



SWISS MEDITEC

SAFETY DATA SHEET
(REACH regulation (EC) Nr 1907/2006 - Nr 453/2010)
Product Name:Medi-Dised Art.Nr.: 10016

SECTION 1 : Identification of the substances/mixture and of the company/undertaking

1.1. Product identifier:

Product name : Medi-Dised/ Formaldehyde Free
Product Art.Nr:10016

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 : Swiss MediTec.
Address : Gfellen. Postfac 513.6162 Finsterwald.Switzerland.
Telephone : +41 79 482 32 98.
info@swiss-meditec.ch
http://www.swiss-meditec.ch

1.4. Emergency telephone number : +41 79 482 32 98.

SECTION 2 : hazard identification

2.1. Classification of the substance or mixture

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

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

Acute toxicity ,Inhalation (category 4),H332.

Skin irritation, Category 2 (Skin Irrit. 2, H311).

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

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

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

Reproductive toxicity, Category 1B (Repr. 1B, H360).

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).

Skin irritation (Xi, R 38).

Eye irritation (Xi, R 36).

Skin sensitisation (Xi, R 43).

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

Category 2 reproductive toxin (T, R 61 Repr. Cat. 2).

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

Pictograms:



GHS07

GHS05

GHS08

Signal Word :

Danger

GHS07 GHS08

Product identifiers :Medi-Dised

Additional labeling :

For professional dental use only.

Hazard statements :

H301 + H311

Toxic if swallowed or in contact with skin

H314

Causes severe skin burns and eye damage.

Product Name: Medi-Dised Art.Nr.: 10016

H332	Harmful if inhaled.
H335	May cause respiratory irritation.
H341	Suspected of causing genetic defects.
H373	May cause damage to organs through prolonged or repeated exposure.
H411	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 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: Contact Poison center, doctor/physician.
P302 + P352	if on skin: Wash with plenty of soap and water.
P305 + P351 + P338	if in eye : Rinse carefully with plenty of 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.
P337 + P313	If eye irritation persists: Get medical advice/attention.
Precautionary statements - Disposal :	
P501	Dispose of contents/container

2.3. Other hazards

The mixture contains substances classified as 'Substances of Very High Concern' (SVHC) by the European Chemicals Agency (ECHA) under article 57 of REACH:

This mixture contains no components considered to be either persistent, bioaccumulative and toxic (PBT), or very persistent and very bioaccumulative (vPvB) at levels of 0.1% or higher. Vesicant, Rapidly absorbed through skin.

Section-3 : Composition/information on ingredients**3.1. Substances : Mixture**

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

3.2. Mixtures

Composition :

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

Component	Classification	Concentration%
Guaiacol CAS-No. 90-05-1 EC-No. 201-964-7	Acute Tox.4; Skin Irrit. 2, Eye Irrit. 2; H302, H315, H319	25 ≤ x < 50
Phenol CAS-No. 108-95-2 EC-No. 203--632-7	Acute Tox.3; Skin Corr.1B; Muta.2; STOT RE2; Aquatic Chronic2; H301, H331, H311, H314, H341, H373, H41 Concentration limits: >= 3 %: Skin Corr.1B, H314; 1 -< 3 %: Skin Irrit.2, H315; 1 <- 3 %: Eye Irrit.2, H319	10 ≤ x < 20
p-cresol CAS-No. 93-51-6 EC-No. 202-252-9	Acute Tox.4; Skin Irrit.2; Eye Irrit.2; STOT SE3; H302, H315, H319, H335	30 ≤ x < 50

For the full text of the H-Statements mentioned in this Section, see Section 16

Section 4: First aid measures**4.1. Description of first aid measures**

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

Product Name: Medi-Dised Art.Nr.: 10016

Take off contaminated clothing and shoes immediately. Wash off with soap and plenty of water. Take victim immediately to hospital. 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

Do NOT induce vomiting. 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

Remove the person exposed to fresh air and seek immediate medical attention.

SECTION 5 : Firefighting measures

5.1. Extinguishing media

Suitable methods of extinction

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

5.2. Special hazards arising from the substance or mixture

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_x)

gas / irritant vapours

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.

Wear self-contained breathing apparatus for firefighting if necessary.

5.4 Further information

Use water spray to cool unopened containers.

SECTION 6 : ACCIDENTAL RELEASE MEASURES

6.1. Personal precautions, protective equipment and emergency procedures

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

Contain and control the leaks or spills with non-combustible absorbent materials such as sand, earth, in drums for waste disposal. Prevent any material from entering drains or waterways.

