SAFETY DATA SHEET

ACCORDING TO EC-REGULATIONS 1907/2006 (REACH) & 1272/2008 (CLP)

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

1.1 Product identifier

Trade name	PEEK-CLASSIX™ BC1-WH; BC2-WH; BC3-WH Granules

1.2 Other means of identification

CAS No.	PEEK Polymer (31694-16-3 or 29658-26-2) Titanium dioxide: 13463-67-7
EC No.	Polyaryletherketone: Not Applicable. Titanium dioxide: 236-675-5
REACH Registration No.	Polyaryletherketone: Not Applicable. Titanium dioxide: 01-2119489379-17-0000

1.3 Recommended use of the substance and restrictions on use

Identified use(s)	The material is designed for medical device applications requiring blood or tissue contact for less than 30days. The materials are generally used for injection moulding and extrusion operations.
Uses advised against	This material is not for long term implantation

1.4 Details of the supplier of the safety data sheet

1.4.1 Manufacturer Details

Company Identification	Invibio Ltd. Hillhouse International, Thornton-Cleveleys Lancashire, UK FY5 4QD
Telephone	+ 44 (0) 1253 898000
E-Mail (competent person)	RAPS@invibio.com

1.4.2 Only Representative details

Company Identification	Stewardship Chemicals 40, Dlugosza 67, 43-188 Orzesze, Poland
Telephone:	+48 501168430
E-Mail (competent person)	pawelskiba@stewardshipsolutions.eu

1.4.3 Regional Importer Address — See section 16 for regional importer/supplier information

1.5 Emergency telephone number

Emergency Phone No.	+ 44 (0) 1253 898000 – UK +484 342 6004 – US 010-65007035 – China Hours of operation 09:00-17:00 (Monday-Friday)

SECTION 2: HAZARDS IDENTIFICATION

2.1 Classification of the substance or mixture

2.1.1 Regulation (EC) No. 1272/2008 (CLP). EUH212: Warning! Hazardous respirable dust may be formed

2.2 Label elements (GHS) According to Regulation (EC) No. 1272/2008 (CLP). Commission delegated Regulation (EU) 2020/217

Hazard pictogram(s) None.

Signal word(s) EUH212: Warning! Hazardous respirable dust may be formed
EUH210: Safety Data Sheet available on request

Hazard statement(s) EUH212: Warning! Hazardous respirable dust may be formed

Precautionary statement(s) Obtain special instructions before use.
Do not handle until all safety precautions have been understood
Wear protective gloves / protective clothing / eye protection / face protection.

2.3 Other hazards Not classified as PBT or vPvB.

PEEK polymer does not contain components considered to have endocrine disrupting properties according to REACH Article 57(f) or Commission Delegated regulation (EU) 2017/2100 or Commission Regulation (EU) 2018/605 at levels of 0.1% or higher

Not explosive.
See section 9.2 below.

2.4 Additional Information None

SECTION 3: COMPOSITION/INFORMATION ON INGREDIENTS

3.1 Substances

Polyetheretherketone polymer (CAS No. 29658-26-2 or 31694-16-3)
Titanium dioxide (CAS No. 13463-67-7)
This product does not contain any reportable hazardous materials

Classification according to Regulation EC No. 1272/2008 [CLP]:

Hazardous ingredient(s)	%W/W	EC No.	CAS No.	REACH Registration No.	Hazard statement(s)
Titanium dioxide [in powder form containing 1 % or more of particles with aerodynamic diameter ≤ 10 µm]	10	236-675-5	13463-67-7	01-2119489379-17-0000	H351 Suspected of causing cancer (Inhalation)*[1]

3.2 Additional Information

For full text of H/P phrases see section 16.

The granule products contain up to 93% synthetic polymer microparticles*[2] as defined in Entry 78 of Annex XVII to Regulation (EC) No 1907/2006.

*[1] Titanium dioxide is encapsulated within the polymer matrix and classed as a solid mixture not in powder form.
The classification as a carcinogen by inhalation applies only to mixtures in **powder form** containing 1 % or more of titanium dioxide which is in the form of or incorporated in particles with aerodynamic diameter ≤ 10 µm.

*[2]polyetheretherketone (PEEK) polymer (CAS No. 29658-26-2 or 31694-16-3)

SECTION 4: FIRST AID MEASURES

4.1 Description of first aid measures

Inhalation	Remove victim to fresh air and keep at rest in a position comfortable for breathing.
Skin Contact	After contact with skin, wash immediately with plenty of soap and water. In the event of contact with molten product: Cool affected area quickly with water. Do not attempt to remove hardened product. Obtain medical attention.
Eye Contact	Flush eyes with water for at least 2 minutes while holding eyelids open.
Ingestion	Call a physician (or poison control centre immediately).Do not induce vomiting wash out mouth with water.

