

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

1.1. Product identifier

Product name:

FILAMENT 3D BioCREATE HT
Black/Coral/Lavender/Reseda Green/White
FILAMENT 3D BioCREATE HT
Black/Coral/Lavender/Reseda Green/White
1,75mm

Trade name:

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, Poland
ul. Hipolitowska 102B
Tel.: +48 783 62 62

Email address of the person

responsible for this safety data sheet: **3d@rosaplast.pl**

1.4. Emergency phone number

112 (emergency telephone -24 hours a day)

Tel.: +48 783 62 62 open 7.00 a.m. – 3.00 p.m. (Mon.-Fri.)

SECTION 2: Hazards identification

2.1. Classification of the substance or mixture

The mixture does not meet the criteria for classification in any hazard class or category in accordance with 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 (OJ L 353, 31.12.2008, as amended).

2.2. Label elements

Pictograms: Not applicable

Signal word: Not applicable

Hazard statements: Not applicable

Precautionary statements: Not applicable

Supplemental hazard information: Not applicable

Unique formula identifier (UFI): Not applicable

2.3. Other hazards

The mixture does not contain PBT/vPvB/PMT/vPvM substances or substances with endocrine disrupting properties listed in the list established in accordance with Article 59(1) according to the criteria laid down in Regulation (EU) 2017/2100 or Regulation (EU) 2018/605 in a concentration equal to or greater than 0.1%. The mixture does not contain substances in a nanoform.

SECTION 3: Composition/information on ingredients

3.1. Substances

Not applicable.

3.2. Mixtures

The mixture does not contain in a concentration 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 in accordance with the criteria set out in Annex XIII,
- vPvB in accordance with the criteria set out in Annex XIII,
- substances included in the list established in accordance with Article 59(1) for reasons other than the hazards referred to in point (a), such as endocrine disrupting properties,
- identified as having endocrine disrupting properties in accordance with the criteria set out in Delegated Regulation (EU) 2017/2100 or Regulation (EU) 2018/605;

c) 0,1 % of a substance classified as skin sensitizer category 1 or 1B, respiratory sensitizer category 1 or 1B, or carcinogenic category 2;

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

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4.1. Description of first aid measures

Ingestion:	Do not give anything to drink to an unconscious person. Contact a doctor if you feel unwell, show the label.
Eye contact:	Rinse with plenty of water, continue for at least 15 minutes. Avoid a strong stream of water due to the risk of corneal damage. Contact a doctor if symptoms persist.
Skin contact:	Take off contaminated clothing, rinse the exposed skin area with plenty of cool water, continue for at least 15 minutes. In case of direct contact of hot components directly with the skin, cool immediately. Do not use force or solvents to remove the product from the skin. Contact a doctor.
Inhalation:	Move the exposed person to fresh air. In case of breathing difficulties or feeling unwell, contact a doctor.

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

Acute symptoms of exposure:	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, CO ₂ , water mist, dispersed water stream. Adjust appropriately to the surroundings.
Unsuitable extinguishing media:	A compact stream of water.

5.2. Special hazards arising from the substance or mixture

During combustion, harmful substances may be released, including products of incomplete combustion such as carbon monoxide, as well as toxic substances resulting from the thermal decomposition of the polymer. Do not inhale smoke and fumes generated during combustion.

For hazardous decomposition products, see Section 10.6.

5.3. Advice for firefighters

Use specialized personal protective equipment. Stay on the upwind side to avoid inhaling gases, vapours, and smoke. Cool containers exposed to heat with dispersed water streams and, if possible, remove them to a safe place. Cool containers exposed to fire with water until the fire is extinguished. Collect runoff water used for firefighting in accordance with national regulations; do not allow it 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: Restrict access of bystanders. Notify the surrounding area. Evacuate to a safe place.

For emergency responders: Remove in accordance with the recommendations detailed in Section 6.3. In case of hot components, allow to cool down or cool with water and then collect mechanically. Collect hot and warm components using heat-resistant gloves complying with the EN 407 standard.

6.2. Environmental precautions

Prevent from entering sewage systems, watercourses, groundwater, and surface waters.

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 protection.

For waste disposal methods, see SECTION 13: Disposal considerations.

SECTION 7: Handling and storage

7.1. Precautions for safe handling

Ensure adequate ventilation at the workplace. In contact with hot and warm components, use heat-resistant gloves complying with the EN 407 standard and respiratory protection, 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 at a concentration >1% for which occupational exposure limits have been established.

Dusts not classified due to toxicity:

- inhalable fraction: OEL = 10 mg/m³, STEL = -, CL = -.

Inhalable fraction – the aerosol fraction entering through the nose and mouth, which, after deposition in the respiratory tract, poses a health hazard, determined in accordance with the PN-EN 481 standard.

Methods for determining substances in workplace air:

PN-Z-04507:2022-05 Air purity protection -- Determination of the inhalable aerosol fraction at workplaces by the gravimetric method.

PN-Z-04008-7:2002 Air purity protection -- Sampling -- Principles of air sampling in the workplace environment and interpretation of results.

