

4films resist bio

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

1.1. Product identifier

4films resist bio

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

Use of the substance/mixture:

Blown film products used in lamination, printing and thermoforming applications

1.3. Details of the supplier of the safety data sheet

Company name: 4films GmbH
Street: Westendhof 3
Place: D-45143 Essen
Information Telephone: +49 201 56 57 77 70
Information Telefax: +49 201 56 57 77 60
E-Mail (competent person): info@4-films.com
Website: www.4-films.com

1.4. Emergency telephone number

+49 (0) 30 19240

(Giftnotruf Berlin, Berliner Betrieb für Zentrale Gesundheitliche Aufgaben, Institut für Toxikologie)

SECTION 2: Hazards identification

2.1. Classification

This product is NOT classified according to 29 CFR 1910.1200
Hazard Communication Standard 2012

2.2. Hazard Statement

None required

2.3. Precautionary Statement

None

2.4. Signal word

None

2.5. Pictogram

None

2.6. Potential health effects

See Section 11 for more information

2.7. Environmental precautions

See Section 12 for more information.

2.8. Other Hazards

If small particles are generated during further processing, handling, or by other means, combustible dust concentrations in air may form. See Section 7 and 8 for additional information.

SECTION 3: Composition/information on ingredients

Chemical Name	Weight %	CAS Number	OSHA Exposure Limits	ACGIH Exposure Limits
Poly lactide Resin	80 - 99 *	9051-89-2	-	-
Proprietary Additives	0 - 10	N/A	-	-
Titanium Dioxide (Pigmented Films Only)	2 - 12	13463-67-7	15 mg/m ³ TWA (total dust); 5 mg/m ³ TWA (respirable fraction) (related to particulates)	10 mg/m ³ TWA (inhalable particles, recommended); 3mg/m ³ TWA (respirable particles, recommended) (related to Particulates)

*Remaining % of substances concentration doesn't contribute to products hazard classification

Other Standards

This material can generate Particulates Not Otherwise Classifiable (PNOC). The Occupational Safety and Health Administration (OSHA) PEL/TWA for PNOC is 15 mg/m³ for total dust and 5 mg/m³ for the respirable fraction.

The American Conference of Governmental Industrial Hygienists (ACGIH) TLV/TWA for PNOC is 10 mg/m³ for inhalable particulates and 3 mg/m³ for respirable particulates.

SECTION 4: First aid measures

4.1. Description of first aid measures

General information: When in doubt or if symptoms are observed, get medical advice.

After inhalation: Provide fresh air. If experiencing respiratory symptoms: Call a doctor.

After contact with skin: After contact with molten product, cool skin area rapidly with cold water. Burns caused by molten material must be treated clinically. In case of skin reactions, consult a physician.

After contact with eyes: Rinse immediately carefully and thoroughly with eye-bath or water. Remove contact lenses, if present and easy to do. Continue rinsing. If eye irritation persists: Get medical advice/attention.

After ingestion: Drink water as a precaution. Never give anything by mouth to an unconscious person. Do not induce vomiting without medical advice. Call a physician immediately.

4.2. Most important symptoms and effects, both acute and delayed

No information available.

4.3. Indication of any immediate medical attention and special treatment needed

Treat symptomatically.

SECTION 5: Firefighting measures

5.1. Flammability

Autoignition temperature: 388°C (730°F)

5.2. Flammability Limits in Air

Flammable limits in air - lower (%): Not determined

Flammable limits in air - upper (%): Not determined

5.3. Suitable extinguishing media

Foam, Water, Carbon dioxide (CO₂), Dry chemical, Alcohol resistant foams are preferred if available. General-purpose synthetic foams (including AFFF) or protein foams may function, but much less effectively.

5.4. Unsuitable extinguishing media: None known

5.5. Special protective equipment for firefighters

As in any fire, wear self-contained breathing apparatus pressure-demand, MSHA/NIOSH (approved or equivalent) and full protective gear. Under fire conditions: Cool containers / tanks with water spray. Water mist may be used to cool closed containers. Fine dust dispersed in air may ignite. Risks of ignition followed by flame propagation or secondary explosions shall be prevented by avoiding accumulation of dust, e.g. on floors and ledges.

SECTION 6: Accidental release measures

6.1. Personal precautions

Use personal protective equipment. Avoid contact with skin and eyes. Avoid dust formation. Remove all sources of ignition. Sweep up to prevent slipping hazard.

6.2. Environmental precautions

Do not flush into surface water or sanitary sewer system. Do not allow material to contaminate ground water system.

6.3. Methods for cleaning up

Clean up promptly by scoop or vacuum. Sweep up and shovel into suitable containers for disposal.

SECTION 7: Handling and storage

7.1. Safe handling advice

Use personal protective equipment. Avoid contact with skin and eyes. Low hazard for usual industrial or commercial handling. Workers should be protected from the possibility of contact with molten material during fabrication. Avoid dust formation. If small particles are generated during further processing, handling, or by other means, combustible dust concentrations in air may form.

