

ENZYMEX LD

DETERGENT ENZIMATIC PENTRU MAȘINI DE
SPĂLAT AUTOMATE ȘI PRIN IMERSARE

SURGICAL INSTRUMENTS



AUTOMATIC WASHING MACHINES



SOAKING



BENEFICIILE PRODUSULUI

- Puterea de curățare a ENZYMEX LD permite mai multe tipuri de aplicații:
 - Curățare manuală
 - Curățare în cuve cu ultrasunete
 - Curățare în mașini de spălat automate
- Contine 5 enzime
- Îndepărtează murdăria găsită în locuri greu accesibile cu o perie sau un șervețel.
- Compatibil cu o gamă largă de materiale
- Sechestranții permit ca produsul să fie folosit cu toate tipurile de apă



DETERGENT ENZIMATIC PENTRU MAȘINI DE SPĂLAT AUTOMATE ȘI PRIN IMERSARE

INSTRUCȚIUNI DE UTILIZARE

- **Utilizarea în mașini de spălat automate**
 - Concentrația recomandată 0.3% to 0.5%
 - Temperatura recomandată: 45°C
 - Timpul de contact recomandat: 4 minutes

Concentrația necesită de a fi ajustată în dependență de tipul de sistemă, calitatea apei și a nivelului de contaminare
- **Utilizarea în băi cu ultrasunete**
 - Concentrația recomandată 0.3% to 1%
 - Temperatura recomandată: 20 to 60°C
 - Timpul de contact recomandat: 3 to 15 minutes
- **Utilizarea prin imersare (curățarea manuală)**
 - Concentrația recomandată 0.3% to 1%
 - Temperatura recomandată: 20 to 40°C
 - Timpul de contact recomandat: 3 to 15 minutes

PRECAUȚII DE UTILIZARE

Vezi Fișa de Date de Securitate

PROPRIETĂȚI

- Aspect: **Lichid**
- Color: **Galben pal**
- pH at 0.3%: **8**
- Expiration date: **2 ani**

COMPOZIȚIA

- **5 enzime**
- **Secheștranti**
- **Surfactanți**

AMBALAJ

- ① Box of 12 x 1Lref. **1027116**
- ② Box of 4 x 5Lref. **1027120**
- ③ Box of 2 x 10Lref. **1027122**



Medical device Class I.

ENZYMEX LD

ENZYMATIC DETERGENT FOR AUTOMATIC WASHING MACHINES AND BY SOAKING

SURGICAL INSTRUMENTS



AUTOMATIC WASHING MACHINES



SOAKING



■ PRODUCT BENEFITS

- The cleaning power of ENZYMEX LD allows several types of application:
 - Manual cleaning
 - Cleaning in ultrasound vats
 - Cleaning in automatic washing machines
- Contains 5 enzymes
- Remove soilings found in places difficult to reach with a brush or swab.
- Compatible with a large range of materials
- Sequestrants allows the product to be used with all types of water



ENZYMEX LD

ENZYMATIC DETERGENT FOR AUTOMATIC WASHING MACHINES AND BY SOAKING

■ INSTRUCTIONS FOR USE

- **Automatic washing machines use :**
 - Recommended concentration: 0.3% to 0.5%
 - Recommended temperature: 45°C
 - Recommended contact time: 4 minutesConcentration is to be adapted depending on the type of system, the quality of the washing water and the degree of soiling.
- **Ultrasound vats use:**
 - Recommended concentration: 0.3% to 1%
 - Recommended temperature: 20 to 60°C
 - Recommended contact time: 3 to 15 minutes
- **Use by soaking (manual cleaning):**
 - Recommended concentration: 0.3% to 1%
 - Recommended temperature: 20 to 40°C
 - Recommended contact time: 3 to 15 minutes

■ PRECAUTIONS OF USE

See Safety Data Sheet

■ FEATURES

- Aspect: Liquid
- Color: Clear yellow
- pH at 0.3%: 8
- Expiration date: 2 years

■ COMPOSITION

- 5 enzymes
- Sequestrants
- Surfactants

■ PACKAGING

- ① Box of 12 x 1Lref. **1027116**
- ② Box of 4 x 5Lref. **1027120**
- ③ Box of 2 x 10Lref. **1027122**



Medical device Class I.

