

## SDS Service Summary

No.: SHACPCH24001369301

Date: 29 Jan 2024

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SGS Job No.	:	SHCPCH24000401
Applicant	:	Shanghai Uretech Film Material Co., Ltd
Product Name	:	Dental Film
Composition/Ingredient of product (as per applicant submission)	:	See <i>section 3 Composition/information on ingredients</i> on the SDS
Job Receiving Date	:	18 Jan 2024
Last Information Date	:	29 Jan 2024
SDS Preparation Period	:	18 Jan 2024-29 Jan 2024
Service Requested	:	Preparation of Safety Data Sheet (SDS) for the product with submitted information, with calculation of the classification and labeling requirement according to the submitted composition and European Commission Regulation (EC) No 1272/2008.
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 2020/878, and is provided per attached.

### Disclaimer

This Safety Data Sheet (SDS) is provided to applicant to fulfill European Commission Regulation (EC) No 1907/2006 and communicate the hazard information of chemicals through the supply chain to ensure safe use. It is not a test report or a certificate ensuring the safety of a product.

SGS has consolidated product information based on documents provided by Applicant (i.e. product name, the supplier details, product composition, available physical data, etc) without independent verification from SGS. The information is provided without any warranty, express or implied, regarding its correctness.



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Echo Cai  
Project Engineer

**Safety data sheet**  
Regulation (EC) No.1907/2006 and No.1272/2008

Printing date 29.01.2024

Version number 1

Revision date 19.01.2024

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

- **1.1 Product identifier**
- **Trade name:** *Dental Film*
  
- **1.2 Relevant identified uses of the substance or mixture and uses advised against**
- **Application of the substance / the mixture:**  
*It is for making orthodontic appliances, orthodontic retainers, oral protectors and jaw pads, etc.*
  
- **1.3 Details of the supplier of the safety data sheet**
- **Manufacturer/Supplier:**  
*Shanghai Uretech Film Material Co., Ltd*  
*Floor 1, Building 2, No. 88, Lane 819, Duhui Road, Minhang District, Shanghai.*  
*Tel: 15274888158*  
*E-mail: info@uretech.cn*
- **Only Representative/ other EU contact point:** *Not available*
  
- **1.4 Emergency telephone number:**  
*IRELAND*  
*National Poisons Information Centre*  
*Tel: +353 (01) 809 2566 (For healthcare professionals)*  
*+353 (01) 809 2166 (For public; 8am - 10pm)*
  
- **1.5 Reference Number:** *SHCPCH24000401; SHACPCH24001369301*
  
- **1.6 Remark:**  
*This product is likely to be classified as article and medical device and is out of scope of a SDS as set out in Regulation (EC) No 1907/2006. This SDS is generated for applicant's reference only.*

### SECTION 2: Hazards identification

- **2.1 Classification of the substance or mixture**
- **Classification according to Regulation (EC) No 1272/2008**  
*The substance 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** *Not applicable*
- **Hazard pictograms** *Not applicable*
- **Signal word** *Not applicable*
  
- **Hazard-determining components of labelling:** *Not applicable*
- **Hazard statements** *Not applicable*
- **Precautionary statements** *Not applicable*
  
- **2.3 Other hazards**
- **Results of PBT and vPvB assessment**
- **PBT:** *Not applicable.*
- **vPvB:** *Not applicable.*
- **Determination of endocrine-disrupting properties** *Not applicable*

### SECTION 3: Composition/information on ingredients

- **3.1 Substances**
- **CAS No. Description:**  
*Copolyester*
- **Remark:** *This product contains Copolyester 100% by weight.*

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### SECTION 4: First aid measures

- **4.1 Description of first aid measures**
- **General information:** No special measures required.
- **After inhalation:** Supply fresh air; consult doctor in case of complaints.
- **After skin contact:**  
Wash with water and soap and rinse thoroughly.  
If skin irritation continues, consult a doctor.
- **After eye contact:**  
Rinse opened eye for several minutes under running water. If symptoms persist, consult a doctor.
- **After swallowing:**  
Never give anything by mouth to an unconscious person.  
Rinse out mouth with water.  
Seek medical treatment.
- **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:**  
Wear fully protective suit.  
Mouth respiratory protective device.

### SECTION 6: Accidental release measures

- **6.1 Personal precautions, protective equipment and emergency procedures**  
Avoid formation of dust.  
Ensure adequate ventilation.  
Keep away from ignition sources.  
Use respiratory protective device against the effects of fumes/dust/aerosol.
- **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.  
Dispose contaminated material as waste according to section 13.
- **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**  
Ensure good ventilation/exhaustion at the workplace.  
Keep away from heat and direct sunlight.  
Prevent formation of dust.