4.2 Most important symptoms and effects, both acute and delayed — Unlikely to be required but if necessary treat symptomatically.

4.3 Indication of any immediate medical attention and special treatment needed — Unlikely to be required but if necessary treat symptomatically.

SECTION 5: FIRE-FIGHTING MEASURES

5.1 Extinguishing media

Suitable Extinguishing Media	In case of fire, use water spray, foam, dry powder or CO2 for extinction.
Unsuitable Extinguishing Media	None.

5.2 Special hazards arising from the substance or mixture — In case of fire the following can develop: Oxides of carbon.

5.3 Advice for fire-fighters — A self contained breathing apparatus and suitable protective clothing should be worn in fire conditions.

		Dust is ignitable but will not sustain combustion. A high temperature source of ignition is required. Insensitive to sparks. The minimum spark energy required for ignition of a dust cloud is greater than 5000 mJ. It will not train fire, e.g. along beams etc.
5.4	**Other**	Dispose of contaminated extinction water according to official regulations.

SECTION 6: ACCIDENTAL RELEASE MEASURES

6.1	**Personal precautions, protective equipment and emergency procedures**	Avoid inhalation and contact with eyes or skin. Ensure sufficient supply of air. Avoid build up of dust. Remove possible cause of ignition – do not smoke. Take precautionary measures against static discharge.
6.2	**Environmental precautions**	Avoid release to the environment. Prevent surface and ground water infiltration, as well as ground penetration. The granule product contains synthetic polymer microparticles as amended by Regulation (EU) 2023/2055. The synthetic polymer microparticles supplied is subject to conditions laid down by entry 78 of Annex XVII to Regulation (EC) No 1907/2006 of the European Parliament and of the Council.
6.3	**Methods and material for containment and cleaning up**	Sweep up carefully with non-sparking tools. Transfer to a lidded container for disposal or recovery.
6.4	**Reference to other sections**	Refer to Section 13 for disposal considerations and Section 8 for Personal Protection.
6.5	**Additional Information**	None.

SECTION 7: HANDLING AND STORAGE

7.1	**Precautions for safe handling**	General hygiene measures for the handling of chemicals are applicable. Eating, drinking, smoking, as well as food storage, is prohibited in work room. Avoid build up of dust. Local Exhaust Ventilation at the workplace or on the processing machines required. Note: Danger of explosive dust. Machine Cleaning (purging): Purging with other polymers (e.g Polyethylene) at high temperatures can be hazardous. Auto ignition may also occur. Local exhaust ventilation is required. The relevant Safety Data Sheet for the purge material to be used should be consulted. Additional information can be obtained from the Invibio Processing Guide.
7.2	**Conditions for safe storage, including any incompatibilities**	
	Storage Temperature	stored enclosed in the original packaging at room temperature in a controlled environment (limiting exposure to direct sunlight or ultraviolet sources)

Storage Life	20 Years.
Incompatible materials	None known

7.3 Specific end use(s)

The material is designed for medical device applications requiring blood or tissue contact for less than 30 days
The materials are generally used for injection moulding, extrusion or machining operations.

SECTION 8: EXPOSURE CONTROLS/PERSONAL PROTECTION

8.1 Control parameters Ensure adequate ventilation.

8.1.1 Occupational exposure limits None.

SUBSTANCE.	CAS No.	LTEL (8 hr TWA ppm)	LTEL (8 hr TWA mg/m^3)	STEL (ppm)	STEL (mg/m^3)	Note:
Dust. (general dust limit value)	-	-	10			Inhalable Dust
			4			Respirable Dust.

8.1.2 Biological limit value None

8.1.3 PNECs and DNELs Not available.

8.2 Exposure controls

8.2.1 Appropriate engineering controls Local Exhaust Ventilation at the workplace or on the processing machines required.

