

## **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 mucous membrane antiseptic

### **1.3. Details of the supplier of the safety data sheet**

B. Braun Melsungen AG

Carl-Braun-Straße 1

D-34212 Melsungen

B. Braun Medical AG

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CH-6204 Sempach

### **Responsible Department**

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## **SECTION 2: Hazards identification**

### **2.1. Classification of the substance or mixture**

Indications of danger: Xi - Irritant

R phrases:

Irritating to eyes.

Harmful to aquatic organisms, may cause long-term adverse effects in the aquatic environment.

#### **GHS classification**

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**

Danger symbols:

Xi - Irritant



Xi - Irritant

### **Hazardous components which must be listed on the label**

Polyvidone-iodine

#### **R phrases**

36 Irritating to eyes.

52/53 Harmful to aquatic organisms, may cause long-term adverse effects in the aquatic environment.

#### **S phrases**

26 In case of contact with eyes, rinse immediately with plenty of water and seek medical advice.

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61 Avoid release to the environment. Refer to special instructions / Safety data sheets.

## **2.2. Label elements (GHS classification)**

**Signal word:**

Danger

**Pictograms:**

GHS05



### **Hazardous components which must be listed on the label**

Polyvidone-iodine

#### **Hazard statements**

H318 Causes serious eye damage.

H412 Harmful to aquatic life with long lasting effects.

#### **Precautionary statements**

P280 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.

P310 Immediately call a POISON CENTER or doctor/physician.

P273 Avoid release to the environment.

#### **Additional advice on labelling**

Applies for those countries where this product is classified as medicinal product; as ready for use medicinal product, this product is not subject to labelling obligation according to the CE directives in these countries.

## **2.3. Other hazards**

Not known.

## **SECTION 3: Composition/information on ingredients**

### **3.2. Mixtures**

#### **Chemical characterization**

Aqueous solution

#### **Hazardous components**

EC No	Chemical name	Quantity
CAS No	Classification	
Index No	GHS classification	
REACH No		
	Polyvidone-iodine	< 10 %
25655-41-8	Xi - Irritant, N - Dangerous for the environment R38-41-51-53	
	Skin Irrit. 2, Eye Dam. 1, Aquatic Chronic 2; H315 H318 H411	

Full text of R and H phrases: 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.

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**SECTION 5: Firefighting measures**

**5.1. Extinguishing media**

**Suitable extinguishing media**

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

**Extinguishing media which must not be used for safety reasons**

Full water jet.

**5.2. Special hazards arising from the substance or mixture**

Fire may produce:  
Iodine compounds.  
Carbon monoxide (CO), carbon dioxide (CO<sub>2</sub>) and nitrogen oxides (NO<sub>x</sub>).

**5.3. Advice for firefighters**

Use breathing apparatus with independent air supply.

**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.

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**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/groundwater.

**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 look up chapter 13.

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**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.

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## **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 mucous membrane antiseptic

## **SECTION 8: Exposure controls/personal protection**

### **8.1. Control parameters**

### **8.2. Exposure controls**

#### **Occupational exposure 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.

#### **Respiratory protection**

No personal respiratory protective equipment normally required.

#### **Eye protection**

Safety goggles with side protection.

#### **Skin protection**

Long sleeved clothing.

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## **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

	<b>Test method</b>
pH-Value (at 20 °C):	5 - 6

#### **Changes in the physical state**

Melting point:	Approx. 0 °C
Boiling point:	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
Water solubility:	Miscible
(at 20 °C)	

Viscosity / dynamic:

Approx. 3 mPa·s

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## **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**

Iodine compounds.

Carbon monoxide (CO), carbon dioxide (CO<sub>2</sub>) and nitrogen oxides (NO<sub>x</sub>).

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## **SECTION 11: Toxicological information**

### **11.1. Information on toxicological effects**

#### **Acute toxicity**

No toxicological data available.

#### **Irritation and corrosivity**

Skin irritation: Not classified.

Eye irritation: Causes serious eye damage.

#### **Sensitising effects**

Not classified.

#### **Severe effects after repeated or prolonged exposure**

STOT/Single exposure: Not classified.

STOT/Repeated exposure: Not classified.

Aspiration hazard: Not classified.

#### **Carcinogenic/mutagenic/toxic effects for reproduction**

Carcinogenicity: Not classified.

Mutagenicity: Not classified.

Teratogenicity: Not classified.

#### **Additional information on tests**

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

#### **Empirical data on effects on humans**

May cause skin irritation with susceptible persons.

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## **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.

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#### **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.

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### **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 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.

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### **SECTION 14: Transport information**

#### **Other applicable information**

No hazardous material as defined by the transport regulations.

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### **SECTION 15: Regulatory information**

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

##### **EU regulatory information**

1999/13/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.

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### **SECTION 16: Other information**

#### **Full text of R phrases referred to under Sections 2 and 3**

36 Irritating to eyes.

38 Irritating to skin.

41 Risk of serious damage to eyes.

51 Toxic to aquatic organisms.

52/53 Harmful to aquatic organisms, may cause long-term adverse effects in the aquatic environment.

53 May cause long-term adverse effects in the aquatic environment.

**Safety Data Sheet** according to Regulation (EC) No 1907/2006

B. Braun Melsungen AG

Revision date: 27.03.2013

Revision No: 1,01

**Braunol**

00056-0017

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**Full text of H statements referred to under Sections 2 and 3**

H315 Causes skin irritation.

H318 Causes serious eye damage.

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)

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