ReForm - Organic rPLA

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

1.1 Product identification

Product name: ReForm - Organic rPLA

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

Identified uses: Filament for FDM 3D printing / pellets for FGF 3D printing.

1.3 Data on the supplier of the safety data sheet

Supplier: FormFutura BV

Address: Tarweweg 3, 6534 AM, Nijmegen, the Netherlands

Phone: +31 (0)88 743 4000

Email: product.compliance@formfutura.com

1.4 Emergency telephone number

112

SECTION 2: Hazards identification

2.1 Classification of the substance or mixture

Product is not classified as hazardous for human life and health and for the environment.

2.2 Label elements

Hazard pictograms and signal words: None
 Names of substances mentioned on label: None
 Hazard statements: None
 Precautionary statements: None

Markings according to EC guidelines: According to the method of calculating the "General Classification Guideline for the Production of the EC" in the latest valid version, the product does not require labeling. The normal safety measures for handling chemicals should be observed.

2.3 Other hazards

The substances contained in the product do not meet criteria for PBT or vPvB in accordance with Annex XIII of REACH Regulation. The product does not contain substances included in the list established in accordance with Article 59 (1) for having endocrine disrupting properties, or substances identified as having endocrine disrupting properties in accordance with the criteria set out in Commission Delegated Regulation (EU) 2017/2100 or Commission Regulation (EU) 2018/605 at a concentration equal to or greater than 0.1 % by weight.

SECTION 3: Composition/information on ingredients

3.1. Substances

Not applicable.

3.2 Mixtures

Product based on polylactide [CAS 26100-51-6] with addition of coloring agents. Product does not contain components which are classified as hazardous. Product does not contain components with European Union level exposure limit in the workplace.

SECTION 4: First aid measures

4.1. Description of first aid measures





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The filament is not hazardous to human health. The information on first aid provided below relates to the situation when the exposure was caused by working with the hot product during printing.

Eye contact: During printing process: splashes of liquid filament may cause burns. Put on

sterile dressing. Contact an ophthalmologist immediately.

Skin contact: <u>During printing process:</u> possible thermal burns. Rinse damaged skin with

cold water. Put on sterile dressing. Contact doctor.

Inhalation: <u>During printing process:</u> remove the victim to fresh air. Keep warm and calm.

Consult a doctor, if disturbing symptoms occur.

Ingestion: exposure by this route does not typically occur. If swallowed, rinse mouth with

water. Do not induce vomiting. Contact a doctor, show container or label.

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

There are no significant effects or critical hazards reported under normal conditions of use. Prolonged inhalation of fumes evolved during the printing process may cause headaches, poor concentration, exhaustion.

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

Physician makes a decision regarding further medical treatment after thoroughly examination of the injured. Symptomatic treatment.

SECTION 5: Firefighting measures

5.1. Extinguishing agents

Suitable extinguishing media:

Carbon dioxide, extinguishing powder, extinguishing foam, water spray.

Unsuitable extinguishing media:

Water jet – risk of fire propagation

5.2. Specific hazards associated with a substance or mixture

During combustion harmful fumes consisting of carbon oxides, oxides of nitrogen and other harmful products of thermal decomposition may be produced. Do not inhale combustion products, it may cause health risk.

5.3. Information for the firefighters

Personal protection typical in case of fire. Do not stay in the fire zone without self-contained breathing apparatus and protective clothing resistant to chemicals. Do not let extinguishing water to reach drainage system, surface water and groundwater. Collect used extinguishing media.

SECTION 6: Accidental release measures

6.1. Personal precautions, protective equipment and emergency procedures

Ensure adequate ventilation. Do not inhale aerosol. Ensure that effects of the breakdown are removed only by qualified personnel. Avoid inhalation of fumes evolved during the printing process.

6.2. Environmental precautions

In case of release of large amounts of the product, it is necessary to take appropriate steps to prevent it from spreading into the environment.



