Safety Data Sheet

SECTION 1: Identification of the substance/mixture and of the company/undertaking

1.1 Product identifier **CASTING RING LINER**

1.2. Relevant identified uses of the substance or mixture and uses advised against
Maintain spacing, allows expansion of investment material and provides precise castings.

1.3 Details of the supplier of the safety data sheet

		Production:
Manufacturer/Supplier:	INTERDENT d.o.o.	INTERDENT d.o.o.
Street:	Opekarniška cesta 26	Dol 1
Country code /Postal code/City:	SI-3000 Celje	SI-3342 Gornji Grad
Telephone:	+386(0) 425-62-00	
Fax:	+368(0) 490-62-02	

1.4 Emergency telephone number

Emergency phone:	112 (EU) +386(0) 425-62-00 (Mon. – Fri.: 8.00 – 16.00)

SECTION 2: Hazards Identification

2.1 Classification of the substance or mixture
Classification according to Regulation (EC) No 1272/2008:

Hazard class	Hazard category	Hazard statements
Carcinogenicity (inhalation)	1B	H350i May cause cancer by inhalation.

2.2 Label elements
Labelling according to Regulation (EC) No. 1272/2008:

Hazard pictograms:

Signal word: DANGER

Hazard Statement(s):
H350i: May cause cancer by inhalation.

Precautionary statements:
Prevention:
P201 Obtain special instructions before use.
P261 Avoid breathing dust/fumes/gas/mist/vapors/spray.
P280 Wear protective gloves/protective clothing/eye protection/face protection

Response: .
P308 + P313 IF exposed or concerned: Get medical advice / attention.

Disposal:
P501 Dispose of contents/container in accordance with national legislation.

Component on the label:
Refractory ceramic fibres

2.3 Other hazards:
No data available

SECTION 3: Composition / information on ingredients

3.1 Mixture

Chemical Name	**INDEX number** **EC-Number** **CAS Nr.**	**%**	**Classification according to EC 1272/2008**	
			Hazardous class/hazardous category	Hazardous phrases
Refractory ceramic fibres	650-017-00-8 142844-00-6	20-25	Carc. 1B	H350i

SECTION 4: First Aid Measures

4.1 Description of first aid measures
Inhalation:
Fiber dust may be released into the air during use. If irritating to nose and throat, withdraw into fresh air.

Eye contact:
In the event of contact with the eyes, rinse eyes under running water with eyelids open for at least 15 minutes. Consult an eye doctor if irritation persists.

Skin Contact:
In case of contact with the skin, wash off with plenty of water for at least 15 minutes. Remove contaminated clothing at once. In any case call in physician. Acid burns that are not treated lead to wounds that are difficult to heal.

Ingestion:

Low possibility of ingestion. Give person drink plenty of water. Obtain medical assistance.

4.2 Most important symptoms and effects, both acute and delayed
Symptoms/effects after inhalation: mechanical irritation
Symptoms/effects after contact with skin: mechanical irritation
Symptoms/effects after ingestion: mechanical irritation

4.3 Indication of any immediate medical attention and special treatment needed
Symptomatic treatment: No specific recommendations.

SECTION 5: Firefighting measures

5.1 Extinguishing media
Suitable extinguishing media:
CO_2, foam, powder, dispersed jet of water

Unsuitable:
Don't use water jet.

5.2 Special hazards arising from the substance or mixture
The product itself is not combustible.

5.3 Advice for firefighters
Use suitable breathing apparatus that is independent of ambient air. Use protective clothing for fire-fighting so as to avoid skin and eye contact. Stay in the danger zone only with suitable, impervious chemical protection suit.

Other instructions: Avoid penetration of fire-fighting water in surface waters or groundwater.

SECTION 6: Accidental release measures

6.1 Personal precautions, protective equipment and emergency procedures
For untrained staff:
Wear protective clothing in accordance with section 8 of this safety data sheet.
Emergency procedures: Prohibit unauthorized persons.

For rescuers:
Protective equipment: Provide adequate ventilation. For individual protection, see section 8.

6.2 Environmental precautions
Do not allow to enter water/ soil/ sewage system.

6.3 Methods and material for containment and cleaning up
Pick up mechanically. Avoid dust formation. You can vacuum the dust with a vacuum cleaner that contains a filter to hold air particles very efficiently (HEPA).

6.4 Reference to other sections

Safe handling: see section 7. Personal protection equipment: see section 8. Disposal: see section 13.

SECTION 7: Handling and storage

7.1 Precautions for safe handling

Obtain special instructions before use. Avoid contact with eyes. Do not eat, drink or smoke while using this product. Clean dirty surfaces well. Use personal protective equipment as required. Dust formation should be avoided. Provide good workplace ventilation.

7.2 Conditions for safe storage, including any incompatibilities

Keep product only in original packaging. Keep closed in a dry and cool place.

7.3 Specific end use(s)

For professional use.

