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	**CERAMILL PEEK by JUVORA™ Dental Discs Oyster White**

1.2 Other means of identification

CAS No.	Polyaryletherketone: 29658-26-2 or 31694-16-3 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 materials are generally used for injection moulding and extrusion operations or machining for use in long term human implantation.

1.4 Supplier details

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

Only Representative details

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

1.5 Emergency telephone number

Emergency Phone No.	+ 44 (0) 1253 898000

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)**	N According to Regulation (EC) No. 1272/2008 (CLP). Commission delegated Regulation (EU) 2020/217
	Product name	CERAMILL PEEK by JUVORA™, Oyster White
	Hazard pictogram(s)	None.
	Signal word(s)	EUH212: Warning! Hazardous respirable dust may be formed EU210: 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.
2.2	**Other hazards**	None
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)

EC Classification Number: 1272/2008

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 CO_2 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.
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**	None.
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 (LEV) at the workplace or on the processing machines required. 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
	Storage Temperature	Store at room temperature.
	Storage Life	> 10 Year(s).
	Incompatible materials	None known
7.3	**Specific end use(s)**	The materials are generally used for injection moulding and extrusion operations or machining for use in long term human implantation.

SECTION 8: EXPOSURE CONTROLS/PERSONAL PROTECTION

8.1 Control parameters

8.1.1 Occupational exposure limits

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
Explosive properties	Not explosive
Oxidising properties	Not oxidising

9.2 Other information None

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)**	When Glowing and during combustions, CO/CO_2 (oxides of carbon) is generated.

SECTION 11: TOXICOLOGICAL INFORMATION

11.1	**Information on toxicological effects**	This product is essentially inert and non-toxic. Where appropriate the material has been tested in accordance with with ISO 10993-1. Please contact Juvora Ltd for details. The following information is based on a consideration of the properties of the main components of this mixture
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	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	**Other information**	None

SECTION 12: ECOLOGICAL INFORMATION

12.1	**Toxicity**	Low toxicity to aquatic organisms.
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	**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.

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	None
	EU Medical Device Directive – 93/42/EEC	Complies
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: 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.juvoradental.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 ≤ 10 μ m.

Manufactured in the UK, under a Quality System approved to ISO 13485.

Additional information on the properties, processing and application of JUVORA™ Dental Discs is available at www.juvoradental.com.
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.

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