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6.3. Methods and materials preventing the spread of contamination and used for cleaning up Collect mechanically. Collected material should be reused or treated as a waste.

6.4. Reference to other sections

Appropriate conduct with waste product - section 13.

SECTION 7: Handling and storage

7.1. Safe handling advice

Handle in accordance with good occupational hygiene and safety practices. Use only as intended. In case of rubbing or friction, accumulation of electrostatic charges on the filament surface may occur. Accumulated electric charge can be transferred to the user and may be a source of ignition - use extreme caution when working with flammable materials.

7.2. Conditions for safe storage, including any incompatibilities

Store filament only in a cool, dry place protecting against weather (direct sunlight, frost, precipitation). Protect from sources of fire and naked flames. Do not store with incompatible materials (see subsection 10.5).

7.3. Specific end use(s)

No information about uses other than mentioned in subsection 1.2.

SECTION 8: Exposure controls/personal protection

8.1. Control parameters

Product does not contain components with occupational exposure limit values established on the European Union level.

Legal Basis: Commission Directive 91/322/EEC, 2000/39/EC, 2006/15/EC, 2009/161/EU, 2017/164/EU, 2019/1831/EU.

Please check also any national occupational exposure limit values in your country.

8.2. Exposure controls

Engineering measures:

Observe good occupational hygiene and safety practices. Do not eat, drink or smoke when using the product. Wash hands thoroughly before breaks and after work.

Individual protection measures, such as personal protective equipment:

The necessity to use and selection of appropriate personal protective equipment should take into account the type of risk created by the product, conditions at the workplace and the manner of handling the product. The personal protective equipment used must meet the requirements of Regulation (EU) 2016/425 and the relevant standards.

General safety and hygiene:

Keep away from foodstuffs, beverages, and food.

Do not eat, drink, smoke.

Do not breathe dust / smoke.

Avoid contact with eyes and skin.

Wash hands before breaks and after work.





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Breathing equipment:

Under normal conditions of use is not required. In emergency situation, when exposed to high concentrations of fumes evolved in printing process appropriate respiratory protective equipment should be worn.

Hand and body protection:

Use protective gloves and protective clothing if a risk assessment indicates this is necessary (EN 374).

Eye protection:

Use tightly fitting protective glasses if risk assessment indicates that it is necessary (EN 166).

Thermal hazards:

If contact with the hot product is expected, use heat-resistant gloves in accordance with EN 407 standard.

Environmental exposure controls:

Avoid release of large amounts of the product to groundwater, drainage system or soil.

SECTION 9: Physical and chemical properties

9.1. Information on basic physical and chemical properties

Physical state: Solid

Appearance: Wire, filament, or pellets. **Color:** According to assortment.

Odor:

PH:

Not determined.

Vapor pressure:

Not determined.

Vapor density:

Evaporation rate:

Not determined.

Not determined.

Not determined.

Not determined.

Not determined.

octanol/water):

Density: Not determined.

Decomposition temperature: Not determined.

Boiling point / boiling range: Not determined.

Melting point / melting range: Not determined.

Autoignition temperature: Not determined, product is not self-igniting

Freezing point: Not determined.
Flash point: Not determined.

Flammability: Non-flammable mixture. Flammability Limits in Air: No information available.

Water solubility: Not determined. Solubility in other solvents: None known.

Solubility: No information available.

Other Standards: None

9.2. Other standards

No additional test results.

SECTION 10: Stability and reactivity

10.1. Reactivity



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Product is resistant to chemicals. See also subsections 10.3-10.5.

10.2. Chemical stability

The product is stable under normal conditions of handling and storage.

10.3. Conditions to avoid

Protect from direct sunlight, sources of fire and heat, except from processes connected directly with using of the product.

10.4. Materials to avoid

Strong oxidizers and basis.

10.5. Hazardous decomposition products

Not known.

