

Product name:Medi-ZOE (Powder) - Art.Nr. 10039**Swiss MediTec***Safety data sheet*

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

Printing date 05.01.2015

Version 2.1 (06/02/2014)

Section 1: Identification of the substance/mixture and of the company/undertaking**1.1 Product identifier**

Trade name: Medi-ZOE (Powder)

Article number: 10039

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

Application of the substance /To mix with Medi-ZOE Liquid

For dental professionals use only

1.3 Details of the supplier of the safety data sheet

Manufacturer/Supplier: Swiss MediTec,

Gfellen POBox 513, 6162 Finsterwald; Switzerland

Tel. (+)41 56 624 02 37

Further information obtainable from: www.swiss-meditec.ch, info@swiss-meditec.ch**1.4 Emergency telephone number: (+) 41 79 482 32 98****Section 2: Hazards identification****2.1 Classification of the substance or mixture****In compliance with EC regulation No. 1272/2008 and its amendments**

Eye irritation, Category 2 (Eye Irrit. 2, H319).

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.

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:



GHS08



GHS07



GHS09

Signal word

WARNING

Product identifiers :

CAS 30525-89-4 Paraformaldehyde

Hazard statements :

H317	May cause an allergic skin reaction.
H319	Causes serious eye irritation.
H351	Suspected of causing cancer .
H410	Very toxic to aquatic life with long lasting effects.

Precautionary statements - Prevention :

P201	Obtain special instructions before use.
P261	Avoid breathing dust and vapours.
P264	Wash hands thoroughly after handling.
P273	Avoid release to the environment.

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P280	Wear protective gloves according to the hygienic rules in force in dental surgeries.
P202	Do not handle until all safety precautions have been read and understood.
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.
P333 + P313	IF skin irritation or rash occurs: Get medical advice/attention.
P337 + P313	If eye irritation persists: 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.

2.3 Other hazards

In use, may form flammable/explosive dust-air mixture. The mixture contains substances classified as 'Substances of Very High Concern' (SVHC) $\geq 0.1\%$ published by the European. The mixture satisfies neither the PBT nor the vPvB criteria for mixtures in accordance with annexe XIII of the REACH regulations EC 1907/2006.

Section3: Composition/information on ingredients**3.2 Mixtures**

Composition:

Hazardous ingredients according to Regulation (EC) No 1272/2008

Product identification	(EC) 1272/2008	67/548/EEC	Weight%	EC Number
Paraformaldehyde (1,2) CAS:30525-89-4	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	1<=<5	200-001-8
Zinc Oxide(2) INDEX: 030-013-00-7 CAS: 1314-13-2	-	-	30<=x<50	215-222-5
Thymol Iodide CAS: 552-22-7	GHS07 Wng Acute Tox. 4, H302	Xn Xn;R22	2<=x<10	209-007-5
Barium sulfate CAS:7727-43-7	-	-	10<=x<40	231-784-4

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**4.1 Discription of first aid measures**

General information:

Symptoms of poisoning may even occur after several hours; therefore medical observation is vital.

After inhalation: Supply fresh air; consult doctor in case of complaints.**After skin contact:** wash off with soap and plenty of water.Consult a physician.**After eye contact:** Rinse opened eye for several minutes under running water and consult physician.**After swallowing:** Never give anything by mouth to an unconscious person. Rins mouth with**4.2 Most important symptoms and effects, both acute and delayed Breeding system irritation**

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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,consult your physician or refer to hospital.

Section5: Firefighting measures

Non-flammable

5.1 Extinguishing media

Suitable extinguishing agents:

CO2, powder or water spray. Fight larger fires with water spray or alcohol resistant 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)
- sulphur dioxide (SO2)
- metallic oxide smokes
- formaldehyde vapors
- halogenic compounds

5.3 Advice for firefighters

Wear self contained breathing apparatus for fire fighting is necessary

5.4 Further information

No data available

Section6: Accidental release measures

6.1 Personal precautions, protective equipment and emergency procedures Not required.

Use personal protective equipment. Avoid breathing vapours, mist or gas. Ensure adequate ventilation. For personal protection see section 7 and 8.

For non first aid worker

Avoid any contact with the skin and eyes.

Avoid inhaling the vapours.

Avoid generating dusts.

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: Do not allow to enter sewers/ surface or ground water.

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

Soak up with inert absorbent material and dispose of as hazardous waste. Keep insuitable, closed containers for disposal.

