

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 and Stockshapes
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, may form dust-air mixture if dispersed. See section 9.2 below.
2.4 Additional Information	See section 3 below

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)

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)*

3.2 Additional Information

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

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.

SECTION 4: FIRST AID MEASURES



4.1 Description of first aid measures

Inhalation

Remove patient from exposure. Keep patient at rest and give oxygen if breathing difficult. If exposed or concerned: get medical advice / attention.

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.

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| 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

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| 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. |
| 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 | Store products enclosed, in original packing. Store locked up. The chemical structure and highly stable nature of PEEK-CLASSIX polymers are such that the polymer's properties will not be affected by aging at ambient temperatures |

Storage Temperature	Store at room temperature.
Storage Life	> 10 Year(s).
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
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, (section 9, nanoparticles)

9.2 Other information

None

9.2.1 Information with regard to physical hazard classes

Explosives

Not explosive, may form explosible dust clouds in air.

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. Please contact Invibio Ltd for details - biocompatibility statement is available on request.
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)*
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 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.

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 None
Authorisations and/or restrictions on use EU Medical Device Directive – 93/42/EEC
Complies

15.1.2 National regulations

USA

TSCA – PEEK Polymer
TSCA- Titanium dioxide

Listed - ACTIVE

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: No major updates, general review and template update.

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)*

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

* 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 $\leq 10 \mu\text{m}$.

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.

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](tel:+14843426004)

Invibio (Beijing) Trading Co., Ltd.

Room 7108, Building 7
No. 5 Xiang Jun Lane (South)
Chaoyang District, Beijing 100020
China
Tel: [010-65007035](tel:010-65007035)

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Invibio Limited

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