

Safety Data Sheet

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

1.1 Product identifier **PEARL ADHESIVE**

1.2. Relevant identified uses of the substance or mixture and uses advised against
 Product is used for bonding pearls of polystyrene on the wax model.

1.3 Details of the supplier of the safety data sheet

Manufacturer/Supplier:	INTERDENT d.o.o.	<i>Production:</i> 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
Flammable liquids	Hazard Category 2	H225 Easy inflammable liquid and vapour.
Aspiration hazard	Hazard Category 1	H304: May be fatal if swallowed and enters airways.
Skin corrosion/irritation	Hazard Category 2	H315 Skin corrosion/irritation
Serious eye damage/eye irritation	Hazard Category 2	H319 Extremely irritate eyes.
Specific target organ toxicity – Single exposure	Hazard Category 3, Narcosis	H336 Can cause drowsiness and dizziness.
Reproductive toxicity	Hazard category 2	H361d Suspected of damaging fertility.
Specific target organ toxicity – Repeated exposure	Hazard Category 2	H373 May cause damage to organs

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Hazardous to the aquatic environment– Chronic Hazard	Chronic Hazard, Category 2	H411 Toxic to aquatic life with long lasting effects.
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2.2 Label elements

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

Hazard pictograms:



Signal word: DANGER

Hazard statements:

- H225 Easy inflammable liquid and vapour.
- H304 May be fatal if swallowed.
- H315 Skin corrosion/irritation
- H319 Extremely irritate eyes.
- H336 Can cause drowsiness and dizziness.
- H361d Suspected of damaging fertility.
- H373 May cause damage to organs
- H411 Toxic to aquatic life with long lasting effects.

Precautionary statement:

Preventions:

- P210 Keep away from heath/sparks/open flame/hot surface. No smoking.
- P233 Keep container tightly closed.
- P260 Avoid breathing dust / fume / gas / mist / vapors / spray.
- P264 Wash your hands thoroughly after handling.

Response:

- P301 + P310: IF SWALLOWED: Immediately call a poison center or physician.
- P305 + P351 + P338 IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and if you can do it without problems. Continue rinsing.
- P331 Do not induce vomiting.

Disposal

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P501 Dispose of contents/containers in accordance with local regulation

Component on the label:

Colophony, organic solvents

2.3 Other hazards

PBT and vPvB evaluations are in section 12.5

SECTION 3: Composition / information on ingredients

3.1 Substance

See section 3.2

3.2 Mixture

Chemical name	CAS Nr. EC-Number INDEX number	%	Classification according to EC 1272/2008	
			Hazardous class/hazardous category	Hazardous phrases
Colophony	650-015-00-7 232-475-7 8050-09-7	20-30	Skin.Sens. 1	H317 EUH208
Hydrocarbons C6-C7, isoalkanes, cyclical, <5% n-hexane	/ 265-192-2 64742-89-8	10-20	Flam. Liq.2 Asp.Tox.1 Aquatic Chronic 2	H225 H304 H411
Acetone	606-001-00-8 200-662-2 67-64-1	10-20	Flam. Liq. 2 Eye irrit. 2 STOT SE 3	H225 H319 H336 EUH066
Toluene	601-021-00-3 203-625-9 108-88-3	0,1- 0,50	Flam.Liq.2 Asp.Tox. 1 STOT RE 1 Skin irrit 2 STOT SE 3	H225 H304 H373 H315 H336

SECTION 4: First Aid Measures

4.1 Description of first aid measures

Inhalation:

Remove to fresh air, loosen tight clothing and, if necessary, call your doctor; the use of artificial respiration is not permitted to use mouth-to-mouth; if necessary, call your doctor. If you develop dizziness, nausea, headache, seek advice from a doctor.

Skin contact:

Wash with water and soap. Remove the contaminated clothing immediately.

Eye contact:

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Rinse with clear water or solution for rinsing eyes, holding the eyelids apart for at least 15 minutes. If symptoms persist, consult a doctor.

Ingestion:

Rinse the mouth and drink at least 100mL. Call the doctor. Do not induce vomiting.

4.2 Most important symptoms and effects, both acute and delayed

Dizziness, sleekness, headache, vomiting, unconsciousness.

4.3 Indication of any immediate medical attention and special treatment needed

Specific treatment: First aid, decontamination, treatment of symptoms.