PN-EN 689+AC:2019-06 Workplace exposure -- Measurement of exposure by inhalation to chemical agents -- Strategy for testing compliance with occupational exposure limit values.

PN-EN 481:2023-02 Workplace atmospheres — Size fraction definitions for measurement of airborne particles.

PN-EN 482:2021-08 Workplace exposure — Procedures for the determination of the concentration of chemical agents — Basic performance requirements.

Legal acts:

Regulation of the Minister of Health of 2 February 2011 on tests and measurements of agents harmful to health in the workplace environment (Journal of Laws 2023 item 419; Journal of Laws 2024 item 1110).

Regulation of the Minister of Family, Labour and Social Policy of 12 June 2018 on maximum admissible concentrations and intensities of agents harmful to health in the workplace environment (Journal of Laws 2024 item 1017; Journal of Laws 2023 item 1661; Journal of Laws 2021 item 325; Journal of Laws 2020 item 61).

PNEC, DNEL:

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8.2. Exposure control

8.2.1 Relevant technical control measures

Ensure adequate ventilation at the workplace; if possible, provide local exhaust ventilation or process isolation. Personal protective equipment should only be used when exposure cannot be adequately controlled by engineering control measures.

8.2.2 Individual protection measures such as personal protective equipment

a) Eye or face protection: In case of a risk of contact with eyes, use protective goggles complying with EN 166 – Personal eye-protection - Specifications.

b) Skin protection

Hand protection:

Use appropriate heat-resistant gloves complying with the EN 407 standard – Protective gloves and other hand protective equipment against thermal risks (heat and/or fire).

Protection of other parts of the body:

Depending on the level of exposure and the occupational risk assessment conducted at the workplace, use protective clothing and safety footwear appropriately matched to the risk.

c) Respiratory protection:

If adequate exhaust ventilation is not provided or if the occupational risk assessment at the workplace indicates such a need, use a mask/half-mask with a filter against organic vapours and/or dusts/aerosols. Recommended type of

protection in case of vapours: minimum A. Recommended type of protection in case of dust/aerosols: P2 filter. In case of combined protection against vapours and dusts/aerosols, use a combined filter AP2 complying with the EN 14387 standard – Respiratory protective devices - Gas filter(s) and combined filter(s) - Requirements, testing, marking.

d) Thermal hazards:

Use heat-resistant gloves complying with the EN 407 standard – Protective gloves and other hand protective equipment against thermal risks (heat and/or fire).

8.2.3 Environmental exposure control

Comply with the Regulation of the Minister of Maritime Economy and Inland Navigation of 12 July 2019 on substances particularly harmful to the aquatic environment and the conditions to be met when introducing wastewater into waters or into the ground, as well as when discharging rainwater or snowmelt into waters or into water devices. Regulation of the Minister of Climate of 24 September 2020 on emission standards for certain types of installations, fuel combustion sources, and waste incineration or co-incineration plants.

SECTION 9: Physical and chemical properties

9.1. Information on basic physical and chemical properties

State of matter:	Solid
Colour:	According to the product range, depending on the used pigment
Odour:	Odourless
Melting/freezing point:	No data available
Boiling point or initial boiling point and boiling range:	Not marked
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:	0,5 - 0,9 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

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No data available.

9.2.2. Other safety features

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 be avoided

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 or thermal decomposition, harmful substances may be released, including products of incomplete combustion such as carbon monoxide, as well as toxic substances resulting from the thermal degradation of the material, in particular carbon dioxide, nitrogen oxides, and other organic decomposition products. Depending on the combustion conditions, the formation of other hazardous components cannot be ruled out. Do not inhale smoke and vapors generated as a result of fire or overheating of the material.

SECTION 11: Toxicological information

11.1. Information on the hazard classes 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 concentration limit. Based on the 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 concentration limit. Based on the available data, the classification criteria are not met.

d) Respiratory or skin sensitisation

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

g) Reproductive toxicity

The mixture does not contain substances classified in this hazard class above the general/specific concentration limit. Based on the 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 the 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 the 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 concentration limit. Based on the 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 in accordance with Article 59(1) in accordance with the criteria set out in Regulation (EU) 2017/2100 or Regulation (EU) 2018/605 at a concentration 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 the available data, the classification criteria are not met.

12.2. Persistence and degradability

It does not decompose easily. Reprocessing (recycling) is recommended.

12.3. Bioaccumulation potential

Bioaccumulation is not expected due to its 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 the soil, does not penetrate into groundwater, and is not absorbed into the soil.

12.5. Results of PBT and vPvB property 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 in accordance with Article 59(1) in accordance with the criteria set out in Regulation (EU) 2017/2100 or Regulation (EU) 2018/605 at a concentration equal to or greater than 0.1%.

12.7. Other adverse effects

None known.

SECTION 13: Disposal considerations

13.1. Waste treatment methods

Product treatment

Do not discharge into sewage systems and watercourses. Consider the possibility of reuse. Waste should be recovered or disposed of in authorized incineration plants or waste treatment facilities, in accordance with applicable regulations.

