

Swiss MediTec



Name:Medi-Buckley -Art.Nr.10011

SAFETY DATA SHEET
(REACH regulation (EC)no. 1907/2006-n° 453/2010)

Section 1: IDENTIFICATION OF THE SUBSTANCE/MIXTURE AND OF THE COMPANY/UNDERTAKING**1.1 Product identifier**

Product name: Medi-Buckley
Product code :10011

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

Recommended Use: Sterelisation and disinfectant solution, For Dental professional use only.
For dental professional use only.

1.3 Details of the supplier of safety data sheet

Registered company name: Swiss MediTec
Address: Gfellen. Postfach 513. 6162 Finsterwald.Switzerland
Telephone: + 41 56 624 02 37
info@swiss-meditec.ch
<http://www.swiss-meditec.ch>

1.4 Emergency telephone number : +41 79 482 32 98

Dr. Kurosh Sohi

Section 2- HAZARDS IDENTIFICATION**2.1 Classification of the substance or mixture****2.1.1 Classification according to Regulation (EC) No 1272/2008**

Acute toxicity (T), Oral(Category 3), H301
Acute toxicity, Dermal(Category 3), H311
Skin corrosion(Category 1B), H314,R24/25,R34

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

2.2 Label elements

Labelling according Regulation (EC) No 1272/2008

Pictogram



Danger

Signal word

Hazard statement(s)

Contains:Cresol,Formaldehyde

H301 + H311

Toxic if swallowed or in contact with skin

H314

Causes severe skin burns and eye damage.

Precautionary statement(s)

P280

Wear protective gloves/ protective clothing/ eye protection/ face protection.

P301 + P310

IF SWALLOWED: Immediately call a POISON CENTER or doctor/ physician.

P305 + P351 + P338

IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.

P310

Immediately call a POISON CENTER or doctor/ physician.

Supplemental Hazard

none

Statements

2.3 Other hazards

none

Hazard statements :

H302

Harmful if swallowed.

H315

Causes skin irritation.

H317

May cause an allergic skin reaction.

H318

Causes serious eye damage.

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) nr. 1907/2006.

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3.2 Mixtures:

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Hazardous Components	CAS-Nr (EC)1272/2008	Substance Classification	Quantity %
m-Cresol (3-Methylphenol)	CAS. 108-39-4 EC. 203-577-9	Eye Irrit.2;Skin Sens.1 H317,H319	20
P-Cresol (4-Methylphenol)	CAS:106-44-5 EC:203-398-6	Eye Irrit.2;Skin Sens.1 H317,H319	15
Formaldehyde	CAS:50-00-0 EC:200-001-8	Acute Tox 3 (Inhalation) H331 Skin Corr. 1B H314 Skin Sens. 1 H317	<18
Glycerine (Glycerol)		Not established	<25

Refer to Section 16 for the full text of the EU Classifications and R Phrases.

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 :

Remove the person exposed to fresh air. Keep warm and at rest.

In the event of contact with eyes :

Wash thoroughly with soft, clean water for 10 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 :

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.

Most important symptoms and effects, both acute and delayed Breathing system irritation.

Indication of any immediate medical attention and special treatment needed

Section5: FIREFIGHTING MEASURES

Non-flammable.

5.1 Extinguishing media : Use carbon dioxide, foam or dry chemical. Use water to cool exposed containers.

Suitable methods of extinction

In the event of a fire, use :

sprayed water or water mist.

5.2 Special hazards arising from the substance or mixture

Combustible liquid. Burning generates carbon dioxide, carbon monoxide, and oxides of carbon.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

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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

Evacuate spill area and keep unprotected personnel away. Wear appropriate protective clothing, gloves and eye protection. Respiratory protection is required. In the United States, refer to OSHA 1910.1048 for specific requirements

6.1 Personal precaution, protective equipment and emergency procedures

6.1.1 For non fire-fighters

Avoid any contact with the skin and eyes.
Avoid inhaling the vapours.

6.1.2 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. Report releases as required by local and national authorities.

6.3 Methods and material for containment and cleaning up

Collect using an inert non-combustible absorbent material and place in appropriate containers for disposal. Clean spill area thoroughly.

