



Safety Data Sheet (SDS)

According to regulations (EU) 2020/878 & (EU) 2017/746

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IPI SDS

No. SDS_PT_2023_02_EN

Revision date: June 08, 2023

Product: IPI Pathotape®

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

1.1 Product identifier

IPI Pathotape® Multifunctional Coverslipping Film

1.2 Relevant identified uses of substance or mixture and uses advised against

Relevant identified uses:

Coverslipping film for the use in coverslipping machines in pathology/histology investigations to cover the specimen long-lasting, according to the enclosed manual and the instructions of use of the respective manufacturer of the coverslipping machine.

Uses advised against:

Do not use for other applications than the above mentioned!

Do not use with chlorinated solvents, the base material can be permanently damaged.

1.3 Details of the supplier of the safety data sheet

Name: Island Polymer Industries GmbH
Address: Andresenstraße 6
City: 06766 Bitterfeld-Wolfen, OT Wolfen
Country: Germany

Phone: +49 (0) 3494-39211-10
Fax: +49 (0) 3494-39211-12
E-Mail: wolfen@islandpolymer.com or pathomed@islandpolymer.com

Information contact: Medical Products Department (pathomed@islandpolymer.com)

1.4 Emergency telephone number:

Not necessary

For further information of the product and the application see contact details under 1.3

SECTION 2: Hazards identification

2.1 Classification of the substance or mixture

The mixture or product is not classified as dangerous within the meaning of the EU regulation 2017/746 (IVDR) and the regulation (EC) No 1272/2008.



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2.2 Label elements

Notes on labelling: none

2.3 Other hazards

No information is available.

SECTION 3: Composition / information on ingredients

3.2 Mixtures

Chemical characterization

| | |
|---------------------|---|
| Base material: | Cellulose ester film with plasticizer content |
| Functional coating: | mixture of polyacrylates with plasticizer content |
| Other substances: | Traces of physico-chemical bound solvents resulting of the production process of the base material and the functional coating (< 0,5 % by weight) |

Hazardous ingredients

A release of hazardous substances at the intended use within the predefined environmental conditions is not expected.

SECTION 4: First aid measures

4.1 Description of first aid measures

General information

If the product is used in accordance with the manual, and the general laboratory safety and hygiene regulations are taken into account and are respected, this product does not present any direct danger.

Given that the film is relatively thin and stiff and the roll is cut off in the coverslipping machine by a blade, the resulting cut edges may carry a risk of injury by improper handling.

Following inhalation

No special measures are necessary.

Following skin contact

If the skin is injured by a cut edge (corner parts) of the film, the standard measures for wound care have to be taken and if necessary a doctor has to be consulted.

Following regular skin contact no other measures are necessary besides washing the affected area with water and soap.

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Following eye contact

If a cut edge of the product impacted on the eyes, an eye doctor should be consulted as a precaution to exclude the possibility of cornea damage.

Following ingestion

After ingestion of film parts a doctor should be consulted as a precaution, given that the cut edges of the very thin film product may injure the mucosa.

4.2 Most important symptoms and effects, both acute and delayed

So far no acute or delayed symptoms and effects are known.

4.3 Indication of any immediate medical attention and special treatment needed

No indications available.

SECTION 5: Firefighting measures**5.1 Extinguishing media****Suitable extinguishing media**

Water spray jet, foam, carbon dioxide, powder, spray mist (water)
Adapt the extinguishing measures to the surroundings.

Unsuitable extinguishing media

Do not use a high volume water jet as it may scatter and spread the fire.

5.2 Special hazards arising from the substance or mixture

The product has a normal flammability and burns only with persistently high thermal exposure with normal smoke development.

At temperatures above 250°C a thermal decomposition with an emission of carbon monoxide, carbon dioxide and other irritant gases and vapors may take place.

In case of fire a formation of dangerous gases and vapors (e.g. phosphorus oxychloride) is possible.

5.3 Advice for firefighters

Stay in danger area only with self-contained breathing apparatus.

Suppress leaking vapors with water.

Prevent fire extinguishing water from contaminating surface or ground waters as well as soil.

Avoid skin contact by wearing suitable protective clothing and keeping safe distance.

SECTION 6: Accidental release measures**6.1 Personal precautions, protective equipment and emergency procedures**

No special measures needed.

6.2 Environmental precautions

Do not allow product reach sewage system or waters.