SECTION 11: Toxicological information

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

Based on available data, the classification criteria are not met. Acute toxicity:

Skin corrosion/irritation Based on available data, the classification criteria are not met.

· Serious eye Based on available data, the classification criteria are not met. damage/irritation

Respiratory or skin Based on available data, the classification criteria are not met. sensitization

 Germ cell mutagenicity Based on available data, the classification criteria are not met.

 Carcinogenicity Based on available data, the classification criteria are not met.

Based on available data, the classification criteria are not met. Reproductive toxicity STOT-single exposure Based on available data, the classification criteria are not met.

 STOT-repeated Based on available data, the classification criteria are not met.

exposure

Based on available data, the classification criteria are not met. Aspiration hazard Information on likely

Routes of exposure: skin contact, eye contact, inhalation. See subsection 4.2 for more information on the effects from each

possible route of exposure.

· Symptoms related to No data. the physical, chemical and toxicological

characteristics Delayed and immediate No data.

routes of exposure

effects as well as chronic effects from short and long-term exposure

11.2. Information on other hazards

 Endocrine disrupting properties

The product does not contain substances included in the list established in accordance with Article 59 (1) for having endocrine disrupting properties, or substances identified as having endocrine disrupting properties in accordance with the criteria set out in Commission Delegated Regulation (EU) 2017/2100 or Commission Regulation (EU) 2018/605 at a concentration equal to or greater than 0.1 % by weight.





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• Other information No data.

SECTION 12: Ecological information

12.1. Ecotoxicity effects

Product is not classified as hazardous for the environment.

12.2. Persistence and degradability

No data available.

12.3. Bioaccumulation

No bioaccumulative potential

12.4. Mobility in soil

Product is not mobile in soil.

12.5. Results of PBT and vPvB assessment

Product does not contain ingredients, which meet criteria for PBT or vPvB in accordance with Annex XIII of REACH Regulation.

12.6. Endocrine disrupting properties

The product does not contain substances included in the list established in accordance with Article 59 (1) for having endocrine disrupting properties, or substances identified as having endocrine disrupting properties in accordance with the criteria set out in Commission Delegated Regulation (EU) 2017/2100 or Commission Regulation (EU) 2018/605 at a concentration equal to or greater than 0.1 % by weight...

12.7. Other adverse effects

Product has no influence on global warming and destruction of the ozone layer. Consider other harmful effects of individual components of the mixture on the environment (e.g., global warming potential).

SECTION 13: Disposal considerations

13.1. Waste treatment methods

Waste material should be stored in designated place for recycling or utilization. Waste product should be recovered or disposed of in authorized incineration plants or waste facility in accordance with local regulations.

Legal basis: Directive 2008/98/EC as amended, 94/62/EC as amended.

SECTION 14: Transport information

14.1. UN number or ID number

Not applicable. Product is not classified as dangerous during transportation.

14.2. UN proper shipping name

Not applicable.

14.3. Transport hazard class(es)

Not applicable.

14.4. Packing group

Not applicable.



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14.5. Environmental hazards

Not applicable.

14.6. Special precautions for user

Not applicable.

14.7. Maritime transport in bulk according to IMO instruments

Not applicable.

SECTION 15: Regulatory information

15.1. Safety, health and environmental regulations/legislation specific for the substance or mixture Regulation (EC) No 1907/2006 of the European Parliament and of the Council of 18 December 2006 concerning the Registration, Evaluation, Authorization and Restriction of Chemicals (REACH), establishing a European Chemicals Agency, amending Directive 1999/45/EC and repealing Council Regulation (EEC) No 793/93 and Commission Regulation (EC) No 1488/94 as well as Council Directive 76/769/EEC and Commission Directives 91/155/EEC, 93/67/EEC, 93/105/EC and 2000/21/EC as amended.

Commission Regulation (EU) No 2020/878 of 18 June 2020 amending Annex II to Regulation (EC) No 1907/2006 of the European Parliament and of the Council concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH).

