



Material Safety Data Sheet

1. Product and Company Information

Product name: One-Piece Urostomy System

Max Cut: 20mm~100mm

Implementation Date: 20/07/2022

Company: Zhejiang Ailebao Medical Technology Co., LTD.

Address: No.599, Haijing Rd., Longgang City, Wenzhou, Zhejiang, China 325802

2. USE

One-Piece Urostomy System is used to store Urine excreted by a stoma patient through the stoma.

3. Composition

The One-Piece Urostomy System ingredients listed below:

Name	CAS no.	Risks
Sodium carboxy methyl cellulose (CMC)	117385-93-0	No risks have been identified
Medical hot melt adhesive	—	No risks have been identified
Isobutene-, homopolymer	9003-27-4	No risks have been identified
Polyvinylpyrrolidone	25249-54-1	No risks have been identified
Propanediol	26264-14-2	No risks have been identified
PEVA film	—	No risks have been identified
PET film	25038-59-9	No risks have been identified
Nonwoven spunlace	—	No risks have been identified
Medical acrylic adhesive	—	No risks have been identified
Glassine paper with silicone	—	No risks have been identified
High barrier film	—	No risks have been identified
Non-woven fabric	—	No risks have been identified
Ethylene Vinyl Acetate Copolymer	24937-78-8	No risks have been identified



4. Hazards identification

Product poses no immediate hazard but can give rise to toxic fumes in a fire. Discharge of large product quantities into natural water systems could result in toxicological effects on water organisms.

5. Physical and chemical properties

Appearance: light yellow, flake

Flash point: Not relevant

Boiling point: Not relevant

Solubility: Not relevant

Odor: Slight odor

6. Stability and reactivity

The product is stable under ambient conditions. Heating may produce toxic fumes.

7. Toxicological information

This product is a medical device and has been tested according to the requirements of medical devices.

According to current knowledge this product is considered low-toxic.

8. Ecological information

Eco toxicological data have not been determined specifically for this product.

9. Health Effects

Swallowed, Eye, Inhaled:



Not routes of exposure for the One-Piece Urostomy System.

Skin:

The One-Piece Urostomy System is manufactured to be non-irritating and non-sensitizing. However, in some patients a rash has been observed on the covered skin. This has been attributed to either poor hygiene or to the product being applied too tightly. Should a rash appear, stop use followed by 12 hours rest. If the rash persists, discontinue treatment, and consult your physician.

Chronic:

Like all chemicals, has a possibility of causing skin irritation or sensitization in susceptible individuals.

10. First Aid Measures

Skin contact: If irritation occurs or sensitization develops, wash thoroughly with soap and water. Obtain medical attention.

Eye contact: Not relevant.

Inhalation: Not relevant.

Ingestion: Not relevant.

11. Precautions for Use

Controls: No engineering controls required.

Personal Protection: No personal protection requirements necessary.

Flammability: Not a readily combustible material. Will burn under fire conditions.

12. Safe Handling Information

General: Refer to information provided with the product.



Storage and Transport:

Store in a dry place (Room temperature).

No special transport requirements.

Not a Dangerous Good, Workplace Hazardous Substance or Scheduled Poison.

Spills and Disposal

Spillage: place in the normal waste system.

Disposal: in accordance with local waste regulations. May be disposed of to the domestic waste. May be incinerated in an approved facility.

Used: Non-Reusable

Extinguishing Media:

According to the surrounding area. Any standard fire extinguisher may be used.

13. Environmental Issues

No environmental issues expected. One-Piece Urostomy System may be disposed of to normal domestic waste.

14. Other Information

Conditions to Avoid: Overheating.

Hazardous Decomposition Products: Smoke, fumes, carbon monoxide, carbonic acid.

15. Transport information

UN no. None

ADR None

IMDG None

16. Regulatory information

The information provided in this safety data sheet is adhering to Commission Directive 91/155/EEC.

USERS RESPONSIBILITY/DISCLAIMER OF LIABILITY

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 laws and local regulations remains the responsibility of the user.

This bulletin cannot cover all possible situations which the user may experience during processing. Each aspect of your operation should be examined to determine if, or were, additional precautions may be necessary.

All health and safety information contained in this bulletin should be provided to your employees or customers. It is your responsibility to develop appropriate work practice guidelines and employee instructional programs for your operation.