Dispose product parts, plastic core and packing material according to local disposal regulations.

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6.3 Methods and material for containment and cleaning up

No special measures needed.

6.4 Reference to other sections

Safe handling: see article 7
Personal protective equipment: see article 8
Disposal: see article 13

SECTION 7: Handling and storage**7.1 Precaution for safe handling****Advice on safe handling**Opening the packing

After transportation and storage of the vacuum-packed product at temperatures > 25°C it may happen that inside the gastight secondary packaging a netting process can lead to a minor leakage of physically-chemically bound organic residual solvents, which may temporarily be smelled when opening the package.

Because of the low absolute amount (<100 mg) and the thinning effect by the surrounding air no impairments are to be expected when keeping a distance of more than 30 cm while opening the package.

Handling of the film

The transversal cut edge of the thin and stiff film can be sharp-edged and cause skin injuries by improper handling. In addition to a prudent approach the use of safety gloves is recommended.

Advice on protection against fire and explosion

No special fire protection measures are needed.

7.2 Conditions for safe storage, including any incompatibilities**Requirements for storage and containers**

Keep the product sealed inside the vacuum packing until usage.

Store at temperatures between +5°C and +30°C and air moisture within 30% and 70%.

Combined storage

No special measures needed.

7.3 Specific end uses

Coverslipping film for the use in coverslipping machines in order to perform pathology/histology investigations. During the coverslipping process attention should be paid to the instructions of use and safety of the machine manufacturer and the instruction manuals of the used mounting media and solvents.

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SECTION 8: Exposure controls / personal protection**8.1 Control parameters**

Not necessary

8.2 Exposure controls**Precaution and occupational hygiene**

Wash hands and if necessary face before breaks and at the end of work.

Eye / face protection

Wear eye protection.

Hand protection

Safety gloves with a cutting protection according to the definition in regulation EN 388:2019 are recommended for the process of film arrangement inside the coverslipping machine.

Body protection

Wear suitable protective clothing while working in laboratories.

Respiratory protection

At an intended use of the product no respiratory protection is necessary.

SECTION 9: Physical and chemical properties**9.1. Information on basic physical and chemical properties****General information**

| | |
|-----------------|---|
| Physical state: | solid |
| Appearance: | one-sided matt structured film, after coverslipping process high transparent |
| Color: | single layer colorless / multiple layers colorless to yellowish |
| Odor: | odorless to slightly acrylic-like |
| Density: | 1.25 - 1.31 g/cm ³ |

Status changes

| | |
|-------------------------------|---------------|
| Melting point/freezing point: | not specified |
| Boiling point: | not specified |

Flammability

| | |
|--------------|------------------|
| Flash point: | not applicable |
| Solid: | normal ignitable |

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| | | |
|--|--------------------------------------|-----------------------------|
| Lower and upper explosion limit | not applicable | |
| Auto-ignition temperature | not applicable | |
| Decomposition temperature: | > 250°C | |
| pH | not specified | |
| Kinematic viscosity | not applicable | |
| Solubility in water | not soluble | |
| Solubility in other solvents | | |
| Xylene: | Basic material: functional layer: | not soluble well soluble |
| Acetone: | Basic material: functional layer: | not soluble well soluble |
| Distribution coefficient | not applicable | |
| Vapour pressure | not specified | |
| Vapour density | not applicable | |
| Particle characteristics | not specified | |

9.2 Other information

| | |
|--|---|
| Explosives: | not applicable |
| Self-reactive substances and mixtures | not applicable |
| Pyrophoric solids | not applicable |
| Self-heating substances and mixtures | not applicable |
| Substances and mixtures, which emit flammable gases in contact with water | not applicable |
| Corrosive to metals | not applicable |
| Solid content: | > 97,5 % (Remainder: water, traces of organic solvents) |
| Oxidizing properties: | not oxidizing |

SECTION 10: Stability and reactivity**10.1 Reactivity**

At proper handling and storage no dangerous reactions occur.



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10.2 Chemical stability

The product is long-term stable under the specified conditions of storage.

10.3 Possibility of hazardous reactions

No information available.

10.4. Conditions to avoid

Long lasting conditions of temperatures > 40°C.

Intense exposure to sunlight / UV-light.

10.5 Incompatible materials

Halogenated solvents (cause dissolution of the product)

Highly oxidizing substances / mixtures

10.6 Hazardous decomposition products

A continued exposure to temperatures > 250°C may cause a split-off of carbon monoxides, phosphorus oxides and acrylic monomers.

