

Safety Data Sheet

according to Regulation (EC) No 1907/2006

Ultrana HaftFIX

Revision date: 09.05.2023

Product code: 2509

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

1.1. Product identifier

Ultrana HaftFIX

UFI: QJ8N-K0WN-R00W-KXN7

1.2. Relevant identified uses of the substance or mixture and uses advised against

Use of the substance/mixture

Medical Devices: Adhesives, sealants.

Uses advised against

This information is not available.

1.3. Details of the supplier of the safety data sheet

Company name:	Ultrana GmbH	
Street:	Mackstraße 112	
Place:	D-88348 Bad Saulgau	
Telephone:	+49 (0) 7581 2007298	Telefax: +49 (0) 7581 2007685
Contact person:	Joachim Traub	
e-mail:	info@ultrana.de	
Internet:	www.ultrana.de	

1.4. Emergency telephone number:

Outside normal business hours:
 French + 33 (0)1 45 42 59 59 Netherlands : +31(0)30 274 8888 Latvia +371 67042473 Lithuania +370 (85) 2362052 Estonia: nationally 16662, calling from abroad (+372) 7943 794

SECTION 2: Hazards identification

2.1. Classification of the substance or mixture

Regulation (EC) No 1272/2008

Flam. Liq. 2; H225
 Eye Irrit. 2; H319
 STOT SE 3; H336

Full text of hazard statements: see SECTION 16.

2.2. Label elements

Regulation (EC) No 1272/2008

Hazard components for labelling

Propan-2-ol, Isopropyl alcohol

Signal word: Danger

Pictograms:



Hazard statements

H225	Highly flammable liquid and vapour.
H319	Causes serious eye irritation.
H336	May cause drowsiness or dizziness.

Precautionary statements

P101	If medical advice is needed, have product container or label at hand.
P102	Keep out of reach of children.
P210	Keep away from heat, hot surfaces, sparks, open flames and other ignition sources. No

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P233	smoking.
P370+P378	Keep container tightly closed.
P405	In case of fire: Use water to extinguish.
P501	Store locked up.
	Dispose of contents/container to an appropriate recycling or disposal facility.

Additional advice on labelling

Labelling according to Regulation (EC) No. 1272/2008 [CLP].

2.3. Other hazards

Special danger of slipping by leaking/spilling product.
Results of PBT and vPvB assessment: The substances in the mixture do not meet the PBT/vPvB criteria according to REACH, annex XIII.
Endocrine disrupting properties: This product does not contain a substance that has endocrine disrupting properties with respect to humans as no components meets the criteria. This product does not contain a substance that has endocrine disrupting properties with respect to non-target organisms as no components meets the criteria.

SECTION 3: Composition/information on ingredients

3.2. Mixtures

Chemical characterization

The product is a mixture based on: Water, Isopropyl alcohol, Polyvinylpyrrolidone.

Hazardous components

CAS No	Chemical name			Quantity
	EC No	Index No	REACH No	
	Classification (Regulation (EC) No 1272/2008)			
67-63-0	Propan-2-ol, Isopropyl alcohol			40 - < 45 %
	200-661-7	603-117-00-0	01-2119457558-25	
	Flam. Liq. 2, Eye Irrit. 2, STOT SE 3; H225 H319 H336			

Full text of H and EUH statements: see section 16.

Specific Conc. Limits, M-factors and ATE

CAS No	EC No	Chemical name	Quantity
	Specific Conc. Limits, M-factors and ATE		
67-63-0	200-661-7	Propan-2-ol, Isopropyl alcohol	40 - < 45 %
	inhalation: LC50 = 30 mg/l (vapours); dermal: LD50 = 12400 mg/kg; oral: LD50 = 5050 mg/kg		

SECTION 4: First aid measures

4.1. Description of first aid measures

General information

When in doubt or if symptoms are observed, get medical advice.