ENZYMEX LD

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 LD

Product code: 010271

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

Enzymatic detergent.

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.

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 a health hazard with the exception of possible occupational exposure thresholds (see paragraphs 3 and 8).

This mixture does not present a hazard to the environment. Ecological damages are not known or expected under normal uses.

2.2. Label elements

Detergent mixture (see section 15).

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

Additional labeling:

EUH210

Safety data sheet available on request.

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>

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/INFORMATIONS ON INGREDIENTS

3.2. Mixtures

Composition:

Identification	(EC) 1272/2008	Note	%
CAS: 532-32-1 EC: 208-534-8 SODIUM BENZOATE	GHS07 Wng Eye Irrit. 2, H319		$0 \leq x \% < 2.5$

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

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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 the label.

In the event of splashes or contact with skin:

Wash thoroughly with water

In the event of swallowing:

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

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

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

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 with 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 eyewash stations will be required in facilities where the mixture is constantly handled.

Fire prevention:

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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 equipments 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/PERSONNAL PROTECTION

8.1. Control parameters

No data available

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, wear safety goggles with protective sides accordance with standard EN166.

Prescription glasses are not considered as protection.

Individuals wearing contact lenses should wear prescription glasses during work where they may be exposed to irritant vapours.

Provide eyewash stations in facilities where the product is handled constantly.

- Hand protection

Wear suitable protective gloves in the event of prolonged or repeated skin contact.

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

- 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

SECTION 9: PHYSICAL AND CHEMICAL PROPERTIES

9.1. Information on basic physical and chemical properties

General information

Physical state: Fluid liquid.

Important health, safety and environmental information

pH: Not stated.
Slightly basic.

Flash point interval: Not relevant.

Vapour pressure (50°C): Not relevant.

Density: > 1

Water solubility: Soluble.

Melting point/range: Not stated.

Self-ignition point/range: Not stated.

Decomposition point/range: Not stated.

9.2. Other information

No data available.

SECTION 10: STABILITY AND REACTIVITY

ENZYMEX LD

10.1.Reactivity

No data available.

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

No data available.

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:

SODIUM BENZOATE (CAS: 532-32-1)

Oral route:

LD₅₀ = 3450mg/kg

11.1.2.Mixture

No toxicological data available for the mixture.

SECTION 12: ECOLOGICAL INFORMATION

12.1.Toxicity

12.1.2. Mixtures

No aquatic toxicity data available for the mixture.

12.2.Persistence and degradability

No data available.

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.

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.

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Give to a certified disposal contractor.

SECTION 14: TRANSPORT INFORMATION

Exempted from Transport classification and labeling.

14.1.UN number

-

14.2.UN proper shipping name

-

14.3.Transport hazard classe(s)

-

14.4.Packing group

-

14.5.Environmental hazards

-

14.6.Special precautions for user

-

SECTION 15: REGULATION INFORMATION

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

- Classification and labeling information included in section 2:

The following regulations have been used:

- EU Regulation No. 1272/2008 amended by EU Regulation No. 2020/217 (ATP 14)

- Container information:

No data available.

- Particular provisions :

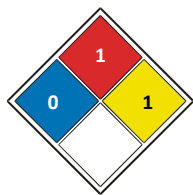
No data available.

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

- Less than 5%: anionic surfactants
- Less than 5%: nonionic surfactants
- Enzymes
- Preservation agents

- Standardized American system for the identification of hazards presented by the product in view of emergency procedures (NFPA 704)

NFPA 704, Labeling: Health=0 Inflammability=1 Instability/Reactivity=1 Specific Risk=none



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:

H319

Causes serious eye irritation.

Abbreviations:

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

IMDG: International Maritime Dangerous Goods.

IATA: International Air Transport Association.

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ICAO: International Civil Aviation Organization

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

PBT: Persistent, bioaccumulable and toxic.

vPvB : Very persistent, very bioaccumulable.

SVHC: Substances of very high concern.