SECTION 11: Toxicological information

11.1 Information on hazard classes as defined in Regulation (EC) No 1272/2008

Acute toxicity

No information available for this product

Skin corrosion / irritation

Based on the available information the classification criteria are not met.

Respiratory or skin sensitization

No information available for this product

Specific Target Organ Systemic Toxicity (single exposure)

No information available for this product

Severe affects after repeated or prolonged exposure

No information available for this product

Carcinogenicity, mutagenicity and reproductive toxicity

No information available for this product

Aspiration hazard

No information available for this product

Other information on testing

In accordance with the RoHS directive the product does not contain substances, which are classified as hazardous or substances of very high concern (SVHC/REACH).



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11.2 Information on other hazards

Endocrine disrupting properties

not applicable

SECTION 12: Ecological information

12.1 Toxicity

Data for the evaluation of the ecotoxicity of the product are not available. Models to obtain information from are not available.

12.2 Persistence and degradability

The product was not tested. Models to obtain information from are not available.

12.3 Bioaccumulative potential

The product was not tested. Models to obtain information from are not available.

12.4. Mobility in soil

The product was not tested.

12.5 Results of PBT and vPvB assessment

The product was not tested.

12.6 Endocrine disrupting properties

Not applicable.

12.7 Other adverse effects

No information available.

Additional information

Avoid release into the environment.

SECTION 13: Disposal considerations

13.1 Waste treatment methods

Dispose product parts and packing material in accordance to national and local regulations.

Do not allow product to reach sewage system or waters.

SECTION 14: Transport information

Land transport (ADR/RID) / Inland marine transport (ADN) / Sea transport (IMDG) / air transport (ICAO)

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- 14.1 UN-No.** Not a hazardous material with respect to these transportation regulations.
- 14.2 UN proper shipping name:** Not a hazardous material with respect to these transportation regulations.
- 14.3 Transport hazard class:** Not a hazardous material with respect to these transportation regulations.
- 14.4 Packing group:** Not a hazardous material with respect to these transportation regulations.
- 14.5. Environmental hazards:** Endangering the environment: No
- 14.6 Special precautions for user:** Ensure the recommended transportation temperatures.
- 14.7 Maritime transport in bulk according to IMO instruments:** Not applicable.

Additional information:

This information does not have the target to give all specific regulations or operational requirements and information related to the product.

Transport classifications on different packing sizes and types may differ depending on the regional or country specific regulations.

Additional information referring to the transport system can be inquired at authorized sales or service representatives.

It is in the responsibility of the transport company to follow all relevant laws, regulations and rules with regard to the transportation of this product.

SECTION 15: Regulatory information**15.1 Safe, health and environmental regulations / legislation specific for the substance or mixture****National regulations:**

- Distribution / conformity assessment: German medical products law (MPG)
- Water pollution class (Germany): 1 – slightly hazardous to water (only anticipated at prolonged exposition to water)

EU regulations:

- Distribution / conformity assessment: EU-Regulation 2017/746
- Regulation (EC) No 1907/2006 (REACH): From the production process this product does not contain substances which need to be registered in



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accordance to this regulation. This information relating to the REACH registration status was given at good faith and considered correct at the date of publication. However, no guarantee can be given, whether expressed or implied.

Substances of very high concern (SVHC/REACH):

This product does not contain substances of very high concern exceeding the legal concentration limit of $\geq 0,1$ % (w/w) in accordance to the Regulation (EC) No 1907/2006, Art. 57.

15.2 Chemical safety assessment

For this product a chemical safety assessment was not carried out.

SECTION 16: Other information

Indication of changes:

Regulations applied.

Abbreviations and acronyms:

Accessible at common research sources, e.g. www.wikipedia.org

Training advice

Ensure appropriate information, instruction and training for the user.

Further information:

This product is classified as accessory article for in vitro diagnostic medical devices and is intended for single use.

The above listed information is an indication for a safe handling at storage, processing, transportation and disposal of the product mentioned in this safety data sheet and is only applicable for the product as it is dispatched.

Hence, the information is not transferable to other products or other usage areas of the product.

The information in this safety data sheet complies with our best knowledge at the date of printing.

However, no guarantee can be given, whether expressed or implied.

It is in the responsibility of the buyer / user to follow the laws of superordinate (e.g. European level), federal, national and local level during the working process.