

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

1.1. Product identifier

Product name: FILAMENT 3D BioCREATE HT
Trade name: FILAMENT 3D BioCREATE HT 1,75mm

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

Relevant identified uses: Thermal processing in the FDM 3D printing process.
Uses advises against: All others not mentioned above.

1.3. Details of the supplier of the safety data sheet

Supplier: ROSA PLAST Sp. z o.o.
05-074 Hipolitów, Polska
ul. Hipolitowska 102B
Tel.: +48 783 62 62

E-mail address of the person responsible for this safety datasheet: 3d@rosaplast.pl

1.4. Emergency telephone number

112 (emergency phone - 24 hours a day)

Section 2. Hazards identification

2.1. Classification of the substance or mixture

The mixture does not meet the criteria for classification in any of the hazard classes and categories according to the Regulation of the European Parliament and of the Council (EC) No 1272/2008 of December 16, 2008 on classification, labeling and packaging of substances and mixtures (Official Journal of the EU L 353 of 31.12.2008, as amended).

2.2. Label elements

Pictograms: not applicable

Signal word: not applicable

Hazard statements: not applicable

Precautionary statements: not applicable

Supplementary hazard information: not applicable

Unique identifier of active form (UFI): not applicable

2.3. Other hazards

The mixture does not contain substances with PBT and vPvB properties or substances with endocrine disrupting properties included in the list established pursuant to Article 59 (1) in accordance with the criteria set forth in Regulation 2017/2100/EU or Regulation 2018/605/EU in concentrations equal to or greater than 0.1%. The mixture does not contain substances present in nano form.

Section 3. Composition/information on ingredients

3.1. Substances

Not applicable.

3.2. Mixtures

The mixture does not contain in concentrations equal to or greater than:

(a) 1 % by weight:

(i) substances presenting a health or environmental hazard within the meaning of Regulation (EC) No. 1272/2008; or

(ii) substances for which EU maximum allowable concentrations have been established in the working environment;

(b) 0.1% by weight for substances meeting any of the following criteria:

- PBT according to the criteria in Annex XIII,

- vPvB in accordance with the criteria in Annex XIII,

- substances included in the list established in accordance with Article 59 (1) for reasons other than the hazards listed in paragraph (a) such as endocrine disrupting properties,

- identified as having endocrine disrupting properties in accordance with the criteria set forth in Delegated Regulation (EU) 2017/2100 or Regulation (EU) 2018/605;

(c) 0.1% of a substance classified as a category 1 or 1B skin sensitizer, a category 1 or 1B respiratory sensitizer, or a category 2 carcinogen;

(d) 0.01% of a substance classified as a category 1A skin sensitizer or a category 1A respiratory sensitizer;

(e) 0.1 specific concentration limit of a substance classified as a skin sensitizer or respiratory sensitizer with a specific concentration limit;

(f) 0.1% of a substance classified as a reproductive toxicant of category 1A, 1B or 2 or affecting lactation, or harmful effects on breastfed children.

Section 4. First aid measures

4.1. Description of first aid measures

Ingestion:	do not give anything to drink to an unconscious person. Contact physician if unwell, show label.
Eye contact:	flush with plenty of water, continue for at least 15 minutes. Avoid strong water spray due to risk of corneal damage. Contact a doctor if symptoms persist.
Skin contact:	remove contaminated clothing, rinse exposed part of skin with plenty of cool water, continue for at least 15 minutes. In case of direct contact of hot parts directly with the skin, cool down immediately. Do not use force or solvents to remove the product from the skin. Contact a physician.
Inhalation:	take exposed person to fresh air. Contact a doctor if breathing difficulties or feeling unwell.

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

Acute exposure symptoms: none known.

Symptoms of chronic or long-term exposure: none known.

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

Treat symptomatically. Maintain vital functions.

Section 5. Firefighting measures

5.1. Extinguishing media

Suitable extinguishing media: powder, foam, CO₂, water mist, dispersed water jet. Match appropriately to the environment.

