SECTION 1: IDENTIFICATION OF THE SUBSTANCE/MIXTURE AND OF THE COMPANY/UNDERTAKING

1.1	**Product identifier**	
	Product name:	**PLA filament**
	Other means of identification:	not available
	Registration number:	not required, the product is a mixture, not a compound
1.2	**Relevant identified uses of the substance or mixture and uses advised against**	
	Identified uses:	material for 3D-printing
	Uses advised against:	not set
1.3	**Details of the supplier of the safety data sheet**	
	Distributor: *(responsible for marketing)*	Zemědělské družstvo Haňovice Haňovice 18 783 21 Chudobín Czech Republic tel.: +420 585 100 308 e-mail: info@plastymladec.cz web: www.filament-pm.com
	Competent person responsible for the safety data sheet: PharmDr. Vladimír Végh, PHARMIS, info@pharmis.sk	
1.4	**Emergency telephone number**	
	Toxicology Information Centre, Na Bojišti 1, Praha; 24-h non-stop: +420-224919293 / +420-224915402. Information only on health risks: acute intoxications of people / animals.	

SECTION 2: HAZARDS IDENTIFICATION

General classification of the mixture: the mixture **is not** classified as hazardous in compliance with Regulation (EC) 1272/2008. The mixture does not contain substances presenting a health or environmental hazard within the meaning of Regulation (EC) No. 1272/2008, with assigned a Community workplace exposure limit, classified as PBT/vPvB nor included in the Candidate List of Substances of very high Concerns (SVHC).

Compilation of the Safety Data Sheet is not required for this mixture; however this Safety Data Sheet provides important information on safety at work, storage, transport and other manipulation.

	Important health effects:	No adverse effects for human health are expected for the mixture under normal conditions of usage, the mixture is biologically inert. When melted, it can cause serious burns if contacted with skin and eyes. Ingestion of a small amount should not cause any troubles. Inhaling of loosen dust or potential decomposition products of melted/overheated mixture in high concentration can irritate moderately respiratory system and mucous membranes.
	Important environmental effects:	No adverse effects in the environment are expected for the mixture. Within the environment the mixture underlies biological decomposition (biodegradable).
2.1	**Classification of the substance or mixture**	
	Classification in accordance with 1272/2008/EC:	not classified as hazardous
2.2	**Label elements**	
	Contains:	not required
	Hazard pictograms:	not required
	Signal word:	not required
	Hazard statements:	not required

	Supplemental hazard information:	not required
	Supplemental label elements for certain mixtures:	not required
	Precautionary statements:	not required
	Other required labeling:	not required
2.3	**Other hazards** Results of PBT and vPvB assessment: The substances in the mixture do not meet the PBT/vPvB criteria according to REACH, annex XIII; no substances of the mixture in the amount of ≥ 0.1 % are included in the Candidate List of Substances of very high concerns (SVHC).	

SECTION 3: COMPOSITION/INFORMATION ON INGREDIENTS

Product based on polylactic acid (PLA) with additives.

3.1 Substances
does not apply

3.2 Mixtures
Substances presenting a health or environmental hazard within the meaning of Regulation (EC) No. 1272/2008, assigned a Community workplace exposure limit, classified as PBT/vPvB or included in the Candidate List: not included

Substance ***REACH Registration number***	**Content (% w/w)**	**EC Number** **CAS Number** **Index Number**	**Classification 1272/2008/EC***		**Exposure limits**
-	-	-	-	-	-

** For full wording of used classification abbreviations and Hazard Statements (H-phrases) see Section 16.*

Other compounds
Other substances not presenting a health or environmental hazard within the meaning of Regulation (EC) No. 1272/2008, without a Community workplace exposure limit, not classified as PBT/vPvB nor included in the Candidate List:

