

**GRANULOTEC LIQUID - ART.11573**



**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 : GRANULOTEC LIQUID

Product code : ART.11573.

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

For dental professional use only.

To mix with GRANULOTEC POWDER.

**1.3. Details of the supplier of the safety data sheet**

Registered company name : PRODUITS DENTAIRES SA.

Address : Rue des Bosquets 18 .1800 .Vevey .Switzerland.

Telephone : +41 21 921 26 31. Fax : +41 21 921 39 79.

info@pdsa.ch

http://www.pdsa.ch

**1.4. Emergency telephone number : +41 21 921 26 31.**

Association/Organisation : .

**SECTION 2 : HAZARDS IDENTIFICATION**

**2.1. Classification of the substance or mixture**

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

Acute oral toxicity, Category 3 (Acute Tox. 3, H301).

Acute dermal toxicity, Category 3 (Acute Tox. 3, H311).

Acute inhalation toxicity, Category 3 (Acute Tox. 3, H331).

Skin corrosion, Category 1B (Skin Corr. 1B, H314).

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

Skin sensitisation, Category 1 (Skin Sens. 1, H317).

Germ cell mutagenicity, Category 2 (Muta. 2, H341).

Carcinogenicity, Category 1B (Carc. 1B, H350).

Specific target organ toxicity (single exposure), Category 3 (STOT SE 3, H335).

Specific target organ toxicity (repeated exposure), Category 2 (STOT RE 2, H373).

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**

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

Hazard pictograms :



GHS06



GHS05



GHS08

Signal Word :

DANGER

Product identifiers :

604-001-00-2

PHENOL

604-031-00-6

GUAIACOL

605-001-00-5

FORMALDEHYDE

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EC 214-646-8

ACETATE DE DEXAMETHASONE

Additional labeling :

For professional use only.

Hazard statements :

H301 + H311 + H331

Toxic if swallowed, in contact with skin or if inhaled.

H314

Causes severe skin burns and eye damage.

H317

May cause an allergic skin reaction.

H335

May cause respiratory irritation.

H341

Suspected of causing genetic defects .

H350

May cause cancer .

H373

May cause damage to organs through prolonged or repeated exposure (if inhaled, if swallowed, in contact with skin).

Precautionary statements - Prevention :

P201

Obtain special instructions before use.

P202

Do not handle until all safety precautions have been read and understood.

P260

Do not breathe vapours.

P264

Wash hands thoroughly after handling.

P280

Wear protective gloves according to the hygienic rules in force in dental surgeries.

Precautionary statements - Response :

P301 + P310

IF SWALLOWED: Immediately call a POISON CENTER/doctor/...

P301 + P330 + P331

IF SWALLOWED: Rinse mouth. Do NOT induce vomiting.

P302 + P352

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

P304 + P340

IF INHALED: Remove person to fresh air and keep comfortable for breathing.

P305 + P351 + P338

IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.

P308 + P313

IF exposed or concerned: Get medical advice/attention.

P311

Call a POISON CENTER/doctor/...

P314

Get medical advice/attention if you feel unwell.

P333 + P313

If skin irritation or rash occurs: Get medical advice/attention.

P361 + P364

Take off immediately all contaminated clothing and wash it before reuse.

P362 + P364

Take off contaminated clothing and wash it before reuse.

Precautionary statements - Disposal :

P501

Dispose of contents/container according to the hygienic rules in force in dental surgeries and according to the legislation in force.

**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>

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: 604-001-00-2 | GHS06, GHS08, GHS05 | [1]  | 25 <= x % < 50 |
| CAS: 108-95-2       | Dgr                 | [2]  |                |
| EC: 203-632-7       | Muta. 2, H341       |      |                |
|                     | Acute Tox. 3, H331  |      |                |
| PHENOL              | Acute Tox. 3, H311  |      |                |
|                     | Acute Tox. 3, H301  |      |                |
|                     | STOT RE 2, H373     |      |                |
|                     | Skin Corr. 1B, H314 |      |                |

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|  |   |                   |                |
|--|---|-------------------|----------------|
| INDEX: 604-031-00-6<br>CAS: 90-05-1<br>EC: 201-964-7<br><br>GUAIACOL     | GHS07<br>Wng<br>Acute Tox. 4, H302<br>Eye Irrit. 2, H319<br>Skin Irrit. 2, H315   |                   | 25 <= x % < 50 |
| INDEX: 605-001-00-5<br>CAS: 50-00-0<br>EC: 200-001-8<br><br>FORMALDEHYDE | GHS06, GHS05, GHS08<br>Dgr<br>Acute Tox. 3, H301<br>Acute Tox. 3, H311<br>Skin Corr. 1B, H314<br>Skin Sens. 1, H317<br>Acute Tox. 3, H331<br>STOT SE 3, H335<br>Muta. 2, H341<br>Carc. 1B, H350 | B D<br>[1]<br>[2] | 10 <= x % < 25 |
| CAS: 1177-87-3<br>EC: 214-646-8<br><br>ACETATE DE DEXAMETHASONE          | GHS07, GHS08<br>Wng<br>Skin Sens. 1, H317<br>STOT RE 2, H373  |                   | 0 <= x % < 1   |

**Information on ingredients :**

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

[2] Carcinogenic, mutagenic or reprotoxic (CMR) substance.

