

Name: DEVITEC - ART.11401/11402



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 : DEVITEC

Product code : ART.11401/11402.

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

For dental professional use only.

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 4 (Acute Tox. 4, H302).

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).

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

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.

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

Acute oral toxicity: harmful (Xn, R 22).

Acute inhalation toxicity: harmful (Xn, R 20).

Skin irritation (Xi, R 38).

Serious eye damage (Xi, R 41).

Irritant for the respiratory tract (Xi, R 37).

Skin sensitisation (Xi, R 43).

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

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.

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Hazard pictograms :



GHS07



GHS05



GHS08

Signal Word :

DANGER

Product identifiers :

CAS 30525-89-4 POLYOXYMETHYLENE
EC 200-803-8 HYDROCHLORATE DE LIDOCAINE
EC 202-589-1 EUGENOL

Hazard statements :

H302 Harmful if swallowed.
H315 Causes skin irritation.
H317 May cause an allergic skin reaction.
H318 Causes serious eye damage.
H335 May cause respiratory irritation.
H351 Suspected of causing cancer .

Precautionary statements - Prevention :

P201 Obtain special instructions before use.
P261 Avoid breathing dust/fume/gas/mist/vapours/spray.
P264 Wash hands thoroughly after handling.
P280 Wear protective gloves/protective clothing/eye protection/face protection.

Precautionary statements - Response :

P301 + P312 IF SWALLOWED: Call a POISON CENTER or doctor/physician if you feel unwell.
P302 + P352 IF ON SKIN: Wash with plenty of soap and water.
P304 + P340 IF INHALED: Remove victim to fresh air and keep at rest in a position 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.
P330 Rinse mouth.
P332 + P313 If skin irritation occurs: Get medical advice/attention.
P333 + P313 If skin irritation or rash occurs: Get medical advice/attention.

Precautionary statements - Disposal :

P501 Dispose of contents/container to ...

2.3. Other hazards

The mixture does not contain any substances classified as 'Substances of Very High Concern' (SVHC) by the European Chemical 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

3.1. Substances

No substances fulfil the criteria set forth in annexe II section A of the REACH regulation (EC) n° 1907/2006.

3.2. Mixtures

Composition :

Identification	(EC) 1272/2008	67/548/EEC	Note	%
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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]	25 <= x % < 50
CAS: 6108-05-0 EC: 200-803-8 HYDROCHLORATE DE LIDOCAINE	GHS06 Dgr Acute Tox. 3, H301	Xn Xn;R22		25 <= x % < 50
CAS: 97-53-0 EC: 202-589-1 EUGENOL	GHS07 Wng Eye Irrit. 2, H319 Skin Sens. 1B, H317	Xi Xi;R36-R43		10 <= x % < 25
CAS: 87-44-5 EC: 201-746-1 BETA-CARYOPHYLLENE	GHS08 Dgr Asp. Tox. 1, H304	Xn Xn;R65		1 <= x % < 2.5
CAS: 103-41-3 EC: 203-109-3 BENZYL CINNAMATE	GHS07, GHS09 Wng Skin Sens. 1B, H317 Aquatic Chronic 2, H411	Xi,N Xi;R43 N;R51/53		0 <= x % < 1
CAS: 621-82-9 EC: 210-708-3 CINNAMIC ACID				0 <= x % < 1
CAS: 93-28-7 EC: 202-235-6 EUGENYL ACETATE	GHS07 Wng Acute Tox. 4, H302	Xn Xn;R22		0 <= x % < 1
CAS: 7212-44-4 EC: 230-597-5 NEROLIDOL (ISOMER UNSPECIFIED)	GHS07, GHS09 Wng Eye Irrit. 2, H319 Aquatic Acute 1, H400 M Acute = 1 Aquatic Chronic 1, H410 M Chronic = 1	N N;R50/53		0 <= x % < 1

Information on ingredients :

[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.

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.

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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 :

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, 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.

Rinse the mouth with water.