Substance ***REACH Registration number***	**Content (% w/w)**	**EC Number** **CAS Number** **Index Number**	**Classification 1272/2008/EC***		**Exposure limits**
polylactic acid (PLA) 1,4-Dioxane-2,5-dione, 3,6-dimethyl-, (3R,6R)-, polymer with rel-(3R,6S)-3,6-dimethyl-1,4-dioxane-2,5-dione and (3S,6S)-3,6-dimethyl-1,4-dioxane-2,5-dione *REACH not available yet*	< 100	618-575-7 9051-89-2 -	*not classified as hazardous*		-

SECTION 4: FIRST AID MEASURES

4.1 Description of first aid measures
Health hazard is no minimal, being neither irritating, corrosive, volatile, nor toxic. Effects of over exposure: There are no hazards under normal use conditions. Observe all user considerations and safety measures stated on the packaging. In case of any health problem or uncertainty seek medical attention and provide information from this Material Safety Data Sheet. Unconscious persons place in the stabilized position and observe the breathing. Never give any fluids to unconscious persons. Be careful when manipulating hot products - danger of skin burns.

	Inhalation:	No adverse effects are expected under normal conditions of use. Direct inhalation exposure is not expected. Dust or potential decomposition products of melted/overheated mixture in high concentration can cause airway irritation. In this case remove the affected persons to a fresh air. For those providing assistance, avoid exposure to yourself or others. Use adequate respiratory protection. If respiratory irritation, dizziness, nausea, or unconsciousness occurs, seek immediate medical assistance. If breathing has stopped, assist ventilation with a mechanical device or use mouth-to-mouth resuscitation. Call immediately medical emergency.
	Skin contact:	No adverse effects are expected under normal conditions of use - no special requirements needed. In case of a skin contact with melted polymer do not remove it from the skin. Cool down the burnt area with a stream of cold water and call the professional medical help.
	Eye contact:	No adverse effects are expected under normal conditions of use - no special requirements needed. Dust or potential decomposition products of melted polymer can cause eye irritation. Seek medical advice if the eye irritation persists. Direct contact of eye with melted product can cause serious eye damage. Seek professional medical help immediately.
	Ingestion:	No adverse effects are expected under normal conditions of use - no special requirements needed. This type of exposure is not expected.
4.2	**Most important symptoms and effects, both acute and delayed** No adverse effects for human health are expected for the mixture under normal conditions of usage, the mixture is biologically inert. When melted, it can cause serious burns if contacted with skin and eyes. Ingestion of a small amount should not cause any troubles. Inhaling of loosen dust or potential decomposition products of melted/overheated mixture in high concentration can irritate moderately respiratory system and mucous membranes.	
4.3	**Indication of any immediate medical attention and special treatment needed** No specific therapy known. Use supportive and symptomatic treatment.	

SECTION 5: FIREFIGHTING MEASURES

5.1	**Extinguishing media**	
	Suitable extinguishing media:	water spray, alcohol resistant foam, dry-powder, carbon dioxide
	Unsuitable extinguishing media:	direct water stream - could spread fire
5.2	**Special hazards arising from the substance or mixture** Flammable. Incomplete combustion and thermolysis may produce toxic, irritating and flammable decomposition products (such as carbon monoxide, carbon dioxide, sooth, aldehydes and other products of organic compounds decomposition). Do not inhale smokes.	
5.3	**Advice for fire-fighters** Fire Fighting Procedures: Keep people away. Isolate fire and deny unnecessary entry. Use water spray to cool fire exposed containers and fire affected zone until fire is out and danger of re-ignition has passed. Fight fire from protected location or safe distance. Move container from fire area if this is possible without hazard. If possible, avoid leaked water to enter sewage system or environment. Special Protective Equipment for Firefighters: Wear positive-pressure self-contained breathing apparatus (SCBA) and protective firefighting clothing (includes firefighting helmet, coat, trousers, boots, and gloves). Avoid contact with this material during firefighting operations. If contact is likely, change to full chemical resistant firefighting clothing with self-contained breathing apparatus. For protective equipment in post-fire or non-fire clean-up situations, refer to the relevant sections 6 and 8.	