7.2. Storage

Store at temperatures not exceeding 50 °C/ 122 °F.
Keep cool. No special restrictions on storage with other products.

7.3. Precautions

No special precautions required.

SECTION 8: Exposure controls/personal protection

8.1. Engineering measures

Where reasonably practicable this should be achieved by the use of local exhaust ventilation and good general extraction. Provide appropriate exhaust ventilation at places where dust is formed.

8.2. Exposure limits

None established. This material can generate Particulates Not Otherwise Classifiable (PNOC). The Occupational Safety and Health Administration (OSHA) PEL/TWA for PNOC is 15 mg/m³ for total dust and 5 mg/m³ for the respirable fraction. The American Conference of Governmental Industrial Hygienists (ACGIH) TLV/TWA for PNOC is 10 mg/m³ for inhalable particulates and 3 mg/m³ for respirable particulates.

8.3. Personal protective equipment

Eye protection: Safety glasses with side-shields. Goggles.

Skin and body protection: Impervious clothing.

8.4. Respiratory protection

Respirator must be worn if exposed to dust. Wear respirator with dust filter. Respiratory protection is needed if any of the exposure limits in Section 3 are exceeded. Consult an industrial hygiene professional prior to respirator selection and use. Use a positive-pressure air supplied respirator if there is any potential for an uncontrolled release, exposure levels are not known, or any other circumstances where air-purifying respirators may not provide adequate protection.

WARNING: Air purifying respirators do not protect workers in oxygen-deficient atmospheres.

8.5. Hand protection: Preventive skin protection.

8.6. Hygiene measures: Avoid contact with skin, eyes and clothing.

8.7. Special hazard: Workers should be protected from the possibility of contact with molten material during fabrication



SECTION 9: Physical and chemical properties

Physical state	Solid
Appearance	Clear, translucent, opaque, film.
Color	Clear, Translucent, Opaque
Odor	Sweet
pH	Not applicable
Vapor pressure	Not determined
Vapor density	Not determined
Evaporation rate	Not determined
Density	1.25
Decomposition temperature	482 °F (250 °C)
Boiling point / boiling range	Not applicable
Melting point / melting range	150 - 180 °C (302 - 356 °F), Tg: 55 - 60 °C (131 - 140 °F)
Autoignition temperature	388 °C
Water solubility	Insoluble
Solubility in other solvents	Not determined

SECTION 10: Stability and reactivity

10.1. Reactivity

None expected under conditions of normal use.

10.2. Chemical stability

Stable under recommended storage conditions

10.3. Conditions to avoid

Temperatures above 446 °F (230 °C).
Avoid keeping resin molten for excessive periods of time at elevated temperatures.
Prolonged exposure will cause polymer degradation.

10.4. Materials to avoid

Oxidizing agents, Strong bases

10.5. Hazardous decomposition products

Burning produces obnoxious and toxic fumes, Aldehydes,
Carbon monoxide (CO), carbon dioxide (CO²)

10.6. Possibility of hazardous reactions

None expected under conditions of normal use.

SECTION 11: Toxicological information

11.1. Information on toxicological effects

Principle routes of exposure

Eye contact, Skin contact, Inhalation, Ingestion.

Acute toxicity

There were no target organ effects noted following ingestion or dermal exposure in animal studies.

Local effects

Product dust may be irritating to eyes, skin and respiratory system. Resin particles, like other inert materials, are mechanically irritating to eyes. Ingestion may cause gastrointestinal irritation, nausea, vomiting and diarrhea.

Specific effects

May cause skin irritation and/or dermatitis. Ingestion may cause gastrointestinal irritation, nausea, vomiting and diarrhea. Inhalation of dust may cause shortness of breath, tightness of the chest, a sore throat and cough. Burning produces irritant fumes.

Long term toxicity

Did not cause skin allergic reactions in skin sensitization studies using guinea pigs.

Mutagenic effects

Not mutagenic in AMES Test.

Reproductive toxicity

No data is available on the product itself.

Carcinogenic effects

None of the components of this product are listed as carcinogens by IARC, NTP, or OSHA.

Target organ effects

There were no target organ effects noted following ingestion or dermal exposure in animal studies.

Skin: LD50 / dermal / rabbit > 2000 mg/kg

Ingestion: LD50 / oral / rat > 5000 mg/kg

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according to Regulation (EC) No 1907/2006
Revision date: 16.03.2023

SECTION 12: Ecological information

12.1. Ecotoxicity effects

EC50 / 72h / algae > 1100 mg/L

12.2. Persistence and degradability

Inherently biodegradable under industrial composting

12.3. Bioaccumulation

Not expected to bioconcentrate or bioaccumulate.

