

MIRACLEAN TECHNOLOGY CO.,LTD.

NO.18 RONGSHUXIA INDUSTRIAL ZONE, TONGLE COMMUNITY, LONGGANG DISTRICT, SHENZHEN, CHINA
518116

SGS Job No. : CP20-063334 - SZ
Sample Name : Disposable Sampling Swab
End Uses : Collect biological samples from human body for testing in medical institutions.
Composition/Ingredient of sample (as per client submission) : See *section 3 Composition/information on ingredients* on the SDS report
Job Receiving Date : 03 Dec 2020
SDS Preparation Period : 03 Dec 2020-09 Dec 2020

Service Requested : Safety Data Sheet (SDS) for the sample with submitted composition.

Summary : As per request, the contents and formats of the SDS are prepared in accordance with European Commission Regulation (EC) No 1907/2006, Regulation (EC) No 1272/2008 and Regulation (EU) No 2015/830, and is provided per attached.

Remark:

The SDS is prepared based on the information provided by client.

* This sample is likely to be classified as medical device and is out of scope of a SDS as set out in Regulation (EC) No 1907/2006. This SDS is generated for client's reference only.

Signed for and on behalf of
SGS-CSTC Standards Technical Services Co., Ltd. Guangzhou Branch

Zm guan
Approved Signatory



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Attention: To check the authenticity of testing /inspection report & certificate, please contact us at telephone: (86-755) 8307 1443, or email: CN.Doccheck@sgs.com

Safety data sheet

Regulation (EC) No. 1907/2006 and 1272/2008

Printing date 09.12.2020

Version number 1

Revision: 09.12.2020

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

- **1.1 Product identifier**
- **Trade name:** *Disposable Sampling Swab*
- **1.2 Relevant identified uses of the substance or mixture and uses advised against**
- **Application of the substance / the mixture:**
Collect biological samples from human body for testing in medical institutions.
- **1.3 Details of the supplier of the safety data sheet**
- **Manufacturer / Supplier:** *MIRACLEAN TECHNOLOGY CO.,LTD.*
- **Full address:**
NO.18 RONGSHUXIA INDUSTRIAL ZONE, TONGLE COMMUNITY, LONGGANG DISTRICT, SHENZHEN, CHINA 518116
- **Phone number:** *86-755-89161773*
- **Email:** *2853001573@qq.com*
- **Only Representative / other EU contact point:** *Not available*
- **Further information obtainable from:** *MIRACLEAN TECHNOLOGY CO.,LTD.*
- **1.4 Emergency telephone number:**
GERMANY
Poison Center Berlin - Institute of Toxicology
Tel: +49 030 192 40
- **1.5 Reference Number:** *CANEC2021492501,CP20-063334 - SZ*
- **1.6 Remark:**
** This sample is likely to be classified as medical device and is out of scope of a SDS as set out in Regulation (EC) No 1907/2006. This SDS is generated for client's reference only.*

SECTION 2: Hazards identification

- **2.1 Classification of the substance or mixture**
- **Classification according to Regulation (EC) No 1272/2008**
The product is not classified according to the CLP regulation.
- **Information concerning particular hazards for human and environment:**
The product has not to be labelled due to the calculation procedure of Regulation (EC) No. 1272/2008.
- **Classification system:**
The classification is according to the latest edition of EU Regulation (EC) No. 1272/2008, and extended by company and literature data.
- **2.2 Label elements**
- **Labelling according to Regulation (EC) No. 1272/2008** *Void*
- **Hazard pictograms** *Void*
- **Signal word** *Void*
- **Hazard statements** *Void*
- **2.3 Other hazards:**
- **Results of PBT and vPvB assessment**
- **PBT:** *Not applicable.*
- **vPvB:** *Not applicable.*

SECTION 3: Composition/information on ingredients

- **3.2 Mixtures**
- **Description:**
Mixture of the substances listed below with nonhazardous additions.
For the wording of the listed hazard statements refer to section 16.

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· Composition:

CAS: 32472-85-8	1,3-Isobenzofurandione, polymer with 2,2'-oxybis(ethanol)	97%
CAS: 7732-18-5 EINECS: 231-791-2	Water	3%

· **Remark:** All ingredients listed above are not classified according to Regulation (EC) No. 1272/2008.

SECTION 4: First aid measures

- **4.1 Description of first aid measures**
- **General description:** No special measures required.
- **After inhalation:** Supply fresh air; consult doctor in case of complaints.
- **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:** If symptoms persist consult doctor.
- **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:** No special measures required.

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:** Pick up mechanically.
- **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:**
No special measures required.
For the general occupational hygienic measures refer to Section 8.
- **Information about fire - and explosion protection:** No special measures required.
- **7.2 Conditions for safe storage, including any incompatibilities**
- **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:** None.

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

SECTION 8: Exposure controls/personal protection

- **8.1 Control parameters**
- **Ingredients with limit values that require monitoring at the workplace:**
The product does not contain any relevant quantities of materials with critical values that have to be monitored at the workplace.
- **DNELs:** Not available
- **PNECs:** Not available
- **Additional information:** *The lists valid during the making were used as basis.*
- **8.2 Exposure controls**
Based on the composition shown in Section 3, the following measures are suggested for occupational safety measure.
- **Appropriate engineering controls:** *See Section 7 for information about design of technical facilities.*
- **Personal protective equipment**
- **Respiratory protection:** *Not required.*
- **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.*
- **Environmental exposure controls:**
Control measures must be made in accordance with Community environmental protection legislation.