After inhalation

Provide fresh air. In case of accident or unwellness, seek medical advice immediately (show directions for use or safety data sheet if possible).

After contact with skin

Wash with plenty of water. Take off contaminated clothing and wash it before reuse.

After contact with eyes

After contact with the eyes, rinse with water with the eyelids open for a sufficient length of time, then consult an ophthalmologist immediately. Protect uninjured eye. Remove contact lenses, if present and easy to do. Continue rinsing.

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After ingestion

Rinse mouth immediately and drink plenty of water.

4.2. Most important symptoms and effects, both acute and delayed

No information available.

4.3. Indication of any immediate medical attention and special treatment needed

Treat symptomatically.

SECTION 5: Firefighting measures**5.1. Extinguishing media****Suitable extinguishing media**Water spray jet, Carbon dioxide (CO₂), Foam, Extinguishing powder.**Unsuitable extinguishing media**

Full water jet.

5.2. Special hazards arising from the substance or mixture

Flammable. Vapours can form explosive mixtures with air.

In case of fire may be liberated: Carbon monoxide, Carbon dioxide (CO₂), Nitrogen oxides (NO_x).

Special danger of slipping by leaking/spilling product.

5.3. Advice for firefighters

In case of fire: Wear self-contained breathing apparatus.

Fire class B (Fires of liquids or liquid turning substances)

Additional information

Use water spray jet to protect personnel and to cool endangered containers. Suppress gases/vapours/mists with water spray jet. Collect contaminated fire extinguishing water separately. Do not allow entering drains or surface water.

SECTION 6: Accidental release measures**6.1. Personal precautions, protective equipment and emergency procedures****General advice**

Remove all sources of ignition. Provide adequate ventilation.

For non-emergency personnel

Use personal protection equipment.

For emergency responders

Wear breathing apparatus if exposed to vapours/dusts/aerosols. Remove persons to safety.

6.2. Environmental precautions

Do not allow uncontrolled discharge of product into the environment. Danger of explosion

Do not allow to enter into surface water or drains.

6.3. Methods and material for containment and cleaning up**For containment**

Prevent spread over a wide area (e.g. by containment or oil barriers).

For cleaning up

Absorb with liquid-binding material (sand, diatomaceous earth, acid- or universal binding agents). Treat the recovered material as prescribed in the section on waste disposal. Clear contaminated areas thoroughly. Wash with plenty of water.

Other information

Ventilate affected area.

6.4. Reference to other sections

Safe handling: see section 7

Personal protection equipment: see section 8

Disposal: see section 13

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SECTION 7: Handling and storage**7.1. Precautions for safe handling****Advice on safe handling**

No special measures are necessary.

Advice on protection against fire and explosion

Keep away from sources of ignition - No smoking. Take precautionary measures against static discharges.

Vapours can form explosive mixtures with air.

Advice on general occupational hygiene

Remove contaminated, saturated clothing immediately. Wash hands and face before breaks and after work and take a shower if necessary. When using do not eat or drink.

7.2. Conditions for safe storage, including any incompatibilities**Requirements for storage rooms and vessels**

Keep container tightly closed. Keep away from heat, hot surfaces, sparks, open flames and other ignition sources. No smoking.

Hints on joint storage

Do not store together with: Oxidizing agent. Pyrophoric or self-heating substances.

Keep away from: Food and feedingstuffs.

Further information on storage conditions

Keep at temperatures between 10 and 35°C. Protect against: Heat, UV-radiation/sunlight.

7.3. Specific end use(s)

Medical Devices: Adhesives, sealants.

