

ENZYMEX P

ENZYMATIC POWDER DISINFECTANT
DETERGENT FOR THE PRE-DISINFECTION
OF MEDICAL DEVICES

SURGICAL INSTRUMENTS



OPHTHALMOLOGY AND CONTACTOLOGY



AREAS OF APPLICATION

- Operating room, endoscopy, ophthalmology and contactology

PRODUCT ADVANTAGES

- Anti-microbial activity from 5 minutes
- Effectiveness on biofilms
- Keeps the integrity of medical and surgical equipment
- Can be used in an ultrasonic cleaner



Fb Franklab®
notre expertise l'Ultra-Propreté



CE
0459

ENZYMEX P

ENZYMATIC POWDER DISINFECTANT DETERGENT FOR THE PRE-DISINFECTION OF MEDICAL DEVICES

INSTRUCTIONS FOR USE

Preparation of the solution at 0.5%:

- Wear suitable personal protective equipment (see Safety Data Sheet)
- Pour 25g of product in 5L water and homogenize the solution

Preparation of the solution at 0.4%:

- Wear suitable personal protective equipment (see Safety Data Sheet)
- Pour 20g of product in 5L water and homogenize the solution

Use :

- Fully immerse the soiled medical devices in the solution
- Scrub the medical devices and use a swab if necessary
- Contact time: 5 minutes for a 0.5% concentration or 15 minutes for a 0.4% concentration.
- Thoroughly rinse

Renew the solution for each use (or follow the local recommendations in force)

DISINFECTING PROPERTIES

Activity	Standards	Concentration	Contact time
Bactericidal	EN 13727	0.5%	5 minutes
		0.4%	10 minutes
	EN 14561	0.5%	5 minutes
		0.4%	10 minutes
Yeasticidal	EN 13624	0.5%	5 minutes
		0.4%	15 minutes
	EN 14562	0.5%	5 minutes
		0.4%	10 minutes
Virucidal	EN 14476 + A1 : 2015 PRV (Hepatitis B model virus)	0.5%	5 minutes
		0.4%	15 minutes
	EN 14476 + A1 : 2015 Herpes virus	0.4%	10 minutes
		EN 17111 : 2018 Vaccinia virus	0.4%

PRECAUTIONS OF USE

See Safety Data Sheet

FEATURES

- Aspect: Powder
- Color: White
- pH at 0.5%: 10.8
- pH at 0.4%: 10.7
- Expiration date: 2 years

COMPOSITION

- Non-ionic surfactants
- Quaternary ammonium
- Enzymes
- Sequestrants

PACKAGING

- Box of 2 buckets of 4Kg ref. **1043613**
- Box of 2 buckets of 2Kg réf. **10436138**
- Box of 2 buckets of 1 Kg réf. **10436112**



Hazardous product - Follow precautions of use. Always read label and product information before use. Class IIb Medical Device.



REGISTRUL DE STAT AL DISPOZITIVELOR MEDICALE

Nr	Denumire	Den.comerc.	Model	Nr. catalog	Tara	Producatorul	Reprezentant	Ordin	Data
						franklab			
DM000436587	DETERGENT PENTRU CURĂȚAREA SUPRAFEȚELOR DISPOZITIVELOR MEDICALE	DDN SURF	1 L, DOSING BOTTLE	1076016	Franta	FRANKLAB	SOFRAGRUP S.R.L.	Rg04-000041	24-02-2023
DM000436588	DETERGENT PENTRU CURĂȚAREA SUPRAFEȚELOR DISPOZITIVELOR MEDICALE	DDN SURF	5 L, CANISTRE	1076020	Franta	FRANKLAB	SOFRAGRUP S.R.L.	Rg04-000041	24-02-2023
DM000426558	SERVEȚELE DEZINFECTANTE	VIRO'WIPES	150 BUC.	23120L139	Franta	FRANKLAB	SOFRAGRUP S.R.L.	Rg04-000022	31-01-2023
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

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Содержит([Producatorul], 'franklab').

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SAFETY DATA SHEET

(REACH regulation (EC) n° 1907/2006 - n° 453/2010)

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

1.1. Product identifier

Product name: ENZYMEX P
Product code: 010436

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

Powder disinfectant detergent enzymatic for manual soaking of 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
Téléphone : +33 1 39 44 93 40 Fax : +33 1 39 44 93 41
contact@franklab.com
www.franklab.com

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

Association/Organisation : 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).

