B. Braun Medical AG

Melsept SF

Revision date: 01.06.2015 Revision No: 1,1

Product code: 00056-0008

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

1.1. Product identifier

Melsept SF

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

Use of the substance/mixture

Disinfectant for surfaces

1.3. Details of the supplier of the safety data sheet

Manufacturer

B. Braun Medical AG Company name:

Street: Seesatz 17

Place: CH-6204 Sempach

Responsible Department: Telephone: +41 (0) 58 / 258 50 00

E-Mail: info.bbmch@bbraun.com Responsible for the safety data sheet: sds@gbk-ingelheim.de

Supplier

Company name: B. Braun Melsungen AG Carl-Braun-Straße 1 Street: Place: D-34212 Melsungen

Responsible Department: Zentrale Service-Bereiche / Logistik und Supply Chain

> Telephone: +49 (0) 5661 / 71-4422 E-Mail: logistics.service@bbraun.com

1.4. Emergency telephone number: INTERNATIONAL: +49 - (0) 6132 - 84463, GBK GmbH (24h - 7d/w - 365d/a) England and Wales: NHS Direct - 0845 4647; Scotland: NHS 24 - 08454 24 24 24

SECTION 2: Hazards identification

2.1. Classification of the substance or mixture according to 1272/2008/EC

Hazard categories:

Acute toxicity: Acute Tox. 4

Skin corrosion/irritation: Skin Corr. 1B

Serious eye damage/eye irritation: Eye Dam. 1 Respiratory or skin sensitisation: Resp. Sens. 1 Respiratory or skin sensitisation: Skin Sens. 1

Germ cell mutagenicity: Muta. 2

Specific target organ toxicity - single exposure: STOT SE 3 Hazardous to the aquatic environment: Aquatic Acute 1 Hazardous to the aquatic environment: Aquatic Chronic 3

Hazard Statements:

Harmful if swallowed or if inhaled.

May cause allergy or asthma symptoms or breathing difficulties if inhaled.

May cause respiratory irritation.

Causes severe skin burns and eye damage.

May cause an allergic skin reaction. Suspected of causing genetic defects.

Very toxic to aquatic life.

Harmful to aquatic life with long lasting effects.

2.2. Label elements

Hazardous components which must be listed on the label

Glutaraldehyde

Glvoxal

(R)-p-Mentha-1,8-diene

Didecyldimethylammonium chloride

Signal word: Danger

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Pictograms:



Hazard statements

H302+H332 Harmful if swallowed or if inhaled.

H334 May cause allergy or asthma symptoms or breathing difficulties if inhaled.

H335 May cause respiratory irritation.

H314 Causes severe skin burns and eye damage.

H317 May cause an allergic skin reaction.
H341 Suspected of causing genetic defects.

H400 Very toxic to aquatic life.

H412 Harmful to aquatic life with long lasting effects.

Precautionary statements

P201 Obtain special instructions before use.

P260 Do not breathe vapour.

P280 Wear protective gloves/protective clothing/eye protection/face protection.

P303+P361+P353 IF ON SKIN (or hair): Take off immediately all contaminated clothing. Rinse skin with

water/shower.

P305+P351+P338 IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if

present and easy to do. Continue rinsing.

P301+P312 IF SWALLOWED: Call a POISON CENTER/doctor if you feel unwell.

P304+P340 IF INHALED: Remove person to fresh air and keep comfortable for breathing.

P308+P313 IF exposed or concerned: Get medical advice/attention.

P405 Store locked up.

2.3. Other hazards

Not known.

