

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@franklab.com

www.franklab.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).

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-DIDECYL-N-METHYLPOLY(OXYETHYL)AMMONIUM PROPIONATE

Hazard statements:-

H314

Causes severe skin burns and eye damage.

H410

Very toxic to aquatic life with long lasting effects.

Precautionary statements - Prevention:

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/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.

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 annex XIII of the REACH regulations EC 1907/2006.

ENZYMEX L9

SECTION 3: COMPOSITION/INFORMATION ON INGREDIENTS

3.2. Mixtures:

Composition:

Identification	(CE) 1272/2008	Nota	%
FATTY ALCOHOL ALCOXYLATE	GHS07 Wng Skin Irrit. 2, H315		10 ≤ x % < 25
CAS: 94667-33-1 REACH: 01-2119950327-36-000 N-DIDECYL-N-METHYLPOLY(OXYETHYL)AMMONIUM PROPIONATE	GHS07, GHS05, GHS09 Dgr Acute Tox. 4, H302 Skin Corr. 1B, H314 Aquatic Acute 1, H400 M Acute = 1 Aquatic Chronic 1, H410 M Chronic = 1		2.5 ≤ x % < 10
CAS: 7173-51-5 EC: 230-525-2 DIDECYLDIMETHYLAMMONIUMCHLORIDE	GHS07, GHS05, GHS09 Dgr Acute Tox. 4, H302 Skin Corr. 1B, H314 Aquatic Chronic 2, H411 Aquatic Acute 1, H400 M Acute = 10		2.5 ≤ x % < 10
CAS: 94441-92-6 EC: 305-318-6 N-(2-CARBOXYETHYL)-N-(2-ETHYLEXYL)-?-SODIUM ALANINATE	GHS05 Dgr Eye Dam. 1, H318		2.5 ≤ x % < 10

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.

ENZYMEX L9

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 (CO₂)

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.

ENZYMEX L9

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

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 NF EN166

- Hand protection

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

- Body protection

Avoid skin contact.

Wear suitable protective clothing.

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:	Fluid liquid.
Odour:	No data available
Odour threshold:	No data available

Important health, safety and environmental information:

pH:	Not stated. Slightly basic.
Melting point/freezing point:	No data available
Initial boiling point et and boiling range:	No data available
Flash point:	Not applicable.
Evaporation rate:	No data available
Inflammability (solid, gas):	Not applicable
Upper/lower flammability or explosive limits:	No data available
Vapour pressure (50°C):	Lower than 110 kPa (1.10 bar).
Vapour density:	No data available
Relative density:	> 1
Solubility:	Soluble in water.
he n-octyl alcohol/water partition coefficient:	No data available
Auto-ignition temperature:	No data available
Decomposition temperature:	No data available
Viscosity:	No data available
Explosive properties:	No data available

9.2. Other information

No data available.

ENZYMEX L9

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 (CO₂)

SECTION 11: TOXICOLOGICAL INFORMATION

11.1. Information on toxicological effects

11.1.1. Substances

Acute toxicity:

N-(2-CARBOXYETHYL)-*N*-(2-ETHYLHEXYL)-?- SODIUM ALANINATE (CAS : 94441-92-6)

Oral route: DL50 > 5000 mg/kg
Species: Rat

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

Oral route: DL50 = 1157/ mg/kg
Species: Rat

FATTY ALCOHOL ALCOXYLATE

Oral route: DL50 > 2000 mg/kg

Skin corrosion/skin irritation:

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

Corrosivity: Causes severe skin burns.
Species: Rabbit

Serious damage to eyes/eye irritation:

N-(2-CARBOXYÉTHYL)-*N*-(2-ÉTHYLHEXYL)-?-ALANINATE DE SODIUM (CAS : 94441-92-6)

Causes serious eye damage.
Corneal haze: Average score >= 3
Iritis: Average score > 1,5

Respiratory or skin sensitisation:

N-(2-CARBOXYÉTHYL)-*N*-(2-ÉTHYLHEXYL)-?-ALANINATE DE SODIUM (CAS : 94441-92-6)

Buehler Test: Non-sensitizer.