Notes for the doctor: Treat symptomatically.

SECTION 5: Firefighting measures

5.1 Extinguishing media

Suitable:

Foam, powder, carbon dioxide, inert gas or INERGEN FM 200 (for beginning of firefighting), water fog

Unsuitable:

Water jet, except water mist to cool containers with flammable products.

5.2 Special hazards arising from the substance or mixture

The preparation is combustible. Combustion products or gases may form explosive gas-air mixtures. In case of fire may liberate carbone monoxide CO. Remove all possible sources of ignition: open flame, lit cigarette, sparks from tools and equipment. After using close the product.

5.3 Advice for firefighters

Special protective equipment for firefighters: Wear a self-contained breathing apparatus and chemical protective clothing. Collect contaminated water used for firefighting separately. Do not release it in sewage system.

Endangered drums or containers with hazardous substances must be cooled with water spray.

SECTION 6: Accidental release measures

6.1 Personal precautions, protective equipment and emergency procedures

Wear protective clothing. With larger release, use respiratory protection. Eliminate sources of ignition and sparking. Ensure good ventilation.

6.2 Environmental precautions

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Prevent release into the water and drains and the accumulation of vapors in closed rooms.

6.3 Methods and material for containment and cleaning up

Spilled liquid should be taken up through the absorbent (sand, soil, universal binder). Contaminated material should not be disposed of with household waste. Do not allow to enter sewer system. Throw off in an appropriate container. Packaging waste should be deferred in accordance with official regulations.

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

Avoid repeated contact with the skin, do not inhale vapor or haze. Ensure good ventilation of the places where the product is used. If you did not use the entire contents of the product, you should tightly close the container after work. Avoid contact with hot elements sparks, flame and sources of ignition. Avoid the possibility of electrostatic charge. When refilling larger quantities, ensure conductivity with the bonding and grounding of all equipment.

Do not eat, drink or smoke during work. Avoid inhaling the vapours. Close the product tightly after use. Wear protective gloves, glasses and clothing.

7.2 Conditions for safe storage, including any incompatibilities

Store in dry well ventilated place and in tightly closed package, protected from sunlight, source of burning, heat and electrostatic charge. The floor in the warehouse need to be solvent-resistant and impermeable. Avoid frost. Do not store together with food, beverages or fodder.

7.3. Specific end use(s)

Product is intended for use in dental laboratory.

SECTION 8: Exposure controls/personal protection

8.1 Control parameters

Directive 98/24/EC with all amendments

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

Chemical name	OEL (mg/m ³)	OEL (ml/m ³ ,	Short term exposure	Note

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		PPM)	
Acetone	1210	500	K EU BAT
Toluene	192	50	K EU BAT

BAT

Chemical name	Characteristical index Biological sample Time of the sampling (BAT)
Toluene	toluene blod after working 10,85 mmol/mol kreatinin* - last breath out air in the time of the exposure 0,83 mmol/l Hipuric acid urine after working 1,58 mol/mol kreatinin* o-krezol urine after working 1,58 mol/mol kreatinin*
Acetone	Acetone blood after working 0,34 mmol/l

DNEL

Chemical name	Population exposure effects value (unit)
Colophony	Workers long-term inhalation Systemic effect 117 mg/m3 Workers long-term dermal sistemic effect 17 mg/kg/ body weight/day Users long-term inhalation Systemic effect 35 mg/m3 Users long-term dermaln systemic effect 10 mg/kg/body weight / day Users long-term oral systemic effect 10 mg/kg/body weight / day
C6-C7, isoalkanes, cyclical < 5% n-hexane	Workers long-term inhalation Systemic effect 5306 mg/m3 Workers long-term dermal sistemic effect 13964 mg/kg/ body weight/day Users long-term inhalation Systemic effect 1131 mg/m3 Users long-term dermal systemic effect 1377 mg/kg/body weight / day Users long-term oral systemic effect 1301 mg/kg/body weight / day
Acetone	Workers long-term dermal systemic effect 186 mg/kg/bw/d Workers long-term inhalation systemic effect 1210 mg/m3 Workers short-term inhalation local effect 2420 mg/m3 Users long-term inhalation systemic effect 200 mg/m3 Users long-term dermal systemiceffect 62 mg/kg/bw/d Users long term oral systemic effect 62 mg/kg/bw/d
Toluene	Workers Long-term inhalation systemic effects 192 mg/m3 Workers long-term inhalation local effects 192 mg/m3 Users short term inhalaton systemic effects 226 mg/m3 Users short term inhalation local effects 226 mg/m3