8.2.2 Personal protection equipment

Eye/face protection

Eye protection with side protection (EN 166)

Skin protection (Hand protection/ Other)

Impervious Gloves. Plastic or synthetic rubber gloves.
Additional information on hand protection – No tests have been performed.
When dealing with heated material: Insulating gloves EN 407 (heat)

Respiratory protection

If above exposure limits are likely to be exceeded, breathing mask with fine dust filter (EN 143)

8.2.3 Environmental Exposure Controls No special requirements.

SECTION 9: PHYSICAL AND CHEMICAL PROPERTIES

9.1 Information on basic physical and chemical properties

Appearance	Solid (Granulate)
Colour.	white
Odour	Odourless
Odour threshold (ppm)	None
pH (Value)	Not applicable

Melting point (°C)	343°C
Boiling point/boiling range (°C):	Not known.
Flash point (°C)	Not known.
Evaporation rate	Not known.
Flammability (solid, gas)	Solid , Non-flammable
Explosive limit ranges	Not explosive.
Vapour pressure (Pascal)	39.6 (@107°C)
Vapour density (Air=1)	Not known
Bulk Density (g/ml)	~1.4
Solubility (Water)	Insoluble
Solubility (Other)	Insoluble
Partition coefficient (n-Octanol/water)	Not known
Auto ignition point (°C)	595°C
Decomposition temperature (°C)	> 450°C
Viscosity (mPa. s)	Not known
Kinematic viscosity (mm^2/s)	Not applicable
Particle characteristics	Granule (pellets) dimensions: Length 2.0 – 4.0mm; diameter 2.0 – 3.5mm

No 'Nanoparticles' or 'Nanomaterial' substances (per the definition in EU Commission Recommendation 2022/3689/EU) have been generated in the manufacturing process, nor intentionally added to the Invibio grades detailed above.

9.2	**Other information**	None
9.2.1	**Information with regard to physical hazard classes**	
	Explosives	Not explosive.

SECTION 10: STABILITY AND REACTIVITY

10.1	**Reactivity**	Stable under normal conditions.
10.2	**Chemical stability**	Stable under normal conditions.
10.3	**Possibility of hazardous reactions**	Stable under normal conditions.
10.4	**Conditions to avoid**	Stable under normal conditions. Electrostatic charge. Open flame, ignition sources. Decomposes at temperatures above 450°C.
10.5	**Incompatible materials**	Concentrated Sulphuric acid
10.6	**Hazardous Decomposition Product(s)**	Oxides of carbon

SECTION 11: TOXICOLOGICAL INFORMATION

11.1	**Information on toxicological effects**	This product is essentially inert and non-toxic. Biocompatability statements available on request. Please contact Invibio Ltd for details.
11.1.1	**Substances**	
	Acute toxicity	
	Ingestion	Predicted to be low toxicity under normal conditions of handling and use.
	Inhalation	H351: Suspected of causing cancer (Inhalation)*[1]
	Skin Contact	Repeated and/or prolonged skin contact may cause irritation.

		In the event of contact with molten product: Thermal Burns (molten polymer will adhere to skin and cause severe burns).
	Eye Contact	No data. Dust may have irritant effect on eyes. Permanent damage is unlikely.
	Hazard label(s)	See section 2.2 above
	Serious eye damage/irritation	Not known
	respiratory or skin sensitization	Not known
	Mutagenicity	Not known
	Carcinogenicity	Titanium dioxide powder - Suspected of causing cancer (Inhalation) – Category 2*
	Reproductive toxicity	Not known
	STOT - single exposure	Not known
	STOT - repeated exposure	Not known
	Aspiration hazard	Not known
11.1.2	**Mixtures**	PEEK polymer + Titanium dioxide solid mixture. See Section 3 above
11.2	**Information on other hazards**	None
11.2.1	**Endocrine disrupting properties**	PEEK polymer does not contain components considered to have endocrine disrupting properties according to REACH Article 57(f) or Commission Delegated regulation (EU) 2017/2100 or Commission Regulation (EU) 2018/605 at levels of 0.1% or higher
11.2.2	**Other information**	None

SECTION 12: ECOLOGICAL INFORMATION

12.1	**Toxicity**	Low toxicity to aquatic organisms. Insoluble in water
12.2	**Persistence and degradability**	Not readily biodegradable.
12.3	**Bioaccumulative potential**	Not classified as PBT or vPvB.
12.4	**Mobility in soil**	The product has low mobility in soil. The product has low mobility in sediment.
12.5	**Results of PBT and vPvB assessment**	Not classified as PBT or vPvB.
12.6	**Endocrine disrupting properties**	PEEK polymer does not contain components considered to have endocrine disrupting properties according to REACH Article 57(f) or Commission Delegated regulation (EU) 2017/2100 or Commission Regulation (EU) 2018/605 at levels of 0.1% or higher
12.7	**Other adverse effects**	None anticipated

SECTION 13: DISPOSAL CONSIDERATIONS

13.1	**Waste treatment methods**	Disposal should be in accordance with local, regional, state or national legislation.

