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

Printing date 06.09.2017 Revision: 06.09.2017

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

· 1.1 Product identifier

· Trade name: HistoPot - 10% Buffered Formalin

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· Article number: (S) 10-B-FOR-

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 Fixative for Histology

· 1.3 Details of the supplier of the safety data sheet

Manufacturer/Supplier:

Serosep Ltd.

Annacotty Business Park

Annacotty
Co. Limerick
Ireland

· Further information obtainable from:

Tel: +353 61 358190 Fax: +353 61 358191

E-mail: acoonerty@serosep.com

1.4 Emergency telephone number:

Emergency medical information: 8am-10pm (seven days) contact National Poisons Information Centre,

Beaumont Hospital, Dublin 9. Tel 01 8092566.

SECTION 2: Hazards identification

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



GHS08 health hazard

Muta. 2 H341 Suspected of causing genetic defects.

Carc. 1B H350 May cause cancer.



Skin Sens. 1 H317 May cause an allergic skin reaction.

- · 2.2 Label elements
- Labelling according to Regulation (EC) No 1272/2008

The product is classified and labelled according to the CLP regulation.

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· Hazard pictograms





GHS07 GHS08

- Signal word Danger
- · Hazard-determining components of labelling:

formaldehyde

· Hazard statements

H317 May cause an allergic skin reaction.

H341 Suspected of causing genetic defects.

H350 May cause cancer.

Precautionary statements

P261 Avoid breathing dust/fume/gas/mist/vapours/spray.

P280 Wear protective gloves/protective clothing/eye protection/face protection.

P308+P313 IF exposed or concerned: Get medical advice/attention.

P321 Specific treatment (see on this label).

P405 Store locked up.

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.

· Dangerous components:				
CAS: 50-00-0	formaldehyde	4.0%		
EINECS: 200-001-8	Acute Tox. 3, H301; Acute Tox. 3, H311; Acute Tox. 3, H331; & Muta. 2, H341; Carc. 1B, H350; Acute Tox. 1B, H314; Acute Tox. 3, H331; & Muta. 2, H341; Carc. 1B, H350; Acute Tox. 3, H331;			
CAS: 67-56-1	methanol	1.0%		
EINECS: 200-659-6	♦ Flam. Liq. 2, H225; ♦ Acute Tox. 3, H301; Acute Tox. 3, H311; Acute Tox. 3, H331; ♦ STOT SE 1, H370			

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

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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 and to be sure call for a doctor.

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

- · After skin contact: Immediately wash with water and soap and rinse thoroughly.
- · 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:

Dilute with plenty of water.

Do not allow to enter sewers/ surface or ground water.

6.3 Methods and material for containment and cleaning up:

Absorb with liquid-binding material (sand, diatomite, acid binders, universal binders, sawdust).

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.

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SECTION 7: Handling and storage

· 7.1 Precautions for safe handling

Ensure good ventilation/exhaustion at the workplace.

Open and handle receptacle with care.

Prevent formation of aerosols.

- · Information about fire and explosion protection: Keep respiratory protective device available.
- · 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.
- 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 monito	ring at the workplace:

50-00-0 formaldehyde

OEL Short-term value: 0.4 ppm

Long-term value: 0.2 ppm

Carc 1B, Sens

67-56-1 methanol

OEL Long-term value: 260 mg/m³, 200 ppm

Sk, IOELV

- · 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.

Immediately remove all soiled and contaminated clothing

Wash hands before breaks and at the end of work.

Store protective clothing separately.

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.

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If egineeriing contols cannot provide adequate protectionthen a certified respirator, fitted with an appropriate chemical vapour cartridge such as an A2B2E2K2P3 rated filter should be used.

Users must be trained in the care, use, and replacement of respirators and filters.

· 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.

Nitrile chemical gloves should be used when handling formaldehyde solutions.

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:



Tightly sealed goggles

suitable eye protection, for example, chemical rated safety glasses, goggles or face shield, should be used.

SECTION 9: Physical and chemical properties

- · 9.1 Information on basic physical and chemical properties
- · General Information
- · Appearance:

Form: Fluid

Colour: According to product specification

Odour: Characteristic
Odour threshold: Not determined.

· **pH-value:** Not determined.

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Change in condition Melting point/freezing point: Initial boiling point and boiling range	Undetermined. : 100 °C
Flash point:	Not applicable.
Flammability (solid, gas):	Not applicable.
Ignition temperature:	
Decomposition temperature:	Not determined.
Auto-ignition temperature:	Product is not selfigniting.
Explosive properties:	Product does not present an explosion hazard.
Explosion limits: Lower: Upper:	Not determined. Not determined.
Vapour pressure at 20 °C:	23 hPa
Density: Relative density Vapour density Evaporation rate	Not determined. Not determined. Not determined. Not determined.
Solubility in / Miscibility with water:	Fully miscible.
Partition coefficient: n-octanol/water:	Not determined.
Viscosity: Dynamic: Kinematic:	Not determined. Not determined.
Solvent content: Organic solvents: Water: VOC (EC)	5.0 % 94.0 % 5.00 %
Solids content: 9.2 Other information	90.0 % No further relevant information available.

SECTION 10: Stability and reactivity

· 10.1 Reactivity No further relevant information available.

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- · 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 Based on available data, the classification criteria are not met.
- · LD/LC50 values relevant for classification:

50-00-0 formaldehyde

Oral LD50 >200 mg/kg (rat)

- · 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

May cause an allergic skin reaction.

- CMR effects (carcinogenity, mutagenicity and toxicity for reproduction)
- · Germ cell mutagenicity

Suspected of causing genetic defects.

Carcinogenicity

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 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 2 (German Regulation) (Self-assessment): hazardous for water Do not allow product to reach ground water, water course or sewage system.

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Danger to drinking water if even small quantities leak into the ground.

- 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.
- Recommended cleansing agents: Water, if necessary together with cleansing agents.

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

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SECTION 15: Regulatory information

- · 15.1 Safety, health and environmental regulations/legislation specific for the substance or mixture
- · Directive 2012/18/EU
- · Named dangerous substances ANNEX I formaldehyde, methanol
- · REGULATION (EC) No 1907/2006 ANNEX XVII Conditions of restriction: 3
- · National regulations:
- Information about limitation of use:

Workers are not allowed to be exposed to the hazardous carcinogenic materials contained in this preparation. Exceptions can be made by the authorities in certain cases.

· 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

H225 Highly flammable liquid and vapour.

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.

H341 Suspected of causing genetic defects.

H350 May cause cancer.

H370 Causes damage to organs.

- · Department issuing SDS: Chemical Laboratory
- · Contact: A. Coonerty
- 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)

LC50: Lethal concentration, 50 percent

LD50: Lethal dose, 50 percent

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PBT: Persistent, Bioaccumulative and Toxic vPvB: very Persistent and very Bioaccumulative

Flam. Liq. 2: Flammable liquids – Category 2
Acute Tox. 3: Acute toxicity – Category 3
Skin Corr. 1B: Skin corrosion/irritation – Category 1B
Skin Sens. 1: Skin sensitisation – Category 1
Muta. 2: Germ cell mutagenicity – Category 2
Carc. 1B: Carcinogenicity – Category 1B
STOT SE 1: Specific target organ toxicity (single exposure) – Category 1