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- For the general occupational hygienic measures refer to Section 8.
- **Information about fire - and explosion protection:** Normal measures for preventive fire protection.
- **7.2 Conditions for safe storage, including any incompatibilities**
- **Requirements to be met by storerooms and receptacles:** Store in a cool location.
- **Information about storage in one common storage facility:** Store away from foodstuffs.
- **Further information about storage conditions:** Store in cool, dry conditions in well sealed receptacles.
- **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:** Data not available
- **PNECs:** Data 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.
- **Individual protection measures, such as personal protective equipment**
- **Respiratory protection:** Suitable respiratory protective device recommended.
- **Hand protection**  
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.
- **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.
- **Eyeface protection** Goggles recommended during refilling.
- **Body protection:** Protective work clothing
- **Thermal hazards:** Not required for normal conditions of use.
- **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**
- **Physical state** Solid
- **Colour:** Transparent
- **Odour:** Odorless
- **Odour threshold:** Data not available
- **Melting point/freezing point:** Data not available
- **Boiling point or initial boiling point and boiling range** Data not available
- **Flammability** Data not available

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· <b>Lower and upper explosion limit</b>	
· <b>Lower:</b>	Data not available
· <b>Upper:</b>	Data not available
· <b>Flash point:</b>	Data not available
· <b>Auto-ignition temperature:</b>	Data not available
· <b>Decomposition temperature:</b>	Data not available
· <b>pH</b>	Data not available
· <b>Viscosity:</b>	
· <b>Kinematic viscosity</b>	Data not available
· <b>Dynamic viscosity:</b>	Data not available
· <b>Solubility</b>	
· <b>water:</b>	Data not available
· <b>Partition coefficient n-octanol/water (log value)</b>	Data not available
· <b>Vapour pressure:</b>	Data not available
· <b>Density and/or relative density</b>	
· <b>Density:</b>	Data not available
· <b>Relative density:</b>	Data not available
· <b>Relative vapour density:</b>	Data not available
· <b>Particle characteristics:</b>	Data not available

· **9.2 Other information**

· <b>Appearance:</b>	
· <b>Form:</b>	Solid

· <b>Information with regard to physical hazard classes</b>	
· <b>Explosives</b>	Not applicable
· <b>Flammable gases</b>	Not applicable
· <b>Aerosols</b>	Not applicable
· <b>Oxidising gases</b>	Not applicable
· <b>Gases under pressure</b>	Not applicable
· <b>Flammable liquids</b>	Not applicable
· <b>Flammable solids</b>	Not applicable
· <b>Self-reactive substances and mixtures</b>	Not applicable
· <b>Pyrophoric liquids</b>	Not applicable
· <b>Pyrophoric solids</b>	Not applicable
· <b>Self-heating substances and mixtures</b>	Not applicable
· <b>Substances and mixtures, which emit flammable gases in contact with water</b>	Not applicable
· <b>Oxidising liquids</b>	Not applicable
· <b>Oxidising solids</b>	Not applicable
· <b>Organic peroxides</b>	Not applicable
· <b>Corrosive to metals</b>	Not applicable
· <b>Desensitised explosives</b>	Not applicable
· <b>Other safety characteristics</b>	Data not available

## SECTION 10: Stability and reactivity

- **10.1 Reactivity:** No decomposition if used according to specifications.
- **10.2 Chemical stability:** Stable under recommended storage conditions.
- **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.

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- **10.6 Hazardous decomposition products:** No dangerous decomposition products known.

### 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.
- **LD/LC50 values relevant for classification:** Data 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 sensitisation** 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.
- **Aspiration hazard** Based on available data, the classification criteria are not met.

- **11.2 Information on other hazards**

- **Endocrine disrupting properties**

Substance is not listed.

- **Other information** No further relevant information available.

### 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 Endocrine disrupting properties**
- **The product does not contain substances with endocrine disrupting properties.**
- **12.7 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

- **14.1 UN number or ID number**
- **ADR/RID/ADN, IMDG, IATA** Not applicable

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· 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 · Label	Not applicable Not applicable
· 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
· 14.7 Maritime transport in bulk according to IMO instruments	Not applicable
· 14.8 Transport/Additional information:	Not dangerous according to the above specifications.
· UN "Model Regulation":	Not applicable

### 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 Substance is not listed.

· REGULATION (EU) 2019/1021 on persistent organic pollutants (POP)

Substance is not listed.

· Regulation (EU) No 649/2012

Substance is not listed.

· REGULATION (EU) 2019/1148

· Annex I - RESTRICTED EXPLOSIVES PRECURSORS (Upper limit value for the purpose of licensing under Article 5(3))

Substance is not listed.

· Annex II - REPORTABLE EXPLOSIVES PRECURSORS

Substance is not listed.

· Regulation (EC) No 273/2004 on drug precursors

Substance is not listed.

· Regulation (EC) No 111/2005 laying down rules for the monitoring of trade between the Community and third countries in drug precursors

Substance is not listed.

· REGULATION (EC) No 1005/2009 on substances that deplete the ozone layer – ANNEX I (Ozone-depleting potential)

Substance is not listed.

· Other regulations, limitations and prohibitive regulations

· SVHC Candidate List of REACH Regulation Annex XIV Authorisation (14/6/2023)

Substance is not listed.

· REACH Regulation Annex XVII Restriction ((25/9/2023)

See Section 16 for information about restriction of use.

Substance is not listed.

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· **REACH Regulation Annex XIV Authorisation List (8/4/2022)**

Substance is not 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 2020/878.

#### 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 reasons, 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.

#### · Abbreviations and acronyms:

ADR: Accord relatif au transport international 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  
 CAS: Chemical Abstracts Service (division of the American Chemical Society)  
 DNEL: Derived No-Effect Level (REACH)  
 PNEC: Predicted No-Effect Concentration (REACH)  
 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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