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

1. IDENTIFICATION OF THE SUBSTANCE/PREPARATION AND OF THE COMPANY/UNDERTAKING

1.1 Product identifier

Trade name	**JUVORA™ Dental Disc**
CAS No.	31694-16-3 or 29658-26-2
EINECS No.	Not available
REACH Registration No.	Not applicable

1.2 Relevant identified uses of the substance or mixture and uses advised against

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

1.3 Details of the supplier of the safety data sheet

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

1.4 Emergency telephone number

Emergency Phone No.	++ 44 (0) 1253 866812

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**	None.
2.3	**Other hazards**	None.
2.4	**Additional Information**	

3. COMPOSITION/INFORMATION ON INGREDIENTS

3.1 Substances

EC Classification No. 1272/2008

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

EC Classification No. 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.

4. FIRST AID MEASURES

4.1 Description of first aid measures

Inhalation	Remove 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 15 minutes while holding eyelids open.
Ingestion	Call a physician (or poison control centre immediately).Do not induce vomiting wash out mouth with water. Call a physician (or poison control centre immediately).

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

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

5. FIRE-FIGHTING MEASURES

5.1	Extinguishing media	
	Suitable Extinguishing Media	Extinguish with waterspray, foam or dry chemical.
	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.

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

6.5 Additional Information

7. HANDLING AND STORAGE

7.1 Precautions for safe handling

See Section: 6.1. 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. They may emit decomposition fumes which contain oxides of carbon and irritants. 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

Requirements for storage rooms and containers:
Not to be stored in gangways or stair wells. Store products enclosed, in original packing.
Special storage conditions:
The chemical structure and highly stable nature of PEEK-OPTIMA® polymers are such that the polymer's properties will not be affected by aging at ambient temperature.
See Section: 10.2.

Storage Temperature: Ambient.

Storage Life: Providing the product is suitably stored (dry storage avoiding extensive exposure to direct sunlight) and remains packaged in its original form, PEEK polymers will remain stable and therefore may be stored for extended periods of time prior to use. Tests have shown that polymer viscosity remains stable over a period of up to 20 years.

7.3 Specific end use(s): Industrial use only.

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/m³)	STEL (ppm)	STEL (mg/m³)	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.

9. PHYSICAL AND CHEMICAL PROPERTIES

9.1 Information on basic physical and chemical properties

Appearance	Solid (Granulate)
Colour	White (Powder) Grey/Brown. (Granulate)
Odour	Odourless
Odour Threshold (ppm)	None
pH (Value)	Not applicable
Melting Point (°C) / Freezing 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)	~1.3
Solubility (Water)	Insoluble
Solubility (Other)	Insoluble
Partition Coefficient (n-Octanol/water)	Not known
Auto Ignition Temperature (°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

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.
10.5 Incompatible materials	Concentrated Sulphuric acid
10.6 Hazardous Decomposition Product(s)	Oxides of carbon

11. TOXICOLOGICAL INFORMATION

This product is essentially inert and non-toxic. Where appropriate the material has been tested in accordance with the following tests:
US Pharmacopoeia Class VI
ISO 10993 – 1 Guidance
ISO 10993 – 5 Cytotoxicity
ISO 109933 – 10 Sensitisation
Please contact Invibio Ltd for details.
The following information is based on a consideration of the properties of the main components of this mixture.

11.1 Information on toxicological effects

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

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

13. DISPOSAL CONSIDERATIONS

13.1	**Waste treatment methods**	Disposal should be in accordance with local, state or national legislation.
13.2	**Additional Information**	None

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

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**	None
15.2	**Chemical Safety Assessment**	Not relevant for this material.

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.victrex.com

Additional Information

Manufactured in the UK under a Quality System approved to ISO 9001:2008 by Victrex Plc.

GLOSSARY

WEL: Workplace Exposure Limit (UK HSE EH40) / Bmgv: Biological monitoring guidance value (UK HSE EH40) / EH40 – UK Occupational Exposure Limits.

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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