Braunovidon Ointment 10%

Safety Data Sheet

according to the REACH Regulation (EC) 1907/2006 amended by Regulation (EU) 2020/878
Issue date: 5/7/2012 Revision date: 3/20/2023 Supersedes: 4/13/2021 Version: 2.1
SDS No: 00056-0166

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

1.1. Product identifier

Product form : Mixture
Product name : Braunovidon Ointment 10%
UFI : 236P-57WS-K130-87NX

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

1.2.1. Relevant identified uses

Use of the substance/mixture : Skin and wound antiseptic

1.2.2. Uses advised against

No additional information available

1.3. Details of the supplier of the safety data sheet

Manufacturer
B. Braun Medical AG
Seesatz 17
CH-6204 Sempach
Switzerland
T +41 (0) 58 / 258 50 00
info.bbmch@bbraun.com

Supplier
B. Braun Melsungen AG
Carl-Braun-Straße 1
34212 Melsungen, Deutschland
Zentrale Service-Bereich / Logistik und Supply Chain
T +49 (0) 5661 / 71-4422
logistics.service@bbraun.com

E-mail address of competent person responsible for the SDS: sds@gbk-ingelheim.de

1.4. Emergency telephone number

Emergency number : INTERNATIONAL: +49 - (0) 6132 - 84463, GBK GmbH (24h - 7d/w - 365d/a)

SECTION 2: Hazards identification

2.1. Classification of the substance or mixture

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

Serious eye damage/eye irritation, Category 1	H318
Hazardous to the aquatic environment – Chronic Hazard, Category 3	H412

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

Adverse physicochemical, human health and environmental effects

Harmful to aquatic life with long lasting effects.

2.2. Label elements

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

Hazard pictograms (CLP) :

GHS05

Signal word (CLP) : Danger
Contains : Polyvidone-iodine
Hazard statements (CLP) : H318 - Causes serious eye damage.
H412 - Harmful to aquatic life with long lasting effects.
Precautionary statements (CLP) : P280 - Wear eye 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, a doctor.
P501 - Dispose of contents and container to an approved waste disposal plant.

Extra phrases : 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.

Labelling according to: exemption for packages of a capacity of 125ml or less

Hazard pictograms (CLP) :

GHS05

Signal word (CLP) : Danger

Hazardous ingredients : Polyvidone-iodine

Hazard statements (CLP) : H318 - Causes serious eye damage.
H412 - Harmful to aquatic life with long lasting effects.

Precautionary statements (CLP) : P280 - Wear eye 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, a doctor.

Extra phrases : 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

Contains no PBT/vPvB substances ≥ 0.1% assessed in accordance with REACH Annex XIII.

The mixture does not contain substance(s) included in the list established in accordance with Article 59(1) of REACH for having endocrine disrupting properties, or substance(s) are not identified as having endocrine disrupting properties in accordance with the criteria set out in Commission Delegated Regulation (EU) 2017/2100 or Commission Regulation (EU) 2018/605 at a concentration equal to or greater than 0,1 %

SECTION 3: Composition/information on ingredients

3.1. Substances

Not applicable

3.2. Mixtures

Chemical characterization : Hydrophilic ointment / ointment gauze

Name	Product identifier	%	Classification according to Regulation (EC) No. 1272/2008 [CLP]
Polyvidone-iodine	CAS-No.: 25655-41-8	≥ 5 – < 10	Skin Irrit. 2, H315 Eye Dam. 1, H318 Aquatic Chronic 2, H411

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

SECTION 4: First aid measures

4.1. Description of first aid measures

First-aid measures general : Data of item 4 do partly not refer to the use and the regular employing of the product (in this sense consult package leaflet and expert information), but to liberation of major amounts in case of accidents and irregularities. Take off immediately all contaminated clothing. Wash contaminated clothing before reuse.

First-aid measures after inhalation : Remove person to fresh air and keep comfortable for breathing. In the event of symptoms refer for medical treatment.