SECTION 8: Exposure controls/personal protection**8.1. Control parameters****Occupational exposure limits**

CAS No	Substance	ppm	mg/m ³	fib/cm ³	Category	Origin
56-81-5	(OLD) Glycerol, mist	-	10		TWA (8 h)	
67-63-0	Propan-2-ol	200	-		TWA (8 h)	
		400	-		STEL (15 min)	

Biological limit values

CAS No	Substance	Parameter	Value	Test material	Sampling time
67-63-0	2-Propanol	Acetone	40 mg/L	Urine	End of shift at end of workweek

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DNEL/DMEL values

CAS No	Substance	Exposure route	Effect	Value
67-63-0	Propan-2-ol, Isopropyl alcohol			
Worker DNEL, long-term		dermal	systemic	888 mg/kg bw/day
Worker DNEL, long-term		inhalation	systemic	500 mg/m ³
Consumer DNEL, long-term		oral	systemic	26 mg/kg bw/day
Consumer DNEL, long-term		dermal	systemic	319 mg/kg bw/day
Consumer DNEL, long-term		inhalation	systemic	89 mg/m ³
56-81-5	Glycerol			
Consumer DNEL, long-term		inhalation	local	33 mg/m ³
Consumer DNEL, long-term		oral	systemic	229 mg/kg bw/day

PNEC values

CAS No	Substance	Value
67-63-0	Propan-2-ol, Isopropyl alcohol	
Freshwater		140,9 mg/l
Freshwater (intermittent releases)		140,9 mg/l
Marine water		140,9 mg/l
Freshwater sediment		552 mg/kg
Marine sediment		552 mg/kg
Secondary poisoning		160 mg/kg
Micro-organisms in sewage treatment plants (STP)		2251 mg/l
Soil		28 mg/kg
56-81-5	Glycerol	
Freshwater		0,885 mg/l
Freshwater (intermittent releases)		8,85 mg/l
Marine water		0,0885 mg/l
Freshwater sediment		3,3 mg/kg
Marine sediment		0,330 mg/kg
Micro-organisms in sewage treatment plants (STP)		1000 mg/l
Soil		0,141 mg/kg

8.2. Exposure controls

Individual protection measures, such as personal protective equipment

Eye/face protection

Eye protection: not required.

Hand protection

Hand protection is not required.

Skin protection

Body protection: not required.

Respiratory protection

Usually no personal respiratory protection necessary.

Thermal hazards

not relevant.

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Environmental exposure controls

Do not allow to enter into surface water or drains.

SECTION 9: Physical and chemical properties

9.1. Information on basic physical and chemical properties

Physical state:	liquid: viscous
Colour:	light yellow, clear
Odour:	like: Isopropyl alcohol
Odour threshold:	not determined

Test method

Melting point/freezing point:	not determined	
Boiling point or initial boiling point and boiling range:	82,5 °C	
Flammability:	not applicable	
Lower explosion limits:	2 vol. %	
Upper explosion limits:	13 vol. %	
Flash point:	16 °C	ASTM D 56
Auto-ignition temperature:	420 °C	
Decomposition temperature:	not determined	
pH-Value (at 20 °C):	pH 5,5	
Viscosity / kinematic: (at 20 °C)	3700 - 4900 mm ² /s	
Water solubility: (at 20 °C)	completely miscible	
Solubility in other solvents	not determined	
Partition coefficient n-octanol/water:	not determined	
Vapour pressure: (at 20 °C)	42 hPa	
Vapour pressure: (at 50 °C)	123 hPa	
Density (at 20 °C):	1,0 g/cm ³	
Relative vapour density:	not determined	

9.2. Other information

Information with regard to physical hazard classes

Explosive properties

Vapours can form explosive mixtures with air.

Oxidizing properties

The product is not: oxidising.

Other safety characteristics

Evaporation rate: not determined

Solid content: not determined

SECTION 10: Stability and reactivity

10.1. Reactivity

Flammable.

10.2. Chemical stability

The product is stable under storage at normal ambient temperatures.

10.3. Possibility of hazardous reactions

No known hazardous reactions.

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10.4. Conditions to avoid

Keep away from sources of heat (e.g. hot surfaces), sparks and open flames. Vapours can form explosive mixtures with air.