6.4 Reference to other sections

No data available.

Section7 : 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,Keep containers closed when not in use. 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.

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.

Section8 : EXPOSURE CONTROLS/PERSONAL PROTECTION

8.1 Control parameters

No data available.

Personal protection measures, such as personal protective equipment

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.

8.2 Exposure controls

Hand protection

Wear gloves according to the hygienic rules in force in dental surgeries.

Body protection

Avoid skin contact.

Respiratory protection

Avoid breathing vapours.

Section-9: PHYSICAL AND CHEMICAL PROPERTIES

9.1 Information on basic physical and chemical properties

Appearance: Clear,amber liquid

Odor: Formaldehyde and phenol

Odor threshold: Not available

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pH:	4.0 at 25°C
Density:	1.15@ 25°C
Melting/freezing point:	Not available
Solubility:	Miscible
Flash point:	Not available
Autoignition:	Not available
Flammability:	Combustible
Explosive property:	None
Oxidising property:	None
Percent volatile	30%V/V

9.2 Other information

No data available

Section-10 Stability and Reactivity

10.1 Reactivity

No polymerization.

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

Avoid ignition sources.

10.4 Conditions to avoid

Avoid heat

10.5 Noncompatible materials

Strong oxidising agents

10.6 Hazardous decomposition products

Does not decompose when used for intended uses

No known hazardous decomposition products.

Section11- Toxicological Information

11.1 Information on toxicological effects

Mixtures

Potential health Effects:

Eyes: Causes burns to eyes with redness, pain and tearing. Eye damage is possible.

Skin: If spilled on skin, numbness is followed promptly by pain and reddening. Chemical burns are possible. Toxic when absorbed through skin with symptoms similar to ingestion. May cause an allergic skin reaction.

Ingestion: Swallowing causes intense burning of mouth and throat. Cause epigastric pain, muscular weakness, headache,dizziness, nausea, vomiting, collapse, shock, CNS depression, and death. May cause injury to the kidneys, liver, heart,pancreas, and spleen. Symptoms may be delayed.

Inhalation: Inhalation of mists may cause mucous membrane and upper respiratory tract irritation. Toxic when inhaled with symptoms similar to ingestion. May cause an allergic reaction Substances.

Chronic Health Effects: May cause injury to the kidneys, liver, heart, pancreas, lungs, and spleen.

Carcinogenicity: Formaldehyde is listed by IARC as "Carcinogenic to Humans", (Group 1), by NTP a "Known to be a Human Carcinogen", by ACGIH as a "Suspected Human Carcinogen" (A2), by the European Union as a Carcinogen Category 3. Cresol Isomers- Possible human carcinogen. Based on an increased incidence of skin papillomas in mice in an initiation-promotion study. The three cresol isomers produced positive results in genetic toxicity studies both alone and in combination. None of the components are listed as a carcinogen by IARC, NTP, OSHA, ACGIH or the EU Substances Directive.

Mutagenicity: No data available

Medical Conditions Aggravated by Exposure: Employees with pre-existing eye, skin, kidneys, liver, heart, pancreas,lungs, and spleen disorders may be at increased risk from exposure.

Acute Toxicity Data:

Cresol Isomers: Oral rat LD50 242 mg/kg; Skin rabbit LD50 2030 mg/kg; Inhalation rat LC50 >710 mg/m³/1hr

Formaldehyde: Oral rat LD50 100 mg/kg; Skin rabbit LD50 0.27 mL/kg; Inhalation rat LC50 203 mg/m³/1hr

Reproductive Toxicity Data: No data available for mixture. In a reproductive study, rats were exposed to 0-40 ppm formaldehyde for 6 hr/days on days 6-20 of gestation. At 40 ppm, maternal toxicity was

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observed. Formaldehyde is slightly fetotoxic at 20 ppm. Neither embryolethal nor teratogenic effects were observed following inhalation exposure at levels up to 40 ppm.

Specific Target Organ Toxicity (STOT):

Single Exposure: Exposure to high doses of formaldehyde (>100 ppm) showed salivation, acute dyspnea, vomiting, cramps and death in laboratory animals. Mice treated with formaldehyde on skin developed severe liver damage.

