



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 : ENZYMATIC DISINFECTANT DETERGENT INSTRUMENTS
Product code : 2760000.

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

Cleaning and pre-disinfection of medical devices
For further information on product indication, please see the label.

1.3. Details of the supplier of the safety data sheet

Registered company name : PROCLINIC S.A..
Address : C/Botánica, 137 - 139 (Poligono Gran Via Sur).08908.L'Hospitalet de Llobregat.España.
Telephone : 00.34.900.39.39.39. Fax : .
mangeles.bravo@proclinic.es

1.4. Emergency telephone number : +34 91 562 04 20.

Association/Organisation : SMIT (Servicio Médico de Información Toxicológica) - España.

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 - Acute hazard, Category 1 (Aquatic Acute 1, H400).
Hazardous to the aquatic environment - Chronic hazard, Category 1 (Aquatic Chronic 1, H410).
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).
This mixture being intended for professional use only, the labelling for contents under detergent regulation does not appear on the label but is resumed in section 15

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

Hazard pictograms :



GHS05

GHS09

Signal Word :

DANGER

Product identifiers :

EC 619-057-3 N,N-DIDECYL-N-METHYL-POLY(OXYETHYL)AMMONIUM PROPIONATE
CAS 71060-57-6 ALCOHOLS, C8-10, ETHOXYLATED

Hazard statements :

H314 Causes severe skin burns and eye damage.
H410 Very toxic 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 :

P301 + P330 + P331 IF SWALLOWED: rinse mouth. Do NOT induce vomiting.

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 or doctor/physician.

Precautionary statements - Disposal :

P501 Dispose of unused product and its container as hazardous waste.

2.3. 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>

No other hazard identified in the current state of knowledge.

SECTION 3 : COMPOSITION/INFORMATION ON INGREDIENTS

Title for H and EUH statements: see § 16.

3.2. Mixtures

Composition :

| Identification | (EC) 1272/2008 | Note | % |
|--|---|------|---------------------|
| CAS: 94667-33-1 EC: 619-057-3 REACH: 01-2119950327-36 N,N-DIDECYL-N-METHYL-POLY(OXYETHYL)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 | | 10 \leq x % < 25 |
| CAS: 71060-57-6 ALCOHOLS, C8-10, ETHOXYLATED | GHS07, GHS05 Dgr Acute Tox. 4, H302 Eye Dam. 1, H318 | | 2.5 \leq x % < 10 |
| CAS: 107-21-1 EC: 203-473-3 REACH: 01-2119456816-28 ETHYLENE GLYCOL | GHS07, GHS08 Wng Acute Tox. 4, H302 STOT RE 2, H373 | [1] | 0 \leq x % < 2.5 |
| CAS: 90640-43-0 EC: 292-562-0 REACH: 01-2119957843-25 AMINES, N-C12-14-ALKYLTRIMETHYLENEDI- | GHS06, GHS05, GHS09, GHS08 Dgr Acute Tox. 3, H301 Skin Corr. 1B, H314 STOT RE 1, H372 Aquatic Acute 1, H400 M Acute = 100 Aquatic Chronic 1, H410 M Chronic = 1 | | 0 \leq x % < 2.5 |
| CAS: 18472-51-0 EC: 242-354-0 D-GLUCONIC ACID, COMPOUND WITH N,N"-BIS(4-CHLOROPHENYL)-3,12-DIIMINO-2,4,11,13-TETRAAZATETRADECANEDIAMIDINE (2:1) | GHS05, GHS09 Dgr Eye Dam. 1, H318 Aquatic Acute 1, H400 M Acute = 10 Aquatic Chronic 1, H410 M Chronic = 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.
Reminder: any unconscious person must be placed in the lateral recovery position.

4.1. Description of first aid measures

In the event of exposure by inhalation :

Move the person away from the place of exposure and take him/her outside.

In the event of splashes or contact with eyes :

If applicable, remove contact lenses.

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

Take care not to introduce rinsing water in the undamaged eye.

Additional treatment to be provided immediately in an eye clinic or by an ophthalmologist. Show this container or label.

Continue rinsing until medical advice is obtained.

In the event of splashes or contact with skin :

If possible, wear rubber gloves when giving first aid.

Remove all contaminated or stained clothing immediately. Do not use them again until they have been decontaminated.

