

# SAFETY DATA SHEET

## 1. Identification of the substance or mixture and of the supplier

### Product identifier

Product Family:

Thermoforming Sheet

### Additional identification

Chemical name:

Copolyester

This SDS covers all alphanumeric suffixes for the following product models. Suffixes designate sheet dimension and w/o surface protection film.

**Product model:** M-EC-BW1, M-EC-BA1

### Recommended use and restriction on use

Recommended use:

Orthodontic and oral care appliances

Restrictions on use:

None identified.

### Details of the supplier of the safety data sheet

#### Supplier

Company Name:

Shanghai Maxflex Medical Technology Co.,Ltd.

Address:

1169YuanquRD,  
AntingTown, adingDistrict  
Shanghai,China  
+8621-59560800

Telephone:

**Emergency telephone number: +8621-59560800**

## 2. Hazards identification

### Classification of the substance or mixture

Prepared according to Global Harmonized System (GHS) standards.

### GHS Classification

This product is not hazardous in the form in which it is shipped by the manufacturer.

### GHS Label Elements

Signal word:

Warning

Hazard statements:

If fine particles are generated during further processing, handling or by other means, product may form combustible dust concentrations in air.

**Other hazards which do not result in GHS classification:**

None identified.

## 3. Composition/Information on Ingredients

### Mixtures

Chemical name	CAS number	Percent by Weight
Copolyester	Proprietary	>95%
Pigment	Proprietary	<5%

## 4. First aid measures

## Description of first aid measures

<b>Inhalation:</b>	Remove exposed person to fresh air if adverse effects are observed. Treat symptomatically. If symptoms persist, call a physician.
<b>Eye contact:</b>	In the case of contact with eyes, rinse immediately with plenty of water and seek medical advice
<b>Skin Contact:</b>	Wash off with soap and water. If symptoms persist, call a physician. Cool skin rapidly with cold water after contact with molten material. Do not peel solidified product off the skin. Burns must be treated by a physician.
<b>Ingestion:</b>	Treat symptomatically. Get medical attention.
<b>Personal Protection for First-aid Responders:</b>	When providing first aid always protect yourself against exposure to chemicals or blood born diseases by wearing gloves, masks and eye protection. After providing first aid wash your exposed skin with soap and water.

**Most important symptoms and effects, both acute and delayed:** The molten product can cause serious burns.

**Indication of any immediate medical attention and special treatment needed**  
**Treatment:** Treat symptomatically.

## 5. Fire-fighting measures

<b>General Fire Hazards:</b>	No unusual fire or explosion hazards noted.
<b>Extinguishing media</b> <b>Suitable extinguishing media:</b>	Water spray Dry chemical Carbon dioxide (CO <sub>2</sub> )
<b>Unsuitable extinguishing media:</b>	Do not use a solid water stream as it may scatter and spread fire.
<b>Specific hazard arising from the chemical:</b>	Avoid generating dust; fine dust dispersed in air in sufficient concentrations, and in the presence of an ignition source is a potential dust explosion hazard.
<b>Advice for firefighters</b>  <b>Special fire fighting procedures:</b>	Thermoplastic polymers can burn. Protect product from flames; maintain proper clearance when using heat devices, etc. Irritating or toxic substances will be emitted upon burning, combustion or decomposition. Large masses of molten polymer held at elevated temperatures for extended periods of time may auto-ignite.
<b>Special protective equipment for fire-fighters:</b>	Wear full protective firegear including self-containing breathing apparatus operated in the positive pressure mode with full facepiece, coat, pants, gloves and boots.

## 6. Accidental Release Measures

<b>Personal precautions, protective equipment and emergency procedures:</b>	Wear appropriate personal protective equipment.
<b>Environmental Precautions:</b>	Avoid release to the environment. Prevent further leakage or spillage if safe to do so.
<b>Methods and material for containment and</b>	Pick up free solid for recycle and/or disposal.

**cleaning up:**

**Reference to other sections:**

See sections 8 and 13 for additional information.

## 7. Handling and Storage:

**Advice on protection against fire and explosion:**

Minimize dust generation and accumulation.  
Do not steam sterilize articles made with thermoplastic polyurethanes. Methylene dianiline can be generated as a result.  
Avoid breathing dust/fume/gas/mist/vapors/spray. Avoid contact with eyes, skin, and clothing. Observe good industrial hygiene practices. Provide adequate ventilation. Wear appropriate personal protective equipment. Wash hands thoroughly after handling. Contaminated work clothing should not be allowed out of the workplace. Launder contaminated clothing before reuse. Avoid environmental contamination.

