

Swiss MediTec



Safety data sheet
(REACH regulation (EC) Nr 1907/2006 -Nr 453/2010)

Revision: 05.11.2015

Product: Medi-Devit (Paste), Art.Nr.10015

Section 1: Identification of the substance/mixture and of the company/undertaking

1.1 Product identifier

Product name: Medi-Devit/Paste

Article number: 10015/10015-10

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

Application of the substance / For dental professionals use only

1.3 Details of the supplier of the safety data sheet

Manufacturer/Supplier: Swiss MediTec,

POB 513, 6162 Finsterwald; Switzerland

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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.

Classification according to Regulation (EC) No 1272/2008 and its 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.

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

Labelling according to Regulatory (EC) No 1272/2008 and its amendments.

Hazard Pictograms:

Product: Medi-Devit (Paste), Art.Nr.10015

GHS05



GHS07



GHS08

Signal Word : DANGER

Product identifiers :

CAS 30525-89-4 Paraformaldehyde
 EC 200-803-8 Lindocane Hydrochloride
 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.
 P305 + P351 + P338 IF IN EYES: Rinse cautiously with water for several minutes.
 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 appropriate authority

2.3. Other hazards

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

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) No 1907/2006.

3.2. Mixtures

Composition :

Component	(EC) 1272/2008	67/548/EEC	Concentration %
CAS: 30525-89-4 *Paraformaldehyde	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	20 < 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% < 45

Product: Medi-Devit (Paste), Art.Nr.10015

Component	(EC) 1272/2008	67/548/EEC	Concentration %
CAS: 93-28-7 EC: 202-235-6 EUGENYL ACETATE	GHS07 Wng Acute Tox. 4, H302	Xn Xn;R22	0<x%<2
CAS: 6108-05-0 EC: 200-803-8 Lidocaine Hydrochloride	GHS06 Dgr Acute Tox. 3, H301	Xn Xn;R22	20<x%<40
CAS:50-03-3 EC:200-004-4 Hydrocortisone acetate salt	H361 Repr.	Xn,R63	1<x%<3
CAS:7646-85-7 EC:231-592-0 Zinc chloride	Acute Tox.4; Skin Corr.1B; Aquatic Acute1; Aquatic Chroni1; H302, H314, H410	C, N, R22 -R34 -R50/53	5<x%<15
CAS:177-87-3 EC:214-646-8 Dexamethasone acetate	Aquatic Chroni1; H302, H314, H410	R43,	1<x%<5

* Carcinogenic, mutagenic or reprotoxic

Section 4:First aid measures**4.1 Description of first aid measure****General advice**

Consult a physician. Show this safety data sheet to the doctor in attendance.

If inhaled

If breathed in, move person into fresh air. If not breathing, give artificial respiration. Consult a physician.

In case of skin contact

Wash off with soap and plenty of water. Consult a physician.

In case of eye contact

Rinse thoroughly with plenty of water for at least 15 minutes and consult a physician.

If swallowed

Never give anything by mouth to an unconscious person. Rinse mouth with water. Consult a physician

4.2 Most important symptoms and effects, both acute and delayed

The most important known symptoms and effects are described in the labelling (see section 2.2) and/or in section 11

4.3 Indication of any immediate medical attention and special treatment needed no data available**Section 5:Firefighting measures**

Non-fammable.

5.1 Extinguishing media**Suitable extinguishing media**

Use water spray, alcohol-resistant foam, dry chemical or carbon dioxide.

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 breath in smoke.

In the event of a fire, the following may be formed :

carbon monoxide (CO)

carbon dioxide (CO₂)

nitrogen oxide (NO_x)

formaldehyde vapors

5.3 Advice for firefighters

Wear self contained breathing apparatus for fire fighting if necessary.

Product: Medi-Devit (Paste), Art.Nr.10015

5.4 Further information

no data available

Section 6:Accidental release measures

6.1 Personal precautions, protective equipment and emergency procedures

Use personal protective equipment. Avoid dust formation. Avoid breathing vapours, mist or gas.

Ensure adequate ventilation. Avoid breathing vapours.

For personal protection see section 8.

6.2 Environmental precautions

Prevent further leakage or spillage if safe to do so. Do not let product enter drains. Discharge into the environment must be avoided.

