

SAFETY DATA SHEET

reach regulation (CE) No. 1907/2006 - n° 2015/830

EnzyClear

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

1.1. Product identifier

Product name EnzyClear®

Product code 413029

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

Disinfectant detergent for pre-disinfection and cleaning by immersion

1.3. Details of the supplier of the safety data sheet

INTERSCIENCE

30, chemin du Bois des Arpents

78860 Saint Nom la Bretèche

FRANCE

Tel. : + 33 (0)1 34 62 62 61

Email : info@interscience.com Website : www.interscience.com

1.4. Emergency telephone number

ORFILA

Tel. : + 33 (0)1 45 42 59 59

SECTION 2. HAZARDS IDENTIFICATION

2.1. Classification of the substance or mixture

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

Skin irritation, Category 2 (Skin Irrit. 2, H315).

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

Hazardous to the aquatic environment – Chronic hazard, category 3 (Aquatic Chronic 3, H412).

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).

The mixture is a disinfectant cleaner product for medical device use.

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

Hazard pictograms:



GHS05

Signal Word : DANGER

Product identifiers :

CAS 26183-52-8

ETHOXYLATED ALCOHOL C10

EC 230-525-2

DIDECYLDIMETHYLAMMONIUM CHLORIDE

Hazard statements :

H315

Causes skin irritation.

H318

Causes serious eye damage.

H412

Harmful to aquatic life with long lasting effects

Precautionary statements – General :

P102

Keep out of reach of children.

Precautionary statements - Prevention :

P273

Avoid release to the environment.

P280

Wear protective gloves/protective clothing/eye protection/face protection.

Precautionary statements - Response :

P302 + P352

IF ON SKIN: Wash with plenty of water/...

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/...

Precautionary statements - Disposal :

P501

Dispose of content/container as hazardous waste.

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 fulfils 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

3.1. Mixtures

Composition :

Full text of H-phrases: see section 16

Identification	(EC) 1272/2008	Note	%
INDEX: 011-005-00-2 CAS: 497-19-8 EC: 207-838-8 REACH :01-2119485498-19 SODIUM CARBONATE	GHS07 Wng Eye Irrit. 2, H319		25 <= x % < 50
CAS: 68439-46-3 ETHOXYLATED ALCOHOL C16-	GHS07, GHS05 Dgr Acute Tox. 4, H302 Eye Dam. 1, H318		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
INDEX: 603-117-00-0 CAS: 67-63-0 EC: 200-661-7 REACH: 01-2119457558-25 PROPAN-2-OL	GHS02, GHS07 Dgr Flam. Liq. 2, H225 Eye Irrit. 2, H319 STOT SE 3, H336	[1]	0 <= 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 contaminated clothing and wash the skin thoroughly with soap and water or a recognised cleaner. 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.

In the event of swallowing :

Do not give the patient anything orally.

In the event of swallowing, if the quantity is small (no more than one mouthful), rinse the mouth with water and consult a doctor. Keep the person exposed at rest. Do not force vomiting.

Seek medical attention immediately, showing the label.

If swallowed accidentally, call a doctor to ascertain whether observation and hospital care will be necessary. Show 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

In the event of a fire, use :

sprayed water or water mist

foam

multipurpose ABC powder

BC powder

carbon dioxide (CO₂)

Chemical powders, carbon dioxide and other extinguishing gas are suitable for small fires.

Unsuitable methods of extinction

In the event of a fire, do not use :

water jet

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

Fire-fighting personnel are to be equipped with autonomous insulating breathing apparatus.

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

Retrieve the product by mechanical means (sweeping/vacuuming) : do not generate dust.

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 :

Handle in well-ventilated areas.

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. Avoid eye contact with this mixture at all times.

Packages which have been opened must be reclosed carefully and stored in an upright position.

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

Storage

Keep out of reach of children.

Keep the container tightly closed in a dry, well-ventilated place.

Store at a temperature between 5°C and 35°C.

Packaging

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

7.3. Specific end use(s)

No data available.

SECTION 8. EXPOSURE CONTROLS/PERSONAL PROTECTION

8.1. Control parameters

Occupational exposure limits:

UK / WEL (Workplace exposure limits, EH40/2005, 2011) :

CAS	TWA :	STEL :	Ceiling :	Definition :	Criteria :
67-63-0	400 ppm 999 mg/m3	500 ppm 1250 mg/m3			

8.2. Exposure controls

Used at the dose of use, the product is not classified and does not require the wearing of personal protective equipment.

