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® Biopsy Container
UFI: V300-W0XH-N00A-GKJU
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.jacobsen@axlab.dk
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. 1A;H317 Acute Tox. 4;H332 Muta. 2;H341 Carc. 1B;H350
2.2. Label elements:

DANGER

Contain: Formaldehyde
H317: May cause an allergic skin reaction.
H332: Harmful if inhaled.
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 Regulation 2023/707.
Endocrine disrupting properties: The substances are not identified as having endocrine disrupting properties in accordance with the criteria set out in Regulation 2023/707.

SECTION 3: Composition/information on ingredients

3.2. Mixtures:

% w/w	Substance name	CAS-no.	EC-no.	Index-no.	REACH reg.-no.	Classification	Note
3.8-4.2	Formaldehyde	50-00-0	200-001-8	605-001-00-5	01-2119488953-20	Acute Tox. 2;H330 Acute Tox. 4;H302 Skin Corr. 1B;H314 Skin Sens. 1A;H317 Muta. 2;H341 Carc. 1B;H350 Eye Dam. 1;H318 EUH071	1
<0.2	Methanol	67-56-1	200-659-6	603-001-00-X	01-2119433307-44	Flam. Liq. 2;H225 Acute Tox. 3;H301+H311+H331 STOT SE 1;H370	2

1) SCL (Specific Concentration limits) for classification (harmonized): Eye Irrit. 2;H319: 5% ≤ C < 25%; STOT SE 3;H335: C ≥ 5%; Skin Corr. 1B;H314: C ≥ 25%; Skin Irrit. 2;H315: 5% ≤ C < 25%. ATE (oral) = 500 mg/kg; ATE (inhalation, gasses) = 100 ppm V.
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:

Occupational exposure limit values (2024):	**8-hour TWA**	**15-min STEL**	**Notes**
Formaldehyde*	0.3 ppm / 0.37 mg/m^3	0.6 ppm / 0.738 mg/m^3	BOELV, Carc1B
Methanol	200 ppm / 260 mg/m^3	-	Sk

* Limit value 0.5 ppm/0.62 mg/m^3 for the health care, funeral and embalming sectors until 11.07.2024.
Sk: Substances which have the capacity to penetrate intact skin when they come in contact with it and be absorbed into the body.
A substantial contribution to the total body burden via dermal exposure is possible.

DNEL:	**Exposure**	**Value**	**Population**	**Effects**
Formaldehyde	Long term - inhalation	9 mg/m^3	Worker	Systemic
	Long term - inhalation	375 µg/m^3	Worker	Local
	Long term - dermal	240 mg/kg/d	Worker	Systemic
	Short term - dermal	37 µg/cm^2	Worker	Local
	Short term - inhalation	750 µg/m^3	Worker	Local
	Long term - dermal	102 mg/kg/d	Consumer	Systemic
	Long term - dermal	12 µg/cm^2	Consumer	Local
	Long term - inhalation	3,2 mg/m^3	Consumer	Systemic
	Long term, oral	4,1 mg/kg/d	Consumer	Systemic
	Long term - inhalation	100 µg/m^3	Consumer	Local
Methanol	Long term - inhalation	260 mg/m^3	Worker	Systemic
	Long term - dermal	40 mg/kg/d	Worker	Systemic
	Short term - dermal	40 mg/kg/d	Worker	Systemic
	Short term - inhalation	260 mg/m^3	Worker	Systemic/Local
	Long term - dermal	8 mg/kg/d	Consumer	Systemic
	Long term - inhalation	50 mg/m^3	Consumer	Systemic
	Long term, oral	8 mg/kg/d	Consumer	Systemic
	Long term - inhalation	50 mg/m^3	Consumer	Local

PNEC:	**Medium**	**Value**
Formaldehyde	Freshwater	440 µg/l
	Marine water	440 µg/l
	Freshwater sediment	2,3 mg/kg
	Sea water sediment	2,3 mg/kg
	Intermittent release	4,44 mg/l
	STP	190 µg/l
	Soil	200 mg/kg
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

SECTION 8: Exposure controls/personal protection (continued)

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 (EN ISO 16321-1) 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 (°C):	~ 100
Flammability (solid, gas):	Not relevant
Lower and upper explosion limit (vol-%):	Not determined
Flash point (°C):	Not determined
Auto-ignition temperature (°C):	Not determined
Decomposition temperature (°C):	Not determined
pH:	7.0 (±0.1)
Kinematic viscosity (mm^2/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:	Not determined
Particle characteristics:	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: Acute Tox. 4;H332 Harmful if inhaled.
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. 1A;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.

