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	**JUVORA™ Dental Disc White**

1.2 Other means of identification

CAS No.	Polyaryletherketone: 29658-26-2 or 31694-16-3 Titanium dioxide: 13463-67-7
EINECS No.	Polyaryletherketone: Not Applicable. Titanium dioxide: 236-675-5
REACH Registration No	Not Applicable.

1.3 Recommended use of the substance and restrictions on use

Identified use(s)	The materials are generally used for injection moulding, extrusion or machining operations for use in long term human implantation.

1.4 Supplier details

Company Identification	Juvora Ltd. Technology Centre, Hillhouse International, Thornton-Cleveleys Lancashire, UK FY5 4QD
Telephone	+ 44 (0) 1253 897333
Fax:	+ 44 (0) 1253 898001
E-Mail (competent person)	sds@victrex.com

1.5 Emergency telephone number

Emergency Phone No.	+ 44 (0) 1253 866812

SECTION 2: HAZARDS IDENTIFICATION

2.1 Classification of the substance or mixture

Preparation is not classified as hazardous in the sense of directive 1999/45/EC and 2006/121/EC.

2.1.1	**Regulation (EC) No. 1272/2008 (CLP).**	Not classified as dangerous for supply/use.
2.1.2	**Directive 67/548/EEC & Directive 1999/45/EC.**	Not classified as dangerous for supply/use.
2.2	**Label elements (GHS)**	None.
	Hazard pictogram(s)	None.
	Signal word(s)	None.
	Hazard statement(s)	None.
	Precautionary statement(s)	None.

2.3 Other hazards None.

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

EC Classification Number: 1272/2008

Hazardous ingredient(s)	%W/W	EC No.	REACH Registration No.	Hazard statement(s)
None.	-	-	-	-

EC Classification Number: 67/548/EEC

Hazardous ingredient(s)	%W/W	EC No.	REACH Registration No.	EC Classification and Risk Phrases
None.	-	-	-	-

3.2 Additional Information

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

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 symptoms develop, obtain medial 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 15 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.
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 storage is prohibited in the work room. Avoid buikd up of dust. Local Exhaust Ventilation (LEV) at the work place or on the processing machines required. Note: Danger of explosive dust. Machine Cleaning (purging): Purging with other polymerts (e.g. Polyethylene) at high temperatures can be hazardous. Auto ignition may also occur. LEV 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.

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 or maching operations for use in long term human implantation.

SECTION 8: EXPOSURE CONTROLS/PERSONAL PROTECTION

8.1 Control parameters

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
Explosive properties	Not explosive, May form explosible dust clouds in air.
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/CO2 (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 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	Mechanical irritation of the respiratory tract.
	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)	Not known
	Serious eye damage/irritation	Not known
	respiratory or skin sensitization	Not known
	Mutagenicity	Not known
	Carcinogenicity	Not known
	Reproductive toxicity	Not known
	STOT - single exposure	Not known
	STOT - repeated exposure	Not known
	Aspiration hazard	Not known
11.1.2	**Mixtures**	Not applicable
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, state or national legislation.
13.2	**Additional Information**	The 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**	Not classified as dangerous for supply/use.
15.1.1	**EU regulations**	
	Authorisations and/or restrictions on use	None
15.1.2	**National regulations**	
	USA	
	TSCA – PEEK Polymer	Listed - ACTIVE
	TSCA – Titanium dioxide	Listed - ACTIVE
	OSHA	Not classified as a hazardous material under the criteria outlines 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: 1-16.

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): None

Training advice: www.juvoradental.com

Additional Information

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.
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.

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