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. Prescription glasses are not considered as protection.

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

Hand protection

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

Gloves must be selected according to the application and duration of use at the workstation.

Protective gloves need to be selected according to their suitability for the workstation in question : other chemical products that may be handled, necessary physical protections (cutting, pricking, heat protection), level of dexterity required.

Type of gloves recommended :

Nitrile rubber (butadiene-acrylonitrile copolymer rubber (NBR))

Recommended properties :

Impervious gloves 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

Suitable type of protective clothing :

Wear protective clothing against solid chemicals and particles suspended in the air (type 5) in accordance with standard EN13982-1 to prevent 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.

Respiratory protection

Avoid breathing dust.

Type of FFP mask :

Wear a disposable half-mask dust filter in accordance with standard EN149.

SECTION 9. PHYSICAL AND CHEMICAL PROPERTIES

9.1. Information on basic physical and chemical properties

General information :

Physical state :	Powder or dust.
Geruch/	Almond
Color :	White powder

Important health, safety and environmental information

pH :	Not relevant.
Boiling point/boiling range :	Not relevant.
Flash point interval :	Not relevant.
Vapour pressure (50°C):	Not relevant.
Density :	0.72 +/- 0.03 g/mL
Water solubility :	Soluble.
Melting point/melting range :	Not relevant.
Self-ignition temperature :	Not relevant.

Decomposition point/decomposition range : Not relevant.

9.2. Other information

pH at 0.5% in aqueous solution : 11.2 +/- 0.5 (demineralized water)
pH at 0.5% in aqueous solution : 10.3 +/- 0.5 (hard water)

SECTION 10. STABILITY AND REACTIVITY

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

When exposed to high temperatures, the mixture can release hazardous decomposition products, such as carbon monoxide and dioxide, fumes and nitrogen oxide.

10.4. Conditions to avoid

Avoid :

formation of dusts

Dusts can form an explosive mixture with air.

To handle water-soluble doses with wet hands

10.5. Incompatible materials

Aluminium

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

May cause irreversible damage to the skin: namely inflammation of the skin or the formation of erythema and eschar or oedema following exposure up to four hours.

May have irreversible effects on the eyes, such as tissue damage in the eye, or serious physical decay of sight, which is not fully reversible by the end of observation at 21 days.

Serious eye damage is typified by the destruction of cornea, persistent corneal opacity and iritis.

11.1.1. Substances

Acute toxicity :

DIDECYLDIMETHYLAMMONIUM CHLORIDE (CAS: 7173-51-5)

Oral route : LD50 = 329 mg/kg
Species : Rat
OECD Guideline 401 (Acute Oral Toxicity)

Dermal route : LD50 > 1000 mg/kg
Species : Rabbit

Skin corrosion/skin irritation :

DIDECYLDIMETHYLAMMONIUM CHLORIDE (CAS: 7173-51-5)

Corrosivity : Causes severe skin burns.
OECD Guideline 404 (Acute Dermal Irritation/ Corrosion)
Effect observed : Overall irritation score
Species : rabbit
OECD Guideline 404 (Acute Dermal Irritation / Corrosion)

Respiratory or skin sensitisation :

DIDECYLDIMETHYLAMMONIUM CHLORIDE (CAS: 7173-51-5)

Buehler Test : Non-sensitiser.
Species : Guinea pig
Other guideline

Germ cell mutagenicity :

DIDECYLDIMETHYLAMMONIUM CHLORIDE (CAS: 7173-51-5)

Mutagenesis (in vivo) : Negative.
Species : Rat
OECD Guideline 475 (Mammalian Bone Marrow Chromosome Aberration Test)

Mutagenesis (in vitro) : Negative.
Species : Bacteria
OECD Guideline 471 (Bacterial Reverse Mutation Assay)

Ames test (in vitro) : Negative.

11.1.2. Mixture

Acute Toxicity

Product in solution at 0,5% : According to OECD Guideline 401, LDO > 40 000mg/kg – Not dangerous in case of accidental ingestion.

Pure product : According to OECD Guideline 401, The preparation is not dangerous if swallowed accidentally – DL0 > 2000 mg/ Kg.