SECTION 6: ACCIDENTAL RELEASE MEASURES

6.1	**Personal precautions, protective equipment and emergency procedures** No special requirements are needed. Observe all user considerations and safety measures. All unprotected persons should be restraint. Additional protective measures may be necessary, depending on the specific circumstances and/or the expert judgment of the emergency responders.
6.2	**Environmental precautions** No special requirements are needed.

6.3	**Methods and materials for containment and cleaning up** Collect mechanically. All storage vessels have to be labeled. Dispose according to valid legislation (see Section 13); recycle.
6.4	**Reference to other sections** Adhere to instructions in the section 8 and 13.

SECTION 7: HANDLING AND STORAGE

7.1	**Precautions for safe handling** Observe all user considerations, safety measures and exposure limits. See Section 8 for advice on the minimum requirements for personal protective equipment. Avoid breathing decomposition products or loosened dust. Use only with adequate ventilation. Observe all fire protection measures (work with open flame is prohibited, remove all possible sources of ignition, smoking is prohibited). During the product's thermal treatment small amounts of volatile organic compounds may be released. Thus suction and discharge of these emissions must be locally secured. Dust from the product represents a potential explosion hazard and as such it must be continuously removed. All devices must be properly grounded.
7.2	**Conditions for safe storage, including any incompatibilities** Observe all fire protection measures (work with open flame is prohibited, remove all possible sources of ignition, smoking is prohibited). Keep away from direct sunlight and heat sources.
7.3	**Specific end uses** material for 3D-printing

SECTION 8: EXPOSURE CONTROLS/PERSONAL PROTECTION

8.1 Control parameters

Indicative occupational exposure limit EC: not set

CAS	*Substance name*	*Indicative occupational exposure limit*
-	-	-

National work-place / occupational exposure limits (only selected lands are displayed):

CAS	*Substance name*	*Occupational exposure limits*
-	polylactic acid (PLA) *as: polymeric materials dust*	*Czech republic* PELc 5.0 $mg.m^{-3}$ *(Government Regulation no. 361/2007 Coll.)*

* *because of physical status, this type of exposure is not expected, however mechanical grinding/ cutting can release the dust*

Indicative biological limits: not set

Other recommended values: not set

CAS	*Substance name*	*OEL - equivalents*
-	-	-

DNEL: not available for the mixture.

PNEC: not available for the mixture.

8.2 Exposure controls

Appropriate engineering controls:

Avoid contact with skin, eyes and mucous membranes. Avoid prolonged or repeated contact with skin. Always observe good personal hygiene measures, such as washing after handling the material and before eating, drinking, and/or smoking. Routinely wash work clothing and protective equipment to remove contaminants. Discard contaminated clothing and footwear that cannot be cleaned. Personal protective equipment selections vary based on potential exposure conditions such as applications, handling practices, concentration and ventilation. Information on the selection of protective equipment for use with this material, as provided below, is based upon intended, normal usage.

Individual protection measures, such as personal protective equipment:

a) Eye / face protection
No special requirements are needed under normal conditions of usage. Avoid contact with eyes. If risk of eye contact exists, use safety glasses with side shields (EN 166).

b) Skin protection:
No special requirements are needed under normal conditions of usage. When manipulating with heated/hot material use heat isolating gloves made of para-aramid/carbon with thermal isolation up to 270°C and forearm protection. Example of recommended gloves: KCL, Karbo TECT with leather forearm cuffs, with thermal isolation up to 350°C.

