

Safety Data Sheet

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

1.1 Product identifier **INTERSKIN**

1.2. Relevant identified uses of the substance or mixture and uses advised against
 Product is used as disinfectant agent for hands in dental laboratories.

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.

Flammable liquids	Hazard Category 2	H225 Highly flammable liquid and vapor.
Serious eye damage/eye irritation	Hazard Category 2	H319: Causes serious eye irritation.

2.2 Label elements

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

Hazard pictograms:



Signal word: DANGER

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Hazard statements:

H225: Highly flammable liquid and vapor.

H319: Causes serious eye irritation.

Precautionary statement:
Prevention

P102: Keep out of reach of children.

P210 Keep away from heat/sparks/open flames/hot surfaces. — No smoking.

P233 Keep container tightly closed.

P261 Avoid breathing vapours.

Response

P305+P351+P338 IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.

Disposal

P501 Dispose of contents/container to in accordance with local/regional/national/international regulation (to be specified).

Hazardous components on the label

Ethanol, Propan-2-ol

2.3 Other hazards

PBT and vPvB evaluations are in chapter 12.5.

SECTION 3: Composition / information on ingredients
3.1 Substances

/

3.2 Mixture

Water, Ethanol, Propan-2-ol, Glycerin, Citric acid, Methyl Ethyl keton (possible impurity)

Chemical name	Index number EC number CAS number	%	Classification according to EC 1272/2008	
			Hazardous class/hazardous category	Hazardous phrases
Ethanol	603-003-00-0 200-661-7 67-63-0	70	Flam.Liq.2 Eye Irrit. 2	H225 H319
Propan-2-ol	603-117-00-0 200-661-7 67-63-0	< 5	Flam. Liq.2 Eye Irrit.2 STOT SE3	H225 H319 H336
Glycerin	/	< 3	/	/

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	200-289-5 56-81-5			
Citric acid	/ 201-069-1 5949-29-1	< 3	Eye Irrit.2	H319
Methyl Ethyl keton	606-002-00-3 201-159-0 78-93-3	< 1	Flam. Liq.2 Eye Irrit.2 STOT SE3	H225 H319 H336

SECTION 4: First Aid Measures

4.1 Description of first aid measures

Inhalation:

Remove victim to the fresh air, keep him warm. If not breathing: artificial respiration. In the case of unconsciousness keep victim in position of unconscious. Ask for medical help when difficulties appear.

Skin contact:

Product doesn't irritate skin.

Eye contact:

Wash off open eye with plenty of water for 15 minutes. Ask for medical help when difficulties appear.

Ingestion:

First wash mouth with water and then drink 100 mL of water. Do not induce vomiting. Ask for medical help.

4.2 Most important symptoms and effects, both acute and delayed

Symptoms: Refer to Section 11 – Toxicological information for detailed information.

4.3 Indication of any immediate medical attention and special treatment needed

Symptomatic treatment.

SECTION 5: Firefighting measures

5.1 Extinguishing media

Suitable:

CO₂, dust, dispersed jet of water. Large fire extinguishers with dispersed jet of water or foam resistant to alcohol.

Unsuitable:

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Direct water jet

5.2 Special hazards arising from the substance or mixture

Easy flammable. Dangerous products of thermal decomposition are formed like carbon monoxide, carbon dioxide.

5.3 Advice for firefighters

Protective equipment for firefighters: protective clothing (SIST EN 469:2006/A1:2007) with helmet (SIST EN 443: 2008), protective gloves (SIST EN 659: 2003 + A1: 2008/AC: 2009), shoes (SIST EN 15090: 2012), breathing apparatus (SIST EN 137: 2006).

Collect contaminated water used for firefighting separately. Do not release it in sewage system.

SECTION 6: Accidental release measures

6.1 Personal precautions, protective equipment and emergency procedures

Wear protective equipment. Insure against source of fire and heat.

6.2 Environmental precautions

Do not allow enter sewage system or waters. Prevent soil penetrating.

6.3 Methods and material for containment and cleaning up

Absorb with sand, earth, diatomic earth, blotting paper, sawdust. Dispose in accordance with law about waste material.

