

#### SAFETY DATA SHEET

Safety data sheet according to (EC) No. 1907/2006

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

#### 1.1. Product identifier:

BiopSafe®

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

For laboratory, research and analytical purposes. Restricted to professional users.

#### 1.3. Details of the supplier of the safety data sheet:

BiopSafe ApS

Bygstubben 4 Phone: +45 30 76 28 51

DK-2950 Vedbaek

Responsible person for the safety data sheet (e-mail): lone@biopsafe.com

## 1.4. Emergency telephone number:

National Poisons Information Centre (Ireland): +353 (1) 809 2166 (8.00 a.m. to 10.00 p.m. 7 days a week).

Healthcare Professionals: +353 (1) 809 2566 (24-hour service)

## **SECTION 2: Hazards identification**

## 2.1. Classification of the substance or mixture:

Carcinogenic, sensitizing fluid with long-term effects. Suspected of causing genetic defects.

CLP (1272/2008): Skin Sens. 1;H317 Muta. 2;H341 Carc. 1B;H350

DANGER

## 2.2. Label elements:



Contain: Formaldehyde

H317: May cause an allergic skin reaction. H341: Suspected of causing genetic defects.

H350: May cause cancer.

P201: Obtain special instructions before use. P261: Avoid breathing vapours/spray.

P280: Wear protective gloves/eye protection/face protection.
P333+P313: If skin irritation or rash occurs: Get medical advice/attention.
P308+P313: IF exposed or concerned: Get medical advice/attention.
P501: Dispose of contents/container to local waste disposal facility.

Restricted to professional users.

#### 2.3. Other hazards:

PBT/vPvB: No ingredients are PBT/vPvB, according to the criteria in REACH Annex XIII.

Endocrine disrupting properties: The substances are not identified as having endocrine disrupting properties in accordance with the criteria set out in Regulation 2017/2100 or Regulation 2018/605.



# **SECTION 3: Composition/information on ingredients**

## 3.2. Mixtures:

% W	w Substance name	CAS-no.	EC-no.	Index-no.	REACH regno.	Classification	Note
3.8-4	.2 Formaldehyde	50-00-0	200-001-8	605-001-00-5	-	Acute Tox. 3;H301+H311+H	[331 1
						Skin Corr. 1B;H314	
						Skin Sens. 1;H317	
						Muta. 2;H341 Carc. 1B;H350	)
< 0.2	Methanol	67-56-1	200-659-6	603-001-00-X	-	Flam. Liq. 2;H225	2
						Acute Tox. 3;H301+H311+H	[331
						STOT SE 1:H370	

- 1) SCL (Specific Concentration limits) for classification (harmonized): Eye Irrit. 2;H319:  $5\% \le C < 25\%$ ; STOT SE 3;H335:  $C \ge 5\%$ ; Skin Corr. 1B;H314:  $C \ge 25\%$ ; Skin Irrit. 2;H315:  $5\% \le C < 25\%$ ; Skin Sens. 1;H317:  $C \ge 0.2\%$ . ATE (oral) = 100 mg/kg; ATE (dermal) = 270 mg/kg; ATE (inhalation, vapour) = 0.57 mg/l
- 2) SCL (Specific Concentration limits) for classification (harmonized): STOT SE 1;H370: C ≥ 10%; STOT SE 2;H371: 3% ≤ C < 10%. ATE (oral) = 100 mg/kg; ATE (dermal) = 300 mg/kg; ATE (inhalation, vapour) = 3 mg/l.

Wording of hazard statements - see section 16.

## **SECTION 4: First-aid measures**

#### 4.1. Description of first aid measures:

Inhalation: Move the affected person to fresh air. Mild cases: Keep at rest. If needed: get medical attention.

Severe cases: Place the person in recovery position and keep warm. If respiration has stopped, administer

artificial respiration. Seek medical advice immediately.

Skin contact: Remove contaminated clothing and wash skin with water and mild soap. In case of rash, wound, or other skin

irritation: Seek medical advice.

Eye contact: Immediately flush with water or physiological salt water for at least 15 minutes, holding eye lids open, remember

to remove contact lenses, if any. If irritation persists: Seek medical attention; continue to flush on the way.

Ingestion: Rinse mouth and drink plenty of water. Do not induce vomiting. If vomiting occurs keep head down to avoid

vomit in the lungs. Call a physician or ambulance immediately.

## 4.2. Most important symptoms and effects, both acute and delayed:

Irritation of the lungs, skin and eyes. Inhalation may cause headaches, nausea, dizziness, drowsiness, visual disturbances, vomiting and in greater amounts, possibly unconsciousness and blindness. Organic solvents can cause damage to the liver, kidneys and central nervous system (including brain damage). May cause cancer and are suspected of causing genetic defects. Sensitization.