**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 exposure by inhalation :**

In the event of massive inhalation, remove the person exposed to fresh air. Keep warm and at rest.

If the person is unconscious, place in recovery position. Notify a doctor in all events, to ascertain whether observation and supportive hospital care will be necessary.

**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 :**

In the event of an allergic reaction, seek medical attention.

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.

Be careful with product which can remain between the skin and the clothes, the watch, the jewels.

Wash the skin thoroughly with soap and fresh water.

**In the event of swallowing :**

In the event of swallowing, if the quantity is small (no more than one mouthful), rinse the mouth with water, administer activated medical charcoal and consult a doctor.

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

Keep the person exposed at rest. Do not force vomiting.

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

Irritation, corrosion, cough, breathing difficulties, dizziness, migraine.

**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**

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In the event of a fire, use :

- foam
- carbon dioxide (CO<sub>2</sub>)
- powder

**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 (CO<sub>2</sub>)
- gas / irritant vapours
- formaldehyde vapors

**5.3. Advice for firefighters**

Wear self-contained 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 inhaling the vapors.

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).

Avoid inhaling the vapors.

Avoid any contact with the skin and 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.

Prevent any material from entering drains or waterways.

**6.3. Methods and material for containment and cleaning up**

Neutralise with an alkaline decontaminant, such as an aqueous solution of sodium carbonate or similar.

Clean preferably with a detergent, do not use solvents.

**6.4. Reference to other sections**

No data available.

**SECTION 7 : HANDLING AND STORAGE**

Respect storage precautions mentioned on the packaging or in the instructions for use.

**7.1. Precautions for safe handling**

Always wash hands after handling.

The persons who have medical histories of cutaneous reactions must use this product with all the required precautions.

Avoid any contact with skin and eyes.

Avoid inhaling vapours.

**Fire prevention :**

Prevent access by unauthorised personnel.

**Recommended equipment and procedures :**

For personal protection, see section 8.

Do not inhale vapours.

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

**GRANULOTEC LIQUID - ART.11573****7.2. Conditions for safe storage, including any incompatibilities**

Keep in the original container, respect the storage temperatures mentioned on the container, the leaflet and the box.

**Storage**

Respect storage precautions mentioned on the packaging or in the instructions for use.

**Packaging**

Always conserve in the original packaging.

**7.3. Specific end use(s)**

Consult instructions for use enclosed.

**SECTION 8 : EXPOSURE CONTROLS/PERSONAL PROTECTION****8.1. Control parameters****Occupational exposure limits :**

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

| CAS      | VME-mg/m <sup>3</sup> | VME-ppm | VLE-mg/m <sup>3</sup> | VLE-ppm | Notes |
|----------|-----------------------|---------|-----------------------|---------|-------|
| 108-95-2 | 8                     | 2       | 16                    | 4       | Peau  |

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

| CAS      | TWA : | STEL : | Ceiling : | Definition :  | Criteria : |
|----------|-------|--------|-----------|---------------|------------|
| 108-95-2 | 5 ppm |        |           | Skin; A4; BEI |            |
| 50-00-0  |       |        | 0,3 ppm   | SEN; A2       |            |

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

| CAS      | VME : | VME :                             | Excess | Notes |
|----------|-------|-----------------------------------|--------|-------|
| 108-95-2 |       | 2 ppm<br>8 mg/m <sup>3</sup>      |        | 2(II) |
| 50-00-0  |       | 0,3 ppm<br>0,37 mg/m <sup>3</sup> |        | 2(I)  |

- France (INRS - ED984 :2012) :

| CAS      | VME-ppm : | VME-mg/m <sup>3</sup> : | VLE-ppm : | VLE-mg/m <sup>3</sup> : | Notes : | TMP No : |
|----------|-----------|-------------------------|-----------|-------------------------|---------|----------|
| 108-95-2 | 2         | 7.8                     | 4         | 15.6                    | *       | -        |
| 50-00-0  | 0.5       | -                       | 1         | -                       | C3      | 43       |

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

| CAS      | TWA :                          | STEL :                         | Ceiling : | Definition : | Criteria : |
|----------|--------------------------------|--------------------------------|-----------|--------------|------------|
| 108-95-2 | 2 ppm<br>7,8 mg/m <sup>3</sup> |                                |           | Sk           |            |
| 50-00-0  | 2 ppm<br>2,5 mg/m <sup>3</sup> | 2 ppm<br>2,5 mg/m <sup>3</sup> |           |              |            |

**8.2. Exposure controls****Personal protection measures, such as personal protective equipment**

Pictogram(s) indicating the obligation of wearing personal protective equipment (PPE) :

**- Eye / face protection**

Avoid contact with eyes.