**Advice on safe handling:**

Wash thoroughly after handling. Use only in area provided with appropriate exhaust ventilation. Minimize dust generation and accumulation.

**Avoid of contact:**

Keep tightly closed.

**Conditions for safe storage:**

Store in dry, well ventilated place away from sources of heat and direct sunlight.

**Maximum Storage Temperature:**

Not determined.

## 8. Exposure Controls/Personal Protection

**Control Parameters:**

**Occupational Exposure Limits**

None of the components have assigned exposure limits.

**Appropriate engineering controls:**

Thermal processing operations should be ventilated to control gases and fumes given off during processing. No special requirements under ordinary conditions of use and with adequate ventilation.

**Individual protection measures, such as personal protective equipment**

**General information:**

Use personal protective equipment as required.

**Eye/face protection:**

If contact is likely, safety glasses with side shields are recommended.

**Skin Protection**

**Hand Protection:**

To avoid burns from contact with molten product, use thermal insulating gloves. Suitable gloves can be recommended by the glove supplier.

**Other:**

Gloves, coveralls, apron, boots as necessary to minimize contact. Do not wear rings, watches or similar apparel that could entrap the material. Long sleeve shirt is recommended.

**Respiratory Protection:**

Use respiratory protection unless adequate local exhaust ventilation is provided or exposure assessment demonstrates that exposures are within recommended exposure guidelines. Wear respiratory protection when its use is identified for certain contributing scenario.

**Hygiene measures:**

Observe good industrial hygiene practices. Avoid contact with skin. Contaminated work clothing should not be allowed out of the workplace.

## 9. Physical and Chemical Properties

### Information on basic physical and chemical properties

#### Appearance

<b>Physical state:</b>	Solid
<b>Form:</b>	Sheets
<b>Color:</b>	Milky white or light yellow

<b>Odor:</b>	Odorless
<b>Odor Threshold:</b>	No data available.
<b>pH:</b>	No data available.
<b>Melting Point:</b>	No data available.
<b>Boiling Point:</b>	> 100 °C
<b>Flash Point:</b>	No data available.
<b>Evaporation Rate:</b>	No data available.
<b>Flammability (solid, gas):</b>	No data available.
<b>Upper/lower limit on flammability or explosive limits:</b>	No data available.
<b>Flammability Limit - Upper (%):</b>	No data available.
<b>Flammability Limit - Lower (%):</b>	No data available.
<b>Vapor pressure:</b>	No data available.
<b>Vapor density (air=1):</b>	No data available.
<b>Relative density:</b>	>1.1 (20 °C)
<b>Solubility(ies)</b>	
<b>Solubility in Water:</b>	Insoluble in water
<b>Solubility (other):</b>	No data available.
<b>Partition coefficient (n-octanol/water):</b>	No data available
<b>Autoignition Temperature:</b>	No data available.
<b>Decomposition Temperature:</b>	No data available.
<b>Viscosity:</b>	No data available.
<b>Explosive properties:</b>	No data available.
<b>Oxidizing properties:</b>	No data available.
<b>Pour Point Temperature:</b>	No data available.
<b>Other information</b>	
<b>Bulk density:</b>	No data available

## 10. Stability and Reactivity

<b>Reactivity:</b>	No data available.
<b>Chemical Stability:</b>	Material is stable under normal conditions.
<b>Possibility of hazardous reactions:</b>	Stable
<b>Conditions to avoid:</b>	Minimize dust generation and accumulation.
<b>Incompatible Materials:</b>	Strong oxidizing agents
<b>Hazardous Decomposition Products:</b>	May generate carbon monoxide, carbon dioxide (CO <sub>2</sub> )

## 11. Toxicological Information

## Information on likely routes of exposure

Inhalation:	No data available.
Ingestion:	No data available.
Skin Contact:	No data available.
Eye contact:	No data available.

