

Name : GRANULOTEC POWDER - ART.11563G



SAFETY DATA SHEET

(REACH regulation (EC) n° 1907/2006 - n° 453/2010)

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

1.1. Product identifier

Product name : GRANULOTEC POWDER

Product code : ART.11563G.

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

For dental professional use only.

To mix with GRANULOTEC LIQUID.

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.

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

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

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

Carcinogenicity, Category 2 (Carc. 2, H351).

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.

In compliance with directives 67/548/EEC, 1999/45/EC and their amendments.

Eye irritation (Xi, R 36).

Skin sensitisation (Xi, R 43).

Category 3 carcinogen (Xn, R 40 Carc. Cat. 3).

Aquatic environmental hazard, chronic toxicity: very toxic (N, R 50/53).

This mixture does not present a physical hazard. Refer to the recommendations regarding the other products present on the site.

2.2. Label elements

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

Hazard pictograms :



GHS07



GHS05



GHS09



GHS08

Signal Word :

DANGER

Product identifiers :

CAS 30525-89-4

POLYOXYMETHYLENE

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Hazard statements :

H315	Causes skin irritation.
H317	May cause an allergic skin reaction.
H318	Causes serious eye damage.
H351	Suspected of causing cancer .
H410	Very toxic to aquatic life with long lasting effects.

Precautionary statements - Prevention :

P201	Obtain special instructions before use.
P202	Do not handle until all safety precautions have been read and understood.
P261	Avoid breathing vapours.
P264	Wash hands thoroughly after handling.
P273	Avoid release to the environment.
P280	Wear protective gloves according to the hygienic rules in force in dental surgeries.

Precautionary statements - Response :

P302 + P352	IF ON SKIN: Wash with plenty of soap and 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.
P308 + P313	IF exposed or concerned: Get medical advice/attention.
P332 + P313	If skin irritation occurs: Get medical advice/attention.
P333 + P313	If skin irritation or rash occurs: Get medical advice/attention.
P391	Collect spillage.

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.
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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) >= 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	67/548/EEC	Note	%
INDEX: 030-013-00-7 CAS: 1314-13-2 EC: 215-222-5 ZINC OXIDE	GHS09 Wng Aquatic Acute 1, H400 M Acute = 1 Aquatic Chronic 1, H410 M Chronic = 1	N N;R50/53	[1]	50 <= x % < 100
CAS: 75-47-8 EC: 200-874-5 IODOFORME	GHS07 Wng Acute Tox. 4, H302 Acute Tox. 4, H312 Skin Irrit. 2, H315 Eye Irrit. 2, H319 Acute Tox. 4, H332 STOT SE 3, H335	Xn Xn;R20/21/22 Xi;R36/37/38	[1]	10 <= x % < 25
CAS: 30525-89-4 POLYOXYMETHYLENE	GHS07, GHS05, GHS08 Dgr Acute Tox. 4, H302 Skin Irrit. 2, H315 Skin Sens. 1, H317 Eye Dam. 1, H318 STOT SE 3, H335 Carc. 2, H351	Xn Carc. Cat. 3;R40 Xn;R20/22 Xi;R37/38-R41-R43 F;R11	[2]	2.5 <= x % < 10

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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 and seek medical attention.

In the event of splashes or contact with eyes :

Wash thoroughly with soft, 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.

Wash the skin thoroughly with soap and fresh water.

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

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 and consult a doctor.

Rinse the mouth with water and then drink a lot of water. Seek medical attention.

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

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

Breathing system irritation.

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

In case of very important inhalation of vapors and very strong irritation of lungs, treat with Dexamethasone in spray.

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

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)
- metallic oxide smokes
- formaldehyde vapors
- halogenic compounds

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5.3. Advice for firefighters

Due to the toxicity of the gas emitted on thermal decomposition of the products, 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.

Avoid generating dusts.

Avoid inhaling the vapours.

For first aid worker

First aid workers will be equipped with suitable personal protective equipment (See section 8).

Avoid generating dusts.

Avoid inhaling the vapors.

Avoid any contact with the skin and eyes.

6.2. Environmental precautions

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

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.

Fire prevention :

Prevent access by unauthorised personnel.

Recommended equipment and procedures :

For personal protection, see section 8.

Avoid inhaling dust.

Avoid eye contact with this mixture at all times.

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

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 :

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

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CAS	TWA :	STEL :	Ceiling :	Definition :	Criteria :	
1314-13-2	2 mg/m3	10 mg/m3	-	-	R	
75-47-8	0.6 ppm	-	-	-	-	
- France (INRS - ED984 :2008) :						
CAS	VME-ppm :	VME-mg/m3 :	VLE-ppm :	VLE-mg/m3 :	Notes :	TMP No :
1314-13-2	-	5	-	-	-	-
75-47-8	0.6	10	-	-	-	-
- UK / WEL (Workplace exposure limits, EH40/2005, 2007) :						
CAS	TWA :	STEL :	Ceiling :	Definition :	Criteria :	
75-47-8	0.6 ppm	1 ppm	-	-	-	

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 dust.

