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 – Polyurethane Composite

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

Product model：T-EADA-111

Recommended use and restriction on use

Recommended use: 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: 1169 Yuanqu RD,
Anting Town, Jiading District, Shanghai, China

Telephone: +8621-59560800

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	20 - 80%
Polyurethane	Proprietary	20 - 80%

4. First aid measures

Description of first aid measures

Inhalation: Remove exposed person to fresh air if adverse effects are observed. Treat symptomatically.If symptoms persist, call a physician.

Eye contact: If hot melted material should splash into the eyes, flush eyes immediately with water for 15 minutes while holding the eyelids open. Immediately call a poison center or doctor. Any material that contacts the eye should be washed out immediately with water. If easy to do, remove contact lenses

Skin Contact: Wash skin thoroughly with soap and water. If skin irritation or rash occurs: Get medical attention. Launder contaminated clothing before reuse. For contact with molten product, do not remove contaminated clothing. Flush skin immediately with large amounts of cold water. If possible submerge area in cold water. Pack with ice. Do not attempt to peel polymer from skin. Seek medical attention immediately.

Ingestion: Treat symptomatically. Get medical attention.

Personal Protection for First-aid Responders: 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: See section 11.

Indication of any immediate medical attention and special treatment needed

Treatment: Treat symptomatically.

5. Fire-fighting measures

General Fire Hazards: No unusual fire or explosion hazards noted.

Extinguishing media

Suitable extinguishing media: Water spray
Dry chemical
Carbon dioxide (CO_2)

Unsuitable extinguishing media: Not determined.

Specific hazard arising from the chemical: See section 10 for additional information.

Advice for firefighters

Special fire fighting procedures:	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.
Special protective equipment for fire-fighters:	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

Personal precautions, protective equipment and emergency procedures:	Do not touch damaged containers or spilled material unless wearing appropriate protective clothing. Keep unauthorized personnel away. See Section 8 of the SDS for Personal Protective Equipment.
Environmental Precautions:	Avoid release to the environment. Prevent further leakage or spillage if safe to do so.
Methods and material for containment and cleaning up:	Pick up free solid for recycle and/or disposal.
Reference to other sections:	See sections 8 and 13 for additional information.

7. Handling and Storage:

Precautions for safe handling:

Contact with heated material may cause thermal burns. Wash thoroughly after handling.

Refer to Processing Guide and/or contact your local Technical Service representative for melt processing temperature range. For most thermoplastic polyurethanes, melt processing is in the range of 177 - 232 deg. C (350 - 450 deg. F), however, some products may process at different temperatures. Heating above the maximum handling temperature can generate hazardous decomposition products (see Section 10).

Fume condensates may include hazardous contaminants from additives. Condensate may be combustible and should be periodically removed from exhaust hoods, ductwork, and other surfaces. Impervious gloves should be worn during cleanup operations to prevent skin contact.

Post thermal processing activities necessary to produce molded articles (such as cutting, sanding, sawing, grinding, drilling, or regrinding) may create dust or "fines." Powders, dust, and/or fines may pose a dust explosion hazard. Avoid breathing dust.

Loading and unloading operations may cause nuisance dust to form. Electrostatic buildup may occur when pouring or transferring this product from its container. The spark produced may be sufficient to ignite vapors of flammable liquids. Always transfer product by means which avoid static buildup. Avoid pouring product directly

from its container into combustible or flammable solvent.

Conduct any operations emitting fumes or vapors (including thermo- forming, heat joining, cutting and or sealing of articles and clean up) under well-ventilated conditions. Avoid breathing process vapors. Do not hold product for extended periods of time at elevated temperatures or allow thick masses of hot polymer to accumulate because they can decompose emitting hazardous gasses. Do not taste, swallow, or chew products. Wash thoroughly after processing. Do not store or consume food in processing areas. The major off-gasses from normal melt processing are expected to be water vapor and carbon dioxide. Other trace volatile organic components may also be emitted.

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.

Maximum Handling Temperature: Not determined.

Conditions for safe storage, including any incompatibilities: Store in dry, well ventilated place away from sources of heat and direct sunlight. Store away from incompatible materials. See section 10 for incompatible materials.

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:	Under normal use conditions, respirator is not usually required. Use appropriate respiratory protection if exposure to dust particles, mist or vapors is likely. Cutting operations may create small particles from this product. If inhalation of particles cannot be avoided, wear a dust respirator. Consult with an industrial hygienist to determine the appropriate respiratory protection for your specific use of this material. A respiratory protection program compliant with all applicable regulations must be followed whenever workplace conditions require the use of a respirator.
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	
Physical state:	Solid
Form:	Sheets
Color:	Transparent
Odor:	Odorless
Odor Threshold:	No data available.
pH:	No data available.
Melting Point:	No data available.
Boiling Point:	No data available.
Flash Point:	No data available.
Evaporation Rate:	No data available.
Flammability (solid, gas):	No data available
Upper/lower limit on flammability or explosive limits	
Flammability Limit - Upper (%):	No data available.
Flammability Limit - Lower (%):	No data available.
Vapor pressure:	No data available.
Vapor density (air=1):	No data available.
Relative density:	>1.1 (20 ℃)
Solubility(ies)	
Solubility in Water:	Insoluble in water
Solubility (other):	No data available.
Partition coefficient (n-octanol/water):	No data available.
Autoignition Temperature:	No data available.
Decomposition Temperature:	No data available.
Viscosity:	No data available.
Explosive properties:	No data available.
Oxidizing properties:	No data available.
Pour Point Temperature:	No data available.
Other information	
Bulk density:	No data available.

10. Stability and Reactivity

Reactivity:	No data available.
Chemical Stability:	Material is stable under normal conditions.
Possibility of hazardous reactions:	Will not occur.

Conditions to avoid:	Minimize dust generation and accumulation.
Incompatible Materials:	Strong oxidizing agents, avoid contact with reactive chemicals.
Hazardous Decomposition Products:	May generate carbon monoxide, carbon dioxide (CO_2), May also include isocyanates and small amounts of hydrogen cyanide. Thermal decomposition or combustion may generate smoke, carbon monoxide, carbon dioxide nitrogen oxides, and other products of incomplete combustion.

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.

Dermal

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

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.

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.

Serious Eye Damage/Eye Irritation:

Product:	Remarks: Not classified as a primary eye irritant.

Respiratory sensitization:

Product:	Remarks: Under decomposition conditions, isocyanates may be generated from this product. Isocyanates can cause skin sensitization and/or respiratory sensitization.

Skin sensitization:

Product:	Remarks: Under decomposition conditions, isocyanates may be generated from this product. Isocyanates can cause skin sensitization and/or respiratory sensitization.

Specific Target Organ Toxicity - Single Exposure:	No data available
Aspiration Hazard:	No data available

Chronic Effects

Carcinogenicity:	No data available
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.
Contaminated Packaging:	Container packaging may exhibit hazards.

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:	Apr. 5, 2024
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.