6.3 Methods and materials for containment and cleaning up

Pick up and arrange disposal without creating gas. Sweep up and shovel. Keep in suitable, closed containers for disposal.

6.4 Reference to other sections

No data available

Section7:Handling and storage

7.1 Precautions for safe handling

Avoid contact with skin and eyes. Avoid formation of vapour and aerosols.

Provide appropriate exhaust ventilation at places where gas is formed.

Avoid 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 sealed carefully.

7.2 Conditions for safe storage, including any incompatibilities

Store in cool place.Keep container tightly closed in a dry and well-ventilated place.

Storage

Follow storage precautions reported on the packaging or in the instruction of use.

Packaging

Always store in the original packaging

7.3 Specific end use(s)

Apart from the uses mentioned in section 1.2 no other specific uses are stipulated

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

Handle in accordance with good industrial hygiene and safety practice. Wash hands before breaks and at the end of workday.

Personal protective equipment

Eye/face protection

Safety glasses with side-shields conforming to EN166 Use equipment for eye protection tested and approved under appropriate government standards such as NIOSH (US) or EN 166(EU).

Skin protection

Handle with gloves. Gloves must be inspected prior to use .Avoid skin contact with this product
Disposed of.



Protective gloves

The glove material has to be impermeable and resistant to the product/ the substance/ the preparation.

Body Protection

impervious clothing, The type of protective equipment must be selected according to the concentration and amount of the dangerous substance at the specific workplace.

Respiratory protection

For nuisance exposures use type P95 (US) or type P1 (EU EN 143) particle respirator.For higher level protection use type OV/AG/P99 (US) or type ABEK-P2 (EU EN 143) respirator cartridges.

Use respirators and components tested and approved under appropriate government standards such as

Product: Medi-Devit (Paste), Art.Nr.10015

NIOSH (US) or CEN (EU).

Control of environmental exposure

Prevent further leakage or spillage if safe to do so. Do not let product enter drains. Discharge into the environment must be avoided.

Section9: Physical and chemical properties**9.1 Information on basic physical and chemical properties****General Information**

Appearance:	Form: Paste
Colour:	Light yellow
Odour:	Characteristic of formaldehyde
pH :	Not applicable
Flash point:	Not applicable.
Ignition temperature:	Not relevant
Self-igniting:	Product is not selfigniting.
Danger of explosion:	Product does not present an explosion hazard.
Density at 20°C:	more than 1.6 g/cm3
Solubility in / Miscibility with water:	Insoluble.

9.2 Other information No further relevant information available**Section10: Stability and reactivity****10.1 Reactivity**

no data available

10.2 Chemical stability

Stable under recommended storage conditions

10.3 Possibility of hazardous reactions

no data available

10.4 Conditions to avoidAvoid:
heat**10.5 Incompatible materials**Strong acids
Oxidising agents**10.6 Hazardous decomposition products**The thermal decomposition may release/form :
carbon monoxide (CO)
carbon dioxide (CO₂)
nitrogen oxide (NO)**Formaldehyde vapours****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.

May have irreversible damage of the eyes, such as tissue damage in the eye, or serious physical loss of sight. 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 :**

Eugenol acetate (CAS: 93-28-7)	Oral route : DL50 = 1670 mg/kg
Paraformaldehyde (CAS: 30525-89-4)	Oral route : DL50 = 592 mg/kg
Lindocane hydrochloride (CAS: 6108-05-0)	Oral route : DL50 = 292 mg/kg Species : Mouse

11.1.2 Mixture

No toxicological data available for the mixture.

Section12: Ecological information**12.1 Substances**Paraformaldehyde (CAS: 30525-89-4)
Fish toxicity : LC50 > 10 mg/l
Duration of exposure : 96 h
Crustacean toxicity : EC50 = 42 mg/l
No aquatic toxicity data available for the mixture.
Biodegradability :no degradability data is available

Product: Medi-Devit (Paste), Art.Nr.10015

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.

Section13: 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.

Section14: 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).

Section15: 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 150 gm.

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.

Section16: 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.

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

Eugenol

EC 200-803-8

Lidocaine hydrochlorate

CAS 30525-89-4

Paraformaldehyde

Product: Medi-Devit (Paste), Art.Nr.10015

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.
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
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