B. Braun Medical AG

Braunol

Revision date: 01.06.2015 Revision No: 1.1

Product code: 00056-0017

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

1.1. Product identifier

Braunol

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

Use of the substance/mixture

Skin and muscous membrane antiseptic

1.3. Details of the supplier of the safety data sheet

Manufacturer

Company name: B. Braun Medical AG

Street: Seesatz 17

CH-6204 Sempach Place:

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

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

> 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:

Serious eye damage/eye irritation: Eye Dam. 1

Hazardous to the aquatic environment: Aquatic Chronic 3

Hazard Statements:

Causes serious eye damage.

Harmful to aquatic life with long lasting effects.

2.2. Label elements

Hazardous components which must be listed on the label

Polyvidone-iodine

Signal word: Danger

Pictograms:



Hazard statements

H318 Causes serious eye damage.

Harmful to aquatic life with long lasting effects. H412

Precautionary statements

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

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

present and easy to do. Continue rinsing.

Immediately call a POISON CENTER/doctor. P310

Avoid release to the environment. P273

Additional advice on labelling

Applies for those countries where this product is classified as medicinal product; as ready for use

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medicinal product, this product is not subject to labelling obligation according to the CE directives in these countries.

Wear protective gloves/protective clothing/eye protection/face protection (see Section 8) during filling and emptying of large containers (> 1000 ml).

2.3. Other hazards

Not known.

SECTION 3: Composition/information on ingredients

3.2. Mixtures

Chemical characterization

Aqueous solution

Hazardous components

CAS No	Chemical name			Quantity
	EC No	Index No	REACH No	
	Classification according to Regulation (EC) No. 1272/2008 [CLP]			
25655-41-8	Polyvidone-iodine			< 10 %
	Skin Irrit. 2, Eye Dam. 1, Aquatic Chronic 2; H315 H318 H411			

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 and wash contaminated clothing before re-use.

If you feel unwell, seek medical advice.

After inhalation

Move to fresh air in case of accidental inhalation of fumes from overheating or combustion.

In the event of symptoms refer for medical treatment.

After contact with eyes

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

Seek medical treatment by eye specialist.

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

Causes serious eye damage.

May cause skin irritation with susceptible persons.

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:

lodine compounds.

Carbon monoxide (CO), carbon dioxide (CO2) and nitrogen oxides (NOx).

5.3. Advice for firefighters

Use breathing apparatus with independent air supply.

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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.

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.

When using do not eat, drink or smoke.

Avoid contact with eyes.

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 container tightly closed in a dry, cool and well-ventilated place.

Advice on storage compatibility

Incompatible with:

Reducing agents.

Further information on storage conditions

Keep away from food, drink and animal feeding stuffs.

7.3. Specific end use(s)

Skin and muscous membrane antiseptic

SECTION 8: Exposure controls/personal protection

8.1. Control parameters

8.2. Exposure controls

Appropriate engineering controls

Ensure adequate ventilation, especially in confined areas.

Protective and hygiene measures

When using do not eat, drink or smoke.

Avoid contact with the eyes.

Remove and wash contaminated clothing before re-use.

Eye/face protection

Safety goggles with side protection (EN 166).

Eye wash bottle with pure water (EN 15154).

Hand protection

Protective gloves resistant to chemicals made off nitrile, Minimum coat thickness 0.11 mm, Permeation resistance (wear duration) approx. 480 minutes, i.e. protective glove <Dermatril L 741> made by www.kcl.de.

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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

No personal respiratory protective equipment normally required.

SECTION 9: Physical and chemical properties

9.1. Information on basic physical and chemical properties

Physical state: Liquid Colour: Dark brown

Odour: Slightly like iodine

pH-Value (at 20 °C): 5 - 6

Changes in the physical state

approx. 0 °C Melting point: Initial boiling point and boiling range: approx. 100 °C

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

Upper explosion limits:

Ignition temperature: n.a. Vapour pressure: 23,3 hPa (at 20 °C) Density (at 20 °C): 1,02 g/cm3 Miscible

Water solubility:

(at 20 °C)

Viscosity / dynamic: approx. 3 mPa-s

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 reducing agents.

10.4. Conditions to avoid

To avoid thermal decomposition, do not overheat.

10.5. Incompatible materials

Reducing agents.

10.6. Hazardous decomposition products

lodine compounds.

Carbon monoxide (CO), carbon dioxide (CO2) and nitrogen oxides (NOx).

SECTION 11: Toxicological information

11.1. Information on toxicological effects

Acute toxicity

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

No toxicological data available.

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Irritation and corrosivity

Causes serious eye damage. Skin irritation: Not classified.

Sensitising effects

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

STOT-single exposure

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

Severe effects after repeated or prolonged exposure

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.

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

May cause skin irritation with susceptible persons.

SECTION 12: Ecological information

12.1. Toxicity

Ecological data are not available.

Harmful to aquatic life with long lasting effects.

12.2. Persistence and degradability

No data available.

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.

Further information

Do not flush into surface water or sanitary sewer system.

When low concentrations are discharged correctly into adapted biological sewage treatment plants, interference with the degradation activity of activated sludge is not likely.

SECTION 13: Disposal considerations

13.1. Waste treatment methods

Advice on disposal

Can be disposed of as a solid waste or burned in a suitable installation subject to 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 hazardous 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.

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

SECTION 14: Transport information

Land transport (ADR/RID); Marine transport (IMDG); Air transport (ICAO); Inland waterways transport (ADN):

14.1. UN number:

No hazardous material as defined by the transport regulations.

14.2. UN proper shipping name:

No hazardous material as defined by the transport regulations.

14.3. Transport hazard class(es):

No hazardous material as defined by the transport regulations.

14.4. Packing group:

No hazardous material as defined by the transport regulations.

14.5. Environmental hazards

No hazardous material as defined by the transport regulations.

14.6. Special precautions for user

No hazardous material as defined by the transport regulations.

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

No hazardous material as defined by the transport regulations.

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): 0 %

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

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)

H315 Causes skin irritation.

H318 Causes serious eye damage.

H411 Toxic to aquatic life with long lasting effects.

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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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