Rg04-000271	15-11-2022
DM000388410	DEZINFECTANT ȘI DETERGENT PENTRU DISPOZITIVE MEDICALE	FRANKLAB®	VIROSPRAY, 5L	1092921	Franta	FRANKLAB	SOFRAGRUP S.R.L.	Rg04-000271	15-11-2022
DM000388370	DETERGENT	FRANKLAB®	PHOSPHAX, 200L, DRUM	1031789	Franta	FRANKLAB	SOFRAGRUP S.R.L.	Rg04-000271	15-11-2022

Страница 2 из 4 (Всего элементов: 34) 1 2 3 4

Содержит([Producatorul], 'frank') И Содержит([Reprezentant], 'sofra')

AGENȚIA MEDICAMENTULUI ȘI DISPOZITIVELOR MEDICALE

REGISTRUL DE STAT AL DISPOZITIVELOR MEDICALE

Введите текст для поиска...

Nr	Denumire	Den.comerc.	Model	Nr. catalog	Tara	Producatorul	Reprezentant	Ordin	Data
						frank	sofra		
DM000388406	DEZINFECTANT ȘI DETERGENT PENTRU DISPOZITIVE MEDICALE	FRANKLAB®	ENZYMEX P, 2KG	10317128	Franta	FRANKLAB	SOFRAGRUP S.R.L.	Rg04-000271	15-11-2022
DM000388376	DETERGENT	FRANKLAB®	RINCE L7, 200L, DRUM	1092989	Franta	FRANKLAB	SOFRAGRUP S.R.L.	Rg04-000271	15-11-2022
DM000388367	DETERGENT	FRANKLAB®	PHOSPHAX, LOW 5L, CAN	1031705B	Franta	FRANKLAB	SOFRAGRUP S.R.L.	Rg04-000271	15-11-2022
DM000388368	DETERGENT	FRANKLAB®	PHOSPHAX, 10L, CAN	1031711	Franta	FRANKLAB	SOFRAGRUP S.R.L.	Rg04-000271	15-11-2022
DM000388403	DEZINFECTANT ȘI DETERGENT PENTRU DISPOZITIVE MEDICALE	FRANKLAB®	ENZYMEX L9, 5L	1031711	Franta	FRANKLAB	SOFRAGRUP S.R.L.	Rg04-000271	15-11-2022
DM000388369	DETERGENT	FRANKLAB®	PHOSPHAX, 20L, CAN	1031721	Franta	FRANKLAB	SOFRAGRUP S.R.L.	Rg04-000271	15-11-2022
DM000388374	DETERGENT	FRANKLAB®	RINCE L7, 10L, CAN	1092911	Franta	FRANKLAB	SOFRAGRUP S.R.L.	Rg04-000271	15-11-2022
DM000388373	DETERGENT	FRANKLAB®	RINCE L7, LOW 5L, CAN	1092905B	Franta	FRANKLAB	SOFRAGRUP S.R.L.	Rg04-000271	15-11-2022
DM000388364	DETERGENT	FRANKLAB®	ENZYMEX LD, 5L, CAN	1027105	Franta	FRANKLAB	SOFRAGRUP S.R.L.	Rg04-000271	15-11-2022
DM000388407	DEZINFECTANT ȘI DETERGENT PENTRU DISPOZITIVE MEDICALE	FRANKLAB®	ENZYMEX P, 4KG	1092905	Franta	FRANKLAB	SOFRAGRUP S.R.L.	Rg04-000271	15-11-2022

Страница 1 из 4 (Всего элементов: 34) 1 2 3 4

Содержит([Producatorul], 'frank') И Содержит([Reprezentant], 'sofra')

Franklab®
notre expertise l'Ultra-Propreté

DCE 435
F4v11_09.2022_EN

DECLARATION OF CONFORMITY

The manufacturer: FRANKLAB
Z.A. De L'Observatoire
3 Avenue de Frênes
78180 Montigny-Le-Bretonneux
FRANCE