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

This mixture does not present an environmental hazard. No known or foreseeable environmental damage under standard conditions of use.

2.2. Label elements

Detergent mixture (see section 15).

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

Hazard pictograms:



GHS05

Signal Word:

DANGER

Product identifiers:

EC 287-089-1 Alkyl(C12-14)dimethylbenzylammonium chloride

Hazard statements:

H314 Causes severe skin burns and eye damage.

Precautionary statements - Prevention:

P280 Wear protective gloves/protective clothing/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

Call a POISON center or doctor immediately.

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2.3. Other hazards

In use, may form flammable/explosive dust-air mixture.

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>

The mixture satisfies neither the PBT nor the vPvB criteria for mixtures in accordance with annexe XIII of the REACH regulations EC 1907/2006.

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 SODIUM CARBONATE	GHS07 Wng Eye Irrit. 2, H319		25 \leq x % < 50
CAS: 85409-22-9 EC: 287-089-1 ALKYL(C12-14)DIMETHYLBENZYLAMMONIUM CHLORIDE	GHS07, GHS05, GHS09 Dgr Acute Tox. 4, H302 Skin Corr. 1B, H314 Aquatic Acute 1, H400 M Acute = 1		2.5 \leq x % < 10
INDEX: 607-428-00-2 CAS: 64-02-8 EC: 200-573-9 TETRASODIUM ETHYLENE DIAMINE TETRAACETATE	GHS05, GHS07 Dgr Acute Tox. 4, H302 Eye Dam. 1, H318		2.5 \leq x % < 10
INDEX: 612-131-00-6 CAS: 7173-51-5 EC: 230-525-2 DIDECYLDIMETHYLAMMONIUM CHLORIDE	GHS05, GHS07 Dgr Acute Tox. 4, H302 Skin Corr. 1B, H314		2.5 \leq x % < 10
INDEX: 603-117-00-0 CAS: 67-63-0 EC: 200-661-7 PROPANE-2-OL	GHS02, GHS07 Dgr Flam. Liq. 2, H225 Eye Irrit. 2, H319 STOT SE 3, H336	[1]	0 \leq x % < 2.5

Information on ingredients:

[1] Substance for which maximum workplace exposure limits are available.

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 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.

If there is any redness, pain or visual impairment, consult an ophthalmologist.

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

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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 appropriate extinguishing measures 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 (CO₂)

5.3. Advice for firefighters

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

Prevent any material from entering drains or waterways.

6.3. Methods and material for containment and cleaning up

Collect in a dry state, preferably with a vacuum cleaner with filter. Eliminate in drums. Wash the contaminated area in plenty of water.

Do not collect the product for a reuse.

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.

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.

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.

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Storage

Store in a dry place, away from moisture and heat.

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 limits:

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

CAS	TWA :	STEL :	Ceiling :	Définition :	Critères :
67-63-0	200 ppm	400 ppm	-	-	-

- France (INRS - ED984 :2012) :

CAS	VME -ppm :	VME-mg/m3 :	VLE-ppm :	VLE-mg/m3 :	Notes :	TMP N° :
67-63-0	400	980	-	2	84	-

- Mexico :

CAS	TWA :	STEL :	Ceiling :	Définition :	Critères :
67-63-0	400 ppm	500 ppm	-	-	-

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.

- Hand protection

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

- Body protection

Avoid skin contact.

Wear suitable protective clothing.

These clothes shall be chosen to ensure there is no inflammation or irritation of the skin at the neck and wrist by contact with the powder.

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

Avoid breathing dust.

In case of insufficient ventilation with risk of exceeding the STEL / TWA, wear suitable respiratory equipment.

SECTION 9 : PHYSICAL AND CHEMICAL PROPERTIES

9.1. Information on basic physical and chemical properties

General information

Physical state: Powder.

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Important health, safety and environmental information

pH :	10,8 (0,5% solution) Low base.
Flash point interval:	Not relevant.
Vapour pressure (50°C):	Below 110 kPa (1.10 bar).
Density:	< 1
Water solubility:	Soluble.