First-aid measures after eye contact : Rinse thoroughly and plentifully with water, also under the eyelids. If eye irritation persists, consult a specialist.

First-aid measures after ingestion : Rinse mouth. Drink plenty of water. Do not give an unconscious person anything to drink. Call a physician immediately. Do not induce vomiting without medical advice.

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

Symptoms/effects after skin contact : May cause sensitisation of susceptible persons by skin contact.

Symptoms/effects after eye contact : May cause eye-irritation of susceptible persons.

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

Unsuitable extinguishing media : Do not use a solid water stream as it may scatter and spread fire.

5.2. Special hazards arising from the substance or mixture

Fire hazard : Non flammable.

Explosion hazard : Product is not explosive.

Hazardous decomposition products in case of fire : Toxic fumes may be released. iodine compounds. Carbon monoxide (CO), carbon dioxide (CO2) and nitrogen oxides (NOx).

5.3. Advice for firefighters

Precautionary measures fire : Cool endangered containers with water spray jet.

Firefighting instructions : Move containers from fire area if it can be done without personal risk. Use water spray or fog for cooling exposed containers.

Protection during firefighting : Do not attempt to take action without suitable protective equipment. Self-contained breathing apparatus. Complete protective clothing.

Other information : 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

General measures : Ensure adequate ventilation. Evacuate unnecessary personnel.

6.1.1. For non-emergency personnel

Emergency procedures : Ventilate spillage area. Avoid contact with skin, eyes and clothing.

6.1.2. For emergency responders

Protective equipment : Do not attempt to take action without suitable protective equipment. For further information refer to section 8: "Exposure controls/personal protection".

Emergency procedures : Ventilate area. Stop leak if safe to do so.

6.2. Environmental precautions

Avoid release to the environment. Do not discharge into the drains/surface waters/groundwater.

6.3. Methods and material for containment and cleaning up

For containment : Does not require any specific or particular technical measures.

Methods for cleaning up : Take up liquid spill into absorbent material.

Other information : Dispose of materials or solid residues at an authorized site.

6.4. Reference to other sections

Refer to protective measures listed in sections 7 and 8. Information for disposal see section 13.

SECTION 7: Handling and storage

7.1. Precautions for safe handling

Precautions for safe handling : Keep container tightly closed. Ensure good ventilation of the work station. Wear personal protective equipment. Avoid contact with eyes.

Hygiene measures : Do not eat, drink or smoke when using this product. Always wash hands after handling the product.

7.2. Conditions for safe storage, including any incompatibilities

Storage conditions : Store in a well-ventilated place. Keep cool.

Incompatible materials : Reducing agents.

Information on mixed storage : Keep away from food, drink and animal feeding stuffs.

7.3. Specific end use(s)

See Section 1.

SECTION 8: Exposure controls/personal protection

8.1. Control parameters

8.1.1 National occupational exposure and biological limit values

No additional information available

8.1.2. Recommended monitoring procedures

Monitoring methods	
Monitoring methods	A specific exposure sampling method is not available.
Biological monitoring methods	A specific exposure sampling method is not available

8.1.3. Air contaminants formed

No additional information available

8.1.4. DNEL and PNEC

No additional information available

8.1.5. Control banding

No additional information available

8.2. Exposure controls

8.2.1. Appropriate engineering controls

Appropriate engineering controls:
Ensure good ventilation of the work station.

8.2.2. Personal protection equipment

Personal protective equipment:
Data of item 8 do partly not refer to the use and the regular employing of the product (in this sense consult package leaflet and expert information), but to liberation of major amounts in case of accidents and irregularities.