07 02 13 – Waste plastic

Packaging treatment

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

07 02 13 - Waste plastic 15 01 01 - Paper and cardboard packaging

Regulation of the Minister of Climate of 2 January 2020 on the waste catalogue (Journal of Laws 2020 item 10). Act of 13 June 2013 on packaging and packaging waste management (Journal of Laws 2025 item 870, Journal of Laws 2025 item 1812).

SECTION 14: Transport information

Not classified as dangerous goods according to transport regulations (ADR/IATA/IMDG/RID).

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 users

Not applicable.

14.7. Maritime transport in bulk according to IMO instruments

Not applicable.

SECTION 15: Regulatory information

15.1. Safety, health and environmental legislation specific to 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) (OJ EU L 396, 30.12.2006, p. 1, as amended) applied in its consolidated version – legal status as of the date of compilation of the document.
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 EU L 353, 31.12.2008, p. 1, as amended) applied in its consolidated version – legal status as of the date of compilation of the document.
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 EU L 203, 26.06.2020, p. 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 maximum admissible concentrations and intensities of agents harmful to health in the workplace environment (Journal of Laws 2026 item 447; Journal of Laws 2024 item 1017; Journal of Laws 2023 item 1661; Journal of Laws 2021 item 325; Journal of Laws 2020 item 61).

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 (consolidated text: Journal of Laws 2025 item 647, Journal of Laws 2025 item 1863, Journal of Laws 2025 item 1812, Journal of Laws 2025 item 1080).

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** – Annex XIV to Regulation (EC) No 1907/2006 (REACH): does not contain.
- **Substances of very high concern (SVHC)** – Candidate List: does not contain.
- **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): the product, in the form placed on the market, is not subject to specific restrictions on placing on the market and use resulting from the applicable provisions of the REACH Regulation. The product does not meet the definition of synthetic polymer microparticles listed in entry 78 of Annex XVII to the REACH Regulation.

Seveso (Directive 12/18/EU of the European Parliament and of the Council of 4 July 2012 on the control of major-accident hazards involving dangerous substances, amending and subsequently repealing Council Directive 96/82/EC): not applicable.

POPs (Regulation (EU) 2019/1021 of the European Parliament and of the Council of 20 June 2019 on persistent organic pollutants, OJ EU L 169, 25.06.2019, p. 45, consolidated version – status as of 3 December 2025): not applicable.

PIC (Regulation (EU) No 649/2012 of the European Parliament and of the Council of 4 July 2012 concerning the export and import of hazardous chemicals, (OJ EU L 201, 27.07.2012, p. 60)): the product does not contain substances covered by the scope of this Regulation.

Ozone Depleting Substances (ODS) (Regulation (EU) 2024/590 of the European Parliament and of the Council of 29 April 2024 on substances that deplete the ozone layer, (OJ EU L 2024/590, 30.04.2024)): the product does not contain substances covered by the scope of this Regulation.

Dual-use items (Regulation (EU) 2021/821 of the European Parliament and of the Council of 20 May 2021 setting up a Union regime for the control of exports, brokering, technical assistance, transit and transfer of dual-use items, (OJ EU L 206, 11.06.2021, p. 1)): the product is not covered by the regulation on dual-use items. Explosives precursors (Regulation (EU) 2019/1148 of the European Parliament and of the Council of 20 June 2019 on the marketing and use of explosives precursors, (OJ EU L 186, 11.07.2019, p. 1)): the product does not contain substances covered by the scope of this Regulation.

Drug precursors (Regulation (EC) No 273/2004 of the European Parliament and of the Council of 11 February 2004 on drug precursors, (OJ EU L 47, 18.02.2004, p. 1)): the product does not contain substances covered by the scope of this Regulation.

RoHS (Directive 2011/65/EU of the European Parliament and of the Council of 8 June 2011 (RoHS II) on the restriction of the use of certain hazardous substances in electrical and electronic equipment, together with delegated acts and amendments, (OJ EU L 174, 01.07.2011, p. 88)): not applicable – the product does not constitute electrical or electronic equipment within the meaning of the RoHS Directive, nor does it contain substances listed in the aforementioned RoHS Directive.

15.2. Chemical safety assessment

No chemical safety assessment has been done.

SECTION 16: Other information

Full text of 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.

PMT – persistent, mobile and toxic substance;

vPvM – very persistent and very mobile substance.

NDS – Maximum Admissible Concentration (MAC).

NDSch – Short-Term Exposure Limit (STEL).

NDSP – Ceiling Admissible Concentration.

PNEC – Predicted No-Effect Concentration.

DNEL – Derived No-Effect Level.

ATEmix – Acute Toxicity Estimate of the mixture.

ADR – 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 performed using the calculation method, by applying the classification criteria for each hazard class, taking into account further differentiation contained in Parts 2 to 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.

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FILAMENT 3D BioCREATE HT Black/Coral/Lavender/Reseda

Green/White

Version:1

Date of issue: 5/6/2026

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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