Rinse thoroughly with water during 15 minutes.

If the contaminated area is widespread and/or there is damage to the skin, call the service N°100, an hospitalisation is required. Show the label to the doctor.

In the event of swallowing :

Rinse out the mouth, do not allow to drink, do not induce vomiting. Calm the person down and transfer immediately to hospital or doctor. Show the label to the doctor.

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

Cf. § 11

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

Refer to the recommendation of the doctor.

SECTION 5 : FIREFIGHTING MEASURES

5.1. Extinguishing media

Suitable methods of extinction

Any extinguishing agents are authorized: foam, sand, carbon dioxide, water, powder.

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.

5.3. Advice for firefighters

Use autonomous insulating breathing apparatus and a full protective suit.

SECTION 6 : ACCIDENTAL RELEASE MEASURES

6.1. Personal precautions, protective equipment and emergency procedures

Consult the safety measures listed under headings 7 and 8.

Keep away any unprotected person.

Avoid all contact with skin or eyes.

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.

Do not get rid in natural spaces (waterways, ground and vegetations...)

6.3. Methods and material for containment and cleaning up

Absorb any spilled product with absorbent non-combustible materials, and sweep away or remove with a shovel. Put any waste in drums for disposal. Do not mix with any other waste. Wash the contaminated surface thoroughly with water.

Do not collect the product for re-use.

6.4. Reference to other sections

Disposal considerations: see section 13.

SECTION 7 : HANDLING AND STORAGE

7.1. Precautions for safe handling

Product for external use - do not swallow.

Avoid all contact with skin, eyes and clothes.

Handle in accordance with user instructions on label

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.
Safety shower, eye bath and water point nearby.
Change any contaminated or wet work clothes immediately.
Ensure room is well ventilated.

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
Store ONLY in the original package.
Store between + 5 °C and + 35 °C in a dry, well ventilated place
Do not use after the expiry date mentioned on the packaging.
Keep out of the reach of children

7.3. Specific end use(s)

For professional use only
Refer to paragraph 1 for product indication

SECTION 8 : EXPOSURE CONTROLS/PERSONAL PROTECTION

The information in this chapter refers to the product specifically described in this document. If the product is handled and/or exposed simultaneously with other chemical agents, these must be taken into consideration when choosing personal safety equipment.

The Exposure Threshold Limit Value and the Average Exposure Value given below are quoted by the CAS number of the substance. Paragraph 3 details the chemical name corresponding to the CAS number.

8.1. Control parameters**Occupational exposure limits :**

- European Union (2009/161/EU, 2006/15/EC, 2000/39/EC, 98/24/EC)

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

- Germany - AGW (BAuA - TRGS 900, 21/06/2010) :

| CAS | VME : | VME : | Excess | Notes |
|----------|-------|--------------------|--------|-------|
| 107-21-1 | | 10 ppm 26 mg/m3 | | 2() |

- Belgium (Order of 19/05/2009, 2010) :

| CAS | TWA : | STEL : | Ceiling : | Definition : | Criteria : |
|----------|-------|--------|-----------|--------------|------------|
| 107-21-1 | - | - | 101 | - | - |

- France (INRS - ED984 :2012) :

| CAS | VME-ppm : | VME-mg/m3 : | VLE-ppm : | VLE-mg/m3 : | Notes : | TMP No : |
|----------|-----------|-------------|-----------|-------------|---------|----------|
| 107-21-1 | 20 | 52 | 40 | 104 | * | 84 |

- Spain (Instituto Nacional de Seguridad e Higiene en el Trabajo (INSHT), Mayo 2010) :

| CAS | TWA : | STEL : | Ceiling : | Definition : | Criteria : |
|----------|--------------------|---------------------|-----------|--------------|------------|
| 107-21-1 | 20 ppm 52 mg/m3 | 40 ppm 104 mg/m3 | | vía dérmica | |

- Poland (2014) :

| CAS | TWA : | STEL : | Ceiling : | Definition : | Criteria : |
|----------|----------|----------|-----------|--------------|------------|
| 107-21-1 | 15 mg/m3 | 50 mg/m3 | | | |