9.2. Other information

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:

- formation of dusts
- humidity
- heat

10.5. Incompatible materials

Do not mix with other products.

10.6. Hazardous decomposition products

The thermal decomposition may release/form:

- carbon monoxide (CO)
- carbon dioxide (CO₂)

SECTION 11 : TOXICOLOGICAL INFORMATION

11.1. Information on toxicological effects

11.1.1. Substances

Acute toxicity :

ALKYL(C12-14)DIMETHYLBENZYLAMMONIUM CHLORIDE	
Oral route:	DL50 = 344 mg/kg
	Species : Rat

Skin corrosion/skin irritation:

ALKYL(C12-14)DIMETHYLBENZYLAMMONIUM CHLORIDE	
Corrosivity:	Causes severe skin burns.
	Species: Rabbit

11.1.2. Mixture

No toxicological data available for the mixture.

SECTION 12 : ECOLOGICAL INFORMATION

12.1. Toxicity

12.1.1. Mixtures

ALKYL(C12-14)DIMETHYLBENZYLAMMONIUM CHLORIDE	
Fish toxicity :	LC50 = 0.28 mg/l
	Factor M = 1
	Species: Pimephales promelas
	Duration of exposure : 96 h

12.1.2. Mixtures

No aquatic toxicity data available for the mixture.

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12.2. Persistence and degradability

12.2.1. Substances

ALKYL(C12-14)DIMETHYLBENZYLAMMONIUM CHLORIDE

Biodegradability: Rapidly degradable.

12.3. Bioaccumulative potential

No data available.

12.4. Mobility in soil

No data available.

12.5. Résultats 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.

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 2013 - IMDG 2012 - ICAO/IATA 2014).

14.1. UN number

1759

14.2. UN proper shipping name

UN1759=CORROSIVE SOLID, N.O.S.

(Alkyl(C12-14)dimethylbenzylammonium chloride)

14.3. Transport hazard class(es)

- Classification:



8

14.4. Packing group

III

14.5. Environmental hazards

-

14.6. Special precautions for user

ADR/RID	Class	Code	Pack gr.	Label	Ident.	LQ	Provis.	EQ	Cat.	Tunnel
	8	C10	III	8	80	5 kg	274	E1	3	E

IMDG	Class	2°Label	Pack gr.	LQ	EMS	Provis.	EQ
	8	-	III	5 kg	F-A,S-B	223 274	E1

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IATA	Class	2°Label	Pack gr.	Passager	Passager	Cargo	Cargo	note	EQ
	8	-	III	860	25 kg	864	100 kg	A3	E1
	8	-	III	Y845	5 kg	-	-	A3	E1

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

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:

- EU Regulation No. 1272/2008 amended by EU Regulation No. 487/2013.
- EU Regulation No. 1272/2008 amended by EU Regulation No. 758/2013.
- EU Regulation No. 1272/2008 amended by EU Regulation No. 944/2013.
- EU Regulation No. 1272/2008 amended by EU Regulation No. 605/2014.

- Container information:

No data available.

- Particular provisions:

No data available.

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

- 30 % and more : phosphates
- 5 % or over but less than 15 % : cationic surfactants
- 5 % or over but less than 15 % : nonionic surfactants
- less than 5 % : EDTA and salts thereof
- enzymes
- disinfectants
- perfumes

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:

H225	Highly flammable liquid and vapour.
H302	Harmful if swallowed.
H314	Causes severe skin burns and eye damage.
H318	Causes serious eye damage.
H319	Causes serious eye irritation.
H336	May cause drowsiness or dizziness.
H400	Very toxic to aquatic life.

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Abréviations :

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

IMDG : International Maritime Dangerous Goods.

ATA : International Air Transport Association.

ICAO : International Civil Aviation Organisation.

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

GHS05 : Corrosion.



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 P,

Class IIb Medical device according to rule 15 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: 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 (certificate n°28791 rev. 13 of the 7th May 2021), notified body n°0459.

The product is placed on the market with following packaging:

ENZYMEX P

- Box of 1Kg Ref.: 1043601
- Box of 2Kg Ref.: 1043602
- Box of 4Kg Ref.: 1043604

7th May 2021,

Julien CHARRAT
General Director