## Information on toxicological effects

### Acute toxicity

#### Oral

Product:	May cause irritation of the gastrointestinal tract. Not classified for acute toxicity based on available data.
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#### Dermal

Product:	Not classified for acute toxicity based on available data.
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#### Inhalation

Product:	Overexposure to vapors or mist may cause dizziness, headache, nausea, and/or flu-like symptoms. Persons with sensitive airways (e.g., asthmatics) may react to vapors. Not classified for acute toxicity based on available data.
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### Skin Corrosion/Irritation:

Product:	Remarks: Contact with heated material may cause thermal burns. Pre-existing skin conditions may be aggravated by prolonged or repeated exposure. Not classified as a primary skin irritant.
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### Serious Eye Damage/Eye Irritation:

Product:	Remarks: Not classified as a primary eye irritant.
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### Skin sensitization:

Product:	Remarks: Under decomposition conditions, isocyanates may be generated from this product. Isocyanates can cause skin sensitization and/or respiratory sensitization.
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### Specific Target Organ Toxicity - Single Exposure:

No data available

### Aspiration Hazard:

No data available

### Chronic Effects

Carcinogenicity:	No data available
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### Germ Cell Mutagenicity:

No data available

### Reproductive toxicity:

No data available

### Specific Target Organ Toxicity - Repeated Exposure:

No data available

## 12. Ecological Information

### Ecotoxicity

Fish	No data available
Aquatic Invertebrates	No data available
Toxicity to Aquatic Plants	No data available
Toxicity to soil dwelling organisms	No data available
Sediment Toxicity	No data available
Toxicity to Terrestrial Plants	No data available
Toxicity to Above-Ground Organisms	No data available
Toxicity to microorganisms	No data available

**Persistence and Degradability Biodegradation**

No data available

**Bioaccumulative potential**

**Bioconcentration Factor (BCF)**

No data available

**Partition Coefficient n-octanol / water (log Kow)**

No data available

**Mobility**

No data available

**Other adverse effects**

**Product:**

Harmful to aquatic life with long lasting effects.

### 13. Disposal Considerations

**Disposal instructions:**

Treatment, storage, transportation, and disposal must be in accordance with applicable Federal, State/Provincial, and Local regulations. Dispose of packaging or containers in accordance with local, regional, national and international regulations. Empty container contains product residue which may exhibit hazards of product. Container packaging may exhibit hazards.

**Contaminated Packaging:**

### 14. Transport Information

**IATA**

Not regulated.

**IMDG**

Not regulated.

**Transport in bulk according to Annex II of MARPOL and the IBC Code**

None known

Shipping descriptions may vary based on mode of transport, quantities, temperature of the material, package size, and/or origin and destination. It is the responsibility of the transporting organization to follow all applicable laws, regulations and rules relating to the transportation of the material. For transportation, steps must be taken to prevent load shifting or materials falling, and all relating legal statutes should be obeyed. Review classification requirements before shipping materials at elevated temperatures.

### 15. Regulatory Information

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

**Inventory Status**

**Australia (AICS)**

This product contains a substance that is not listed on the Australia Inventory of Chemical Substances.

**Canada (DSL/NDSL)**

Requires notification in Canada. Research and development samples must comply with CEPA R&D requirements.

**China (IECSC)**

This product contains a substance or polymer that has been notified and is restricted to import by the notifier.

European Union (REACH)

To obtain information on the REACH compliance status of this product, please e-mail  
REACH@SDSInquiries.com.

Japan (ENCS)

All components are in compliance with the Chemical Substances Control Law of Japan.

Korea (ECL)

This product contains a substance or polymer that has been notified and is restricted to import by the notifier.

New Zealand (NZIoC)

This product requires notification before sale in New Zealand.

Philippines (PICCS)

All components are in compliance with the Philippines Toxic Substances and Hazardous and Nuclear Wastes Control Act of 1990 (R.A. 6969).

Switzerland (SWISS)

All components are in compliance with the Environmentally Hazardous Substances Ordinance in Switzerland.

Taiwan (TCSCA)

All components of this product are listed on the Taiwan inventory.

United States (TSCA)

All substances contained in this product are in compliance with section 5 of TSCA or are exempt. This product contains one or more polymers manufactured under the polymer exemption rule.

*The information that was used to confirm the compliance status of this product may deviate from the chemical information shown in Section 3.*

## 16. Other Information

**Other information:**

Contact supplier (see section 1)

**Issue Date:**

09.04.2022

**Disclaimer:**

As the conditions or methods of use are beyond our control, we do not assume any responsibility and expressly disclaim any liability for any use of this product. Information contained herein is believed to be true and accurate, but all statements or suggestions are made without warranty, expressed or implied, regarding accuracy of the information, the hazards connected with the use of the material or the results to be obtained from the use thereof. Compliance with all applicable federal, state, and local regulations remains the responsibility of the user.