10.5. Incompatible materials

No information available.

10.6. Hazardous decomposition products

No known hazardous decomposition products.

SECTION 11: Toxicological information**11.1. Information on hazard classes as defined in Regulation (EC) No 1272/2008****Acute toxicity**

Based on available data, the classification criteria are not met.

CAS No	Chemical name				
	Exposure route	Dose	Species	Source	Method
67-63-0	Propan-2-ol, Isopropyl alcohol				
	oral	LD50 mg/kg	5050	Rat	Publication (1978)
	dermal	LD50 mg/kg	12400	Rabbit	Publication (1974)
	inhalation (4 h) vapour	LC50	30 mg/l	Rat	

Irritation and corrosivity

Causes serious eye irritation.

Skin corrosion/irritation: Based on available data, the classification criteria are not met.

Sensitising effects

Based on available data, the classification criteria are not met.

Carcinogenic/mutagenic/toxic effects for reproduction

Based on available data, the classification criteria are not met.

STOT-single exposure

May cause drowsiness or dizziness. (Propan-2-ol, Isopropyl alcohol)

STOT-repeated exposure

Based on available data, the classification criteria are not met.

Aspiration hazard

Based on available data, the classification criteria are not met.

11.2. Information on other hazards**Endocrine disrupting properties**

This product does not contain a substance that has endocrine disrupting properties with respect to humans as no components meets the criteria.

Further information

The mixture is classified as hazardous according to regulation (EC) No 1272/2008 [CLP].

SECTION 12: Ecological information**12.1. Toxicity**

Based on available data, the classification criteria are not met.

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CAS No	Chemical name					
	Aquatic toxicity	Dose	[h] [d]	Species	Source	Method
67-63-0	Propan-2-ol, Isopropyl alcohol					
	Acute fish toxicity	LC50 10000 mg/l	96 h	Pimephales promelas (fathead minnow)	Publication (1983)	OECD 203
	Acute algae toxicity	ErC50 > 1000 mg/l	72 h	Scenedesmus subspicatus		
	Acute crustacea toxicity	EC50 13299 mg/l	48 h	Daphnia magna (Big water flea)	Information taken from reference works and the literature.	
	Acute bacteria toxicity	(EC50 > 1000 mg/l)		Activated sludge		

12.2. Persistence and degradability

The organic part of the product is biodegradable.

CAS No	Chemical name			
	Method	Value	d	Source
	Evaluation			
67-63-0	Propan-2-ol, Isopropyl alcohol			
	Biodegradation, Activated sludge	53 %	5	
	Readily biodegradable (according to OECD criteria).			

12.3. Bioaccumulative potential

No indication of bioaccumulation potential.

Partition coefficient n-octanol/water

CAS No	Chemical name	Log Pow
67-63-0	Propan-2-ol, Isopropyl alcohol	0,05

12.4. Mobility in soil

The product has not been tested.

12.5. Results of PBT and vPvB assessment

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

12.6. Endocrine disrupting properties

This product does not contain a substance that has endocrine disrupting properties with respect to non-target organisms as no components meets the criteria.

12.7. Other adverse effects

No information available.

Further information

Avoid release to the environment.

SECTION 13: Disposal considerations

13.1. Waste treatment methods

Disposal recommendations

Do not allow to enter into surface water or drains. Dispose of waste according to applicable legislation.