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

Keep away from the source of ignition, prevent from static discharges, use apparatuses protect against explosion and tool which does not spark.

7.2 Conditions for safe storage, including any incompatibilities

Keep in closed vessel away from food and water. Store it on room temperature away from direct sunlight and source of ignition. Do not smoke. Prevent static electric discharge.

7.3. Specific end use(s)

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Product is intended to be used in dental laboratories as disinfectant agent for hands

SECTION 8: Exposure controls/personal protection

8.1 Control parameters

Ingredients with limit values that have to be considered and measured in the working place

Directive 98/24/EC as amended

Official Gazette of the RS, No. 100/01, 39/05, 53/07, 102/10, 43/11 - ZVZD-1, 38/15, 78/18, 78/19; 72/21

Ethanol

OEL	Current exposure: 1920 mg/m ³ , 1000 ppm Long-term exposure: 960 mg/m ³ , 500 ppm Y, BAT
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Propan-2-ol

OEL	Current exposure: 1000 mg/m ³ , 400 ppm Long-term exposure: 500 mg/m ³ , 200 ppm Y, BAT
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Oral	DNEL	26 mg/kg (users-long-term exposure-systemic effect)
Dermal		888 mg/kg (workers-long-term exposure-systemic effect) 319 mg/kg (users-long-term exposure-systemic effect)
Inhalable		500 mg/m ³ (workers-long-term exposure-systemic effect) 89 mg/m ³ (users-long-term exposure-systemic effect)

Ingredients with biological limit values

Propan-2-ol

BAT	25 mg/l Biological sample: blood Time of sampling: at the end of working shift Characteristic indicator: acetone
	25 mg/l Biological sample: blood Time of sampling: at the end of working shift Characteristic indicator: acetone

For Propan-2-ol

Foreseen concentration without effect (PNEC):

Fresh water: 140,9 mg/l

Sea water: 140,9 mg/l

Release intervals: 140,9 mg/l

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Waste water treatment plant: 2251 mg/l
 The sediment associated with the weight of the dry material: 552 mg/kg
 Floor associated with the weight of the dry matter: 28 mg/kg
 Secondary poisoning associated with food: 160 mg/kg

Glycerin

OEL	Current exposure: 400 mg/m ³ (I) Long-term exposure: 200 mg/m ³ (I) (Directive 98/24/EC, 2000/39/EC and all amendments)
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Methyl Ethyl ketone

OEL	Current exposure: 900 mg/m ³ , 300 ppm Long-term exposure: 600 mg/m ³ , 200 ppm K, Y, BAT, EU
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BAT: 2 mg/l, urine, after working

8.2 Exposure controls

Personal protective equipment in accordance with Regulation (EU) 2016/425 (Official Gazette RS, št. 29/05, 23/06, 17/11 – ZTZPUS-1, 76/11 in 33/18) and List of harmonized standards for personal protection equipment 2018/C 209/03.

Personal protective equipment

Respiratory protection:

With sufficient ventilation and with regards to intended use any special protection is not necessary, otherwise when concentration is over the limit OEL mask SIST EN 136 or SIST EN 140 and SIST EN 143 with filter type A in accordance with SIST EN14387:2004+A1:2008.

Hand protection:

Not necessary.

Respiratory protection:

With sufficient ventilation and with regards to intended use any special protection is not necessary, otherwise mask EN 140:1998/AC:1999 with protective filter type A [boiling point >65°C (149°F)] (EN14387:2004+A1:2008).

Skin and body protection:

Protective antistatic coat (EN ISO 1149-5:2008) and antistatic footwear (EN ISO 20345:2011).

Eye protection:

Wearing safety goggles (EN 166:2001).

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8.2.2 Environmental exposure controls

General instructions: Do not flush into surface water or sanitary sewer system. Avoid penetrating the ground.