Repeated Exposure: Animal data revealed a qualitative relationship between formaldehyde absorption and hepatotoxicity. These data indicate that exposure to formaldehyde at 3 ppm or less for periods up to 6 months causes adverse effects upon the liver; higher exposure concentrations for shorter time periods produce similar effects upon the liver

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

Bioaccumulative potential

No data available.

Mobility in soil

No data available.

Results of PBT and vPvB assessment

No data available.

Other adverse effects

No data available.

Section-12 : Ecological Information

12.1 Toxicity:

Cresol Isomers: LC50 Pimephales promelas 12.8 mg/L/96 hr

Formaldehyde: LC50 Oncorhynchus mykiss (Rainbow trout, weight 0.63 g) 118 ppm/96 hr

Glycine: LC50 Goldfish >5000 mg/l/24 hr

12.2 Persistence and Degradability:

Cresol Isomers: Cresols biodegrade quickly in soils with half-lives on the order of a few days. Cresols biodegrade quickly in water with half-lives of several days to a few weeks.

Formaldehyde: Formaldehyde readily biodegrades (oxidation) under both aqueous aerobic and anaerobic conditions.

Glycerin: If released to soil, glycerin is expected to undergo rapid biodegradation under aerobic conditions. If released to water, glycerin is expected to rapidly degrade under aerobic conditions.

Proper waste management of the mixture and/or its container must be determined in accordance with Directive 2008/98/EC.

Bio-accumulative Potential:

Cresol Isomers: Bioconcentration in aquatic organisms is low.

Formaldehyde: Formaldehyde is rapidly metabolized with a half-life in the blood of approx 1.5 min.

This half-life is based primarily on primate data although available human data are consistent with this observation of a very short half-life.

Glycerin: Bioconcentration of glycerin in fish and aquatic organisms will not be significant.

Mobility in Soil:

Cresol Isomers: Cresols are expected to have high mobility in soil.

Formaldehyde: formaldehyde is expected to have very high mobility in soil

Glycerin: Will display very high mobility in soil.

Other Adverse Effects: None known.

Results of PBT/vPvB Assessment: Not applicable

Section-13: Disposal Considerations

13.1 Waste treatment methods

Regulations: Dispose in accordance with local and national environmental regulations

Properties (Physical/Chemical) Affecting Disposal: None known.

Waste Treatment Recommendations: None known.

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 IC AO/IATA for air transport(ADR 2013 - IMDG 2012 - ICAO/IATA 2013).

Section-15: Regulatory information

5.1. Safety, health and environmental regulations/legislation specific for the substance or mixture

- Classification and labelling information included in section 2:

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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.

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

For professional users only.

- Particular provisions :
- No data available

Components	CAS Number	Concentration%
Formaldehyde	50-00-0	<20
m-Cresol	108-39-4	21
p-Cresol	106-44-5	14

EU REACH: The substances in this product comply with the EU REACH regulation as applicable.

Section16- Other information

Full text of Classification abbreviations used in Section 2 and 3:

- C Corrosive
- T Toxic
- R20 Harmful by inhalation
- R23/24/25 Toxic by inhalation, contact with skin and if swallowed
- R24/25 Toxic in contact with skin and if swallowed
- R34 Causes burns
- R40 Limited evidence of a carcinogenic effect
- R43 May cause sensitization by skin contact.
- R23/24/25 Toxic by inhalation, in contact with skin and if swallowed.
- R26/27/28 Very toxic by inhalation, in contact with skin and if swallowed
- R35 Causes severe burns.
- Acute Tox 3 (Oral) Acute Oral Toxicity Category 3
- Acute Tox 3 (Dermal) Acute Dermal Toxicity Category 3
- Acute Tox 3 (Inhalation) Acute Inhalation Toxicity Category 3
- Skin Corr. 1B Skin Corrosion Category 1B
- Skin Sens. 1 Skin Sensitizer Category 1
- H301 Toxic if swallowed
- H311 Toxic in contact with skin
- H314 Causes severe skin burns and eye damage.
- H317 May cause an allergic skin reaction.
- H331 Toxic if inhaled
- H351 Suspected of causing cancer