Hereby declares that, the following product:

ENZYMEX L9,
Class IIb Medical device according to rule 15 of annex IX of Medical Device Directive 93/42/EEC

Is manufactured and delivered in accordance with the following directives:

Medical Device Directive 93/42/EEC (14 June 1993)
Public Health Code: Part 5 Book II

This statement of conformity is based on Technical File (DT Générique 1) constituted according annex II.3 of Medical Device Directive 93/42/EEC and the EC certificate delivered by the GMED (Additional document n°38469 rev.2 of June 09, 2022 associated with certificate n°28791 rev.13), notified body n°0459.

The product is placed on the market with the following packaging:

ENZYMEX L9

- 25mL dose — Ref.: 1043565
- 1L dosing bottle — Ref.: 1043501
- 5L can — Ref.: 1043505

26th September 2022,

FRANKLAB SAS
3 av. des Frênes - ZA de l'Observatoire
78180 MONTIGNY LE BRETONNEUX
Tél. 01 39 44 93 40 - Fax 01 39 44 93 41
@internet : http://www.franklab.com
RC Versailles 306 563 206 - APE 2041Z

Nicolas VARAY
President

EQUIVALENCE ENZYMEX L9

Formula code	FRANKLAB Designation	Packaging	FRANKLAB Commercial reference
F010435V4	ENZYMEX L9	5L can	1043505
		1L dosing bottle	1043501
		25mL dose	1043565

Louisa KDYEM
Regulatory Affairs Manager

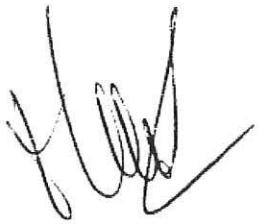
Date of creation : 11/02/2022
Date of update : 11/02/2022

- La différence de titre entre l'essai de suspension virale et le contrôle de l'efficacité de l'arrêt de l'activité du produit F010435V4 est inférieure à 0,5 log (0,125 log $DICT_{50}$ essai 1 et 0,125 log $DICT_{50}$ essai 2)

7 CONCLUSION

Les essais réalisés sur le produit F010435V4 lot n° 5611 ont démontré:

- que le produit **F010435V4** **employé à 0.5 %, a une activité virucide sur le virus DBV, (et donc par extension sur le virus de l'hépatite C)** selon la méthodologie de la norme NF EN 14476+A1, **pour 10 minutes de contact à 20°C, en conditions de saleté.**



FMV1-EN14476-01.22

7. CONCLUSION

Les essais réalisés sur le produit F010435V4 lot n°6451 ont démontré :

- Que le produit F010435V4, **employé dès 0,5% a une activité virucide sur le virus de la vaccine,** selon la méthodologie de la norme NF EN 17111 :2018, **pour 10 minutes de contact à 20°C, en conditions de saleté.**

Writer	Supervisor
Ms Emilie CANTREL, laboratory technician	Ms Stephanie MOROT-BIZOT, director

FuV2-EN 17111-06.2020

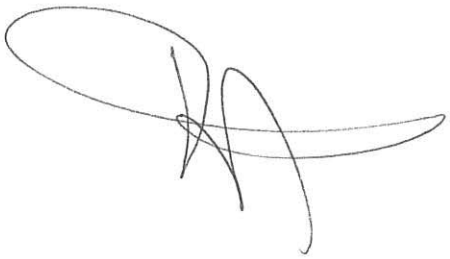
Conclusion

Des tests ont été effectués sur les souches référencées *Staphylococcus aureus* CIP 4.83, *Enterococcus hirae* CIP 58.55, *Pseudomonas aeruginosa* CIP 103.467. Les essais ont été effectués une fois. La réduction avec la souche d'essai limitante *Pseudomonas aeruginosa* en 5 minutes à 0,25% est de $1{,}10.10^5$ soit 5,04 log.