6.4 Reference to other sections

For disposal see section 13

Section7: Handling and storage

7.1 Precautions for safe handling

Avoid contact with skin and eyes. Avoid inhalation of vapour or mist.

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

Fire prevention :

Prevent access by unauthorised personnel.

Recommended equipment and procedures :

For personal protection, see section 8.

Avoid inhaling dust.

Avoid skin and eye contact with this mixture.

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

7.2. Conditions for safe storage, including any incompatibilities

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

Storage

Give special attention to 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)

Refer to the 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) :

CAS	TWA :	STEL :	Ceiling :	Definition :	Criteria :
1314-13-2	2 mg/m ³	10 mg/m ³	-	-	R
30525-89-4	2 mg/m ³	6 mg/m ³	-	-	I

- France (INRS - ED984 :2008) :

CAS	VME-ppm :	VME-mg/m ³ :	VLE-ppm :	VLE-mg/m ³ :	Notes :	TMP No :
1314-13-2	-	5	-	-	-	-
30525-89-4	-	1	-	R2	-	-

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

CAS	TWA :	STEL :	Ceiling :	Definition :	Criteria :
30525-89-4	1 mg/m ³	-	-	-	-

8.2 Exposure controls

Appropriate engineering controlsHandle 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**

Face shield and safety glasses 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. Use proper glove removal technique (without touching glove's outer surface) to avoid skin contact with this product. Dispose of contaminated gloves after use in accordance with applicable laws and good laboratory practices. Wash and dry hands. The selected protective gloves have to satisfy the specifications of EU Directive 89/686/EEC and the standard E374 derived from it.

Body Protection

Complete suit protecting against chemicals, The type of protective equipment must be selected according to the concentration and amount of the dangerous substance at the specific workplace.

Respiratory protection

Where risk assessment shows air-purifying respirators are appropriate use a full-face respirator with multi-purpose combination (US) or type ABEK (EN 14387) respirator cartridges as a backup to engineering controls.

If the respirator is the sole means of protection, use a full-face supplied air respirator. Use respirators and components tested and approved under appropriate government standards such as NIOSH (US) or CEN(EU).Control of environmental exposurePrevent further leakage or spillage if safe to do so. Do not let product enter drains. Discharge into the environment must be avoided.

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



Protective gloves

The glove material has to be impermeable and resistant to the product/ the substance/ the preparation. Due to missing tests no recommendation to the glove material can be given for the product/ the preparation/the chemical mixture.Selection of the glove material on consideration of the penetration times, rates of diffusion and the degradation

Section 9- Physical and chemical properties**9.1 Information on basic physical and chemical properties**

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General information :

Physical state : Powder .
 Colour: Grey white
 Odour: Spicy (presence of Paraformaldehyde)

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 : Not relevant
 Water solubility : Insoluble.
 Melting point/melting range : Not relevant.
 Self-ignition temperature : Not relevant.
 Decomposition point/decomposition range : Not relevant.

9.2 Other safety information

no data available

Section 10-Stability and reactivity

- 10.1 Reactivity no data available
 10.2 Chemical stability Stable under recommended storage conditions in section 7.
 Do not use if expiry date is exceeded
 10.3 Possibility of hazardous reactions no data available
 10.4 Conditions to avoid Formation of dust, heat
 10.5 Incompatible materials Strong oxidizing agents, acids, aluminium, phosphorus
 10.6 Hazardous decomposition products
 The thermal decomposition may release/form :
 - carbon dioxide (CO₂)
 - sulphur dioxide (SO₂)
 - metallic oxide smokes
 - formaldehyde vapors
 - halogenic compounds
 - barium oxide

Section 11-Toxicological information**11.1 Acute toxicity :**

Paraformaldehyde (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)

11.1.2. Mixture

No toxicological data available for the mixture.

Section 12: Ecological information**12.1. Toxicity****12.1.1. Substances**

Paraformaldehyde (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

12.1.2. Mixtures

No aquatic toxicity data available for the mixture.

12.2. Persistence and degradability**12.2.1. Substances**

Paraformaldehyde (CAS: 30525-89-4)

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

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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. transport 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 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=2 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 Paraformaldehyde

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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 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 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.
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 .
H360FD May damage fertility. May damage the unborn child.
H400 Very toxic to aquatic life.
H410 Very 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 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 60.F2 May impair fertility.
R 61.G2 May cause harm to the unborn child.

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.
GHS07 : Exclamation mark
GHS08 : Health hazard
GHS09 : Environment
SVHC : Substances of very high concern.