8.2.2.1. Eye and face protection

Eye protection:
No specific measures are necessary

Eye protection			
Type	**Field of application**	**Characteristics**	**Standard**
Safety glasses with side shields	Liquid splashes may occur		EN 166

8.2.2.2. Skin protection

Skin and body protection:
Long sleeved protective clothing (DIN EN ISO 6530)

Hand protection:
None under normal use

Other skin protection

Materials for protective clothing:
No specific measures are necessary

8.2.2.3. Respiratory protection

Respiratory protection:
No specific measures are necessary

8.2.2.4. Thermal hazards

No additional information available

8.2.3. Environmental exposure controls

Environmental exposure controls:
Avoid release to the environment.

SECTION 9: Physical and chemical properties

9.1. Information on basic physical and chemical properties

Physical state	:	Liquid
Colour	:	Brown.
Appearance	:	Paste-like.
Odour	:	Slightly like iodine.
Odour threshold	:	Not available
Melting point	:	Not available
Freezing point	:	Not available
Boiling point	:	Not available
Flammability	:	Non flammable.
Explosive properties	:	Product is not explosive.
Oxidising properties	:	Not oxidising.
Lower explosive limit (LEL)	:	Not available
Upper explosive limit (UEL)	:	Not available
Flash point	:	Not available
Auto-ignition temperature	:	Not available
Decomposition temperature	:	Not available
pH	:	≈ 4 at 20 °C
pH solution concentration	:	20 %
Viscosity, kinematic	:	Not available
Viscosity, dynamic	:	0.5 – 5 mPa·s
Solubility	:	Water: Miscible
Partition coefficient n-octanol/water (Log Kow)	:	Not available
Vapour pressure	:	Not available
Vapour pressure at 50°C	:	Not available
Density	:	≈ 1.2 g/cm³ at 20 °C
Relative density	:	Not available
Relative vapour density at 20°C	:	Not available
Particle characteristics	:	Not applicable

9.2. Other information

9.2.1. Information with regard to physical hazard classes

No additional information available

9.2.2. Other safety characteristics

VOC content : 0 %

SECTION 10: Stability and reactivity

10.1. Reactivity

The product is non-reactive under normal conditions of use, storage and transport.

10.2. Chemical stability

Stable under normal conditions.

10.3. Possibility of hazardous reactions

No dangerous reactions known under normal conditions of use.

10.4. Conditions to avoid

None under recommended storage and handling conditions (see section 7).

10.5. Incompatible materials

reducing materials.

10.6. Hazardous decomposition products

Under normal conditions of storage and use, hazardous decomposition products should not be produced.

SECTION 11: Toxicological information

11.1. Information on hazard classes as defined in Regulation (EC) No 1272/2008

Acute toxicity (oral) : Not classified (Based on available data, the classification criteria are not met)
Acute toxicity (dermal) : Not classified (Based on available data, the classification criteria are not met)
Acute toxicity (inhalation) : Not classified (Based on available data, the classification criteria are not met)

Polyvidone-iodine (25655-41-8)	
LD50 oral rat	> 4640 mg/kg
LD50 dermal rat	> 2500 mg/kg

Skin corrosion/irritation : Not classified (Based on available data, the classification criteria are not met)
pH: ≈ 4 at 20 °C

Serious eye damage/irritation : Causes serious eye damage.
pH: ≈ 4 at 20 °C

Respiratory or skin sensitisation : Not classified (Based on available data, the classification criteria are not met)
Germ cell mutagenicity : Not classified (Based on available data, the classification criteria are not met)
Carcinogenicity : Not classified (Based on available data, the classification criteria are not met)
Reproductive toxicity : Not classified (Based on available data, the classification criteria are not met)
STOT-single exposure : Not classified (Based on available data, the classification criteria are not met)
STOT-repeated exposure : Not classified (Based on available data, the classification criteria are not met)
Aspiration hazard : Not classified (Based on available data, the classification criteria are not met)

11.2. Information on other hazards

11.2.1. Endocrine disrupting properties

Adverse health effects caused by endocrine disrupting properties : The mixture does not contain substance(s) included in the list established in accordance with Article 59(1) of REACH for having endocrine disrupting properties, or substance(s) are not identified as having endocrine disrupting properties in accordance with the criteria set out in Commission Delegated Regulation (EU) 2017/2100 or Commission Regulation (EU) 2018/605 at a concentration equal to or greater than 0,1 %

11.2.2. Other information

No additional information available

SECTION 12: Ecological information

12.1. Toxicity

Ecology - general : Harmful to aquatic life with long lasting effects.
Hazardous to the aquatic environment, short–term (acute) : Not classified (Based on available data, the classification criteria are not met)
Hazardous to the aquatic environment, long–term (chronic) : Harmful to aquatic life with long lasting effects.