SECTION 3: Composition/information on ingredients

3.2. Mixtures

Chemical characterization

Concentrate with aldehydes and and quaternary ammonium compounds

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Hazardous components

CAS No	Chemical name						
	EC No	Index No	REACH No				
	Classification according to Regulation (EC) No. 1272/2008 [CLP]						
9043-30-5	Alcohol, C9-13-iso, ethoxylated						
	500-027-2						
	Acute Tox. 4, Eye Dam. 1; H302 H318						
7173-51-5	Didecyldimethylammonium chloride						
	230-525-2	612-131-00-6	01-2119945987-15				
	Acute Tox. 4, Skin Corr. 1B, Aquatic Acute 1 (M-Factor = 10); H302 H314 H400						
67-63-0	Propan-2-ol						
	200-661-7	603-117-00-0	01-2119457558-25				
	Flam. Liq. 2, Eye Irrit. 2, STOT SE 3; H225 H319 H336						
111-30-8	Glutaraldehyde						
	203-856-5	605-022-00-X	01-2119455549-26				
	Met. Corr. 1, Acute Tox. 3, Acute Tox. 3, Skin Corr. 1B, Resp. Sens. 1, Skin Sens. 1, Aquatic Acute 1, Aquatic Chronic 2; H290 H301 H331 H314 H334 H317 H400 H411						
107-22-2	Glyoxal						
	203-474-9	605-016-00-7	01-2119461733-37				
	Muta. 2, Acute Tox. 4, Skin Irrit. 2, Eye Irrit. 2, Skin Sens. 1, STOT SE 3; H341 H332 H315 H319 H317 H335						
5989-27-5	(R)-p-Mentha-1,8-diene						
	227-813-5	601-029-00-7	01-2119529223-47				
	Flam. Liq. 3, Skin Irrit. 2, Skin Sens. 1, Asp. Tox. 1, Aquatic Acute 1 (M-Factor = 1), Aquatic Chronic 1; H226 H315 H317 H304 H400 H410						

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

SECTION 4: First aid measures

4.1. Description of first aid measures

General information

Remove contaminated soaked clothing immediately.

If you feel unwell, seek medical advice.

After inhalation

Move to fresh air in case of accidental inhalation of vapours.

In the event of symptoms refer for medical treatment.

After contact with skin

Wash off immediately with soap and plenty of water.

Treat subsequently with skin cream.

Consult a physician.

After contact with eyes

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

Summon a doctor immediately.

After ingestion

Drink plenty of water.

Summon a doctor immediately.

Induce vomiting only upon the advice of a physician.

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

Harmful by inhalation and if swallowed.

May cause respiratory irritation.

May cause allergy or asthma symptoms or breathing difficulties if inhaled.

May cause an allergic skin reaction.

Causes severe skin burns and eye damage.

Suspected of causing genetic defects.

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

Treat symptoms.

SECTION 5: Firefighting measures

5.1. Extinguishing media

Suitable extinguishing media

Product does not burn, fire-extinguishing activities according to surrounding.

Unsuitable extinguishing media

Full water jet.

5.2. Special hazards arising from the substance or mixture

Fire may produce:

Carbon monoxide and carbon dioxide

Irritant/corrosive, flammable as well as toxic distillation gases (carbonization gases).

5.3. Advice for firefighters

Use breathing apparatus with independent air supply.

Protective suit.

Additional information

Cool containers at risk with water spray jet.

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

SECTION 6: Accidental release measures

6.1. Personal precautions, protective equipment and emergency procedures

In case of vapour formation use respirator.

Avoid contact with skin, eyes and clothing.

Ensure adequate ventilation.

Use personal protective clothing.

6.2. Environmental precautions

Do not discharge into the drains/surface waters/ground water.

6.3. Methods and material for containment and cleaning up

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

Shovel into suitable container for disposal.

6.4. Reference to other sections

Observe protective instructions (see Sections 7 and 8).

Information for disposal see section 13.

SECTION 7: Handling and storage

7.1. Precautions for safe handling

Advice on safe handling

Keep container tightly closed.

Keep a good ventilation and air-exhaust at the place of work.

Avoid contact with skin, eyes and clothing.

Advice on protection against fire and explosion

No special protective measures against fire required.

7.2. Conditions for safe storage, including any incompatibilities

Requirements for storage rooms and vessels

Keep containers tightly closed in a dry, well-ventilated place.

Advice on storage compatibility

Incompatible with strong acids and oxidizing agents.

Further information on storage conditions

Keep away from food, drink and animal feeding stuffs.

7.3. Specific end use(s)

Disinfectant for surfaces

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SECTION 8: Exposure controls/personal protection

8.1. Control parameters

Exposure limits (EH40)

CAS No	Substance	ppm	mg/m³	fibres/ml	Category	Origin
111-30-8	Glutaraldehyde	0.05	0.2		TWA (8 h)	WEL
		0.05	0.2		STEL (15 min)	WEL
67-63-0	Propan-2-ol	400	999		TWA (8 h)	WEL
		500	1250		STEL (15 min)	WEL

8.2. Exposure controls

Appropriate engineering controls

Ensure adequate ventilation, especially in confined areas.

Protective and hygiene measures

Do not inhale vapours.

Wash hands before breaks and immediately after handling the product.

When using do not eat, drink or smoke.

Avoid contact with skin, eyes and clothing.

Remove and wash contaminated clothes before re-use.

Eye/face protection

Eye wash bottle with pure water (EN 15154).

Safety goggles with side protection (EN 166).