11.1.2. Mixture

No toxicological data available for the mixture.

SECTION 12: ECOLOGICAL INFORMATION

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

ENZYMEX L9

Crustacean toxicity:	0,01 < CE50 <= 0,1 mg/l Factor M = 10 Species: <i>Daphnia magna</i> Duration of exposure: 48 h
N-(2-CARBOXYETHYL)-N-(2-ETHYLHEXYL)-?- SODIUM ALANINATE (CAS: 94441-92-6)	
Fish toxicity:	CL50 > 100 mg/l Species: <i>Oncorhynchus mykiss</i> Duration of exposure: 96 h
Crustacean toxicity:	CE50 > 100 mg/l Species: <i>Daphnia magna</i> Duration of exposure: 48 h
N-DIDECYL-N-METHYLPOLY(OXYETHYL)AMMONIUM PROPIONATE (CAS: 94667-33-1)	
Fish toxicity:	CL50 = 0.78 mg/l Species: <i>Danio rerio</i> Duration of exposure: 96 h OCDE Guideline 203 (Fish, Acute Toxicity Test)
Crustacean toxicity:	CE50 = 0.07 mg/l Species: <i>Daphnia magna</i> Duration of exposure: 48 h OCDE Guideline 202 (<i>Daphnia</i> sp. Acute Immobilisation Test)
Algae toxicity:	CEr50 = 0.15 mg/l Species: <i>Desmodesmus subspicatus</i> Duration of exposure: 72 h OCDE Guideline 201 (Alga, Growth Inhibition Test)
FATTY ALCOHOL ALCOXYLATE	
Fish toxicity:	1 < CL50 <= 10 mg/l Species: <i>Leuciscus idus</i>

12.1.2. Mixtures

No aquatic toxicity data available for the mixture.

12.2. Persistence and degradability

12.2.1. Substances

N-(2-CARBOXYETHYL)-N-(2-ETHYLHEXYL)-?- SODIUM ALANINATE (CAS: 94441-92-6) (CAS : 94441-92-6)

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

DIDECYLDIMETHYLAMMONIUM CHLORIDE (CAS: 7173-51-5)

Biodegradability: Rapidly degradable.

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

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

FATTY ALCOHOL ALCOXYLATE

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. 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.

ENZYMEX L9

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 2015 - IMDG 2014 - OACI/IATA 2015).

14.1. UN Number

3082

14.2. UN proper shipping name

UN3082= ENVIRONMENTALLY HAZARDOUS SUBSTANCE, LIQUID, N.O.S.
 (N-DIDECYL-N-METHYLPOLY(OXYETHYL)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	Pack gr.	Label	Ident.	LQ	Provis.	EQ	Cat.	Tunnel
	9	M6	III	9	90	5 L	274 335 375 601	E1	3	E

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

IMDG	Class	2°Label	Pack gr.	QL	FS	Provis.	EQ
	9	-	III	5 L	F-A,S-F	274 335 969	E1

Not subject to this regulation if Q <= 5L/5kg (IMDG 2.10.2.7 - DS 969)

IATA	Class	2°Label.	Pack gr.	Passager	Passager	Carqo	Carqo	note	EQ
	9	-	III	964	450 L	964	450 L	A97 A158 A197	E1
	9	-	III	Y964	30 kg G	-	-	A97 A158 A197	E1

Not subject to this regulation if Q <= 5L/5kg (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

No data available.

SECTION 15: REGULATORY INFORMATION

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

ENZYMEX L9

- 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:

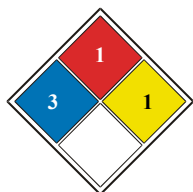
No data available.

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

- 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

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

NFPA 704, Labelling: Health=3 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:

H302	Harmful if swallowed.
H314	Causes severe skin burns and eye damage.
H315	Causes skin irritation.
H318	Causes serious eye damage.
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:

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.