13.2	**Additional Information**	The European waste codes are recommendations based on the scheduled use of this product. For alternative uses and applications, other waste codes may be allocated under certain circumstances. 07 02 13- waste plastic, 07 02 99-waste not otherwise specified. Container must be decontaminated in accordance with all applicable regulations. The granule product contains synthetic polymer microparticles as amended by Regulation (EU) 2023/2055. The synthetic polymer microparticles supplied is subject to conditions laid down by entry 78 of Annex XVII to Regulation (EC) No 1907/2006 of the European Parliament and of the Council. Measures should be taken to prevent releases of synthetic polymer microparticles to the environment. Sweep up spillages immediately and transfer to a container for disposal. Do not release waste to sewers.

SECTION 14: TRANSPORT INFORMATION

14.1	**Land transport (ADR/RID)**	Not classified as dangerous for transport.
	UN number	Not applicable
	Proper Shipping Name	Not applicable
14.2	**Sea transport (IMDG)**	Not classified as dangerous for transport.
	UN number	Not applicable
	Proper Shipping Name	Not applicable
14.3	**Air transport (ICAO/IATA)**	Not classified as dangerous for transport.
	UN number	Not applicable
	Proper Shipping Name	Not applicable
14.4	**Transport in bulk according to Annex II of MARPOL73/78 and the IBC Code**	Not applicable

SECTION 15: REGULATORY INFORMATION

15.1	**Safety, health and environmental regulations/legislation specific for the substance or mixture**	According to Regulation (EC) No. 1272/2008 (CLP). Commission delegated Regulation (EU) 2020/217 EUH212: Warning! Hazardous respirable dust may be formed. See Section 2 above.
15.1.1	**EU regulations**	
	Authorisations and/or restrictions on use	The granule product contains synthetic polymer microparticles as amended by Regulation (EU) 2023/2055. The synthetic polymer microparticles supplied is subject to conditions laid down by entry 78 of Annex XVII to Regulation

		(EC) No 1907/2006 of the European Parliament and of the Council.
15.1.2	**National regulations**	
	USA	
	TSCA – PEEK Polymer	Listed – ACTIVE
	TSCA – Titanium Dioxide	Listed - ACTIVE
	OSHA	Titanium dioxide (TiO2) is a potential carcinogen to rats. Classification in the OSHA Hazard Communication Standard (HCS) (29 CFR 1910.1200).
15.2	**Chemical Safety Assessment**	Not relevant for this material.

SECTION 16: OTHER INFORMATION

The following sections contain revisions or new statements: Updated in line with Regulation (EU) 2020/878 and (EU) 2023/2055.

LEGEND

LTEL	Long Term Exposure Limit
STEL	Short Term Exposure Limit
STOT	Specific Target Organ Toxicity
DNEL	Derived No Effect Level
PNEL	Predicted No Effect Concentration

References: Workplace Exposure Limit (UK HSE EH40)

Risk Phrases and Safety Phrases: None

Hazard statement(s) and Precautionary statement(s):
H351: Suspected of causing cancer (inhalation)*[1]
P201: Obtain special instructions before use
P202: Do not handle until all safety precautions have been understood
P280: Wear protective gloves / protective clothing / eye protection / face protection
P308 + P313: If exposed or concerned: get medical advice / attention
P405: Store locked up
P501: Dispose of contents / container in accordance with local/ regional/national/international regulation.

Training advice: www.invibio.com

Additional Information

***[1]** The classification as a carcinogen by inhalation applies only to mixtures in **powder form** containing 1% or more of titanium dioxide which is in the form of or incorporated in particles with aerodynamic diameter ≤ 10 µm.

Manufactured in the UK by Invibio Ltd, under a Quality System approved to ISO 13485.
Additional information on the properties, processing and application of Invibio polymers is available at www.invibio.com.
These details refer to the product as it is delivered.
Invibio hold data on file on the product to support the storage life stated in section 7.2.
The statements made here should describe the product with regard to the necessary safety precautions – they are not meant to guarantee definite characteristics – but they are based on our present up-to-date knowledge.

Regional Importer Addresses

Invibio Inc.
300 Conshohocken State Road
West Conshohocken
PA, 19428 USA
Tel: +(1) 484 342 6004

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Room 7108, Building 7
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Tel: 010-65007035

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