Hand protection

Protective gloves resistant to chemicals made off nitrile, minimum coat thickness 0.4 mm, permeation resistance (wear duration) approx. 240 minutes, i.e. protective glove <Camatril Velours 730> made by www.kcl.de.

This recommendation refers exclusively to the chemical compatibility and the lab test conforming to EN 374 carried out under lab conditions.

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.

Skin protection

Long sleeved clothing (EN 368).

Respiratory protection

In case of insufficient ventilation wear suitable respiratory equipment (gas filter type A) (EN 14387).

SECTION 9: Physical and chemical properties

9.1. Information on basic physical and chemical properties

Physical state: Liquid Colour: Blue

Odour: Aldehyde-like

pH-Value (at 20 °C): 3,5 Concentrate

Changes in the physical state

Initial boiling point and boiling range: approx. 100 °C

Flash point: n.a. Lower explosion limits: n.a.

Upper explosion limits:

Ignition temperature:

Density (at 20 °C):

Water solubility:

n.a.

1,02 g/cm³

Miscible

(at 20 °C)

Viscosity / dynamic: approx. 20 mPa·s

(at 25 °C)

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Solvent content: < 5 %

9.2. Other information

No data available.

SECTION 10: Stability and reactivity

10.1. Reactivity

No decomposition if stored and applied as directed.

10.2. Chemical stability

Stable under normal conditions.

10.3. Possibility of hazardous reactions

Reactions with acids and strong oxidizing agents.

10.4. Conditions to avoid

To avoid thermal decomposition, do not overheat.

10.5. Incompatible materials

Strong acids and oxidizing agents

10.6. Hazardous decomposition products

Irritant/corrosive, flammable as well as toxic distillation gases (carbonization gases).

Carbon monoxide and carbon dioxide.

SECTION 11: Toxicological information

11.1. Information on toxicological effects

Acute toxicity

Harmful if swallowed or if inhaled.

No toxicological data available.

Irritation and corrosivity

Causes severe skin burns and eye damage.

Sensitising effects

May cause allergy or asthma symptoms or breathing difficulties if inhaled. (Glutaraldehyde)

May cause an allergic skin reaction. (Glutaraldehyde), (Glyoxal), ((R)-p-Mentha-1,8-diene)

STOT-single exposure

May cause respiratory irritation. (Glyoxal)

Severe effects after repeated or prolonged exposure

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

Carcinogenic/mutagenic/toxic effects for reproduction

Suspected of causing genetic defects. (Glyoxal)

Aspiration hazard

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

Additional information on tests

Classification in compliance with the assessment procedure specified in the Regulation (EC) no 1272/2008.

Practical experience

Other observations

Inhalation of vapours in high concentration may cause irritation of respiratory system.

SECTION 12: Ecological information

12.1. Toxicity

Ecological data are not available.

Very toxic to aquatic organisms.

Harmful to aquatic life with long lasting effects.

Didecyldimethylammonium chloride [M = 10]

12.2. Persistence and degradability

No data available.

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CAS No	Chemical name						
	Method	Value	d	Source			
	Evaluation	•	•				
9043-30-5	Alcohol, C9-13-iso, ethoxylated						
	OECD 301 F	> 60 %	28				
7173-51-5	Didecyldimethylammonium chloride						
	modif. Sturm-test	72 %	28				
	Readily biodegradable.						

12.3. Bioaccumulative potential

No data available.

12.4. Mobility in soil

No data available.

12.5. Results of PBT and vPvB assessment

No data available.

12.6. Other adverse effects

Hazardous water pollutant.

Due to dilution in sewage the concentration will rapidly remain under 0,05% for fungistasis and 0,075% for bacteriostasis. The critical concentration according to Formazan-Test is 0,07.

For that reason a solution of the product can be given into a purification plant without problems.

Further information

Product is not allowed to be discharged into aquatic environment.

SECTION 13: Disposal considerations

13.1. Waste treatment methods

Advice on disposal

Where possible recycling is preferred to disposal.

Can be incinerated, when in compliance with local regulations.

Waste disposal number of waste from residues/unused products

070699 WASTES FROM ORGANIC CHEMICAL PROCESSES; wastes from the MFSU of fats, grease, soaps,

detergents, disinfectants and cosmetics; wastes not otherwise specified

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.