According to OECD Guideline 403, no acute inhalation toxicity is observed over a 4-hour exposure period : LC50 > 0.065 mg/L.

Skin corrosion/skin irritation :

Product in 5.5% solution : According to OECD Guideline 404, 0.5% solution in distilled water is non-irritating to the skin.

Serious damage to eyes/irritation :

Product in 0.5% solution : According to OECD Guideline 405, 0.5% solution preparation in distilled water is non irritating to the eye.

Respiratory or skin sensitisation :

Contains at least one sensitizing substance. May Produce an allergic reaction.

Product in 0.5% solution : Non sensitizing skin contact preparation according to OECD Test Guideline 406 (evaluation of skin sensitization potential in guinea pigs).

Monograph(s) from the IARC (International Agency for Research on Cancer) :

CAS 67-63-0 : IARC Group 3 : The agent is not classifiable as to its carcinogenicity to humans.

SECTION 12. ECOLOGICAL INFORMATION

Harmful 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

ETHOXYLATED ALCOHOL C10 (CAS : 26183-52-8)

Crustacean toxicity : EC50 = 15 mg/l
Species : Daphnia sp.
Duration of exposure : 48 h
OECD Guideline 202 (Daphnia sp. Acute Immobilisation Test)

Algae toxicity : ECr50 = 19,6 mg/l
Duration of exposure : 72 h
OECD Guideline 201 (Alga, Growth Inhibition Test)

DIDECYLDIMETHYLAMMONIUM CHLORIDE (CAS: 7173-51-5)

Fish toxicity : LC50 = 0.5 mg/l
Factor M = 1

Species : Brachydanio rerio

Duration of exposure : 96 h

Crustacean toxicity :

EC50 = 0.03 mg/l

Species : Daphnia magna

Duration of exposure : 48 h

NOEC = 0.021 mg/l

Species : Daphnia magna

Duration of exposure : 21 days

OECD Guideline 211 (Daphnia magna Reproduction test)

Algae toxicity :

ECr50 = 0.06 mg/l

Species : Selenastrum capricornutum

Duration of exposure : 96 h

12.1.2. Mixtures

Fish toxicity :

No observed effect.

10 < LC50 <= 100 mg/l

Species : Danio rerio

Duration of exposure : 96 h

OECD Guideline 203 (Fish, Acute Toxicity Test)

EC50 = 2.9 mg/l

Duration of exposure : 48 h

ISO 6341 15 (Water quality - Determination of the Inhibition of the Mobility of Daphnia magna Straus (Cladocera, Crustacea))

ECr50 = 39.6 mg/l

Duration of exposure : 72 h

ISO 8692 (Water Quality - Fresh Water Algal Growth Inhibition Test with Scenedesmus subspicatus and Selenastrum capricornutum)

EC10 = 6.4 mg/l

Duration of exposure : 72 h

ISO 8692 (Water Quality - Fresh Water Algal Growth Inhibition Test with Scenedesmus subspicatus and Selenastrum capricornutum)

12.2. Persistence and degradability

Surfactants in this preparation comply with the standards of biodegradability as defined in Regulation (EC) No 648/2004 on detergents.

The data proving this statement shall be made available to the competent authorities of the Member States and shall be supplied to them at their express request or at the request of the detergent manufacturer.

12.2.1 Substances

DIDECYLDIMETHYLAMMONIUM CHLORIDE (CAS: 7173-51-5)

Biodegradability : Rapidly degradable.

ETHOXYLATED ALCOHOL C10 (CAS : 26183-52-8)

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

12.2.2 Mixtures

This product is fully biodegradable according to OECD 302B criteria : biodegradation greater than 70% in 28 days (94%).

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.

Give to a certified disposal contractor.

SECTION 14. TRANSPORT INFORMATION

Exempt from transport classification and labelling.

14.1. UN number

-

14.2. UN proper shipping name

-

14.3. Transport hazard class(es)

-

14.4. Packing group

-

14.5. Environmental hazards

-

14.6. Special precautions for user

-

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. 2018/669 (ATP 11).

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

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.
H411	Toxic to aquatic life with long lasting effects.

Abbreviations :

WGK : Wassergefährdungsklasse (Water Hazard Class).

GHS05 : Corrosion

PBT: Persistent, bioaccumulable and toxic.

vPvB : Very persistent, very bioaccumulable.

SVHC : Substances of very high concern.