SECTION 9: Physical and chemical properties

- **9.1 Information on basic physical and chemical properties**
- **Appearance**
- **Form:** Solid
- **Colour:** White
- **Odour:** Odourless
- **Odour threshold:** Not available
- **pH-value:** Not available
- **Change in condition**
- **Melting point/Freezing point:** Not available
- **Initial boiling point and boiling range:** Not available

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· Flash point:	Not available
· Flammability (solid, gas):	Not available
· Auto-ignition temperature:	Not available
· Decomposition temperature:	Not available
· Self-igniting:	Product is not selfigniting.
· Explosive properties:	Product does not present an explosion hazard.
· Explosion limits	
Lower:	Not available
Upper:	Not available
· Oxidising properties:	Not available
· Vapour pressure:	Not available
· Density:	Not available
· Relative density:	Not available
· Vapour density:	Not available
· Evaporation rate:	Not available
· Solubility in / Miscibility with water:	Not available
· Partition coefficient: n-octanol/water:	Not available
· Viscosity	
Dynamic:	Not available
Kinematic:	Not available
· 9.2 Other information	No further relevant information available.

SECTION 10: Stability and reactivity

- **10.1 Reactivity:** Data not available
- **10.2 Chemical stability:** Data not available
- **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:** Not available
- **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:** Based on available data, the classification criteria are not met.
- **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.
- **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.

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- **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.
- **12.5 Results of PBT and vPvB assessment**
- **PBT:** Not applicable.
- **vPvB:** Not applicable.
- **12.6 Other adverse effects** No further relevant information available.
- **12.7 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.

SECTION 13: Disposal considerations

- **13.1 Waste treatment methods**
- **Recommendation:** Smaller quantities can be disposed of with household waste.
- **Uncleaned packaging**
- **Recommendation:** Disposal must be made according to official regulations.

SECTION 14: Transport information

- | | |
|--|--|
| · 14.1 UN-Number | |
| · ADR/RID/ADN, IMDG, IATA | Not applicable |
| · 14.2 UN proper shipping name | |
| · ADR/RID/ADN, IMDG, IATA | Not applicable |
| · 14.3 Transport hazard class(es) | |
| · ADR/RID/ADN, IMDG, IATA | |
| · Class | Not applicable |
| · Label | - |
| · 14.4 Packing group | |
| · ADR/RID/ADN, IMDG, IATA | Not applicable |
| · 14.5 Environmental hazards | |
| · Marine pollutant: | No |
| · 14.6 Special precautions for user: | Not applicable |
| · Danger code (Kemler): | - |
| · 14.7 Transport in bulk according to Annex II of Marpol and the IBC Code | Not applicable |
| · 14.8 Transport/Additional information: | Not dangerous according to the above specifications. |

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· 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**

· **MAK(German Maximum Workplace Concentration)**

None of the ingredients is listed.

· **Directive 2012/18/EU**

· **Named dangerous substances - ANNEX I** None of the ingredients is listed.

· **Seveso category** Not applicable

· **Qualifying quantity (tonnes) for the application of lower-tier requirements** Not applicable

· **Qualifying quantity (tonnes) for the application of upper-tier requirements** Not applicable

· **National regulations:**

· **Waterhazard class:** Water hazard class 1 (Self-assessment): slightly hazardous for water.

· **Other regulations, limitations and prohibitive regulations**

· **SVHC Candidate List of REACH Regulation Annex XIV Authorisation (25/6/2020)**

None of the ingredients is listed

· **REACH Regulation Annex XVII Restriction (20/06/2019)**

See Section 16 for information about restriction of use.

None of the ingredients is listed

· **REACH Regulation Annex XIV Authorisation List (06/2/2020)**

None of the ingredients is listed

· **15.2 Chemical safety assessment:** A Chemical Safety Assessment has not been carried out.

SECTION 16: Other information

· *****

The contents and format of this SDS are in accordance with Regulation (EC) No 1907/2006, 1272/2008 and Regulation (EU) No 2015/830.

DISCLAIMER OF LIABILITY

The information in this SDS was obtained from sources which we believe are reliable. However, the information is provided without any warranty, express or implied, regarding its correctness. The conditions or methods of handling, storage, use or disposal of the product are beyond our control and may be beyond our knowledge. For this and other reason, we do not assume responsibility and expressly disclaim liability for loss, damage or expense arising out of or in any way connected with the handling, storage, use or disposal of the product. This SDS was prepared and is to be used only for this product. If the product is used as a component in another product, this SDS information may not be applicable.

Remark:

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· **Abbreviations and acronyms:**

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)

DNEL: Derived No-Effect Level (REACH)

PNEC: Predicted No-Effect Concentration (REACH)

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LC50: Lethal concentration, 50 percent

LD50: Lethal dose, 50 percent

PBT: Persistent, Bioaccumulative and Toxic

vPvB: very Persistent and very Bioaccumulative

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