REGISTRUL DE STAT AL DISPOZITIVELOR MEDICALE

Nr	Denumire	Den.comerc.	Model	Nr. catalog	Tara	Prodicatorul	Reprezentant	Ordin	Data
						frank	sofra		
DM000388406	DEZINFECTANT SI 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 SI 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 SI DETERGENT PENTRU DISPOZITIVE MEDICALE	FRANKLAB®	ENZYMEX P, 4KG	1092905	Franta	FRANKLAB	SOFRAGRUP S.R.L.	Rg04-000271	15-11-2022

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☒ Содержит([Prodicatorul], '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		
DM000388409	DEZINFECTANT ȘI DETERGENT PENTRU DISPOZITIVE MEDICALE	FRANKLAB®	VIROSPRAY, 1L	1092911	Franta	FRANKLAB	SOFRAGRUP S.R.L.	Rg04-000271	15-11-2022
DM000388398	DEZINFECTANT ȘI DETERGENT PENTRU DISPOZITIVE MEDICALE	FRANKLAB®	DDN 9, 1L	1027101	Franta	FRANKLAB	SOFRAGRUP S.R.L.	Rg04-000271	15-11-2022
DM000388378	DETERGENT	FRANKLAB®	TFD7, 5L, CAN	1020805	Franta	FRANKLAB	SOFRAGRUP S.R.L.	Rg04-000271	15-11-2022
DM000388363	DETERGENT	FRANKLAB®	ENZYMEX LD, 1L, DOSING BOTTLE	1027101	Franta	FRANKLAB	SOFRAGRUP S.R.L.	Rg04-000271	15-11-2022
DM000388405	DEZINFECTANT ȘI DETERGENT PENTRU DISPOZITIVE MEDICALE	FRANKLAB®	ENZYMEX P, 1KG	1031789	Franta	FRANKLAB	SOFRAGRUP S.R.L.	Rg04-000271	15-11-2022
DM000388399	DEZINFECTANT ȘI DETERGENT PENTRU DISPOZITIVE MEDICALE	FRANKLAB®	DDN 9, 5L	1027105	Franta	FRANKLAB	SOFRAGRUP S.R.L.	Rg04-000271	15-11-2022
DM000388401	DEZINFECTANT ȘI DETERGENT PENTRU DISPOZITIVE MEDICALE	FRANKLAB®	ECOSEPTOL FOAM, 750 ML	1031705	Franta	FRANKLAB	SOFRAGRUP S.R.L.	Rg04-000271	15-11-2022
DM000388408	DEZINFECTANT ȘI DETERGENT PENTRU DISPOZITIVE MEDICALE	FRANKLAB®	PERALEX 9 HECTO +, 5L	1092905B	Franta	FRANKLAB	SOFRAGRUP S.R.L.	Rg04-000271	15-11-2022
DM000388381	DETERGENT	FRANKLAB®	TFD7, 20L, CAN	1020821	Franta	FRANKLAB	SOFRAGRUP S.R.L.	Rg04-000271	15-11-2022
DM000388375	DETERGENT	FRANKLAB®	RINCE L7, 20L, CAN	1092921	Franta	FRANKLAB	SOFRAGRUP S.R.L.	Rg04-000271	15-11-2022
Страница 3 из 4 (Всего элементов: 34) < 1 2 3 4 >									
☒ Содержит ([Producatorul], 'frank') И Содержит ([Reprezentant], 'sofra')									



Franklab®
notre expertise l'Ultra-Propreté

DCE 271
F1v2_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 LD

Class I Medical device according to rule 1 of annex VIII of the European Medical Device Regulation 2017/745.

Is manufactured and delivered in accordance with the following regulations:

European Medical Device Regulation 2017/745 (April 5th 2017)
Public Health Code: Part 5 Book II

This statement of conformity is based on Technical File (DT ENZYMEX LD) constituted according to the annex II of the European Medical Device Regulation 2017/745.

The product is placed on the market with following packaging:

ENZYMEX LD (Basic UDI-ID : 37013875271NF)

- 1L Dosing bottle Ref. : 1027101
- 5L Can Ref. : 1027105
- 10L Can Ref. : 1027111

26th September 2022,

FRANKLAB SAS

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Nicolas VARAY
President