List of Wastes Code - residues/unused products

080409 WASTES FROM THE MANUFACTURE, FORMULATION, SUPPLY AND USE (MFSU) OF COATINGS (PAINTS, VARNISHES AND VITREOUS ENAMELS), ADHESIVES, SEALANTS AND PRINTING INKS; wastes from MFSU of adhesives and sealants (including waterproofing products); waste adhesives and sealants containing organic solvents or other hazardous substances; hazardous waste

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List of Wastes Code - used product

080409 WASTES FROM THE MANUFACTURE, FORMULATION, SUPPLY AND USE (MFSU) OF COATINGS (PAINTS, VARNISHES AND VITREOUS ENAMELS), ADHESIVES, SEALANTS AND PRINTING INKS; wastes from MFSU of adhesives and sealants (including waterproofing products); waste adhesives and sealants containing organic solvents or other hazardous substances; hazardous waste

List of Wastes Code - contaminated packaging

150102 WASTE PACKAGING; ABSORBENTS, WIPING CLOTHS, FILTER MATERIALS AND PROTECTIVE CLOTHING NOT OTHERWISE SPECIFIED; packaging (including separately collected municipal packaging waste); plastic packaging

Contaminated packaging

Wash with plenty of water. Completely emptied packages can be recycled.

SECTION 14: Transport information

Land transport (ADR/RID)

14.1. UN number or ID number: UN 1219
14.2. UN proper shipping name: ISOPROPYL ALCOHOL, MIXTURE
14.3. Transport hazard class(es): 3
14.4. Packing group: II
Hazard label: 3



Classification code: F1
Special Provisions: 601
Limited quantity: 1 L
Excepted quantity: E2
Transport category: 2
Hazard No: 33
Tunnel restriction code: D/E

Other applicable information (land transport)

box 20 bottles 60 mL: Transport as "limited quantity" according to chapter 3.4 ADR/RID

Inland waterways transport (ADN)

14.1. UN number or ID number: UN 1219
14.2. UN proper shipping name: ISOPROPYL ALCOHOL, MIXTURE
14.3. Transport hazard class(es): 3
14.4. Packing group: II
Hazard label: 3



Classification code: F1
Special Provisions: 601
Limited quantity: 1 L
Excepted quantity: E2

Other applicable information (inland waterways transport)

box 20 bottles 60 mL: Transport as "limited quantity" according to chapter 3.4. ADN

Marine transport (IMDG)

14.1. UN number or ID number: UN 1219
14.2. UN proper shipping name: ISOPROPYL ALCOHOL, MIXTURE
14.3. Transport hazard class(es): 3

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14.4. Packing group:

Hazard label:

II

3



Special Provisions:

-

Limited quantity:

1 L

Excepted quantity:

E2

EmS:

F-E, S-D

Segregation group:

Other applicable information (marine transport)

box 20 bottles 60 mL: Transport as "limited quantity" according to IMDG-Code 3.4

Air transport (ICAO-TI/IATA-DGR)

14.1. UN number or ID number:

UN 1219

14.2. UN proper shipping name:

ISOPROPYL ALCOHOL, MIXTURE

14.3. Transport hazard class(es):

3

14.4. Packing group:

II

Hazard label:

3



Special Provisions:

A180

Limited quantity Passenger:

1 L

Passenger LQ:

Y341

Excepted quantity:

E2

IATA-packing instructions - Passenger:

353

IATA-max. quantity - Passenger:

5 L

IATA-packing instructions - Cargo:

364

IATA-max. quantity - Cargo:

60 L

14.5. Environmental hazards

ENVIRONMENTALLY HAZARDOUS: No

14.6. Special precautions for user

Warning: Combustible liquid. No special measures are necessary.

14.7. Maritime transport in bulk according to IMO instruments

No transport as bulk according to IBC Code.

SECTION 15: Regulatory information

15.1. Safety, health and environmental regulations/legislation specific for the substance or mixture

EU regulatory information

Restrictions on use (REACH, annex XVII):

Entry 3, Entry 40, Entry 75

2010/75/EU (VOC):

40 % (400 g/l)

Information according to 2012/18/EU (SEVESO III):

P5c FLAMMABLE LIQUIDS

National regulatory information

Employment restrictions:

Observe restrictions to employment for juveniles according to the 'juvenile work protection guideline' (94/33/EC).