SECTION 8: Exposure controls/personal protection

8.1 Control parameters

Council Directive 98/24/EC with all implementations and amendments
Slovenia: Official Gazette RS, No. 100/01, 39/05, 53/07, 102/10, 43/11 – ZVZD-1, 38/15, 78/18, 78/19; 72/21

Substances:

Refractory ceramic fibers	
OEL **Slovenia**	Recommended control procedures WHO-EURO method: Determination of the number of concentrations of fibers in the air; Recommended method with phase contrast optical microscopy (membrane filter method); World Health Organization, Geneva 1997 ISBN 92 4 154496 1.
DNEL/DMEL Long term – local, inhalation	2,17 f/ml

*I – Inhaled fraction

Other informations

The DNEL mentioned in the section on long-term exposure above is based on the incidence rate of lung tumors (insignificant at all treatment levels) in a multiple-dose rat study by Mast et al. (Inhalation Toxicology, 1995, 7 (4), 469-502) and indicating that the NOAEL concentration (level with no detectable adverse effect) is 162 f / ml, meaning that the DNEL calculated for the specific end point is 2.17 f / ml.

SCOEL (Scientific Committee on Occupational Exposure Limits) recommends that the BOELV (occupational exposure limit value) for RCF be 0.3 f / ml based on the measured function of the lungs of exposed workers. At 45 years of exposure, for average cumulative exposures 147.9 (all workers in the high exposure group) and 184.8 fmo / ml (workers over 60 years in the high exposure group) - equal to average fiber concentrations of 0.27 and 0.34 f / ml - These are considered levels with no appreciable adverse effect on lung function, so

SCOEL suggested a BOELV of 0.3 f / ml. This value is significantly lower than the calculated DNEL value.

8.2 Exposure controls
Personal protective equipment in accordance with Regulation (EU) 2016/425 and the List of harmonized standards for OVO-2018 / C 209/03.

Personal protection:
General safety and hygienic precaution:
Avoid contact with eyes. Do not eat, drink or smoke while using this product. Clean dirty surfaces well. Use personal protective equipment as required. Dust formation should be avoided. Provide good workplace ventilation.

Respiratory protection:
Respiratory protection is necessary if there is increased concentration in the air and dust is generated. Type of mask: EN149:2001+A1:2009 (FFP3).

Hand protection:
Safety (leather) gloves EN 374-1:2016.

Eye protection:
Tightly sealing safety goggles with lenses made of safety glass (EN 166:2001) is recommended.

Body protection:
Wear protective work clothing.

SECTION 9: Physical and chemical properties

9.1 Information on basic physical and chemical properties

Physical state	Solid
Colour	White/beige
Odour	odourless
pH	n.a.
Melting point/freezing point	> 1650 °C fibres
Initial boiling point and boiling range	n.a.
Flash point	n.a.
Evaporation rate	n.a.
Flammability	n.a.
Explosive limits	n.a.
Vapor pressure	n.a.
Vapour density	n.a.
Relative density	n.a.
Solubility	water: < 1 mg/l
Partition coefficient: n-octanol/water	n.a.
Auto-ignition temperature	n.a.

Decomposition temperature	n.a.
Viscosity	n.a.
Explosive properties	n.a.
Oxidising properties	n.a.

9.2 Other information
Length-weighted geometric average diameter of the fibers contained in the product: 1,4 – 3 μm.

SECTION 10: Stability and reactivity

10.1 Reactivity:
Not reactive under normal conditions and proper use.

10.2 Chemical Stability:
Stable under normal conditions of use and storage.

10.3 Possibility of Hazardous Reactions:
Not known.

10.4 Conditions to Avoid:
Not known.

10.5 Incompatible Materials:
No data available.

10.6 Hazardous Decomposition Products
Under normal conditions of storage and use, hazardous decomposition products should not be produced. It contains organic matter and can release volatile organic compounds (VOCs) on first heating.

SECTION 11: Toxicological information

11.1 Information on hazard classes as defined in Regulation (EC) No 1272/2008
Acute toxicity: Not classified
Skin corrosion/irritation: Not classified
Serious eye damage/irritation: Not classified
Respiratory or skin sensitization: Not classified
Germ cell mutagenicity: Not classified
Carcinogenicity: May cause cancer by inhalation.
Additional information: fibers
May cause cancer by inhalation.
Method: Inhalation through the nose only. Multiple doses, animal species: rats, dose: 3 mg / m3, 9 mg / m3 and 16 mg / m3 within 24 months, Results: Minimal to mild pulmonary fibrosis at 9 mg / m3 and 16 mg / m3. There is no evidence of RCF-related lung tumors at any of these doses.

Method: Inhalation with the nose only. One dose, animal species: rat, dose: 30 mg / m3. Results: The study was designed to test the chronic toxicity and carcinogenicity of RCF at extreme exposures. The incidence rate of tumors (including mesothelioma) was increased at this dose level. The presence of congestion conditions (detected only after the end of the test), where the dose delivered exceeded the ability to clear the lungs, makes it difficult to make meaningful conclusions in terms of hazard and risk assessments.
Reproductive toxicity: Not classified.
STOT-single exposure: Not classified
STOT-repeated exposure: Not classified
Aspiration hazard: No data available

Further information:
Basic toxicokinetic data:
Exposure occurs mainly by inhalation or ingestion. Handmade glass fibers that are large in size, similar to RCF / ASW, have not been shown to pass from the lungs and / or intestines to other parts of the body. RCF / ASW has a low ability to persist and accumulate in the body compared to many naturally occurring materials (half fiber (> 20 μm half-life in a 3-week rat inhalation test is approximately 60 days).

