

Safety Data Sheet according to Regulation (EU) No. 1907/2006

AESULAP AG

Revision date : 19.09.2008

Revision no. : 1,01

SUTURE MATERIAL IN CASSETTE-PACKS WITH 30 ml ISOPROPANOL

00250-0013

1. Identification of the substance/preparation and of the company/undertaking

Identification of the substance or preparation

SUTURE MATERIAL IN CASSETTE-PACKS WITH 30 ml ISOPROPANOL

Use of the substance/preparation

Medical suture material

Company/undertaking identification

AESULAP AG

Am AESULAP-Platz

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Contact person

Inquiry office

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2. Hazards identification

Explication of special hazards for human health and environment

Highly flammable.

Irritating to eyes.

Vapours may cause drowsiness and dizziness.

3. Composition/information on ingredients

Chemical characterization (preparation)

Suture material in cassette-packs with 30 ml isopropanol

Hazardous components

EC-No.	CAS-No.	Chemical name	Quantity	Classification
200-661-7	67-63-0	Propan-2-ol	30 ml %	F, Xi R11-36-67

Full text of each relevant R phrase can be found in heading 16.

4. First aid measures

General information

No hazards which require special first aid measures.

After inhalation

Move to fresh air in case of accidental inhalation of vapours or decomposition products.

In the event of symptoms refer for medical treatment.

After contact with skin

Wash with water and soap as a precaution.

After contact with eyes

Rinse immediately with plenty of water, also under the eyelids, for at least 15 minutes.

If eye irritation persists, consult a specialist.

After ingestion

Do not induce vomiting.

Induce vomiting only upon the advice of a physician.

Rinse mouth.

Consult a physician.

5. Fire-fighting measures

Suitable extinguishing media

Alcohol-resistant foam, dry chemical, carbon dioxide (CO₂), water-spray.

Extinguishing media which must not be used for safety reasons

Full water jet

Special exposure hazards arising from substance or preparation itself, combustion products, resulting gases

Fire may produce:

Carbon monoxide and carbon dioxide.

Special protective equipment for fire-fighters

In case of fire, wear suitable respiratory equipment with positive air supply.

Protective suit

Additional information

Cool containers at risk with water spray jet.

The vapour/air mixture is explosive, even in empty, uncleaned receptacles.

Fire residues and contaminated firefighting water must be disposed of in accordance with the local regulations.

6. Accidental release measures

Personal precautions

In case of vapour formation use respirator.

Avoid contact with skin, eyes and clothing.

Ensure adequate ventilation.

Environmental precautions

Do not discharge into the drains/surface waters/groundwater.

Methods for cleaning up/taking up

Soak up with inert absorbent material (e.g. sand, silica gel, acid binder, universal binder).

Shovel into suitable container for disposal.

7. Handling and storage

Handling

Advice on safe handling

When using, do not eat, drink or smoke. Do not breathe vapours. Avoid contact with skin, eyes and clothing.

Advice on protection against fire and explosion

Keep product and empty container away from heat and sources of ignition.

Storage

Requirements for storage rooms and vessels

Protect against direct sun radiation.

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Advice on storage compatibility

Incompatible with oxidizing agents.

Further information on storage conditions

Keep away from food, drink and animal feeding stuffs.

Storageclass (VCI)

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8. Exposure controls/personal protection**Exposure limit values****Exposure limits (EH40)**

CAS-No.	Chemical name	ml/m ³	mg/m ³	F/ml	Category	Origin
67-63-0	Propan-2-ol	400	999		TWA (8 h)	WEL
	Propan-2-ol	500	1250		STEL (15 min)	WEL

Additional advice on control parameters

Ensure adequate ventilation, especially in confined areas.

Exposure controls**Protective and hygiene measures**

When using, do not eat, drink or smoke.

Do not inhale vapours.

Respiratory protection

Not required.

Hand protection

Rubber gloves

Requirements can vary as a function of the use. Therefore it is necessary to adhere additionally to the recommendations given by the manufacturer of protective gloves.

Eye protection

Not required.

Skin protection

Not required.