NOTICE: The selection of a specific glove for a particular application and duration of use in a workplace should also take into account all relevant workplace factors such as, but not limited to: Other chemicals which may be handled, physical requirements (cut/puncture protection, dexterity, thermal protection), potential body reactions to glove materials, as well as the instructions/specifications provided by the glove supplier. Immediately change damaged gloves

c) Respiratory protection:
No special requirements are needed under normal use conditions. Ensure appropriate ventilation or exhaustion at the workplace. Do not inhale decomposition products from overheated product or dust produced by mechanical operations. If engineering controls do not maintain airborne contaminant concentrations at a level which is adequate to protect worker health, an approved respirator may be appropriate. Respirator selection, use, and maintenance must be in accordance with regulatory requirements, if applicable. Types of respirators to be considered for this material include: half-face particle filter respirator, type P1 or FFP1filter (European Committee for Standardization (CEN) standards EN 136, 140 and 405 provide respirator masks and EN 149 and 143 (EN 14387+A1) provide filter recommendations).

d) Thermal hazards:
No such risk when normally used.

Environmental exposure controls:
Comply with applicable environmental regulations limiting discharge to air, water and soil. Protect the environment by applying appropriate control measures to prevent or limit emissions. All storage and manipulation are have to be equipped for the sanation of possible leakage. See information in sections 6 and 12.

SECTION 9: PHYSICAL AND CHEMICAL PROPERTIES

9.1 Information on basic physical and chemical properties

Properties	**value**	**method / condition**
Appearance:	solid wire	20°C
Colour:	various / according to specification	-
Odour:	no odour	-
Odour threshold:	information not available	-
pH:	information not available	-
Melting point/freezing point:	> 155°C	ISO 3146-C
Initial boiling point and boiling range:	information not available	-
Flash point:	information not available	-

	Evaporation rate:	information not available	-
	Flammability (solid, gas)	information not available	-
	Upper/lower flammability or explosive limits:	information not available	-
	Vapour pressure:	information not available	-
	Vapour density:	information not available	-
	Relative density:	1,25 g/cm^3	ISO 1183
	Solubility/ies:	insoluble in water	water, 20°C
	Partition coefficient: n-octanol/water:	information not available	-
	Auto-ignition temperature:	information not available	-
	Decomposition temperature:	> 240 °C	-
	Viscosity:	information not available	-
	Explosive properties:	no explosive properties	-
	Oxidising properties:	no oxidative properties	-
9.2	**Other information**		
	-	-	-

SECTION 10: STABILITY AND REACTIVITY

10.1 **Reactivity**
Not reactive under normal conditions of storage and manipulation.

10.2 **Chemical stability**
Mixture is chemically stable under normal conditions of storage and manipulation. Overheating (> 240 °C) may cause thermal decomposition.

10.3 **Possibility of hazardous reactions**
Not known.

10.4 **Conditions to avoid**
Not known. Do not expose to high temperatures and sources of ignition.

10.5 **Incompatible materials**
Strong oxidants, acids and bases.

10.6 **Hazardous decomposition products**
Material does not decompose at ambient temperatures. Incomplete combustion and thermolysis may produce toxic, irritating and flammable decomposition products (such as carbon monoxide, carbon dioxide, sooth, aldehydes and other products of hydrocarbons decomposition).

SECTION 11: TOXICOLOGICAL INFORMATION

11.1 **Information on toxicological effects**
No adverse effects for human health are expected for the mixture under normal conditions of usage, the mixture is biologically inert.

a) *Acute toxicity*
Based on available data, the classification criteria are not met. Based on composition, the mixture has low acute toxicity and no adverse effects for human health are expected under applicable conditions of exposure.

b) *Skin corrosion/irritation*
Based on available data, the classification criteria are not met. The mixture has no direct corrosive / irritating properties. Melted product may cause serious burns following the contact with the skin.

c)	*Serious eye damage/irritation* Based on available data, the classification criteria are not met. The mixture has no direct corrosive / irritating properties. Melted product may cause serious burns following the contact with the eyes.
d)	*Respiratory or skin sensitisation* Based on available data, the classification criteria are not met.
e)	*Germ cell mutagenicity* Based on available data, the classification criteria are not met.
f)	*Carcinogenicity* Based on available data, the classification criteria are not met.
g)	*Reproductive toxicity* Based on available data, the classification criteria are not met.
h)	*STOT-single exposure* Based on available data, the classification criteria are not met. Inhalation of dust loosened dust during manipulation can mechanically irritate airways. However, these effects do not require classification.
i)	*STOT-repeated exposure* Based on available data, the classification criteria are not met.
j)	*Aspiration hazard* Based on available data, the classification criteria are not met.