SECTION 9: Physical and chemical properties

9.1 Information on basic physical and chemical properties

Data are for ethanol	
Physical state	liquid
Colour	colorless
Odour	Alcoholic like
pH	NA
Melting point / melting range	-114°C
Boiling point	78°C
Flashpoint	12°C
Evaporation rate	NA
Autoignition temperature	425°C
Upper explosion limit	15 % (vol)
Lower explosion limit	3,5 % (vol)
Oxidative characteristics	n.a.
Vapour pressure	59 hPa (20°C)
Density	0,79 g/cm ³ (20°C)
Solubility in water	miscible in all ratios
Partition coefficient: n-octanol/water	NA
Thermal decomposition / decomposition	NA
Viscosity	NA
Eksplozivnost	Possibility of explosive mixture gas/air
Data are for propan-2-ol	
pH	neutral
Boiling point	82°C
Flashpoint	12°C
Autoignition	No data available
Upper explosion limit	12 % (vol)
Lower explosion limit	2 % (vol)
Oxidative characteristics	n.a.
Vapour pressure	48 hPa (20°C)
Density	0,785 g/cm ³
Solubility in water	miscible in all ratios
Partition coefficient: n-octanol/water	log Kow 0,05 (OECD Test guideline 107)

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	literature value
Viscosity	2,43 mPa·s (20°C)
Vapour density	n.a.
Evaporation rate	n.a.

9.2 Other information

No additional information

SECTION 10: Stability and reactivity

10.1 Reactivity

Not reactive under normal conditions and proper use.

10.2 Chemical stability

Stable under normal conditions.

10.3 Possibility of hazardous reaction

Exothermic reaction with strong acids. Incompatible with oxidants.

10.4 Conditions to avoid

Warm, heat, flames, spark. Temperature raise causes vapor formation in packaging and packaging can explode, product is spilled. Product is in form of spray and must not be sprayed in the flame.

10.5 Incompatible materials

Strong acids, oxidants

10.6 Hazardous decomposition products

In case of fire: CO₂ and CO

SECTION 11: Toxicological information

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

All values for toxicity related to the pure substance. Prolonged skin contact may cause degreasing of the skin and may cause dermatitis. Inhalation of high vapor concentrations may cause symptoms like headache, dizziness, tiredness, nausea and vomiting. There is a risk that the product gets into the lungs in case of vomiting. Injuries may occur liver. Repeated or prolonged exposure to solvents may cause damage to the brain and nervous system.

Acute toxicity

Chemical name: Ethanol

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Important LD/LC50 sorting values:		
Oral	LD50	>6200 mg/kg (rat)
Dermal		NA
Inhalative		124 mg/ml (rat, 4h)
<p>Skin corrosion/irritation: It degrades the skin, which can become dry and rough. Prolonged or repeated skin contact may cause dermatitis.</p> <p>Serious eye damage/irritation: Wetting the eye can cause severe pain. Vapors are irritating.</p> <p>Respiratory or skin sensitization: Does not cause hypersensitivity in laboratory animals.</p> <p>Germ cell mutagenicity: Not classified</p> <p>Carcinogenicity: Data not available.</p> <p>Reproductive toxicity: Not classified.</p> <p>Teratogenicity: Not classified</p> <p>STOT-single exposure: Not classified as STOT – single exposure.</p> <p>STOT-repeated exposure: Not classified as STOT – repeated exposure.</p> <p>Aspiration hazard: Not classified as aspiration hazard.</p> <p>Chemical name: Glycerin</p>		
Important LD/LC50 sorting values:		
Oral	LD50	>12600 mg/kg (rat)
Dermal		>18700 mg/kg (rabbit)
Inhalative		Slightly irritant
<p>Skin corrosion/irritation: slightly irritant</p> <p>Serious eye damage/irritation: slightly irritant</p> <p>Respiratory or skin sensitization: no data available.</p> <p>Germ cell mutagenicity: No data available.</p> <p>Carcinogenicity: Not classified</p> <p>Reproductive toxicity: Not classified.</p> <p>STOT-single exposure: Not classified</p> <p>STOT-repeated exposure: Not classified</p> <p>Aspiration hazard: No data available</p> <p>Chemical name: Propan-2-ol</p>		
Important LD/LC50 sorting values:		
Oral	LD50	>2000 mg/kg (rat)
Dermal		>2000 mg/kg (rabbit)
Inhalative		20 mg/kg (rat)

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Skin irritation: not irritant

Eye irritation: irritant

Sensitization: Does not cause skin irritation. No sensitizing effects known.

