

Safety Data Sheet

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

1.1 Product identifier MODELCAST, MODELCAST S, INTERVEST K+B SPEED, INTERFINE K+B SPEED, INTERPRESS SPEED, INTERCAST LTS

1.2. Relevant identified uses of the substance or mixture and uses advised against Investment material for fixed and removable prosthetic.

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

Product is classified as hazardous according to Regulation (EC) No 1272/2008.

	8 8	` '
Hazard class	Hazard category	Hazard statements
STOT RE	1	H372 Causes damage to
		organs through prolonged or
		repeated exposure via
		inhalation

2.2 Label elements

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

Hazard pictograms:



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Signal word: DANGER

Hazard statements

H372 Causes damage to organs through prolonged or repeated exposure via inhalation

Precautionary statement

P260 Do not breathe dust.

P285: In case of inadequate ventilation wear respiratory protection

P501 Dispose of contents/container to a facility in accordance with local and national regulations.

Labelling information:

This product contains quartz.

2.3 Other hazards

This product should be handled with care to avoid dust generation. Depending on the type of use, airborne respirable crystalline silica may be generated. Prolonged and/or massive inhalation of respirable crystalline silica dust may cause silicosis. PBT and vPvB evaluations are in section 12.5.

SECTION 3: Composition / information on ingredients

3.1 Mixture

Ingredients: Mixture of quartz, cristobalite, magnesium oxide, aluminum oxide, Ammonium hydrogen phosphate and inorganic colours, α - hemihydrate

CAS Nr. EC-Number INDEX number	CAS No		Classification according to EC 1272/2008	
	0120 1121	%	Hazardous	**
	INDEX number		class/hazardous	Hazardous phrases
	II (DEZI Humber		category	
Quartz (SiO2)	14808-60-7	5 - 10	STOT RE 1	H372



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(fine fraction)	238-878-4			
Cristobalite	14464-46-1	< 5	STOT RE 2	H373
(fine fraction)	238-455-4			

SECTION 4: First Aid Measures

4.1 Description of first aid measures

4.1.1 General information:

No special measures required.

After inhalation:

Move victim to fresh air. Ask for medical help if problems appear.

After skin contact:

Wash with water.

After eye contact:

Wash off open lid with plenty of water, ask for medical help.

After swallowing:

Induce vomiting, ask for medical help.

4.2 Most important symptoms and effects, both acute and delayed

Refer to Section 11 – Toxicological information

4.3 Indication of any immediate medical attention and special treatment needed

Not applicable

SECTION 5: Fire Prevention Regulations

5.1 Extinguishing media

Suitable extinguishing agents:

No limitations

Unsuitable extinguishing agents:

n.a

5.2 Special hazards arising from the substance or mixture

Not known

5.3 Advice for firefighters

Self-contained breathing apparatus (SBA) and full protective equipment is recommended.



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SECTION 6: Accidental Substance Release Regulations

6.1 Personal precautions, protective equipment and emergency procedures

Wear protective clothing. Remove powder from clothing. Use mask with filter, provide good ventilation.

6.2 Environmental precautions

No special measures required.

6.3 Methods and material for containment and cleaning up

To avoid dusting sprinkle with water and collect mechanically.

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

Try to avoid breathing powder and dusting when cleaning.

7.2 Conditions for safe storage, including any incompatibilities

Storage in dry place on room temperature and tightly closed.

7.3. Specific end use(s)

Product has to be used in accordance with instructions for use on the label. For professional use.

SECTION 8: Exposure controls/personal protection

8.1 Control parameters

Occupational exposure limit:

Directive 98/24/EC with all amendments and implementations

Official Gazette RS, nr. 100/01, 39/05, 53/07, 102/10, 43/11 – ZVZD-1, 38/15, 78/18, 78/19; 72/21

Chemical	name:	Quartz
OEI	-	0.1 0.1

OEL $8 \text{ h: 0,1 mg/m}^3 \text{ (A)*}$



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Chemical name: Dust	
OEL	8 h: 10 mg/m ³ (I)*
	8 h: 1,25 mg/m ³ (A)*

^{*} A- alveolar fraction, I- inhalable fraction

8.2 Exposure controls

Personal protective equipment

Personal protection equipment in accordance with Directive (EU) 2016/425 and List for harmonized standards for OVO-2018/C 209/03.

General protection and hygienic measures:

Provide good ventilation. Do not breath dust. Wear personal protective equipment. Do not eat, drink or smoke when working. Wash hands when stop working and during breaks.

Breathing equipment:

Use mask with filter: respirator EN149:2001+A1:2009 (FFP3).

