

**Safety data sheet**  
according to 1907/2006/EC, Article 31

Printing date 14.12.2018

Revision: 14.12.2018

### SECTION 1: Identification of the substance/mixture and of the company/undertaking

- **1.1 Product identifier**
- **Trade name:** Tamponade 2000 soaked
- **Article number:** 1062, 1063
- **1.2 Relevant identified uses of the substance or mixture and uses advised against**  
No further relevant information available.
- **Application of the substance / the mixture** dental drug / Haemostatis and disinfection after tooth extractions
- **1.3 Details of the supplier of the safety data sheet**
- **Manufacturer/Supplier:**  
SPEIKO-Dr. Speier GmbH, Walther-Rathenau-Str. 59. 33602 Bielefeld, GERMANY  
Tel. +49/521/770107-0
- **Further information obtainable from:** SPEIKO-Dr. Speier GmbH, info@speiko.de
- **1.4 Emergency telephone number:**  
Giftnotruf Berlin  
Tel. +49/30/30686 700

### SECTION 2: Hazards identification

- **2.1 Classification of the substance or mixture**
- **Classification according to Regulation (EC) No 1272/2008**



GHS07

Acute Tox. 4 H302 Harmful if swallowed.  
Acute Tox. 4 H332 Harmful if inhaled.

- **2.2 Label elements** Medicinal products are exempted from labelling acc. (EC) No 1272/2008 (Article 1 (5) a))
- **Labelling according to Regulation (EC) No 1272/2008**  
The product is classified and labelled according to the CLP regulation.
- **Hazard pictograms** GHS07
- **Signal word** Warning
- **Hazard-determining components of labelling:**  
iodoform
- **Hazard statements**  
H302+H332 Harmful if swallowed or if inhaled.
- **Precautionary statements**
  - P101 If medical advice is needed, have product container or label at hand.
  - P102 Keep out of reach of children.
  - P103 Read label before use.
  - P261 Avoid breathing dust/fume/gas/mist/vapours/spray.
  - P264 Wash thoroughly after handling.
  - P301+P312 IF SWALLOWED: Call a POISON CENTER/doctor if you feel unwell.
  - P330 Rinse mouth.
  - P304+P340 IF INHALED: Remove person to fresh air and keep comfortable for breathing.
  - P501 Dispose of contents/container in accordance with local/regional/national/international regulations.
- **2.3 Other hazards**
- **Results of PBT and vPvB assessment**
- **PBT:** Not applicable.
- **vPvB:** Not applicable.

### SECTION 3: Composition/information on ingredients

- **3.2 Chemical characterisation: Mixtures**
- **Description:** Mixture of substances listed below with nonhazardous additions.

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**· Dangerous components:**

CAS: 75-47-8	iodoform	⚠ Acute Tox. 4, H302; Acute Tox. 4, H312; Acute Tox. 4, H332	50.0%
EINECS: 200-874-5			

· **Additional information:** For the wording of the listed hazard phrases refer to section 16.

### SECTION 4: First aid measures

· **4.1 Description of first aid measures**

· **General information:**

Symptoms of poisoning may even occur after several hours; therefore medical observation for at least 48 hours after the accident.

· **After inhalation:**

Supply fresh air. If required, provide artificial respiration. Keep patient warm. Consult doctor if symptoms persist.

In case of unconsciousness place patient stably in side position for transportation.

· **After skin contact:** Generally the product does not irritate the skin.

· **After eye contact:** Rinse opened eye for several minutes under running water.

· **After swallowing:** Call for a doctor immediately.

· **4.2 Most important symptoms and effects, both acute and delayed** No further relevant information available.

· **4.3 Indication of any immediate medical attention and special treatment needed**

No further relevant information available.

### SECTION 5: Firefighting measures

· **5.1 Extinguishing media**

· **Suitable extinguishing agents:** Use fire extinguishing methods suitable to surrounding conditions.

· **5.2 Special hazards arising from the substance or mixture** No further relevant information available.

· **5.3 Advice for firefighters**

· **Protective equipment:** Mouth respiratory protective device.

### SECTION 6: Accidental release measures

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

· **6.2 Environmental precautions:** Do not allow to enter sewers/ surface or ground water.

· **6.3 Methods and material for containment and cleaning up:**

Dispose contaminated material as waste according to item 13.

Ensure adequate ventilation.

· **6.4 Reference to other sections**

See Section 7 for information on safe handling.

See Section 8 for information on personal protection equipment.

See Section 13 for disposal information.