9. Physical and chemical properties**General information**

Physical state	Liquid
Colour	Clear
Odour	Alcoholic

Important health, safety and environmental information

		Test method
Changes in the physical state		
Melting point	- 89 °C	*)
Boiling point	82 °C	*)
Flash point	12 °C	*)
Flammability		
Lower explosion limits	2 vol. %	*)
Upper explosion limits		*)
Ignition temperature	n.a.	
Vapour pressure :	43 hPa	*)
at (20 °C)		
Density (at 20 °C) :	0,78 g/cm ³	*)
Water solubility :	Miscible	*)
at (20 °C)		

*) All data refer to the solution

10. Stability and reactivity

Conditions to avoid

To avoid thermal decomposition, do not overheat.

Heating can release vapours which can be ignited.

Materials to avoid

Oxidizing agents.

Hazardous decomposition products

Carbon monoxide and carbon dioxide.

Additional information

No decomposition if stored and applied as directed.

11. Toxicological information

Empirical data on effects on humans

Irritating to eyes.

Vapours may cause drowsiness and dizziness.

Repeated or prolonged exposure may cause skin irritation and dermatitis, due to degreasing properties of the product.

May cause irritation of the mucous membranes.

If appropriately handled and if in accordance with the general hygienic rules, no damages to health have become known.

12. Ecological information

Further information

Do not flush into surface water or sanitary sewer system.

Ecological injuries are not known or expected under normal use.

Slightly water hazardous.

13. Disposal considerations

Advice on disposal

Can be landfilled or incinerated, when in compliance with local regulations.

Where possible recycling is preferred to disposal.

Waste disposal number of waste from residues/unused products

180106 WASTES FROM HUMAN OR ANIMAL HEALTH CARE AND/OR RELATED RESEARCH (except kitchen and restaurant wastes not arising from immediate health care); wastes from natal care, diagnosis, treatment or prevention of disease in humans; chemicals consisting of or containing dangerous substances
Classified as hazardous waste.

Contaminated packaging

Empty containers should be taken for local recycling, recovery or waste disposal.

Contaminated packaging should be emptied as far as possible and after appropriate cleansing may be taken for reuse.

Packaging that cannot be cleaned should be disposed of like the product.

14. Transport information

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Land transport (ADR/RID)

ADR/RID class	3
Classification code :	F1
Hazard-no.	33
UN number	1219
Hazard label	3
ADR/RID packing group	II
Limited quantity :	LQ 4

Description of the goods

Isopropanol

Other applicable information (land transport)

LQ 4: combination packaging: 3 l / 30 kg (total gross mass); trays: 1 l / 20 kg (total gross mass).

Inland waterways transport**Marine transport**

IMDG code	3
UN number	1219
Marine pollutant	No
EmS	F-E; S-D
Limited quantity :	1 L / 30 kg
IMDG packing group	II
Hazard label	3

Description of the goods

ISOPROPANOL

Other applicable information (marine transport)

Limited quantities (chapter 3.4): combination packaging: 1 l / 30 kg (total gross mass); trays: 1 l / 20 kg (total gross mass)

Air transport

ICAO/IATA-DGR	3
UN/ID number	1219
Hazard label	3
IATA-packing instructions - Passenger	305
IATA-max. quantity - Passenger	5 L
IATA-packing instructions - Cargo	307
IATA-max. quantity - Cargo	60 L
ICAO packing group	II
Limited quantity Passenger	Y305 / 1 L

Description of the goodsISOPROPANOL

15. Regulatory information**Labelling**

Additional advice on labelling

According to EC-rules and correspondent national legislation, this product, being a ready medicine, is not subject to mandatory identification.

National regulatory informationWater contaminating class (D)
1999/13/EC (VOC)1 - slightly water contaminating
30 ml

16. Other information

Full text of R-phrases referred to under sections 2 and 3

- | | |
|----|---|
| 11 | Highly flammable. |
| 36 | Irritating to eyes. |
| 67 | Vapours may cause drowsiness and dizziness. |

Further Information

Data of items 4 to 8, as well as 10 to 12, do partly not refer to the use and the regular employing of the product (in this sense consult information on use and on product), but to liberation of major amounts in case of accidents and irregularities.

The information describes exclusively the safety requirements for the product (s) and is based on the present level of our knowledge.

The delivery specifications are contained in the corresponding product sheet.

This data does not constitute a guarantee for the characteristics of the product(s) as defined by the legal warranty regulations.

"(n.a. = not applicable; n.d. = not determined)"

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