Polyvidone-iodine (25655-41-8)	
LC50 fish 1	4.6 – 10 mg/l Leuciscus idus
EC50 Daphnia 1	2.79 mg/l Daphnia magna
ErC50 algae	4.91 mg/l Desmodesmus subspicatus

12.2. Persistence and degradability

Braunovidon Ointment 10%	
Persistence and degradability	The product has not been tested

12.3. Bioaccumulative potential

Braunovidon Ointment 10%	
Bioaccumulative potential	The product has not been tested.

12.4. Mobility in soil

No additional information available

12.5. Results of PBT and vPvB assessment

No additional information available

12.6. Endocrine disrupting properties

Adverse effects on the environment caused by endocrine disrupting properties : The mixture does not contain substance(s) included in the list established in accordance with Article 59(1) of REACH for having endocrine disrupting properties, or substance(s) are not identified as having endocrine disrupting properties in accordance with the criteria set out in Commission Delegated Regulation (EU) 2017/2100 or Commission Regulation (EU) 2018/605 at a concentration equal to or greater than 0,1 %.

12.7. Other adverse effects

Other adverse effects : Slightly hazardous to water.
Additional information : Do not flush into surface water or sewer system

SECTION 13: Disposal considerations

13.1. Waste treatment methods

Waste treatment methods : Dispose of contents/container in accordance with licensed collector's sorting instructions.
Product/Packaging disposal recommendations : Empty containers should be taken for recycling, recovery or waste in accordance with local regulation. 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.
European List of Waste (LoW, EC 2000/532) : 18 01 06* - chemicals consisting of or containing dangerous substances

SECTION 14: Transport information

In accordance with ADR / IMDG / IATA / ADN / RID

ADR	IMDG	IATA	ADN	RID
14.1. UN number or ID number				
Not regulated for transport				
14.2. UN proper shipping name				
Not regulated	Not regulated	Not regulated	Not regulated	Not regulated
14.3. Transport hazard class(es)				
Not regulated	Not regulated	Not regulated	Not regulated	Not regulated
14.4. Packing group				
Not regulated	Not regulated	Not regulated	Not regulated	Not regulated
14.5. Environmental hazards				
Not regulated	Not regulated	Not regulated	Not regulated	Not regulated
No supplementary information available				

14.6. Special precautions for user

Overland transport

Not regulated

Transport by sea

Not regulated

Air transport

Not regulated

Inland waterway transport

Not regulated

Rail transport

Not regulated

14.7. Maritime transport in bulk according to IMO instruments

Not applicable

SECTION 15: Regulatory information

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

15.1.1. EU-Regulations

REACH Annex XVII (Restriction List)

Contains no substance(s) listed on REACH Annex XVII (Restriction Conditions)

REACH Annex XIV (Authorisation List)

Contains no substance(s) listed on REACH Annex XIV (Authorisation List)

REACH Candidate List (SVHC)

Contains no substance(s) listed on the REACH Candidate List

PIC Regulation (Prior Informed Consent)

Contains no substance(s) listed on the PIC list (Regulation EU 649/2012 concerning the export and import of hazardous chemicals)

POP Regulation (Persistent Organic Pollutants)

Contains no substance(s) listed on the POP list (Regulation EU 2019/1021 on persistent organic pollutants)

Ozone Regulation (1005/2009)