Irritation features:
In animal studies (EU method B 4) negative results were obtained for skin irritation. Exposure to breathing through the nose alone causes simultaneous high exposure to the eyes, but there is no report of excessive eye irritation. Animals exposed to respiration similarly show no evidence of respiratory tract irritation. Human data confirm that only mechanical irritation occurs in humans, causing itching. A review at a manufacturer's UK facility did not indicate that there were skin problems associated with fiber exposure in humans.

SECTION 12: Ecological information

12.1 Toxicity
The product is not considered toxic to aquatic organisms and has no long-term adverse effects on the environment.

12.2 Persistence and Degradability
Biodegradation:
Methods for determination of biodegradability are not applicable for inorganic substances.

12.3 Bioaccumulative Potential
No data available.

12.4 Mobility in Soil
No data available.

12.5 Results of PBT and vPvB assessment
No data available.

12.6 Endocrine disrupting properties
No data available.

12.7 Other Adverse Effects
No data available.

SECTION 13: Disposal consideration

13.1 Waste treatment methods
(Directive 2008/98/EC, Official Gazette RS 37/15, 69/15).

Methods of disposal: Dispose in accordance with local regulations about handling with waste.

SECTION 14: Transport Information

	Land-Road/Railwey (ADR/RID):	Inland waterways (ADNR):	Sea (IMDG):
14.1 UN number	No data available		
14.2 UN proper shipping name	No data available		
14.3 Transport hazard class(es)			
14.4 Packing group	No data available		
14.5 Environmental hazards	No data available		
14.6 Special precautions for user	No special precautions		
14.7 Maritime transport in bulk according to IMO instruments	No data available		
Not a dangerous product within the meaning of the transport regulations.			

SECTION 15: Regulatory information

15.1 Safety, health and environmental regulations/legislation specific for the substance or mixture
Product is classified in accordance with Directive EC 1907/2006 and 1272/2008.

15.2 Chemical safety assessment
Chemical safety assessment not performed.

SECTION 16: Other information

Revision:
Version 03 issued on December 2022 in accordance with EC 1907/2006 (Commission Regulation (EU) 2015/830) and EC 1272/2008 with all amendments.

Revision in accordance to changes in COMMISSION REGULATION (EU) 2020/878 amending Annex II to Regulation (EC) No 1907/2006 of the European Parliament and of the

Council concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH).

Legend of abbreviations:
ADR – European agreement concerning the international carriage of dangerous goods by road
CAS – Chemical Abstracts Service
CLP – Classification, Labeling and Packaging
CMR – Carcinogenic, Mutagenic or toxic for Reproduction
DNEL - Derived no-effect level
EC_{50}: Half maximal effective concentration
EmS – Emergency Schedule
GHS – Globally Harmonised System of Classification and Labeling of Chemicals
IATA – International Air Transport Association
IUCLID – International Uniform Chemical Information Database
IMDG – International Maritime Dangerous Goods Code
LC_{50}: Lethal concentration, 50%
LD_{50}: Median lethal dose; the dose causing 50% lethality
MARPOL – International convention for the prevention of pollution from ships
NOEC - No-observed-effect concentration
NOAEL – No-observed-adverse-effect level
NTP- National Toxicology Program
OEL - Occupational exposure limit
OECD - Organisation for Economic Co-operation and Development
PBT – Persistent Bioaccumulative Toxic
PNEC: Predicted no-effect concentration
Ppm – parts per million
REACH – Registration, Evaluation, Authorisation and Restriction of Chemicals
RTECS – The Registry of Toxic Effects of Chemical Substances
RID – Regulation concerning the international carriage of dangerous goods by rail
vPvB – very Persistent and very Bioaccumulative

References:
Safety data sheets of the substances for the product
Directive EC 1907/2006 and 1272/2008 with all amendments and implementations
Council Directive 98/24/EC with all implementations and amendments
Official Gazette RS, No. 100/01, 39/05, 53/07, 102/10, 43/11 – ZVZD-1, 38/15, 78/18, 78/19; 72/21;
Directive 2008/98/EC with all amendments, Official Gazette RS 37/15, 69/15.
Martindale: The Extra Pharmacopoeia, 13. edition
European convention about international transport of hazardous material ADR
International Maritime Dangerous Goods Code IMDG

Disclaimer of expressed and implied warranties:
The information contained in the safety data sheet have been translated from the manufacturer, revised in accordance with the Slovenian legislation. Guidelines for the safe use, handling, disposal, storage and transportation and cannot be used as a guarantee. The information relates only to the specific product and is not suitable for combining with other materials or for use in another process as described in the instructions.