Unsuitable extinguishing media: compact stream of water.

5.2. Special hazards arising from the substance or mixture

During combustion, harmful substances including incomplete combustion products like carbon monoxide and toxic substances formed by thermal decomposition of the polymer may be emitted. Do not inhale smoke and vapors resulting from combustion. See section 10.6 for hazardous decomposition products.

5.3. Advice for firefighters

Use specialized personal protective equipment. Stay on the side of the wind direction to avoid inhalation of gases, vapors, smoke. Cool heat-exposed containers with diffused water currents, and if possible take to a safe place. Cool fire-exposed containers with water until the fire is extinguished. Collect the agents used after extinguishing in accordance with national regulations, do not allow them to enter the environment including soil and watercourses.

Section 6. Accidental release measures

6.1. Personal precautions, protective equipment and emergency procedures

For non-emergency personnel:	limit access to bystanders. Notify the surrounding area. Perform evacuation to a place of safety.
For emergency responders:	remove in accordance with the recommendations detailed in section 6.3. For hot items, allow to cool or cool with water and then collect mechanically. Collect hot and warm elements with heat protective gloves according to EN 407.

6.2. Environmental precautions

Prevent from entering drains, watercourses, groundwater and surface water.

6.3. Methods and material for containment and cleaning up

Protect from further release, after cooling or cooling of hot elements collect mechanically and place in a properly labeled waste container. Transfer for disposal to an authorized waste collector. Wash the surface where the release occurred. Collect hot and warm elements with heat-protective gloves in accordance with EN 407.

6.4. Reference to other sections

For personal protective equipment, see SECTION 8: Exposure controls/personal protective equipment.
For waste disposal methods, see SECTION 13: Waste treatment.

Section 7. Handling and storage

7.1. Precautions for safe handling

Ensure adequate ventilation at the workplace. Wear heat protective gloves in accordance with EN 407 and respiratory protection when handling hot and warm parts, see section 8. Carry out mechanical abrasion, grinding or milling processes in suitable equipment suitable for this purpose with local extraction and evaluate for the possibility of an explosive atmosphere.

7.2. Conditions for safe storage, including any incompatibilities

Store in accordance with good manufacturing practice.

7.3. Specific end use(s)

Refer to section 1.2.

Section 8. Exposure controls/personal protection

8.1. Control parameters

The mixture does not contain substances in concentrations >1% for which occupational exposure limits have been established.

Dusts not classified due to toxicity

- inhalable fraction

MPC = 10 mg/m³, STEL = -, CLV = -.

Inhalable fraction - the fraction of aerosol entering through the nose and mouth, which, when deposited in the respiratory tract, poses a health risk, determined in accordance with EN 481.

Methods of determining substances in the air of the working environment:

PN-EN 481:1998 Workplace atmosphere - Determination of grain composition for the measurement of particles suspended in the air.

Regulation of the Minister of Health of February 2, 2011 on tests and measurements of factors harmful to health in the work environment (Journal of Laws 2011 No. 33, item 166, as amended).

Ordinance of the Minister of Family, Labor and Social Policy of June 12, 2018 on the maximum permissible concentrations and intensities of factors harmful to health in the work environment.

Ordinance of the Minister of Family, Labor and Social Policy of January 9, 2020, amending the Ordinance on maximum permissible concentrations and intensities of harmful factors for health in the work environment.

Ordinance of the Minister of Development, Labor and Technology dated February 18, 2021, amending the Ordinance on maximum permissible concentrations and intensities of factors harmful to health in the work environment.

Ordinance of the Minister of Family, Labor and Social Policy of June 24, 2024, amending the Ordinance on the maximum permissible concentrations and intensities of factors harmful to health in the work environment.

PNEC, DNEL

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8.2. Exposure controls

8.2.1 Relevant technical control measures

Ensure adequate ventilation at the workstation, if possible provide local extraction or process isolation. Use personal protective equipment only if exposure cannot be adequately controlled by technical control measures.