Contains no substance(s) listed on the Ozone Depletion list (Regulation EU 1005/2009 on substances that deplete the ozone layer)

VOC Directive (2004/42)

VOC content : 0 %

Explosives Precursors Regulation (2019/1148)

Contains no substance(s) listed on the Explosives Precursors list (Regulation EU 2019/1148 on the marketing and use of explosives precursors)

Drug Precursors Regulation (273/2004)

Contains no substance(s) listed on the Drug Precursors list (Regulation EC 273/2004 on the manufacture and the placing on market of certain substances used in the illicit manufacture of narcotic drugs and psychotropic substances)

15.1.2. National regulations

No additional information available

15.2. Chemical safety assessment

No chemical safety assessment has been carried out

SECTION 16: Other information

Indication of changes:
All chapters have been modified since the previous version.

Abbreviations and acronyms:	
ADN	European Agreement concerning the International Carriage of Dangerous Goods by Inland Waterways
ADR	European Agreement concerning the International Carriage of Dangerous Goods by Road
ATE	Acute Toxicity Estimate
BCF	Bioconcentration factor
BLV	Biological limit value
BOD	Biochemical oxygen demand (BOD)
COD	Chemical oxygen demand (COD)
DMEL	Derived Minimal Effect level
DNEL	Derived-No Effect Level
EC-No.	European Community number
EC50	Median effective concentration
EN	European Standard
IARC	International Agency for Research on Cancer
IATA	International Air Transport Association
IMDG	International Maritime Dangerous Goods
LC50	Median lethal concentration
LD50	Median lethal dose
LOAEL	Lowest Observed Adverse Effect Level
NOAEC	No-Observed Adverse Effect Concentration

Abbreviations and acronyms:	
NOAEL	No-Observed Adverse Effect Level
NOEC	No-Observed Effect Concentration
OECD	Organisation for Economic Co-operation and Development
OEL	Occupational Exposure Limit
PBT	Persistent Bioaccumulative Toxic
PNEC	Predicted No-Effect Concentration
RID	Regulations concerning the International Carriage of Dangerous Goods by Rail
SDS	Safety Data Sheet
STP	Sewage treatment plant
ThOD	Theoretical oxygen demand (ThOD)
TLM	Median Tolerance Limit
VOC	Volatile Organic Compounds
CAS-No.	Chemical Abstract Service number
N.O.S.	Not Otherwise Specified
vPvB	Very Persistent and Very Bioaccumulative
ED	Endocrine disrupting properties
DOT	Department of Transport
TDG	Transportation of Dangerous Goods
REACH	Registration, Evaluation, Authorisation and Restriction of Chemicals Regulation (EC) No 1907/2006
GHS	Globally Harmonized System of Classification, Labelling and Packaging of Chemicals
IBC-Code	International Code for the Construction and Equipment of Ships carrying Dangerous Chemicals in Bulk
CLP	Classification Labelling Packaging Regulation; Regulation (EC) No 1272/2008
MARPOL 73/78	MARPOL 73/78: International Convention for the Prevention of Pollution From Ships
ADG	Transport of Australian Dangerous Goods

Other information : Data of sections 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.

Full text of H- and EUH-statements:	
Aquatic Chronic 2	Hazardous to the aquatic environment – Chronic Hazard, Category 2
Aquatic Chronic 3	Hazardous to the aquatic environment – Chronic Hazard, Category 3
Eye Dam. 1	Serious eye damage/eye irritation, Category 1
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.

Full text of H- and EUH-statements:	
Skin Irrit. 2	Skin corrosion/irritation, Category 2

Classification and procedure used to derive the classification for mixtures according to Regulation (EC) 1272/2008 [CLP]:		
Eye Dam. 1	H318	Calculation method
Aquatic Chronic 3	H412	Calculation method

This information is based on our current knowledge and is intended to describe the product for the purposes of health, safety and environmental requirements only. It should therefore not be construed as guaranteeing any specific property of the product.