SECTION 14: Transport information

Land transport (ADR/RID)

14.1. UN number: UN 1903

14.2. UN proper shipping name: DISINFECTANT, LIQUID, CORROSIVE, N.O.S. (Glutaraldehyde,

Didecyldimethylammonium chloride)

14.3. Transport hazard class(es):814.4. Packing group:IIIHazard label:8



Classification code:

Limited quantity: 5 L / 30 kg

Excepted quantity: E1
Transport category: 3
Hazard No: 80
Tunnel restriction code: E

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Inland waterways transport (ADN)

14.1. UN number: UN 1903

14.2. UN proper shipping name: DISINFECTANT, LIQUID, CORROSIVE, N.O.S. (Glutaraldehyde,

Didecyldimethylammonium chloride)

14.3. Transport hazard class(es): 8
14.4. Packing group:

Hazard label: 8

E1

Classification code: C9
Limited quantity: 5 L / 30 kg

Marine transport (IMDG)

Excepted quantity:

14.1. UN number: UN 1903

14.2. UN proper shipping name: DISINFECTANT, LIQUID, CORROSIVE, N.O.S. (Glutaraldehyde,

Didecyldimethylammonium chloride)

14.3. Transport hazard class(es): 8
14.4. Packing group: III

Hazard label: 8



Marine pollutant:

Limited quantity:

Excepted quantity:

EmS:

Yes

5 L / 30 kg

E1

EnS:

F-A, S-B

Air transport (ICAO)

14.1. UN number: UN 1903

14.2. UN proper shipping name: DISINFECTANT, LIQUID, CORROSIVE, N.O.S. (Glutaraldehyde,

Didecyldimethylammonium chloride, Solution)

14.3. Transport hazard class(es): 8
14.4. Packing group: |||

Hazard label: 8



Limited quantity Passenger: 1 L
Passenger LQ: Y841
Excepted quantity: E1

IATA-packing instructions - Passenger:852IATA-max. quantity - Passenger:5 LIATA-packing instructions - Cargo:856IATA-max. quantity - Cargo:60 L

14.5. Environmental hazards

ENVIRONMENTALLY HAZARDOUS: yes



14.6. Special precautions for user

Handle in accordance with good industrial hygiene and safety practice.

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14.7. Transport in bulk according to Annex II of MARPOL73/78 and the IBC Code

The transport takes place only in approved and appropriate packaging.

SECTION 15: Regulatory information

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

EU regulatory information

2004/42/EC (VOC): < 5 %

National regulatory information

Employment restrictions: Observe employment restrictions for young people. Observe employment

restrictions for child bearing mothers and nursing.

Water contaminating class (D): 2 - water contaminating

Additional information

Consider Chemical prohibition regulation.

15.2. Chemical safety assessment

For this substance a chemical safety assessment has not been carried out.

SECTION 16: Other information

Abbreviations and acronyms

ADR = Accord européen relatif au transport international des marchandises Dangereuses par Route

RID = Règlement concernant le transport international ferroviaire de marchandises dangereuses

ADN = Accord européen relatif au transport international des marchandises dangereuses par voie de navigation intérieure

IMDG = International Maritime Code for Dangerous Goods

IATA/ICAO = International Air Transport Association / International Civil Aviation Organization

MARPOL = International Convention for the Prevention of Pollution from Ships

IBC-Code = International Code for the Construction and Equipment of Ships Carrying Dangerous Chemicals in Bulk

GHS = Globally Harmonized System of Classification and Labelling of Chemicals

REACH = Registration, Evaluation, Authorization and Restriction of Chemicals

CAS = Chemical Abstract Service

EN = European norm

ISO = International Organization for Standardization

DIN = Deutsche Industrie Norm

PBT = Persistent Bioaccumulative and Toxic

vPvB = Very Persistent and very Bio-accumulative

LD = Lethal dose

LC = Lethal concentration

EC = Effect concentration

IC = Median immobilisation concentration or median inhibitory concentration

Relevant H and EUH statements (number and full text)

H225 Highly flammable liquid and vapour.
H226 Flammable liquid and vapour.
H290 May be corrosive to metals.

H301 Toxic if swallowed. H302 Harmful if swallowed.

H302+H332 Harmful if swallowed or if inhaled.

H304 May be fatal if swallowed and enters airways. H314 Causes severe skin burns and eye damage.

H315 Causes skin irritation.

H317 May cause an allergic skin reaction.
H318 Causes serious eye damage.
H319 Causes serious eye irritation.

H331 Toxic if inhaled. H332 Harmful if inhaled.

H334 May cause allergy or asthma symptoms or breathing difficulties if inhaled.

H335 May cause respiratory irritation.
 H336 May cause drowsiness or dizziness.
 H341 Suspected of causing genetic defects.

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H400 Very toxic to aquatic life.

H410 Very toxic to aquatic life with long lasting effects.
 H411 Toxic to aquatic life with long lasting effects.
 H412 Harmful to aquatic life with long lasting effects.

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.)

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