8.2.2 Individual protection measures such as personal protective equipment

- a) Eye or face protection: if there is a risk of getting into the eyes, use protective goggles, EN166 - Individual eye protection - Requirements.
- b) Skin protection
Hand protection: use suitable heat protective gloves according to EN 407 Protective gloves and other hand protection equipment against heat hazards (heat and/or fire).
- Protection of other parts of the body: depending on the degree of exposure and the occupational risk assessment conducted on the job, use protective clothing and protective footwear tailored to the risk.
- c) Respiratory protection: if adequate exhaust ventilation is not provided or if the occupational risk assessment of the job indicates the need to do so, use a mask/semi-mask with a filter against organic vapors and/or dust/aerosols. Recommended type of protection for vapors: minimum A. Recommended type of protection for dust/aerosols: P2 filter. When using combined protection against vapors dust/aerosols, use AP2 filter-absorber according to EN14387 - Respiratory protective equipment - Respirators and filter-absorbers - Requirements, testing, marking.
- d) Thermal hazards: use heat protective gloves in accordance with EN 407 Protective gloves and other hand protection equipment against thermal hazards (heat and/or fire).

8.2.3 Environmental exposure control

Observe in accordance with the Ordinance of the Minister of Maritime Affairs and Inland Navigation dated July 12, 2019 on substances particularly harmful to the aquatic environment and conditions to be met when discharging wastewater into waters or into the ground, as well as when discharging rainwater or snowmelt into waters or into water facilities. Regulation of the Minister of Climate of September 24, 2020.

On emission standards for certain types of installations, sources of fuel combustion and facilities for combustion or co-incineration of waste.

Section 9. Physical and chemical properties

9.1. Information on basic physical and chemical properties

State of matter:	Solid
Colour:	Depending on the used pigment
Odour:	Odourless
Melting/freezing point:	no data available
Boiling point or initial boiling point and boiling range:	Not determined
Flammability:	Not flammable
Lower and upper explosion limit:	No data available
Flash point:	no data available
Auto-ignition temperature:	no data available
Decomposition temperature:	no data available
pH:	Not applicable
Kinematic viscosity:	Not determined
Solubility:	Does not dissolve in water
Partition coefficient n-octanol/water (log value):	Not applicable to mixtures
Vapor pressure:	Not applicable
Density or relative density:	1,34 g/cm ³
Relative vapor density:	Not applicable
Particle characteristics:	Not applicable, does not occur in nanoform.

9.2. Other information

9.2.1. Information on physical hazard classes

No data available.

9.2.2. Other safety properties

No data available.

Section 10. Stability and reactivity

10.1. Reactivity

The mixture is not reactive under normal conditions of use and storage.

10.2. Chemical stability

The mixture is stable under normal conditions of use and storage.

10.3. Possibility of hazardous reactions

Under normal conditions, they do not occur.

10.4. Conditions to avoid

Do not cause thermal decomposition, see SECTION 9: Physical and chemical properties.

10.5. Incompatible materials

None known.

10.6. Hazardous decomposition products

During combustion, harmful substances may be emitted, including products of incomplete combustion such as carbon dioxide (CO₂), carbon monoxide, nitrogen oxides and other organic compounds. Do not inhale smoke and vapors resulting from fire or thermal decomposition.

Section 11. Toxicological information

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

a) Acute toxicity

ATEmix (oral route) = the mixture does not contain any relevant components classified in this hazard class and exposure route. Based on available data, the classification criteria are not met.

ATEmix (after dermal application) = the mixture does not contain any relevant constituents classified in this hazard class and exposure route. Based on available data, the classification criteria are not met.