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
- stable foams in alcohols

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)
- nitrogen oxide (NO)
- formaldehyde vapors

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 fire-fighters

Avoid any contact with the skin and eyes.

Avoid inhaling the vapours.

For fire-fighters

Fire-fighters 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

Prevent any material from entering drains or waterways.

6.3. Methods and material for containment and cleaning up

No data available.

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 eye contact with this mixture at all times.

Packages which have been opened must be reclosed carefully.

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

No data available.

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.

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- Respiratory protection

Avoid breathing vapours.

SECTION 9 : PHYSICAL AND CHEMICAL PROPERTIES

9.1. Information on basic physical and chemical properties

General information :

Physical state :	paste.
Colour:	green
Odour:	spicy (presence of Paraformaldehyde and Oil of Cloves)

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 :	1.288
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 :
- heat

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)
- nitrogen oxide (NO)
- formaldehyde vapors

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SECTION 11 : TOXICOLOGICAL INFORMATION

11.1. Information on toxicological effects

Harmful if swallowed.

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.

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

May cause an allergic reaction by skin contact.

Suspected human carcinogen.

11.1.1. Substances

Acute toxicity :

EUGENYL ACETATE (CAS: 93-28-7)

Oral route : DL50 = 1670 mg/kg

BENZYL CINNAMATE (CAS: 103-41-3)

Oral route : DL50 = 3280 mg/kg

EUGENOL (CAS: 97-53-0)

Oral route : DL50 = 2300 mg/kg

HYDROCHLORATE DE LIDOCAINE (CAS: 6108-05-0)

Oral route : DL50 = 292 mg/kg
Species : Mouse

POLYOXYMETHYLENE (CAS: 30525-89-4)

Oral route : DL50 = 592 mg/kg
Species : Rat (recommended by the CLP)

Dermal route : DL50 = 0 mg/kg

Inhalation route : LC50 = 1070 mg/m3
Species : Rat (recommended by the CLP)

11.1.2. Mixture

No toxicological data available for the mixture.

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

CAS 97-53-0 : IARC Group 3 : The agent is not classifiable as to its carcinogenicity to humans.

SECTION 12 : ECOLOGICAL INFORMATION

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

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Duration of exposure : 24 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.

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.

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.

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 2013).

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
- Regulation EC 1272/2008 modified by regulation EC 618/2012

- Container information:

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

- Particular provisions :

No data available.

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- 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

Contains :

EC 202-589-1

EC 200-803-8

CAS 30525-89-4

EUGENOL

HYDROCHLORATE DE LIDOCAINE

POLYOXYMETHYLENE

Risk phrase :

R 43

May cause sensitisation by skin contact.

R 37/38

Irritating to respiratory system and skin.

R 20/22

Harmful by inhalation and if swallowed.

R 40

Limited evidence of a carcinogenic effect.

R 41

Risk of serious damage to eyes.

Safety phrase :

S 26

In case of contact with eyes, rinse immediately with plenty of water and seek medical advice.

S 36/37/39

Wear suitable protective clothing, gloves and eye/face protection.

S 45

In case of accident or if you feel unwell, seek medical advice immediately (show the label where possible).

S 60

This material and its container must be disposed of as hazardous waste.

S 9

Keep container in a well-ventilated place.

S 24

Avoid contact with skin.

S 41

In case of fire and/or explosion do not breathe fumes.

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

H301

Toxic if swallowed.

H302

Harmful if swallowed.

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H304	May be fatal if swallowed and enters airways.
H315	Causes skin irritation.
H317	May cause an allergic skin reaction.
H318	Causes serious eye damage.
H319	Causes serious eye irritation.
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.
H411	Toxic to aquatic life with long lasting effects.
R 11	Highly flammable.
R 20/22	Harmful by inhalation and if swallowed.
R 22	Harmful if swallowed.
R 36	Irritating to eyes.
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.
R 51/53	Toxic to aquatic organisms, may cause long-term adverse effects in the aquatic environment.
R 65	Harmful: may cause lung damage if swallowed.

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