CMR effects

Mutagenicity: Not considered as mutagenic.

Carcinogenicity: Not considered to be carcinogenic.

Teratogenicity: No effects on lactation or beyond.

Reproductive toxicity: Not applicable for toxic for reproduction.

Chemical name: Methyl Ethyl keton

Important LD/LC50 sorting values:

Oral	LD50	3300 mg/kg (rat)
Dermal	LD50	5000 mg/kg (rabbit)
Inhalative	LC50	50 mg/kg (mouse)

Other information: Irritating to skin and eyes. Causes degreasing of the skin.

Additional warning: Prolonged exposure causes liver damage. High concentrations can cause fatigue and dizziness.

SECTION 12: Ecological information

12.1 Toxicity

Ethanol

Water:

LC50: 8,150 mg/l (fish *Leuciscus idus*)

EC50: 5000 mg/l (*Scenedesmus quadricauda*; 168 h) (algae)

EC50: 9,268 – 14,221 mg/l (*Daphnia magna*; 48 h)

EC50: 6500 mg/l (*Pseudomonas putida*) cell proliferation inhibition test (bacteria)

Propan-2-ol

Water:

LC50/ 48 h >100 mg/l (fish)

EC50/ 72 h >100 mg/l (algae)

EC50/ 48 h >100 mg/l (daphnia)

Ethylmethylketon:

Water organisms: LC50>1000mg/L

LC50 (fish-*Leuciscus idus*,96 ur): 4600 mg/L

LC50 (*Pseudomonas putida*): 1150mg/L

12.2 Persistence and degradability

Duration of effect: no data available

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Biodegradability: Easy biodegradable.

12.3 Bio accumulative potential

Ethanol: Bioaccumulation result: log Pow -0.35 (24 ° C; pH 7.4) (OECD Test Guideline 107): Does not bioaccumulate.).

12.4 Mobility in soil

Water: The product is water soluble. Air: The product evaporates easily. Soil: Adsorption on soil is unlikely.

12.5 Results of PBT and vPvB assessment

The substance is not considered to be persistent, bio accumulative or toxic. The substance is not considered to be very persistent and very bio accumulative.

12.6 Endocrine disrupting properties

No data available.

12.7 Other adverse effect

Do not allow undiluted product or large quantities of product to reach sewage systems or large areas of water.

SECTION 13: Disposal considerations

Directive 2008/98/EC, Official Gazette RS 37/15, 69/15

13.1 Waste treatment methods

Methods of disposal: It is forbidden to dispose the product with other municipal waste. Dispose in accordance with Statute about handling with waste.

Empty packaging disposal: Packaging that must be disposed should be completely empty. Packaging with the product dispose in accordance with Statue about waste handling.

Waste category: 16 03 05* Organic waste that contain hazardous substances

Empty packaging waste category: 15 01 02 Plastic packaging

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SECTION 14: Transport Information			
	ADR/RID	IMDG	IATA
14.1 UN number	UN 1987		
14.2 UN proper shipping name	ADR/RID: 1987 ALCOHOLS, N.O.S. IMDG: ALCOHOLS, N.O.S. IATA: ALCOHOLS, N.O.S.		
14.3 Transport hazard class(es)			
Class	3 Flammable liquids		
Classification code	F1		
Labels(s)	3		
Hazard identification	33	/	/
Transport category (Tunnel restriction code)	(D/E)	/	/
EmS	/	F-E, S-D	/
14.4 Packing group	II		
14.5 Environmental hazards	No environmental hazard		
14.6 Special precautions for user	Flammable liquids		
14.7 Maritime transport in bulk according to IMO instruments	No data available		
ADR: Limited quantities (LQ)	1 L	/	/
ADR: Excepted quantities	E2	/	/

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 Official gazette RS 101/2002 and 16/2008.

15.2 Chemical safety assessment

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No data available from component's supplier.

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.

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

Council Directive 98/24/EC, Council Directive 80/ 1107/EEC 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

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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.