### SECTION 7: Handling and storage

· **7.1 Precautions for safe handling**

Thorough dedusting.

Ensure good ventilation/exhaustion at the workplace.

· **Information about fire - and explosion protection:** No special measures required.

· **7.2 Conditions for safe storage, including any incompatibilities**

· **Storage:**

· **Requirements to be met by storerooms and receptacles:** No special requirements.

· **Information about storage in one common storage facility:** Not required.

· **Further information about storage conditions:** Keep container tightly sealed.

· **Storage class:** 13

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- 7.3 *Specific end use(s)* No further relevant information available.

### SECTION 8: Exposure controls/personal protection

- *Additional information about design of technical facilities:* No further data; see item 7.

- **8.1 Control parameters**

- **Ingredients with limit values that require monitoring at the workplace:**

- 75-47-8 iodoform

WEL	Short-term value: 16 mg/m <sup>3</sup> , 1 ppm
	Long-term value: 9.8 mg/m <sup>3</sup> , 0.6 ppm

- *Additional information:* The lists valid during the making were used as basis.

- **8.2 Exposure controls**

- **Personal protective equipment:**

- **General protective and hygienic measures:**

Keep away from foodstuffs, beverages and feed.

Wash hands before breaks and at the end of work.

Avoid contact with the eyes and skin.

- **Respiratory protection:**

In case of brief exposure or low pollution use respiratory filter device. In case of intensive or longer exposure use self-contained respiratory protective device.

- **Protection of hands:**



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

- **Material of gloves**

The selection of the suitable gloves does not only depend on the material, but also on further marks of quality and varies from manufacturer to manufacturer. As the product is a preparation of several substances, the resistance of the glove material can not be calculated in advance and has therefore to be checked prior to the application.

- **Penetration time of glove material**

The exact break through time has to be found out by the manufacturer of the protective gloves and has to be observed.

- **Eye protection:** Not required.

### SECTION 9: Physical and chemical properties

- **9.1 Information on basic physical and chemical properties**

- **General Information**

- **Appearance:**

**Form:** Tamponade strips iodoform-soaked

**Colour:** yellowish

· **Odour:** Characteristic

· **Odour threshold:** Not determined.

· **pH-value:** Not applicable.

- **Change in condition**

**Melting point/freezing point:** Undetermined.

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<b>Initial boiling point and boiling range:</b> <i>Undetermined.</i>	
· <b>Flash point:</b>	<i>Not applicable.</i>
· <b>Flammability (solid, gas):</b>	<i>Not determined.</i> <i>Not applicable.</i>
· <b>Decomposition temperature:</b>	<i>Not determined.</i>
· <b>Auto-ignition temperature:</b>	<i>Product is not selfigniting.</i>
· <b>Explosive properties:</b>	<i>Product does not present an explosion hazard.</i>
· <b>Explosion limits:</b>	
Lower:	<i>Not determined.</i>
Upper:	<i>Not determined.</i>
· <b>Vapour pressure:</b>	<i>Not applicable.</i>
· <b>Density:</b>	<i>Not determined.</i>
· <b>Relative density</b>	<i>Not determined.</i>
· <b>Vapour density</b>	<i>Not applicable.</i>
· <b>Evaporation rate</b>	<i>Not applicable.</i>
· <b>Solubility in / Miscibility with water:</b>	<i>Insoluble.</i>
· <b>Partition coefficient: n-octanol/water:</b>	<i>Not determined.</i>
· <b>Viscosity:</b>	
Dynamic:	<i>Not applicable.</i>
Kinematic:	<i>Not applicable.</i>
· <b>Solvent content:</b>	
VOC (EC)	<i>0.00 %</i>
Solids content:	<i>100.0 %</i>
· <b>9.2 Other information</b>	<i>No further relevant information available.</i>

### SECTION 10: Stability and reactivity

- **10.1 Reactivity** *No further relevant information available.*
- **10.2 Chemical stability**
- **Thermal decomposition / conditions to be avoided:** *No decomposition if used according to specifications.*
- **10.3 Possibility of hazardous reactions** *No dangerous reactions known.*
- **10.4 Conditions to avoid** *No further relevant information available.*
- **10.5 Incompatible materials:** *No further relevant information available.*
- **10.6 Hazardous decomposition products:** *No dangerous decomposition products known.*