PNEC

Chemical name	Details of the environment Values
Colophony	Fresh water 0,02 mg/l Sea water 0 mg/l Broken releases 0,16 mg / l Sediments in fresh water 0,007mg / kg dry weight Sediment in seawater 0.001 mg / kg dry weight Earth 0 mg / kg dry weight Wastewater Treatment Plant (STP) 1 mg / l
Acetone	Fresh water 10,6 mg/l Sea water 1,06 mg/l Sediments in fresh water 30,4 mg/l Sediment in seawater 3,04 mg/l

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	Earth 29,5 mg/kg Wastewater Treatment Plant (STP) 100 mg/l
Toluene	Fresh water = 0.68 mg / l Seawater = 0.68 mg / l Broken releases = 0.68 mg / l Wastewater Treatment Plant (STP) = 13.61 mg / l Fresh water sediment = 16.39 mg / kg dry weight Sediment in seawater = 16.39 mg / kg dry weight Earth = 2.89 mg / kg dry weight

8.2 Exposure controls

Personal protective equipment in accordance with Regulation (EU) 2016/425, with the Regulation on personal protective equipment (Ur. L. RS, no. 29/05, 23/06, 17/11 - ZTZPUS-1 and 76/11) and the List harmonized standards for OVO-2018 / C 209/03.

Personal protection

Respiratory protection:

Wear full face protection with "A" filter when used indoors for prolonged periods. If the oxygen concentration in the workplace air falls below 17%, use a self-contained open-circuit breathing apparatus.

Use respiratory mask according to SIST EN 136: 1998 / AC: 2004 Respiratory protection equipment - Gas filters and combi-filters in accordance with Official Journal EC C110 of 11 April 2014.

Eye protection:

Wear safety goggles at lower concentrations in the air and a full face protective mask at higher concentrations.

Whenever a risk assessment indicates it is necessary to wear safety goggles that comply with an approved standard. If contact can occur, chemical safety goggles should be worn in accordance with SIST EN 166: 2002 - Personal eye protection - Specifications and safety goggles design (TYPE 3) established in accordance with Official Journal EC C110 of 11 April 2014.

Recommended: goggles with side protection; the choice should be in line with the product application and be relevant to the risk assessment.

Hand protection:

Longer contact: > 8 hours (time to remove obstruction): Viton® (> 0.7 mm).

Shorter contact: <1 hour (barrier removal time): Chloroprene, Nitrile rubber (0.2 mm).

Please note that the breakthrough time of any glove material varies from manufacturer to manufacturer. In the case of multi-substance mixtures, it is impossible to accurately estimate the protection time with gloves.

Wear safety gloves in accordance with SIST EN 374-1: 2003 to SIST EN

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374-4: 2014-Protective gloves against chemicals and micro-organisms according to EC Official Journal C110 of 11 April 2014.

Skin protection:

Under normal conditions, wear cotton clothing and appropriate footwear. If the policy option is large, use clothing and footwear resistant to chemicals (PVC, rubber).

If there is a risk of ignition due to static electricity, wear antistatic protective clothing. Wear antistatic clothing made of natural fibers (cotton) or heat-resistant synthetic fibers for protection against static discharges. For further information on materials, purpose and test methods, see the European standard SIST EN 1149-5: 2008 / Protective clothing - Electrostatic properties according to EC Official Journal C110 of 11 April 2014. Choose the type of clothing according to the product application or product, according to the risk assessment.

8.3 Control of environment protection

Do not spill into inland water or sewage system. Avoid entering the soil.

SECTION 9: Physical and chemical properties

9.1 Information on basic physical and chemical properties

Physical state	easy flammable viscose liquid
Colour	yellow-brown colour
Odour	like solvent
pH	n.a.
Boiling point	> 50°C
Melting point	n.a.
Inflammation point	< 21°C
Upper explosive limit	1,2 vol%
Lower explosive limit	11,0 vol.%
Decomposition temperature	n.a.
Vapour pressure (20°C):	239 mbar (acetone)
Vapour pressure (50°C):	/
Density (20°C):	cca 0,85 g/cm ³
Solubility in water:	not soluble
Solubility in organic solvent:	soluble
Partition coefficient n-octanol/water (log value)	n.a.
Kinematic viscosity:	max. 500 mPa s
Particle characteristics	n.a.