ATEmix (inhalation, vapor) = the mixture does not contain constituents of concern classified in this hazard class and exposure route. Based on available data, the classification criteria are not met.

b) Skin corrosion/irritation

The mixture does not contain substances classified in this hazard class above the general/specific limit concentration. Based on available data, the classification criteria are not met.

c) Serious eye damage/eye irritation

The mixture does not contain substances classified in this hazard class above the general/specific limit concentration. Based on available data, the classification criteria are not met.

d) Respiratory or skin sensitization

The mixture does not contain substances classified in this hazard class above the general/specific concentration limit. Based on available data, the classification criteria are not met.

e) Germ cell mutagenicity

The mixture does not contain substances classified in this hazard class above the generic/specific concentration limit. Based on available data, the classification criteria are not met.

f) Carcinogenicity

The mixture does not contain substances classified in this hazard class above the general/specific limit concentration. Based on available data, the classification criteria are not met.

g) Reproductive toxicity

The mixture does not contain substances classified in this hazard class above the generic/specific concentration limit. Based on available data, the classification criteria are not met.

h) Toxic effects on target organs - single exposure.

The mixture does not contain substances classified in this hazard class above the general/specific concentration limit. Based on available data, the classification criteria are not met.

i) Toxic effects on target organs - repeated exposure

The mixture does not contain substances classified in this hazard class above the general/specific concentration limit. Based on available data, the classification criteria are not met.

j) Aspiration hazard

The mixture does not contain substances classified in this hazard class above the general/specific limit concentration. Based on available data, the classification criteria are not met.

Information on likely routes of exposure

Eye contact, inhalation, skin contact.

Symptoms related to physical, chemical and toxicological properties.

None known.

Delayed, immediate and chronic effects of short- and long-term exposure.

None known.

11.2. Information on other hazards

11.2.1. Endocrine disrupting properties

The mixture does not contain substances with endocrine disrupting properties included in the list established pursuant to Article 59 (1) in accordance with the criteria set forth in Regulation 2017/2100/EU or Regulation 2018/605/EU in concentrations equal to or greater than 0.1%.

11.2.2. Other information

None known.

Section 12. Ecological information

12.1. Toxicity

The mixture does not contain substances classified in this hazard class. Based on available data, the classification criteria are not met.

12.2. Persistence and degradability

It is not easily decomposed. Reprocessing (recycling) is recommended.

12.3. Bioaccumulative potential

Bioaccumulation is not expected due to consistency and insolubility in water.

12.4. Mobility in soil

It does not dissolve in water. Due to its form (solid), it is not mobile in soil, does not penetrate into groundwater, and is not absorbed in soil.

12.5. Results of PBT and vPvB assessment

The mixture does not contain substances with PBT and vPvB properties.

12.6. Endocrine disrupting properties

The mixture does not contain substances with endocrine disrupting properties included in the list established pursuant to Article 59 (1) in accordance with the criteria set forth in Regulation 2017/2100/EU or Regulation 2018/605/EU in concentrations equal to or greater than 0.1%.

12.7. Other adverse effects

None known.

Section 13. Disposal considerations

13.1. Waste treatment methods

Handling of the product

Do not dispose of in sewers and watercourses. Consider reuse. Recover or dispose of the waste in authorized incinerators or waste disposal plants in accordance with applicable regulations.

07 02 13 - Plastic waste

Handling of packaging

Hand over the packaging for disposal to an authorized waste collector, in accordance with the waste code assigned at the place of manufacture. Recycling is preferred.

07 02 13 - Plastic waste

15 01 01 - Paper and cardboard packaging

Regulation of the Minister of Climate of January 2, 2020 on the waste catalog (Dz.U. 2020 poz. 10). Act of June 13, 2013 on packaging and packaging waste management (Dz.U. 2023 poz. 1658).

Section 14. Transport information

14.1. UN number or ID number

Not applicable.