#### 4.3. Indication of any immediate medical attention and special treatment needed:

In case of unconsciousness: Immediately seek medical advice. Show this safety data sheet to a physician or emergency ward.

## **SECTION 5: Firefighting measures**

#### 5.1. Extinguishing media:

Use water spray (never water jet), dry chemical, foam or carbon dioxide.

## 5.2. Special hazards arising from the substance or mixture:

Do not inhale smoke fumes. In case of fire, the product may form hazardous decomposition products: Oxides of carbon.

## 5.3. Advice for firefighters:

Wear self-contained breathing apparatus when generation of smoke is vigorous.

## **SECTION 6: Accidental release measures**

## 6.1. Personal precautions, protective equipment and emergency procedures:

Use personal protective equipment – see section 8. Avoid further spreading. Ventilate area of leak or spill.

#### 6.2. Environmental precautions:

Do not empty into drains – see section 12. Inform appropriate authorities in accordance with local regulations.

#### 6.3. Methods and material for containment and cleaning up:

Absorb spilled liquid with inert material and place in a suitable container for disposal. Flush area of spill with plenty of water. Further handling of spillage - see section 13.

#### 6.4. Reference to other sections:

See references above.



# **SECTION 7: Handling and storage**

## 7.1. Precautions for safe handling:

AVOID ALL CONTACT! Take off immediately all contaminated clothing. Wash contaminated skin with water and mild soap. Warn laundry staff about the chemical's hazardous properties. Required access to Emergency shower, water and eye wash fountain. Avoid breathing vapours. Provide adequate ventilation. Good personal hygiene is necessary. After use, wash with plenty of soap and water. Do not eat, drink, smoke or store food, beverages and tobacco when there is a risk of contamination by carcinogens.

#### 7.2. Conditions for safe storage, including any incompatibilities:

Store in a tightly closed original container and a well-ventilated area at 10-25°C. Store securely and out of reach of unauthorized personnel and separated from food, feed, drugs etc.

#### 7.3. Specific end use(s):

See section 1.

## **SECTION 8: Exposure controls/personal protection**

#### **8.1. Control parameters:**

<sup>\*</sup> Limit value 0.5 ppm/0.62 mg/m³ for the health care, funeral and embalming sectors until 11.07.2024.

<b>DNEL:</b>	Exposure	Value	Population	<b>Effects</b>
Methanol	Long term - inhalation	260 mg/m <sup>3</sup>	Worker	Systemic
	Long term - dermal	40 mg/kg/d	Worker	Systemic
	Short term - dermal	40 mg/kg/d	Worker	Systemic
	Short term - inhalation	$260 \text{ mg/m}^3$	Worker	Systemic/Local
	Long term - dermal	8 mg/kg/d	Consumer	Systemic
	Long term - inhalation	$50 \text{ mg/m}^3$	Consumer	Systemic
	Long term, oral	8 mg/kg/d	Consumer	Systemic
	Long term - inhalation	$50 \text{ mg/m}^3$	Consumer	Local
PNEC:	Medium	<u>Value</u>		
Methanol	Freshwater	154 mg/l		
	Marine water	15,4 mg/l		
	Intermittent release	1540 mg/l		
	Freshwater sediment	570,4 mg/kg		
	Soil	25,5 mg/kg		

## 8.2. Exposure controls:

Appropriate engineering controls: Provide adequate ventilation.

Personal protective equipment:

Inhalation: In case of in-adequate ventilated working areas: Use an approved mask (EN140) with a gasfilter type Ax+

formaldehyde (brown/olive green - organic vapours and formaldehyde. Particle filter P2 must be used as prefilter.

The filters have a limited lifetime and must be changed. Read the instructions.

Skin: Wear protective gloves (EN374) of butyl rubber. Data about the breakthrough time are not available. Replacing the

glove after use is therefore strongly recommended.

Eyes: Wear tight fitting safety goggles (EN166) when there is risk of contact.

Environmental exposure controls: None particular.