Avoid breathing vapours.

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

Physical state :	Powder or dust.
Colour:	pink
Odour:	spicy (presence of Polyoxymethylene and Iodoform)

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 :	0.85
Water solubility :	Insoluble.
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 :

- formation of dusts
- heat
- exposure to light

10.5. Incompatible materials

Keep away from :

- acids
- strong oxidising agents

10.6. Hazardous decomposition products

The thermal decomposition may release/form :

- carbon monoxide (CO)
- carbon dioxide (CO₂)
- metallic oxide smokes
- formaldehyde vapors
- halogenic compounds

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.

May cause an allergic reaction by skin contact.

Suspected human carcinogen.

11.1.1. Substances

Acute toxicity :

POLYOXYMETHYLENE (CAS: 30525-89-4)

Oral route :

LD50 = 592 mg/kg

Species : Rat (recommended by the CLP)

Dermal route :

LD50 = 0 mg/kg

Inhalation route :

LC50 = 1070 mg/m³

Species : Rat (recommended by the CLP)

IODOFORME (CAS: 75-47-8)

Oral route :

LD50 = 355 mg/kg

Species : Rat (recommended by the CLP)

11.1.2. Mixture

No toxicological data available for the mixture.

SECTION 12 : ECOLOGICAL INFORMATION

Very 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

POLYOXYMETHYLENE (CAS: 30525-89-4)

Fish toxicity :

LC50 > 10 mg/l

Duration of exposure : 96 h

Crustacean toxicity :

EC50 = 42 mg/l

Species : Daphnia magna

Duration of exposure : 24 h

IODOFORME (CAS: 75-47-8)

Fish toxicity :

LC50 = 2.92 mg/l

Species : Pimephales promelas

Duration of exposure : 96 h

12.1.2. Mixtures

No aquatic toxicity data available for the mixture.

12.2. Persistence and degradability

12.2.1. Substances

POLYOXYMETHYLENE (CAS: 30525-89-4)

Biodegradability :

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

IODOFORME (CAS: 75-47-8)

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.

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.

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SECTION 14 : TRANSPORT INFORMATION

Exempt from transport classification and labelling.

Transport product in compliance with provisions of the ADR for road, RID for rail, IMDG for sea and ICAO/IATA for air transport (ADR 2013 - IMDG 2012 - ICAO/IATA 2014).

As per Special Provision A197, this product is not considered as hazardous for transport. In case of bulk transport of more than 5KG, UN N° 3077 is 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:

- Directive 67/548/EEC and its adaptations
- Directive 1999/45/EC and its adaptations

- Container information:

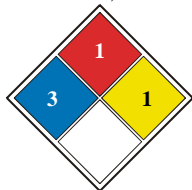
The mixture is contained in packaging that does not exceed 125 ml.

- 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.

In compliance with directives 67/548/EEC, 1999/45/EC and their amendments.

Hazard symbols :



Harmful



Dangerous for the environment

Contains :

CAS 30525-89-4

POLYOXYMETHYLENE

Risk phrase :

R 50/53

Very toxic to aquatic organisms, may cause long-term adverse effects in the aquatic environment.

R 43

May cause sensitisation by skin contact.

R 36

Irritating to eyes.

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R 40	Limited evidence of a carcinogenic effect.
Safety phrase :	
S 36/37	Wear suitable protective clothing and gloves.
S 61	Avoid release to the environment. Refer to special instructions/Safety data sheets.
S 22	Do not breathe dust.
S 26	In case of contact with eyes, rinse immediately with plenty of water and seek medical advice.
S 39	Wear eye/face protection.
S 60	This material and its container must be disposed of as hazardous waste.
S 41	In case of fire and/or explosion do not breathe fumes.
S 57	Use appropriate container to avoid environmental contamination.

Title for H, EUH and R indications mentioned in section 3 :

H302	Harmful if swallowed.
H312	Harmful in contact with skin.
H315	Causes skin irritation.
H317	May cause an allergic skin reaction.
H318	Causes serious eye damage.
H319	Causes serious eye irritation.
H332	Harmful if inhaled.
H335	May cause respiratory irritation.
H351	Suspected of causing cancer .
H400	Very toxic to aquatic life.
H410	Very toxic to aquatic life with long lasting effects.
R 11	Highly flammable.
R 20/21/22	Harmful by inhalation, in contact with skin and if swallowed.
R 20/22	Harmful by inhalation and if swallowed.
R 36/37/38	Irritating to eyes, respiratory system and skin.
R 37/38	Irritating to respiratory system and skin.
R 40.C3	Limited evidence of a carcinogenic effect.
R 41	Risk of serious damage to eyes.
R 43	May cause sensitisation by skin contact.
R 50/53	Very toxic to aquatic organisms, may cause long-term adverse effects in the aquatic environment.

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
GHS07 : Exclamation mark
GHS08 : Health hazard
GHS09 : Environment