

SAFETY DATA SHEET

Date of update : 31-10-2022

Version: 1.0/EN

[In accordance with the criteria of Regulation No 1907/2006 (REACH) as amended]

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

1.1 Product identifier

ReFill PLA + colors

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

Relevant identified uses: filament used in 3D printers.

Uses advised against: not determined.

1.3 Details of the supplier of the safety data sheet

Entity responsible: **FormFutura BV**

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

Telephone: +31 (0)88 743 4000

E-mail address for a competent person responsible for SDS: 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.

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 (3) 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

Skin contact:

Filament: in case of exposure rinse contaminated skin using water with soap.

During printing process: possible thermal burns. Rinse damaged skin with water. Put on sterile dressing. Contact doctor.

Eye contact:

Filament: protect non-irritated eye, remove contact lenses. Rinse contaminated eyes with water for 10-15 minutes. Avoid strong stream of water – risk of damage of the cornea. Contact an ophthalmologist.

During printing process: splashes of liquid filament may cause burns. Put on sterile dressing. Contact an ophthalmologist immediately.

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.

Inhalation:

Filament: exposure by this route does not occur.

During printing process: remove the victim to fresh air. Keep warm and calm. Consult a doctor, if disturbing symptoms occur.

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 media

Suitable extinguishing media: carbon dioxide, extinguishing powder, extinguishing foam, water spray.

Unsuitable extinguishing media: water jet – risk of fire propagation.

5.2 Special hazards arising from the substance or mixture

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

5.3 Advice for 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.

6.3 Methods and material for containment and cleaning up

Collect mechanically. Collected material should be reused or treated as a waste.

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6.4 Reference to other sections

Appropriate conduct with waste product – section 13.

Section 7: Handling and storage

7.1 Precautions for safe handling

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 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

Appropriate engineering controls

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.

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 or face protection if risk assessment indicates that it is necessary (EN 166).

Respiratory protection:

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.

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/filament
Colour:	according to assortment

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Odour:	odourless
Melting point/freezing point:	not determined
Boiling point or initial boiling point and boiling range:	not determined
Flammability:	non-flammable mixture
Lower and upper explosion limit:	not determined
Flash point:	not applicable
Auto-ignition temperature:	not determined, product is not self-igniting
Decomposition temperature:	not determined
pH:	not determined
Kinematic viscosity:	not applicable
Solubility:	not determined
Partition coefficient n-octanol/water (log value):	not applicable
Vapour pressure:	not determined
Density and/or relative density:	not determined
Relative vapour density:	not determined
Particle characteristics:	not determined

9.2 Other information

No additional test results.

Section 10: Stability and reactivity

10.1 Reactivity

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 Possibility of hazardous reactions

Hazardous reactions are not known.

10.4 Conditions to avoid

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

10.5 Incompatible materials

Strong oxidizers and bases.

10.6 Hazardous decomposition products

Not known.

Section 11: Toxicological information

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

Acute toxicity

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

Skin corrosion/irritation

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

Serious eye damage/irritation

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

Respiratory or skin sensitization

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

Germ cell mutagenicity

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

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Carcinogenicity

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

Reproductive toxicity

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

STOT-single exposure

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

STOT-repeated exposure

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

Aspiration hazard

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

Information on likely routes of exposure

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 the physical, chemical and toxicological characteristics

No data.

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

No data.

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 (3) or Commission Regulation (EU) 2018/605 at a concentration equal to or greater than 0.1 % by weight.

Other information

No data.

Section 12: Ecological information

12.1 Toxicity

Product is not classified as hazardous for the environment.

12.2 Persistence and degradability

No data for the mixture.

12.3 Bioaccumulative potential

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 (3) 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 (eg., global warming potential).

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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.

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.

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.

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.

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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

Abbreviations and acronyms

PBT Persistent, Bioaccumulative and Toxic substance
vPvB very Persistent, very Bioaccumulative substance

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.

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The information above is based on a current available data concerning the product, but also on the experience and knowledge in this field of the producer. They are neither a quality description of the product nor a guarantee of particular features. They are to be treated as aid to safety in transport, storage and usage of the product. That does not free the user from the responsibility of improper usage of the information above and also of improper compliance with the law norms in the field.