# **SECTION 9: Physical and chemical properties**

#### 9.1. Information on basic physical and chemical properties:

Physical state: Liquid
Colour: Colourless
Odour: Characteristic
Melting point/freezing point (°C): Not determined

Boiling point or initial boiling point and boiling range ( $^{\circ}$ C):  $\sim 100$  Flammability (solid, gas): Not relevant Lower and upper explosion limit (vol-%): Not determined Flash point ( $^{\circ}$ C): Not determined Auto-ignition temperature ( $^{\circ}$ C): Not determined Decomposition temperature ( $^{\circ}$ C): Not determined pH: 7.0 ( $\pm$ 0.1) Kinematic viscosity (mm²/s, 40°C): Not determined

Solubility: Completely miscible with water

Partition coefficient n-octanol/water (log value): Not determined

Vapour pressure (kPa, 20°C): 0.19
Density and/or relative density: 1.017

Relative vapour density:

Particle characteristics:

Not determined

Not relevant for liquids

9.2. Other information:

Odor threshold 0.05-1

## **SECTION 10: Stability and reactivity**

#### 10.1. Reactivity:

No data available.

#### 10.2. Chemical stability:

Stable under normal conditions (see section 7).

## 10.3. Possibility of hazardous reactions:

None known.

## 10.4. Conditions to avoid:

Avoid excessive heating. Keep away from sources of ignition, sparks and embers.

#### 10.5. Incompatible materials:

Reacts violently with oxidising materials, magnesium carbonate, metals and metal alloys as well as acids (contact with hydrochloric acid may cause formation of the carcinogen bis(chloro methyl)-ether. Contact with alkali metals can initiate polymerization to paraformaldehyde.

#### 10.6. Hazardous decomposition products:

When heated to high temperatures (decomposition) toxic fumes are emitted: Oxides of carbon.

# **SECTION 11: Toxicological information**

## 11.1. Information on hazard classes as defined in Regulation (EC) No 1272/2008:

Acute toxicity: Based on available data, the classification criteria are not met.

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 sensitization: Skin Sens. 1;H317 May cause an allergic skin reaction.

Germ cell mutagenicity: Muta. 2;H341 Suspected of causing genetic defects.

Carcinogenicity: Carc. 1B;H350 May cause cancer.

Reproductive toxicity: Based on available data, the classification criteria are not met.

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 11: Toxicological information (continued)**

Hazard class	Data	Test	Data source
Acute toxicity:			
Inhalation	$LC_{50}$ (rat) = 0.57 mg/l/4H (Formaldehyde)	OECD 403	ECHA
	$LC_{50}$ (rat) = 83.9 mg/l/4H (Methanol)	No info	IUCLID
Dermal	$LD_{50}$ (rabbit) = 270 mg/kg (Formaldehyde)	No info	RTECS
	$LD_{50}$ (rat) = 12800 mg/kg (Methanol)	No info	IUCLID
Oral	$LD_{50}$ (rat) = 100 mg/kg (Formaldehyde)	No info	RTECS
	$LD_{50}$ (rat) = 5300 mg/kg (Methanol)	No info	IUCLID
Corrosion/irritation:	Severe skin- and eye irritation, rabbit, (Formaldehyde)	No info	IUCLID
	No skin irritation, rabbit (Methanol)	OECD 404	IUCLID
	Moderate eye irritation, rabbit (Methanol)	Draize	IUCLID
Sensitization:	Skin sensitization, guinea pig (Formaldehyde)	Buehler	IUCLID
CMR:	$TD_{Lo}$ (oral, rat) = 109000 mg/kg/2Y (continuous):	No info	RTECS
	"Carcinogenic" (Formaldehyde)		
	Genotoxicity, in vivo test, rodent (Formaldehyde)	Micronucleus assay etc	IUCLID
	$TD_{Lo}$ (oral, female rat) = 186 mg/kg 1-21D after conception:	No info	IUCLID
	"Effects on new-born" (Formaldehyde)		
	$TC_{Lo}$ (inhalation, male rat) = 35 $\mu$ g/m <sup>3</sup> /8H 60D before	No info	IUCLID
	mating "Paternal effects" (Formaldehyde)		

Information on likely routes of exposure: Inhalation, skin and ingestion.

Symptoms:

Vapours may cause irritation to the airways. High vapour concentrations may cause water in the lungs Inhalation:

(pulmonary oedema). Symptoms (shortness of breath) may occur several hours after exposure.

Skin: May cause irritation, redness and drying of skin. Methanol and formaldehyde may be absorbed through the

skin and by extensive skin contact cause symptoms like those mentioned under "Inhalation".

Eyes: Splashes and vapours may cause irritation with redness, pain and blurred vision.

Ingestion: Irritation of mouth, throat and stomach with symptoms like discomfort, nausea, vomiting, pain and diarrhoea.

Methanol may be absorbed thought the gastrointestinal tract and cause severe poisoning.