9.2 Other information

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No additional information relevant to safe use of the mixture.

SECTION 10: Stability and reactivity

10.1 Reactivity

Not reactive under normal temperature and proper use.

10.2 Chemical stability

Stable at normal temperature. When used in accordance with the instructions is not degraded.

10.3 Possibility of hazardous reaction

When heated, the pressure and volatile solvents are increased, risk of ignition and explosion.

10.4 Conditions to avoid

High temperature, presence of ignition sources

10.5 Incompatible materials

Strong oxidizing agents.

10.6 Hazardous decomposition products

Corrosive and irritating fumes, CO, CO₂

SECTION 11: Toxicological information

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

Due to the content of toluene and special gasoline overexposure may cause nervous system disorders, kidney damage, liver, heart and lungs.

Chemical name: Acetone

Acute toxicity-Oral: LD50 (rat): 5800 mg/kg

Acute toxicity-Dermal: LD50 (rat): 20000mg/kg

Acute toxicity-Inhalational: LC50 (rat,5h): 42000ppm

Acetone has narcotic effect

Chemical name: Hydrocarbons C6-C7

Acute toxicity-Oral: LD50 (rat): > 2000 mg/kg

Acute toxicity-Dermal: LD50 (rat): > 2000 mg/kg

Acute toxicity-Inhalational: LC50 (rat,4h): 5mg/L

Chemical name: Toluene

Acute toxicity-Oral: LD50 (rat): 636 mg/kg

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Acute toxicity-Dermal: LD50 (rabbit): 8390 mg/kg
Acute toxicity-Inhalational: LC50 (rat,4h): 13 mg/L

Skin corrosion/irritation:

Toxicological data of complete product are not available.

Serious eye damage/irritation:

Toxicological data of complete product are not available.

Respiratory or skin sensitization: Based on the available information, the classification criteria are not fulfilled.

Germ cell mutagenicity: Based on the available information, the classification criteria are not fulfilled. Does not contain a relevant substance that meets the classification criteria.

Carcinogenicity: Based on the available information, the classification criteria are not fulfilled. Does not contain a relevant substance that meets the classification criteria.

Reproductive toxicity: Based on the available information, the classification criteria are not fulfilled. Does not contain a relevant substance that meets the classification criteria.

STOT-single exposure:

Toxicological data of complete product are not available. May cause respiratory irritation.
Calculation method

STOT-repeated exposure: Based on the available information, the classification criteria are not fulfilled.

Aspiration hazard: Based on the available information, the classification criteria are not fulfilled.

SECTION 12: Ecological information

12.1 Toxicity

Can cause long lasting harmful effects to environment.

12.2 Persistence and degradability

No data available.

12.3 Bioaccumulative potential

No data available.

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12.4 Mobility in soil

Possible splitting in the environment.

12.5 Results of PBT and vPvB assessment

No data available.

12.6 Endocrine disrupting properties

No data available.

12.7 Other adverse effect

It is important that pH of material is between 6-10 when release acid or base in sewage system. Higher or lower pH can damage sewage system or purifying plant. The local Regulations should be considered.

SECTION 13: Disposal considerations

13.1 Waste treatment methods

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

Recommendation: Do not dispose with domestic waste. Do not allowed enter sewage system. Detergent that can be used when small amount is spilled is water.

Waste category: 16 03 03* Inorganic disposal that contains hazardous substances

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SECTION 14: Transport Information			
	ADR/RID	IMDG	IATA
14.1 UN number	UN 1133		
14.2 UN proper shipping name	ADHESIVES containing flammable liquid		
14.3 Transport hazard class(es)			
Class	3		
Label(s)	/	/	/
Classification code	F1	/	/
Hazard identification	33	/	/
Tunnel restriction code	2 (D/E)	/	/
EmS	/	/	/
14.4 Packing group	II		
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		

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 and additional changes or national legislation Ur.l. RS 101/2002 and Ur.l.RS 16/2008.

15.2 Chemical safety assessment

No data available from component's supplier.

SECTION 16: Other information

Revision:

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Version 08 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
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
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
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
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
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 refer to the manufacturer's current knowledge and are a guideline for the safe use, handling, disposal, storage and

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transportation, but could not 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.