SECTION 12: ECOLOGICAL INFORMATION

	No adverse effects in the environment are expected for the mixture; the mixture is biologically almost inert.
12.1	**Toxicity** No data measured for the mixture. No adverse effects in the environment are expected for the mixture; the mixture is almost biologically inert.
12.2	**Persistence and degradability** Within the environment the mixture underlies biological decomposition (biodegradable).
12.3	**Bioaccumulative potential** The mixture has no bioaccumulative potential.
12.4	**Mobility in soil** No data for the mixture. Insoluble in water, mobility in soil is not expected.
12.5	**Results of PBT and vPvB assessment** Results of PBT and vPvB assessment: The substances in the mixture do not meet the PBT/vPvB criteria according to REACH, annex XIII; no substances of the mixture in the amount of ≥ 0.1 % are included in the Candidate List of Substances of very high concerns (SVHC).
12.6	**Other adverse effects** not known

SECTION 13: DISPOSAL CONSIDERATIONS

13.1	**Waste treatment methods** It is recommended to dispose all rests in authorized dangerous waste facility. Disposal has to comply all local legal requirements on wastes. <u>Substance or mixture disposal methods:</u> Dispose in accordance with the valid waste legislation. Do not dispose as a common household waste. Dispose in a certified waste facility / recycle. According to the European Waste Catalogue waste codes are not specific for product, but for its use. Therefore, appropriate waste code should assign final user according to his specific use. Proposed waste classification, based on the most common use: 07 Wastes from Organic Chemical Processes 07 02 wastes from the MFSU of plastics, synthetic rubber and man-made fibres Waste type name: waste plastic

	Waste catalog code: 07 02 13 Hazardous waste: no
	Packages disposal methods: Recycle empty packages. Proposed waste classification, based on the most common use: 15 Waste packaging; absorbents, wiping cloths, filter materials and protective clothing not otherwise specified 15 01 packaging (including separately collected municipal packaging waste) Waste type name: paper and card board packaging / plastic packaging Waste catalog code for empty package: 15 01 01 / 15 01 02 Dangerous waste: no

SECTION 14: TRANSPORT INFORMATION

The substance **is not** classified as dangerous for transport according to ADR/RID/IMDG/ICAO/IATA.

14.1	**UN Number: -**				
14.2	**UN proper shipping name**				
	Road transport ADR	*Rail transport RID*	*Int. maritime trans. IMDG*	*Air transport ICAO/IATA*	
	-	-	-	-	
14.3	**Transport hazard class(es)**				
	Road transport ADR	*Rail transport RID*	*Int. maritime trans. IMDG*	*Air transport ICAO/IATA*	
	-	-	-	-	
	Classification code				
	-	-	-	-	
	Hazard identification number (Kemler)				
	-	-	-	-	
	Labels				
	-	-	-	-	
	Other remarks				
	-	-	-	-	
14.4	**Packing group**				
	Road transport ADR	*Rail transport RID*	*Int. maritime trans. IMDG*	*Air transport ICAO/IATA*	
	-	-	-	-	
14.5	**Environmental hazards:** no				
14.6	**Special precautions for user:** not required				
14.7	**Transport in bulk according to Annex II of MARPOL and the IBC Code:** not transported				

SECTION 15: REGULATORY INFORMATION

15.1 **Safety, health and environmental regulations/legislation specific for the substance or mixture**

Relevant legislation European Union:

- Regulation (EC) No 1907/2006 of the European Parliament and of the , concerning the Registration, Evaluation, Authorization 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
- Commission Regulation (EU) 2015/830 of 28 May 2015 amending Regulation (EC) No 1907/2006 of the European Parliament and of the Council on the

Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH)

- 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
- Commission Directive (EU) 2017/164 of 31 January 2017 establishing a fourth list of indicative occupational exposure limit values pursuant to Council Directive 98/24/EC
- Commission Directive (EU) 2019/1831 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
- Directive 2004/37/EC of the European Parliament and of the Council of 29 April 2004 on the protection of workers from the risks related to exposure to carcinogens or mutagens at work
- European Waste Catalogue
- Council Directive 1999/13/EC of 11 March 1999 on the limitation of emissions of volatile organic compounds due to the use of organic solvents in certain activities and installations
- Regulation (EU) No 528/2012 of the European Parliament and of the Council of 22 May 2012 concerning the making available on the market and use of biocidal products Text with EEA relevance
- Regulation (EU) No 526/2013 of the European Parliament and of the Council of 21 May 2013 concerning the European Union Agency for Network and Information Security (ENISA) and repealing Regulation (EC) No 460/2004

Restrictions on the manufacture, placing on the market and use of certain dangerous substances, mixtures and articles: none

Designation of the substance, of the group of substances or of the mixture	*Conditions of restriction*
-	-

15.2 Chemical safety assessment

Chemical safety assessment not carried yet

SECTION 16: OTHER INFORMATION

a) Changes made to the previous version of the safety data sheet

Not applicable, first edition - version 1.0

Key or legend to abbreviations and acronyms used in the safety data sheet

Exp. lim.	Exposure limit
NPEL	The highest permissible exposure limit (Slovak Republic)
PEL	The highest permissible exposure limit (Czech Republic)
OEL	Occupational exposure limit
PBT	Substances persistent, bioacumulative and toxic
vPvB	Substances very persistent and very bioacumulative
VOC	Volatile organic compound
DNEL	Derived No Effect Level
PNEC	Predicted No Effect Concentration
BW	Body weight
LD50	Median lethal Dose
LC50	Median lethal concentration
EC50	Half maximal effective concentration
IC50	Half maximal inhibitory concentration
ADR	European Agreement concerning the International Carriage of Dangerous Goods by Road
RID	International Rule for Transport of Dangerous Substances by Railway
IMDG	International Maritime Dangerous Goods Code
ICAO	International Civil Aviation Organization
IATA	International Air Transport Association

c)	*Key literature references and sources for data* No information
d)	*Methods of evaluating information used for the purpose of classification* The substance was classified by expert judgment and conventional calculations methods in accordance with the Regulation EC No. 1272/2008 (CLP).
e)	*Full wording of used Hazard Statements (H-phrases)* not used
f)	*Advice on any training appropriate for workers* Before handling, storing or using the present substance for the first time, employees must be informed - common training for handling chemicals, occupational safety training.
g)	*Other information* Safety Data Sheet (SDS) is compiled in accordance with the Regulation EC No. 1907/2006 (REACH), Regulation EC No. 1272/2008 (CLP) and Commission Regulation EU No. 2015/830; and contains information on safety use, occupational health protection, and environmental protection. The information contained herein is given in good faith and is accurate to the best of knowledge at the date indicated above. This particular information applies on the product as supplied and may not be valid in mixtures with other substances. If used for other purposes as identified in this SDS, the distributor is not liable for any damage. The information given herein in no way dispenses the user from knowing and applying all provisions regulating his activity. The user bears sole liability for the precautions required when using the product. The regulatory texts indicated herein are intended to aid the user to fulfill his obligations. This list is not to be considered complete and exhaustive. It is the user's responsibility to ensure that he is subject to no other obligations than those mentioned. Compiled: PharmDr. Vladimír Végh, PHARMIS, www.pharmis.cz