Protection of hands:

Use protection in accordance with EN 374-1:2016

Eye protection:

Safety goggles (EN 166:2001).

Protection of skin and body:

Working clothes.

8.3 Control of environment protection

Common instructions: Do not wash rinse with fresh water or to drainage system.

SECTION 9: Physical and chemical properties 9.1 Information on basic physical and chemical properties Physical state powder Colour White Odour odourless Melting point / freezing point NA Boiling point or initial boiling point and boiling range Flammability NA



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Lower and upper explosion limit	NA
Flash point	NA
Auto-ignition temperature	NA
Decomposition temperature	NA
pН	5-8 (in 80% water mixture)
Kinematic viscosity	NA
Solubility	NA
Partition coefficient n-octanol/water (log	NA
value)	
Vapour pressure	NA
Density and/or relative density	NA
Relative vapour density	NA
Particle characteristics	NA

9.2 Other information

Powder is hygroscope and it absorb water.

SECTION 10: Stability and reactivity

10.1 Reactivity

No specific test data related to reactivity available for this product.

10.2 Chemical stability

In the product form is stable under normal storage and handling conditions.

10.3 Possibility of hazardous reaction

No hazardous reaction when handled and stored according to provisions.

10.4 Conditions to avoid

None.

10.5 Incompatible materials

Void

10.6 Hazardous decomposition products

When heating investment, ammoniac is released (OEL 14mg/m³) in oven.

SECTION 11: Toxicological information

11.1 Information on hazard classes as defined in Regulation (EC) No 1272/2008

Acute toxicity: not known.

Skin corrosion/irritation: Not classified



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Serious eye damage/irritation: Not classified Respiratory or skin sensitization: Not classified

Germ cell mutagenicity: Not classified

Carcinogenicity: Not classified

Reproductive toxicity: Not classified. STOT-single exposure: Not classified STOT-repeated exposure: Not classified

Aspiration hazard: Possible getting silicosis when inhale to much powder.

11.2 Information on other hazards

No other information available.

SECTION 12: Ecological information

12.1 Toxicity

Not available for the product.

12.2 Persistence and degradability

Inorganic salts are basically not biodegradable. Easy elimination possible by flocculation or adsorption by sludge.

12.3 Bioaccumulative potential

No data available

12.4 Mobility in soil

Not available for the product.

12.5 Results of PBT and vPvB assessment

The substances in the mixture do not meet the PBT/vPvB criteria according to EC 1907/2006 REACH, annex XIII.

12.6 Other adverse effect

Not known

SECTION 13: Disposal considerations

13.1 Waste treatment methods

Sprinkle powder with water, collect mechanically and dispose with household garbage.

SECTION 14: Transport Information				
	Land-Road/Railwey	Inland waterways	Sea (IMDG):	Air (IATA):
	(ADR/RID):	(ADNR).		



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14.1 UN number	No data available
14.2 UN proper	No data available
shipping name	
14.3 Transport	No data available
hazard class(es)	
14.4 Packing	No data available
group	
14.5	No data available
Environmental	
hazards	
14.6 Special	No special precautions
precautions for	
user	
14.7 Maritime	No data available
transport in bulk	
according to IMO	
instruments	
37 . 1	

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

EU Label Information:

Classification and labeling have been performed according to Regulative 1272/2008.

EU Hazard Symbol and Indication of Danger:

According to Regulation EC 1272/2008 this product is not classified.

15.2 Chemical safety assessment

Chemical safety assessments for substances in this mixture were not carried out.

SECTION 16: Other information

Revision:

Safety data sheet issued on December 2022 in accordance with EC 1907/2006 (Commission Regulation (EU) 2015/830) and EC 1272/2008.

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



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CLP - Classification, Labeling and Packaging

CMR - Carcinogenic, Mutagenic or toxic for Reproduction

DNEL - Derived no-effect level

EC50: 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

LC50: Lethal concentration, 50%

LD50: 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:

Directive 1907/2006 (REACH) with all implementations and amendments Directive 1272/2008 (CLP, EU GHS) with all implementations and amendments 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

Dangerous Goods Regulations (DGR) for the air transport (IATA)

International Maritime Dangerous Goods Code IMDG

Disclaimer of expressed and implied warranties:

The information contained in the safety data sheet is correct to the best of our knowledge at the date of issue. It is intended as a guide for the safe use, handling, disposal, storage and transportation and is not intended as warranty or as a specification. The information relates only to the product specified and may not be suitable for combinations with other materials or in processes other than those specifically described herein.