6.3. Methods and material for containment and cleaning up

Clean preferably with a detergent, do not use solvents.

6.4. Reference to other sections

For disposal see section 13.

SECTION 7 : Handling and storage

7.1. Precautions for safe handling

Always wash hands after handling. Avoid contact with skin and eyes. Avoid inhalation of vapour or mist. Keep away from sources of ignition -No smoking. Take measures to prevent the build up of electrostatic charge

For precautions see section 2.2 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.

Store in cool place. Keep container tightly closed in a dry and well-ventilated place. Containers which are opened must be carefully resealed and kept upright to prevent leakage. Handle and store under inert gas. Air, light, and moisture sensitive. Storage class (TRGS 510): Non-combustible, acute toxic Cat. 1 and 2 / very toxic hazardous materials

Always conserve 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
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/m3 :	VME-ppm :	VLE-mg/m3 :	VLE-ppm :	Notes :
90-05-1	13	5	30	10	-

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.

SECTION 9 : Physical and chemical properties

9.1. Information on basic physical and chemical properties

General information :

Physical state :	fluid liquid.
Colour:	Colourless/pale yellow
Odour:	N/A

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 :	1.08 gm/cm ³
Miscibility :	Ethanol
Water solubility :	Insoluble.
Viscosity :	3.8
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.

10.3. Possibility of hazardous reactions

no data available.

10.4. Conditions to avoid

Avoid :
Heat,
Exposure to light

10.5. Incompatible materials

Keep away from : oxidising agents, acids, bases

10.6. Hazardous decomposition products

Product Name: Medi-Dised Art.Nr.: 10016

The thermal decomposition may release/form : carbon monoxide (CO), carbon dioxide (CO₂), nitrogen oxide (Nox).

SECTION 11 : Toxicological information**11.1. Information on toxicological effects**

Exposure to vapours from solvents in the mixture in excess of the stated occupational exposure limit may result in adverse health effects such as mucous membrane and respiratory system irritation and adverse effects on kidney, liver and central nervous system. Harmful if swallowed. Long exposure may have serious effects on the eyes, such as irritation. Splashes in the eyes may cause irritation and reversible damage. May cause an allergic reaction by skin contact. 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 90-05-1 : IARC Group 3 : The agent is not classifiable as to its carcinogenicity to humans.

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

CAS 93-51-6 : 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 consideration

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 dispose 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.

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

15.1.1 Container information:

The mixture is contained in packaging that does not exceed 150 ml.

Usage restrictions apply to the product : See annex XVII of EC regulation No. 1907/2006.

For professional dental use only.

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



Product Name: Medi-Dised Art.Nr.: 10016**15.2. Chemical safety assessment**

No data available.

SECTION 16 : Other information

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.

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

Hazard symbols :



Toxic

Contains :

90-05-1

Guaiacol

108-95-2

Phenol

93-51-6

p-cresol(mixed)

Risk phrase :

R 43 May cause sensitisation by skin contact.

R 36/38

Irritating to eyes and skin.

R 22

Harmful if swallowed.

Safety phrase :

S 36/37

Wear suitable protective clothing and gloves.

S 45

In case of accident or if you feel unwell, seek medical advice immediately

S 53

Avoid exposure - obtain special instructions before use.

S 26

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

S 38

In case of insufficient ventilation, wear suitable respiratory equipment.

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.

Product submitted to restrictions on the marketing and use: see Regulation (EC) No 1907/2006.

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

H301

Toxic if swallowed.

H302

Harmful if swallowed.

H311

Toxic in contact with skin.

H312

Harmful in contact with skin.

H314

Causes severe skin burns and eye damage.

H315

Causes skin irritation.

H317

May cause an allergic skin reaction.

H319

Causes serious eye irritation.

H331

Toxic if inhaled.

H332

Harmful if inhaled.

R 20/21

Harmful by inhalation and in contact with skin.

R 22

Harmful if swallowed.

R 23/24/25

Toxic by inhalation, in contact with skin and if swallowed.

R 34

Causes burns.

R 36

Irritating to eyes.

R 36/38

Irritating to eyes and skin.

R 40.C3

Limited evidence of a carcinogenic effect.

R 43

May cause sensitisation by skin contact.

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

Product Name:Medi-Dised Art.Nr.: 10016

GHS08 :

Health hazard

SVHC :

Substances of very high concern.