12.4. Mobility

No data available

SECTION 13: Disposal considerations

13.1. Waste from residues / unused products

In accordance with local and national regulations. Should not be released into the environment. Do not contaminate ponds, waterways or ditches with chemical or used container. Contact manufacturer.

13.2. Contaminated packaging

Empty remaining contents. Do not re-use empty containers. Empty containers should be transported/delivered using a registered waste carrier to local recyclers for disposal.

THE COMPANY HAS NO CONTROL OVER THE MANAGEMENT PRACTICES OR MANUFACTURING PROCESSES OF PARTIES HANDLING OR USING THIS MATERIAL. THE INFORMATION PRESENTED HERE PERTAINS ONLY TO THE PRODUCT AS SHIPPED IN ITS INTENDED CONDITION.

SECTION 14: Transport information

14.1. U.S. Department of Transportation (DOT)

Proper shipping name:	None
Hazard class:	Not regulated
UN-No:	None
Packing group:	None
Hazardous substances (RQ):	None

14.2. IMDG

Proper shipping name:	None
Hazard class:	Not regulated
UN/Id No.:	None
Packing group:	None

14.3. ICAO / IATA:

Proper shipping name:	None
Hazard Class:	Not regulated
UN-No.:	None
Packing group:	None

SECTION 15: Regulatory information

(not meant to be all inclusive - selective regulations represented)

Regulatory requirements are subject to change and may differ between locations. It is the User's responsibility to ensure that all activities comply with all federal, state or provincial and local laws and regulations. The following specific information is made for the purpose of complying with numerous national, federal, state or provincial, and local laws and regulations. See other sections for health and safety information.

15.1. U.S. Regulations

Sara 313 title III: Not Listed
TSCA Inventory List: Listed

15.2. State Regulations

California Proposition 65: Not Listed

15.3. International Inventories

Canada DSL Inventory List: Listed
REACH/EU EINECS List: Components are in compliance with and/or are listed.
Japan (ECL): Listed
Australia (AICS): Listed
Korean chemical inventory: Listed
Phillipines (PICCS) inventory: Contact NatureWorks for additional information.
China inventory of existing chemical substances list: Listed

SECTION 16: Other information

This is to certify that all raw materials used in the production of the above referenced product comply with the regulations of U.S. Food & Drug Administration regulations as follows:

16.1. FDA Status

This is to certify that all raw materials used in production of your film from the above referenced product comply with the regulations pursuant to section 201 (s) of the Federal Food, Drug, and Cosmetic Act, and Parts 182, 184, and 186 of the Food Additive Regulation.

16.2. FCN

In the US under FCN 178 (Food Contact Notification) which is inclusive of all food types with the limitation of condition of use B-H.

In Europe as a raw material with 1935/2004/EEC and Regulation 10/2011, this applies to all EU Member States. Regulation 10/2011 specifies overall migration less than 10 mg/dm², there are no SML's for the above referenced grade in Regulation 10/2011.

Under good manufacturing practices this product may be safely used as components of articles that directly contact food, in strictest accordance and subject to the limitations as set forth under conditions of use B through H, as described in Table 2 of 21 CFR 176.170 (c). However, due to the relatively low softening point we recommend the use of above products only under conditions of E through G. All of these applications are without limitation to those described in Table 1 of 21 CFR 176.170 (c)

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according to Regulation (EC) No 1907/2006
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16.3. 21 CFR 178.3297 – Colorants for Polymers –

The substances listed in this section may be safely used as colorants in the manufacture of articles that are intended to come into contact with food subject to the provisions listed in the regulation.

16.4. 21 CFR 175.300 – Resinous and Polymeric Coatings (release agent) –

All the substances used as components of the coatings listed in this regulation may be safely used as food contact surfaces for articles that are intended to come into direct contact with food.

16.5. CONEG

No lead, mercury, cadmium or hexavalent chromium is intentionally added to the manufacturing process. Data provided by the manufacturers of the raw materials used in this product indicate that the total level of trace quantities of lead, mercury, cadmium, and hexavalent chromium is below the 1994 CONEG model legislation limit of 100 ppm.

16.6. Natural Rubber Content

Plastic Suppliers, Inc. hereby certifies that during the manufacture of 4films PLA from our facility, it does not formulate or intentionally add Natural rubber, Dry Natural rubber, or Natural Latex.

16.7. Child Toy Protection Act

4films PLA complies with the “heavy metal” requirements of Hasbro Inc. specifications SRS-044. In addition, conformance to this specification will ensure to ASTM F963 (TMA) specifications, and E.N.-71 (European Standard) as well as various other international specifications.

16.8. Regulation (EC) No. 1272/2008

Because 4films products are made without hazardous ingredients as identified in the regulation above then the Globally Harmonized System for classification, labeling is not required.

16.9. California Proposition 65

This product does not contain any substance known to the State of California to cause cancer or birth defects.