- Czech Republic (Regulation No. 361/2007) :

| CAS | TWA : | STEL : | Ceiling : | Definition : | Criteria : |
|----------|----------|-----------|-----------|--------------|------------|
| 107-21-1 | 50 mg/m3 | 100 mg/m3 | | D | |

- Slovakia (Regulation No. 300/2007) :

| CAS | TWA : | STEL : | Ceiling : | Definition : | Criteria : |
|----------|--------------------|-----------|-----------|--------------|------------|
| 107-21-1 | 20 ppm 52 mg/m3 | 104 mg/m3 | | K | |

- Switzerland (SUVA 2015) :

| CAS | VME | VLE | Valeur plafond | Notations |
|----------|--------------------|--------------------|----------------|-----------|
| 107-21-1 | 10 ppm 26 mg/m3 | 20 ppm 52 mg/m3 | | R SSC |

- UK / WEL (Workplace exposure limits, EH40/2005, 2007) :

| CAS | TWA : | STEL : | Ceiling : | Definition : | Criteria : |
|----------|--------------------|---------------------|-----------|--------------|------------|
| 107-21-1 | 20 ppm 52 mg/m3 | 40 ppm 104 mg/m3 | | Sk | |

8.2. Exposure controls

Suitable technical inspections

Ensure the rooms are well-ventilated. Atmospheric concentrations at the workplace must not exceed the limit values given for normal conditions of use.

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.

Provide eye washes in workshops.

If necessary, the nearest water supply

- 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.

Neoprene or nitrile gloves are particularly recommended.

Gloves must be replaced immediately if they show signs of wear and tear.

- 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.

Change wet and dirty work clothes immediately.

- Respiratory protection

In case of insufficient ventilation, with the risk of exceeding the TLVs (Threshold Limit values)/TWA, wear suitable breathing apparatus (mask which filters organic vapours - type A protection)

SECTION 9 : PHYSICAL AND CHEMICAL PROPERTIES**9.1. Information on basic physical and chemical properties****General information :**

| | |
|------------------|----------------|
| Physical state : | Fluid liquid. |
| Colour: | blue |
| Odour: | sweet-smelling |

Important health, safety and environmental information

| | |
|---|-----------------|
| pH : | Not stated. |
| | Slightly basic. |
| Boiling point/boiling range : | Not specified. |
| Flash point interval : | Not relevant. |
| Vapour pressure (50°C) : | Not relevant. |
| Density : | +/- 1.0 |
| Water solubility : | Soluble. |
| Melting point/melting range : | Not specified. |
| Self-ignition temperature : | Not specified. |
| Decomposition point/decomposition range : | Not specified. |

9.2. Other information

| | |
|------------------|---------|
| pH pure product: | 6.0-9.5 |
|------------------|---------|

SECTION 10 : STABILITY AND REACTIVITY**10.1. Reactivity**

No hazardous reaction if the instructions/indications for storage and handling 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

Cf. § 10.1 and 10.2

10.4. Conditions to avoid

Avoid :

- frost

10.5. Incompatible materials

Do not mix with other products.

10.6. Hazardous decomposition products

At high temperatures, dangerous decomposition products may be produced, such as fumes, carbon dioxide and carbon monoxide, nitrogen oxide.

SECTION 11 : TOXICOLOGICAL INFORMATION

11.1. Information on toxicological effects

11.1.1. Substances

Not specified

11.1.2. Mixture

The toxicological data of the mixture (resulting from studies or in accordance with conventional methods) are outlined below.

Acute toxicity :

Acute toxicity estimate (ATE)* :

Oral ATE : > 2000 mg/kg

* according to the method of calculation describe in the CLP regulation (Classification, Labelling, Packaging) Part 3 Chapter 3.1 based on the data of the different components present in the product.

If swallowed: burns to upper digestive and respiratory tract, abdominal pain, vomiting blood, serious lesions to mucous membranes and risk of perforation.

Skin corrosion/skin irritation :

Severe skin irritation, burns, redness, dermatitis, necrosis of tissue.

Serious damage to eyes/eye irritation :

Serious eyes damage.

Burns, characterized by discomfort or pain, excessive blinking, lacrimation and redness, swelling of the conjunctiva.

Respiratory or skin sensitisation :

On the basis of the available data, classification criteria are not reached.

Germ cell mutagenicity :

On the basis of the available data, classification criteria are not reached.