Regulation (EC) No 1272/2008 of the European Parliament and of the Council of 16 December 2008 on classification, labelling and packaging of substances and mixtures, amending and repealing Directives 67/548/EEC and 1999/45/EC, and amending Regulation (EC) No 1907/2006 as amended.

Regulation (EC) No 1272/2008 of the European Parliament and of the Council of 16 December 2008 on classification, labelling and packaging of substances and mixtures, amending and repealing Directives 67/548/EEC and 1999/45/EC, and amending Regulation (EC) No 1907/2006 as amended.

European Parliament and Council Directive 94/62/EC of 20 December 1994 on packaging and packaging waste as amended.

Directive 2008/98/EC of the European Parliament and of the Council of 19 November 2008 on waste and repealing certain Directives as amended.

Regulation (EU) No 2016/425 of the European Parliament and of the Council of 9 March 2016 on personal protective equipment and repealing Council Directive 89/686/EEC.

Commission Directive 2000/39/EC of 8 June 2000 establishing a first list of indicative occupational exposure limit values in implementation of Council Directive 98/24/EC on the protection of the health and safety of workers from the risks related to chemical agents at work.

Commission Directive 2006/15/EC of 7 February 2006 establishing a second list of indicative occupational exposure limit values in implementation of Council Directive 98/24/EC and amending Directives 91/322/EEC and 2000/39/EC.





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Commission Directive 2009/161/EU of 17 December 2009 establishing a third list of indicative occupational exposure limit values in implementation of Council Directive 98/24/EC and amending Commission Directive 2000/39/EC.

Commission Directive 2017/164/EU of 31 January 2017 establishing a fourth list of indicative occupational exposure limit values pursuant to Council Directive 98/24/EC, and amending Commission Directives 91/322/EEC, 2000/39/EC and 2009/161/EU.

Commission Directive 2019/1831/EU of 24 October 2019 establishing a fifth list of indicative occupational exposure limit values pursuant to Council Directive 98/24/EC and amending Commission Directive 2000/39/EC.

15.2. Chemical safety assessment

It is not necessary to carry out a chemical safety assessment for mixture.

SECTION 16: Other information

Explanations of abbreviations:

- CLP: Regulation No. 1272/2008
- IATA: International Air Transport Association
- IMDG: International Maritime Dangerous Goods
- IMO: International Maritime Organisation
- PBT: Persistent, Bioaccumulative, Toxic
- REACH: Registration, Evaluation and Authorisation of Chemicals
- vPvB: very Persistent, very Bioaccumulative
- STEL: Short-Term Exposure Limit
- LD50: Lethal Dose
- LC50: Lethal Concentration
- EC50: Effective Concentration 50%
- DNEL: Derived No-Effect Level
- PNEC: Predicted No-Effect Concentration
- OEL: Occupational Exposure Limit
- ADR: Agreement concerning the Internatinal Carriage of Dangerous Goods by Road
- AND: European Agreement concerning the International Carriage of Dangerous Goods by Inland Waterways
- RID: regulations for international transport of dangerous goods by rail
- MARPOL: International Convention for the Prevention of Pollution from Ships

Trainings

Before commencing working with the product, the user should learn the Health & Safety regulations, regarding handling chemicals, and in particular, undergo a proper workplace training.

Key literature references and data sources

This sheet was prepared on the basis of on manufacturer's data, literature data, online databases, our knowledge and experience, taking into account the current legislation.

Procedures used to classify the mixture

Classification was based on data on hazardous substances calculation method under the guidance of Regulation 1272/2008/EC (CLP) as amended.

Disclaimer:





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This safety data sheet (SDS) is issued based on the latest reference, data, etcetera currently available. The information in this SDS has been carefully assessed, but no guarantee is given for its accuracy. We cannot anticipate all conditions under which this product may be used. It is the user's responsibility to take appropriate safety measures for handling.