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

**- Hand protection**

Wear gloves according to the hygienic rules in force in dental surgeries.

**- Body protection**

Avoid skin contact.

After contact with the product, all parts of the body that have been soiled must be washed.

**- Respiratory protection**

Avoid breathing vapours.

**GRANULOTEC LIQUID - ART.11573****SECTION 9 : PHYSICAL AND CHEMICAL PROPERTIES****9.1. Information on basic physical and chemical properties****General information :**

|                  |  |
|------------------|--|
| Physical state : | Fluid liquid.  |
| Colour:          | yellowish.   |
| Odour:           | Spicy (presence of Formaldehyde, Phenol, and Guaiacol) |

**Important health, safety and environmental information**

|   |   |
|---|---|
| pH :                                      | 3.00 .<br>Slightly acidic.  |
| Boiling point/boiling range :             | Not relevant.   |
| Flash point interval :                    | Not relevant.   |
| Vapour pressure (50°C) :                  | Not relevant.   |
| Density :                                 | 1.075   |
| Miscibility :                             | Ethanol   |
| Water solubility :                        | Insoluble.  |
| Viscosity :                               | 5.4   |
| Viscosity:                                | v < 7 mm <sup>2</sup> /s (40°C)<br>Method for determining the viscosity :<br>DIN 51562-1 (Viscometry - Measurement of kinematic viscosity by means of the Ubbelohde viscometer - Part 1: Viscometer specification and measurement procedure). |
| Melting point/melting range :             | Not relevant.   |
| Self-ignition temperature :               | Not relevant.   |
| Decomposition point/decomposition range : | Not relevant.   |

**9.2. Other information**

No data available.

**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.

Do not use if the expiry date is exceeded.

**10.3. Possibility of hazardous reactions**

No data available.

**10.4. Conditions to avoid**

Avoid :  
- heat

**10.5. Incompatible materials**

Keep away from :  
- acids  
- bases  
- strong oxidising agents

**10.6. Hazardous decomposition products**

The thermal decomposition may release/form :

- carbon monoxide (CO)
- carbon dioxide (CO<sub>2</sub>)
- gas / irritant vapours
- formaldehyde vapors

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**SECTION 11 : TOXICOLOGICAL INFORMATION**

**11.1. Information on toxicological effects**

Toxic if swallowed.

Toxic in contact with the skin.

Toxic by inhalation.

May cause irreversible damage to the skin; namely, visible necrosis through the epidermis and into the dermis, following exposure between three minutes and one hour.

Corrosive reactions are typified by ulcers, bleeding, bloody scabs, and, by the end of observation at 14 days, by discolouration due to blanching of the skin, complete areas of alopecia, and scars.

Respiratory tract irritation may occur, together with symptoms such as coughing, choking and breathing difficulties.

May cause an allergic reaction by skin contact.

Presumed human carcinogen.

Cause for concern owing to the possibility that it may induce heritable mutations in the germ cells of humans.

May cause severe damage to organs in the event of repeated or prolonged exposure.

**11.1.1. Substances**

No toxicological data available for the substances.

**11.1.2. Mixture**

No toxicological data available for the mixture.

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

CAS 50-00-0 : IARC Group 1 : The agent is carcinogenic to humans.

CAS 108-95-2 : IARC Group 3 : The agent is not classifiable as to its carcinogenicity to humans.

**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.

Give to a certified disposal contractor.

**GRANULOTEC LIQUID - ART.11573****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. 2016/1179. (ATP 9)

**- Container information:**

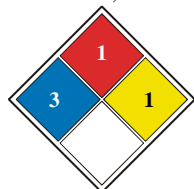
The mixture is contained in packaging that does not exceed 125 ml.

**- Particular provisions :**

No data available.

**- 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 :**

|      |  |
|------|--|
| H301 | Toxic if swallowed.                      |
| H302 | Harmful if swallowed.                    |
| H311 | Toxic in contact with skin.              |
| H314 | Causes severe skin burns and eye damage. |
| H315 | Causes skin irritation.                  |

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|      |   |
|------|---|
| H317 | May cause an allergic skin reaction.                                |
| H319 | Causes serious eye irritation.                                      |
| H331 | Toxic if inhaled.   |
| H335 | May cause respiratory irritation.                                   |
| H341 | Suspected of causing genetic defects .                              |
| H350 | May cause cancer .  |
| H373 | May cause damage to organs through prolonged or repeated exposure . |

**Abbreviations :**

CMR: Carcinogenic, mutagenic or reprotoxic.

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

GHS06 : Skull and crossbones

GHS08 : Health hazard

PBT: Persistent, bioaccumulable and toxic.

vPvB : Very persistent, very bioaccumulable.

SVHC : Substances of very high concern.