Hazard class	Data	Test	Data source
Acute toxicity:			
Inhalation	LC_{50} (rat, gas) = 100 ppm/4h (Formaldehyde)	OECD 403	ECHA
	LC_{50} (rat) = 83.9 mg/l/4h (Methanol)	No info	IUCLID
Dermal	LD_{50} (rat) = 12800 mg/kg (Methanol)	No info	IUCLID
Oral	LD_{50} (rat) = 500 mg/kg (Formaldehyde)	No info	ECHA
	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): "Carcinogenic" (Formaldehyde)	No info	RTECS
	Genotoxicity, in vivo test, rodent (Formaldehyde)	Micronucleus assay etc	IUCLID
	TD_{Lo} (oral, female rat) = 186 mg/kg 1-21D after conception: "Effects on new-born" (Formaldehyde)	No info	IUCLID
	TC_{Lo} (inhalation, male rat) = 35 µg/m^3/8H 60D before mating "Paternal effects" (Formaldehyde)	No info	IUCLID

Information on likely routes of exposure: Inhalation, skin and ingestion.
Symptoms:
Inhalation: Vapours may cause irritation to the airways. High vapour concentrations may cause water in the lungs (pulmonary oedema). Symptoms (shortness of breath) may occur several hours after exposure.
Skin: May cause irritation, redness and drying of skin. Methanol 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_{50} (Lepomis macrochinus, 96h) = 15400 mg/l (Methanol)	No info (FW)	Litterature
	LC_{50} (Pimephales promelas, 96h) = 24,1 mg/l (Formaldehyde)	OECD 203 (FW)	ECHA
Crustacean	EC_{50} (Ceriodaphnia dubia, 48h) = 11 mg/l (Methanol)	No info (FW)	ICULID
	LC_{50} (Daphnia magna, 48h) = 2 mg/l (Formaldehyde)	No info (FW)	IUCLID
	NOEC (Daphnia magna, 21d) = 1,04 mg/l (Formaldehyde)	OECD 211 (FW)	ECHA
Algae	IC_{50} (Pseudokirchneriella sub. 96h) = 15300 mg/l (Methanol)	No info (FW)	EPA Ecotox
	EC_{50} (Pseudokirchneriella sub. 48h) = 4.2 mg/l (Formaldehyde)	No info (FW)	EPA Ecotox

SECTION 12: Ecological information (continued)

12.2. Persistence and degradability:
Methanol and formaldehyde are readily biodegradable (OECD 301).
12.3. Bioaccumulative potential:
Methanol and formaldehyde: Log K_{ow} <1 (no significant bioaccumulative effect).
12.4. Mobility in soil:
Methanol and formaldehyde: K_{oc} < 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 Regulation 2023/707.
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).

Restrictions cf. REACH Annex XVII:
Formaldehyde (point 77)
Methanol (point 69 and 40)
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.
H302:	Harmful if swallowed.
H314:	Causes severe skin burns and eye damage.
H317:	May cause an allergic skin reaction.
H318:	Causes serious eye damage.
H330:	Fatal if inhaled.
H341:	Suspected of causing genetic defects.
H350:	May cause cancer.
H370:	Causes damage to organs.

SECTION 16: Other information (continued)

Abbreviations:
CMR = Carcinogenicity, mutagenicity and reproductive toxicity.
CSR = Chemical Safety Report
DNEL = Derived No-Effect Level
EC_{50} = 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, 8, 11, 12, 15 & 16

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