Conformément à la norme **EN 13727 + A1**, le lot **L372-25/4/14** du produit **F010435V4**, lorsqu'il est concentré à **0,25%** (V/V) dans de l'**eau dure** (Produit utilisé dilué), présente une activité **bactéricide** en **5 minutes** à **20°C**, dans les **conditions de saleté** (3 g/l d'albumine bovine et 3 ml/l de globules rouges de mouton), vis-à-vis de la souche référencée *Pseudomonas aeruginosa*, pour une activité de désinfection des dispositifs médicaux

Clermont-Ferrand, le 08/08/14.

Pr. O. TRAORÉ



Fuv1 - EN13727-11.2021.

8. Conditions de culture des bactéries : sur géloses TSA (Tryptone Soja Agar), à 37°C ± 1°C.

9. Technique d'arrêt de l'action bactéricide : transfert du porte germe dans 10 ml de neutralisant à base de polysorbate 80 (30g/l) et de jaune d'œuf (5%) dans de l'eau distillée.

4. RESULTATS PROPREMENT DITS

Voir feuilles de résultats.

SYNTHESE RESULTATS

Le produit F010435V4 est bien actif vis-à-vis des souches de référence utilisées, car la réduction moyenne obtenue est supérieure à 5 log pour les cellules bactériennes viables :

Sur produit à 0.5% pour 10 min de contact:

- pour *P aeruginosa*, R > 5,22
- pour *E. hirae*, R> 5,27
- pour *S. aureus*, R> 5,22

5. CONCLUSION

Conformément à la norme EN 14561 (Mars 2007), le produit F010435V4, lot n°L372-25/04/14B02:

- **a une activité bactéricide sur les trois souches bactériennes de référence lorsqu'employé à 0.5%, pour 10 min de contact à 20°C, en conditions de saleté (3 g/1 d'albumine bovine et 3 mL/L érythrocytes de mouton).**

FqV1-EN14561.01.22

Remarques à propos des résultats

- ✓ Tous les témoins et le mélange de validation de la méthode donnent des valeurs comprises à l'intérieur des limites de base.
- ✓ Une concentration du produit au moins a présenté une réduction logarithmique d'au moins 4 log.
- ✓ Aucune formation de précipité durant la réalisation de l'essai.
- ✓ Les concentrations d'essai testées n'ont pas permis de mettre en évidence de concentration non active.

Conclusion

Des tests ont été effectués sur la souche référencée *Candida albicans IP 48.72.* Les essais ont été effectués une fois. La réduction avec la souche d'essai *C.albicans* en 5 minutes à 0,125% est de $1{,}38.10^4$ soit 4,14 log.

Conformément à la norme **EN 13624**, le lot **L372-25/4/14** du produit **F010435V4**, lorsqu'il est concentré à **0,125%** (V/V) dans de **l'eau dure** (Produit utilisé dilué), présente une activité **levuricide** en **5 minutes** à **20°C**, dans les **conditions de saleté (BSA 3g/L + GRm 3 ml/L)**, vis-à-vis de la souche référencée *Candida albicans.*

Clermont-Ferrand, le 6/6/14.

Pr. O. TRAORÉ

FuV1 - EN 13624 - 11.2021

4. RESULTATS PROPREMENT DITS

Voir feuilles de résultats.

SYNTHESE RESULTATS

Le produit **F010435V4** est bien actif vis-à-vis des souches de référence utilisées, car la réduction moyenne obtenue est supérieure à 4 log pour les cellules fongiques viables :

- Pour *C. albicans*, R > 4,17 à 0,5% de produit, 10 min de contact

5. CONCLUSION

Conformément à la norme EN 14562 (Septembre 2006), le produit F010435V4 lot n°L372-25/04/14B02:

- **a une activité levuricide sur la souche de référence lorsqu'employé à 0,5%, pour 10 min de contact à 20°C, en conditions de saleté (3 g/l d'albumine bovine finaux + érythrocytes de mouton).**

FuV1 - EN14562 - 01. 22