

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

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.
Technology Centre, 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)

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

Product name JUVORA™ Dental Disc 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 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

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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 | None. |
| 6.5 Additional Information | None. |

SECTION 7: HANDLING AND STORAGE

- | | |
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| 7.1 Precautions for safe handling | <p>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.</p> <p>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.</p> |
| 7.2 Conditions for safe storage, including any incompatibilities
Storage Temperature
Storage Life
Incompatible materials | <p>Store products enclosed, in original packing. Store locked up.</p> <p>Store at room temperature.
> 10 Year(s).
None known</p> |
| 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 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 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

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| 14.1 Land transport (ADR/RID)
UN number
Proper Shipping Name | Not classified as dangerous for transport.
Not applicable
Not applicable |
| 14.2 Sea transport (IMDG)
UN number
Proper Shipping Name | Not classified as dangerous for transport.
Not applicable
Not applicable |
| 14.3 Air transport (ICAO/IATA)
UN number
Proper Shipping Name | Not classified as dangerous for transport.
Not applicable
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	Not classified as a hazardous material under the criteria outlined 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 $\leq 10 \mu\text{m}$.

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.

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.

SDS Date of Preparation: 9 September 2022 – updated from SDS Revision 19 May 2021

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