Water hazard class (D):

1 - slightly hazardous to water

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15.2. Chemical safety assessment

For the following substances of this mixture a chemical safety assessment has been carried out:

Propan-2-ol, Isopropyl alcohol

SECTION 16: Other information**Changes**

This data sheet contains changes from the previous version in section(s): 1,2,6,7,8,9,11,12,15,16.

Abbreviations and acronyms

ADR: Accord européen sur le transport des marchandises dangereuses par Route

(European Agreement concerning the International Carriage of Dangerous Goods by Road)

IMDG: International Maritime Code for Dangerous Goods

IATA: International Air Transport Association

GHS: Globally Harmonized System of Classification and Labelling of Chemicals

EINECS: European Inventory of Existing Commercial Chemical Substances

ELINCS: European List of Notified Chemical Substances

CAS: Chemical Abstracts Service

LC50: Lethal concentration, 50%

LD50: Lethal dose, 50%

Key literature references and sources for data

To create the safety data sheet information from our suppliers, information on chemicals from the European Chemicals Agency (ECHA) and data from the GESTIS substance database were used.

Classification for mixtures and used evaluation method according to Regulation (EC) No 1272/2008 [CLP]

Classification	Classification procedure
Flam. Liq. 2; H225	On basis of test data
Eye Irrit. 2; H319	Calculation method
STOT SE 3; H336	Calculation method

Relevant H and EUH statements (number and full text)

H225 Highly flammable liquid and vapour.

H319 Causes serious eye irritation.

H336 May cause drowsiness or dizziness.

Further Information

The information is based on the present level of our knowledge. It does not, however, give assurance of product properties and establishes no contract legal rights. The receiver of our product is singularly responsible for adhering to existing laws and regulations.

(The data for the hazardous ingredients were taken respectively from the last version of the sub-contractor's safety data sheet.)



ULTRANA

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Konformitätserklärung / Declaration of Conformity

Verordnung (EU) 2017/745 über Medizinprodukte

Regulation (EU) 2017/745 on medical products

Wir erklären in alleiniger Verantwortung, dass das hier beschriebene Produkt in der gelieferten Ausführung den grundlegenden Sicherheits- und Leistungsanforderungen aus Anhang I der Verordnung (EU) 2017/745 über Medizinprodukte entspricht.

We declare under sole responsibility that the delivered products described above are in compliance with the essential safety and performance requirements of Annex I of the Regulation (EU) 2017/745 on medical products.

Produktspezifikation Product details	
Produkt- und Handelsname Product and trade name	Ultrana HaftFIX, Ultrana GmbH
REF REF	4290007320
Produkt Code CND Product Code CND	H900199 Gewebe-Kleber, andere Tissue adhesives, other
Basic UDI-DI Basic UDI-DI	PP 06072 07320 46
UDI-DI (PPN)	110321095658
Zweckbestimmung Intended Use	Hautkleber zum Befestigen von Kompressionstrümpfen Adhesive lotion for compression stockings
Konformitätsbewertungsverfahren Conformity assessment procedure	(EU) 2017/745 (MDR), Anhang IX (EU) 2017/745 (MDR), Annex IX
Klassifizierung Classification	Klasse I Class I
Klassifizierungsregel Classification rule	Regel 1: Alle nicht invasiven Produkte gehören zur Klasse I, weil die Regeln 2, 3 und 4 nicht zutreffen (siehe Zweckbestimmung) Rule 1: All non-invasive devices are in Class I because rules 2, 3 and 4 do not apply (see purpose)
Gültig bis Validity	2026.01.02
SRN des Herstellers SRN of Manufacturer	DE-MF-000006110
CHRN Swiss Single Registration Number	CHRN-MF-20003682

Bad Saulgau, 2024.01.02

Ort, Datum
Place, date

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Isabel Pereira, QMB, 

Name, Funktion, Unterschrift der autorisierten Person
Name, function, signature of authorized person

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