Chronic effects: Formaldehyde is by the Danish labour inspection considered to be a highly potent carcinogen. Excess

> incidence of cancer of the nose and upper airways, leukaemia and brain cancer mortality has been detected in people who have worked with formaldehyde. Formaldehyde may cause allergic skin reactions with symptoms like redness, swelling and itching in susceptible people. Prolonged or frequent exposure to vapours of volatile organic compounds may result in damage on liver, kidneys, blood or central nervous system (including brain

damage). Laboratory tests have shown that formaldehyde may cause damage to the genetic material.

11.2. Information on other hazards: None known.

# **SECTION 12: Ecological information**

#### 12.1. Toxicity:

Akvatisk	Data	Test (Media)	Reference
Fish	LC <sub>50</sub> (Pimephales promelas, 96h) > 10000 mg/l (Methanol)	No info	No info
	LC <sub>50</sub> (Morone saxitilis, 96h) = 6.7 mg/l (Formaldehyde)	Static (FW)	IUCLID
Crustacean	$EC_{50}$ (Ceriodaphnia dubia, 48h) = 11 mg/l (Methanol)	No info (FW)	ICULID
	LC <sub>50</sub> (Daphnia magna, 48h) = 2 mg/l (Formaldehyde)	No info (FW)	IUCLID
Algae	IC <sub>50</sub> (Pseudokirchneriella sub. 96h) = 15300 mg/l (Methanol)	No info (FW)	EPA Ecotox
	EC <sub>50</sub> (Pseudokirchneriella sub. 48h) = 4.2 mg/l (Formaldehyde)	No info (FW)	<b>EPA Ecotox</b>

#### 12.2. Persistence and degradability:

Methanol and formaldehyde are readily biodegradable (OECD 301).

#### 12.3. Bioaccumulative potential:

Methanol and formaldehyde: Log K<sub>ow</sub> <1 (no significant bioaccumulative effect).

### 12.4. Mobility in soil:

Methanol and formaldehyde: K<sub>oc</sub> < 10 (high to very high mobility in soil environments is expected).

## 12.5. Results of PBT and vPvB assessment:

No ingredients are PBT/vPvB, according to the criteria in REACH Annex XIII.

## 12.6. Endocrine disrupting properties:

None known.

### 12.7. Other adverse effects:

Formaldehyde is damaging to protozoans and is a disinfectant.



# **SECTION 13: Disposal considerations**

#### 13.1. Waste treatment methods:

The chemical is to be considered as hazardous waste. To municipal collection point or waste disposal facility.

#### **EWC-code:**

16 05 06 Residues

15 02 02 Absorbent contaminated with product

# **SECTION 14: Transport information**

Not hazardous for transportation (ADR/RID/IMDG/IATA)

14.1. UN number or ID number: None. 14.2. UN proper shipping name: None. 14.3. Transport hazard class(es): None.

14.4. Packing group: None.

14.5. Environmental hazards: No.14.6. Special precautions for user: None.

14.7. Maritime transport in bulk according to IMO instruments: Not relevant.

# **SECTION 15: Regulatory information**

## 15.1. Safety, health and environmental regulations/legislation specific for the substance or mixture:

Must not be used by persons under 18 years of age.

The employer shall assess the working conditions and, if there is any risk to the safety or health and any effects on the pregnancy or breastfeeding of workers, take the necessary measures to adjust the working conditions (Directive 92/85/EEC).

## 15.2. Chemical safety assessment:

No CSR.

# **SECTION 16: Other information**

#### Hazard statements mentioned in section 3:

H225: Highly flammable liquid and vapour.

H301+H311+H331: Toxic if swallowed, in contact with skin or if inhaled.

H314: Causes severe skin burns and eye damage.
H317: May cause an allergic skin reaction.
H341: Suspected of causing genetic defects.

H350: May cause cancer. H370: Causes damage to organs.

#### **Abbreviations:**

CMR = Carcinogenicity, mutagenicity and reproductive toxicity.

CSR = Chemical Safety Report DNEL = Derived No-Effect Level EC<sub>50</sub> = Effect Concentration 50%

FW = Fresh Water

 $LC_{50}$  = Lethal Concentration 50%

 $LD_{50}$  = Lethal Dose 50%

PBT = Persistent, Bioaccumulative, Toxic PNEC = Predicted No-Effect Concentration

vPvB = very Persistent, very Bioaccumulative

#### Literature:

ECHA = REACH Registration Dossier from ECHA's website.

EPA Ecotox = US Environmental Protection Agency

IUCLID = International Uniform ChemicaL Database Information

RTECS = Register of Toxic Effects of Chemical Substances

## Training advice:

No special training is required. However, the user should be well instructed in the execution of his/her task, be familiar with this Safety Data Sheet and have normal training in the use of personal protective equipment.

## Changes since the previous edition:

1, 2, 3, 7, 8, 9 & 11

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