Carcinogenicity :

On the basis of the available data, classification criteria are not reached.

Reproductive toxicant :

On the basis of the available data, classification criteria are not reached.

Specific target organ systemic toxicity - single exposure :

On the basis of the available data, classification criteria are not reached.

Specific target organ systemic toxicity - repeated exposure :

On the basis of the available data, classification criteria are not reached.

Aspiration hazard :

On the basis of the available data, classification criteria are not reached.

SECTION 12 : ECOLOGICAL INFORMATION

Following information is based on data from the compounds.

Avoid any product release into waterways.

12.1. Toxicity

12.1.1. Substances

Not specified

12.1.2. Mixtures

Acute toxicity:

Very toxic to aquatic organisms.

Chronic toxicity:

Very toxic to aquatic life with long lasting effects.

12.2. Persistence and degradability

The surfactant(s) contained in this preparation complies(comply) with the biodegradability criteria as laid down in Regulation (EC) No.648/2004 on detergents.

Data to support this assertion are held at the disposal of the competent authorities of the Member States and will be made available to them, at their direct request or at the request of a detergent manufacturer.

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.

The packages must not be reused.

Do not pour into waterways.

13.1. Waste treatment methods

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.

Soiled packaging :

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

Give to a certified disposal contractor.

Codes of wastes (Decision 2001/573/EC, Directive 2006/12/EEC, Directive 94/31/EEC on hazardous waste) :

18 01 06 * chemicals consisting of or containing dangerous substances

For information :

The waste code is given for indicative purposes.

The waste code must be determined by the user, according to the application of the product.

18 = Wastes from human or animal health care and/or related research (except kitchen and restaurant wastes not arising from immediate health care)

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 - ICAO/IATA 2016).

14.1. UN number

1903

14.2. UN proper shipping name

UN1903=DISINFECTANT, LIQUID, CORROSIVE, N.O.S.

(n,n-didecyl-n-methyl-poly(oxyethyl)ammonium propionate)

14.3. Transport hazard class(es)

- Classification :



8

14.4. Packing group

II

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 |
|---------|-------|------|----------|-------|--------|----|---------|----|------|--------|
|---------|-------|------|----------|-------|--------|----|---------|----|------|--------|

| | | | | | | | | | | |
|------|-------|---------|----------|----------|----------|---------|-------|---------|----|---|
| | 8 | C9 | II | 8 | 80 | 1 L | 274 | E2 | 2 | E |
| IMDG | Class | 2°Label | Pack gr. | LQ | EMS | Provis. | EQ | | | |
| | 8 | - | II | 1 L | F-A,S-B | 274 | E2 | | | |
| IATA | Class | 2°Label | Pack gr. | Passager | Passager | Cargo | Cargo | note | EQ | |
| | 8 | - | II | 851 | 1 L | 855 | 30 L | A3 A803 | E2 | |
| | 8 | - | II | Y840 | 0.5 L | - | - | A3 A803 | E2 | |

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

Not applicable

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 (EC) No. 1272/2008 and its amendments.

- Container information:

No data available.

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

- 5 % or over but less than 15 % : nonionic surfactants
- enzymes
- disinfectants
- perfumes

15.2. Chemical safety assessment

Information from the chemical safety assessment of substances present in the product is included in the appropriate sections of this safety data sheet, whenever necessary.

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.

It is at all times the responsibility of the user to take all necessary measures to comply with legal requirements and local regulations.

It is recommended that the information contained in this safety data sheet is provided to the users, if necessary in an appropriate form.

This information relates to the specifically designated product and may not be valid in combination with any another product. The product must not be used for applications other than those specified in heading 1 without having first obtained written handling instructions.

The information in this safety data sheet must be regarded as a description of the safety requirements relating to the mixture.

Wording of the phrases mentioned in section 3 :

| | |
|------|---|
| H301 | Toxic if swallowed. |
| H302 | Harmful if swallowed. |
| H314 | Causes severe skin burns and eye damage. |
| H318 | Causes serious eye damage. |
| H372 | Causes damage to organs through prolonged or repeated exposure . |
| 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. |

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

PBT: Persistent, bioaccumulable and toxic.

vPvB : Very persistent, very bioaccumulable.

SVHC : Substances of very high concern.