### SECTION 11: Toxicological information

- **11.1 Information on toxicological effects**
- **Acute toxicity**  
*Harmful if swallowed or if inhaled.*
- **Primary irritant effect:**
- **Skin corrosion/irritation** *Based on available data, the classification criteria are not met.*
- **Serious eye damage/irritation** *Based on available data, the classification criteria are not met.*
- **Respiratory or skin sensitisation** *Based on available data, the classification criteria are not met.*
- **CMR effects (carcinogenicity, mutagenicity and toxicity for reproduction)**
- **Germ cell mutagenicity** *Based on available data, the classification criteria are not met.*
- **Carcinogenicity** *Based on available data, the classification criteria are not met.*
- **Reproductive toxicity** *Based on available data, the classification criteria are not met.*

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- *STOT-single exposure* Based on available data, the classification criteria are not met.
- *STOT-repeated exposure* Based on available data, the classification criteria are not met.
- *Aspiration hazard* Based on available data, the classification criteria are not met.

### SECTION 12: Ecological information

- **12.1 Toxicity**
- *Aquatic toxicity: No further relevant information available.*
- **12.2 Persistence and degradability** *No further relevant information available.*
- **12.3 Bioaccumulative potential** *No further relevant information available.*
- **12.4 Mobility in soil** *No further relevant information available.*
- **Additional ecological information:**
- **General notes:**  
*Water hazard class 1 (German Regulation) (Self-assessment): slightly hazardous for water  
Do not allow undiluted product or large quantities of it to reach ground water, water course or sewage system.*
- **12.5 Results of PBT and vPvB assessment**
- **PBT:** *Not applicable.*
- **vPvB:** *Not applicable.*
- **12.6 Other adverse effects** *No further relevant information available.*

### SECTION 13: Disposal considerations

- **13.1 Waste treatment methods**
- **Recommendation**  
*Must not be disposed together with household garbage. Do not allow product to reach sewage system.*
- **Uncleaned packaging:**
- **Recommendation:** *Disposal must be made according to official regulations.*

### SECTION 14: Transport information

- |   |                        |
|---|------------------------|
| · <b>14.1 UN-Number</b><br>· <b>ADR, ADN, IMDG, IATA</b>                                    | <i>Void</i>            |
| · <b>14.2 UN proper shipping name</b><br>· <b>ADR, ADN, IMDG, IATA</b>                      | <i>Void</i>            |
| · <b>14.3 Transport hazard class(es)</b><br>· <b>ADR, ADN, IMDG, IATA</b><br>· <b>Class</b> | <i>Void</i>            |
| · <b>14.4 Packing group</b><br>· <b>ADR, IMDG, IATA</b>                                     | <i>Void</i>            |
| · <b>14.5 Environmental hazards:</b><br>· <b>Marine pollutant:</b>                          | <i>No</i>              |
| · <b>14.6 Special precautions for user</b>  | <i>Not applicable.</i> |
| · <b>14.7 Transport in bulk according to Annex II of Marpol and the IBC Code</b>            | <i>Not applicable.</i> |
| · <b>UN "Model Regulation":</b>   | <i>Void</i>            |

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**SECTION 15: Regulatory information**

- **15.1 Safety, health and environmental regulations/legislation specific for the substance or mixture**
- **Named dangerous substances - ANNEX I** None of the ingredients is listed.
- **15.2 Chemical safety assessment:** A Chemical Safety Assessment has not been carried out.

**SECTION 16: Other information**

*This information is based on our present knowledge. However, this shall not constitute a guarantee for any specific product features and shall not establish a legally valid contractual relationship.*

· **Relevant phrases***H302 Harmful if swallowed.**H312 Harmful in contact with skin.**H332 Harmful if inhaled.*· **Abbreviations and acronyms:***RID: Règlement international concernant le transport des marchandises dangereuses par chemin de fer (Regulations Concerning the International Transport of Dangerous Goods by Rail)**ICAO: International Civil Aviation Organisation**ADR: Accord européen sur le transport des marchandises dangereuses par Route (European Agreement concerning the International Carriage of Dangerous Goods by Road)**IMDG: International Maritime Code for Dangerous Goods**IATA: International Air Transport Association**GHS: Globally Harmonised System of Classification and Labelling of Chemicals**EINECS: European Inventory of Existing Commercial Chemical Substances**ELINCS: European List of Notified Chemical Substances**CAS: Chemical Abstracts Service (division of the American Chemical Society)**VOC: Volatile Organic Compounds (USA, EU)**PBT: Persistent, Bioaccumulative and Toxic**vPvB: very Persistent and very Bioaccumulative**Acute Tox. 4: Acute toxicity – Category 4*

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