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

European Regulations:

1. Regulation (EC) No 1907/2006 of the European Parliament and of the Council of 18 December 2006 concerning the Registration, Evaluation, Authorisation 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 (OJ L 396, 30.12.2006, p. 1, as amended)
2. 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 (OJ L 353, 31.12.2008, as amended)
3. Commission Regulation (EU) 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) (OJ L 2020.203.28)

National Regulations:

1. Act of 25 February 2011 on chemical substances and their mixtures (Journal of Laws 2022, item 1816)
2. Regulation of the Minister of Family, Labour and Social Policy of 12 June 2018 on the maximum permissible concentrations and intensities of harmful factors in the work environment (Journal of Laws 2018, item 1286, as amended)
3. Regulation of the Minister of Climate of 2 January 2020 on the waste catalogue (Journal of Laws 2020, item 10)
4. Act of 27 April 2001 Environmental Protection Law (Journal of Laws 2024, item 54)

Seveso (Directive 1986/609/EEC of the European Parliament and of the Council of 4 July 1986 on the control of major-accident hazards involving dangerous substances, amending and subsequently repealing Council Directive 96/82/EC): not applicable.

Regulation (EC) No 1907/2006 of the European Parliament and of the Council of 18 December 2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH):

- **Substances subject to authorisation procedure – Annex XIV to Regulation (EC) No 1907/2006 (REACH):** None of the components of the product is listed.
- **Substances of Very High Concern (SVHC) – Candidate List:** None of the components of the product is listed.
- **Restrictions on the manufacture, placing on the market and use of certain dangerous substances, mixtures, and articles – Annex XVII to Regulation (EC) No 1907/2006 (REACH):** None of the components of the product is listed

15.2. Chemical safety assessment

No chemical safety assessment has been done.

Section 16. Other information

Expanded hazard statements used in this safety data sheet:

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Explanation of abbreviations and acronyms used in the safety data sheet:

PBT - Persistent, Bioaccumulative, and Toxic substance.

vPvB - Very Persistent and Very Bioaccumulative substances.

MPC - Maximum Permissible Concentration (MPC).

STEL - Maximum Short-Term Exposure Limit (STEL).

CLV - Ceiling Limit Value (CLV)

PNEC - Predicted No Effect Concentration.

DNEL - Derived No Effect Level.

ATEmix - Acute Toxicity Estimate for the mixture.

ADR - European Agreement concerning the International Carriage of Dangerous Goods by Road.

IATA-DGR - Dangerous Goods Regulations by the International Air Transport Association (IATA) - Regulations for the transportation of dangerous goods by air.

IMDG - International Maritime Dangerous Goods Code - Regulations for the transportation of dangerous goods by sea.

RID - Regulations concerning the International Carriage of Dangerous Goods by Rail.

Recommendations regarding any employee training to ensure the protection of human health and the environment: Before use, familiarize yourself with the safety data sheet, personal protective equipment, and safe handling procedures. Required training: general and job-specific instructions.

Additional information:

The classification was determined using the calculation method, by applying the classification criteria for each hazard class with further differentiation provided in parts 2-5 of Annex I to Regulation (EC) No 1272/2008 of 16 December 2008 on classification, labelling, and packaging of substances and mixtures.

Based on:

<https://echa.europa.eu>

The information contained in this safety data sheet is correct to the best of our knowledge, information and belief as of the date of publication. The information provided is intended only as a guide for safe handling, use, processing, storage, transportation, disposal and release and should not be taken as a guarantee or quality specification. The information applies only to a specific material and may not be valid for that material used in combination with other materials or in another process, unless specified in the text. Although some hazards are described in this document, we cannot guarantee that these are the only hazards that exist.

FILAMENT 3D BioCREATE HT

Version: 1

Date of issue: 22.05.2025

Date of update:

Follow training instructions when handling this material. The information contained herein is based on the knowledge we have as of the date of the latest version of this sheet. The user should verify that the information provided is correct and comprehensive in relation to the specific use of the product. This document must not be equated with a guarantee of any specific product property. Since the manufacturer does not have the ability to directly control the use of the product, the user is obliged to comply with the laws and orders in force on hygiene and safety. The manufacturer assumes no responsibility for misuse of the product.



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