# Safety Data Sheet

according to the REACH Regulation (EC) 1907/2006 amended by Regulation (EU) 2020/878 Issue date: 8/31/2012 Revision date: 2/14/2024 Supersedes: 3/20/2023 Version: 3.3 SDS No: 00056-0283

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

# 1.1. Product identifier

Product form Product name UFI MixtureSofta SwabsETP1-RM4G-110P-FF1F

### **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

: Swabs for skin cleansing

#### 1.2.2. Uses advised against

No additional information available

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

Manufacturer	Supplier	
B. Braun Medical AG	B. Braun Melsungen AG	
Seesatz 17	Carl-Braun-Straße 1	
CH-6204 Sempach	D-34212 Melsungen	
Switzerland	Germany	
T +41 (0) 58 / 258 50 00	T +49(0) 5661 / 71-4422	
info.bbmch@bbraun.com	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]

Flammable liquids, Category 2	H225
Serious eye damage/eye irritation, Category 2	H319
Specific target organ toxicity – Single exposure, Category 3,	H336
Narcosis	
Full tout of LL and FLUL statements, and another 40	

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

# Adverse physicochemical, human health and environmental effects

Highly flammable liquid and vapour. May cause drowsiness or dizziness. Causes serious eye irritation.

# 2.2. Label elements

Labelling according to Regulation (EC) No. 1272/2008 [CLP]	
Hazard pictograms (CLP)	
Signal word (CLP)	Danger
Contains	: Propan-2-ol
Hazard statements (CLP)	: H225 - Highly flammable liquid and vapour.
	H319 - Causes serious eye irritation.
	H336 - May cause drowsiness or dizziness.
Precautionary statements (CLP)	<ul> <li>P210 - Keep away from heat, hot surfaces, sparks, open flames and other ignition sources.</li> <li>No smoking.</li> <li>P280 - Wear eye protection.</li> </ul>

# **BBRAUN**

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Extra phrases :	<ul> <li>P304+P340 - IF INHALED: Remove person to fresh air and keep comfortable for breathing.</li> <li>P305+P351+P338 - IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.</li> <li>P312 - Call a POISON CENTER, doctor if you feel unwell.</li> <li>P501 - Dispose of contents and container to an approved waste disposal plant.</li> <li>Applies for those countries where this product is classified as cosmetic; as ready for use cosmetic, this product is not subject to labelling obligation according to the CE directives in these countries.</li> </ul>	
Labelling according to: exemption for packages of a capacity of 125ml or less		
Hazard pictograms (CLP) :	GHS02 GHS07	
Signal word (CLP)	Danger	
Hazardous ingredients	Propan-2-ol	
Extra phrases :	Applies for those countries where this product is classified as cosmetic; as ready for use cosmetic, this product is not subject to labelling obligation according to the CE directives in these countries.	
2.3. Other hazards		

This substance/mixture does not meet the PBT criteria of REACH regulation, annex XIII This substance/mixture does not meet the vPvB criteria of REACH regulation, annex XIII Contains no PBT/vPvB substances  $\geq 0.1\%$  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

Comments

: Swab soaked in 70% isopropanol

Name	Product identifier	%	Classification according to Regulation (EC) No. 1272/2008 [CLP]
Propan-2-ol	CAS-No.: 67-63-0 EC-No.: 200-661-7 EC Index-No.: 603-117-00-0 REACH-no: 01-2119457558-25	≥ 60 – < 65	Flam. Liq. 2, H225 Eye Irrit. 2, H319 STOT SE 3, H336

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

: Informations concern to liquid phase.

 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. Call a poison center or a doctor if you feel unwell.

 First-aid measures after inhalation
 : Remove person to fresh air and keep comfortable for breathing.

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First-aid measures after skin contact First-aid measures after eye contact First-aid measures after ingestion	<ul> <li>Rinse skin with water/shower. Take off immediately all contaminated clothing.</li> <li>Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. If eye irritation persists: Get medical advice/attention.</li> <li>Call a poison center or a doctor if you feel unwell. Rinse mouth. Drink plenty of water.</li> </ul>
4.2. Most important symptoms and eff	ects, both acute and delayed
Symptoms/effects Symptoms/effects after eye contact	<ul><li>May cause drowsiness or dizziness.</li><li>Eye irritation.</li></ul>

# 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 Unsuitable extinguishing media	<ul><li>Water spray. Dry powder. Foam. Carbon dioxide.</li><li>Do not use a solid water stream as it may scatter and spread fire.</li></ul>	
5.2. Special hazards arising from the substance or mixture		
Fire hazard Hazardous decomposition products in case of fire	<ul><li>Highly flammable liquid and vapour.</li><li>Toxic fumes may be released.</li></ul>	
5.3. Advice for firefighters		
Firefighting instructions Protection during firefighting Other information	<ul> <li>Cool containers at risk with water spray jet.</li> <li>Do not attempt to take action without suitable protective equipment. Self-contained breathing apparatus. Complete protective clothing.</li> <li>Vapours are heavier than air and may spread along floors. The vapour/air mixture is explosive, even in empty, uncleaned receptacles.</li> </ul>	

SECTION 6: Accidental release measures		
6.1. Personal precautions, protective equipment and emergency procedures		
6.1.1. For non-emergency personnel		
Emergency procedures	: Ventilate spillage area. No open flames, no sparks, and no smoking. Avoid breathing dust/fume/gas/mist/vapours/spray. Avoid contact with skin and eyes.	
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".	
6.2. Environmental precautions		
Avoid release to the environment.		
6.3. Methods and material for containment and cleaning up		
Methods for cleaning up	: Take up liquid spill into absorbent material. Notify authorities if product enters sewers or	

Other information	public waters. : Dispose of materials or solid residues at an authorized site.
6.4. Reference to other sections	

For further information refer to section 13.

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SECTION 7: Handling and stor	age	
7.1. Precautions for safe handling		
Precautions for safe handling Hygiene measures	<ul> <li>Keep away from heat, hot surfaces, sparks, open flames and other ignition sources. No smoking. Ground/bond container and receiving equipment. Use only non-sparking tools. Take precautionary measures against static discharge. Flammable vapours may accumulate in the container. Use explosion-proof equipment. Wear personal protective equipment. Use only outdoors or in a well-ventilated area. Avoid breathing dust/fume/gas/mist/vapours/spray. Avoid contact with skin and eyes.</li> <li>Do not eat, drink or smoke when using this product. Always wash hands after handling the product.</li> </ul>	
7.2. Conditions for safe storage, including any incompatibilities		
Technical measures Storage conditions	<ul><li>Ground/bond container and receiving equipment.</li><li>Store in a well-ventilated place. Keep cool. Keep container tightly closed. Store locked up.</li></ul>	
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

Propan-2-ol (67-63-0)		
DNEL/DMEL (Workers)		
Long-term - systemic effects, dermal	888 mg/kg bodyweight/day	
Long-term - systemic effects, inhalation	500 mg/m³	
DNEL/DMEL (General population)		
Long-term - systemic effects,oral	26 mg/kg bodyweight/day	
Long-term - systemic effects, inhalation	88 mg/m³	
Long-term - systemic effects, dermal	319 mg/kg bodyweight/day	
PNEC (Water)		
PNEC aqua (freshwater)	140.9 mg/l	
PNEC aqua (marine water)	140.9 mg/l	
PNEC (Sediment)		
PNEC sediment (freshwater)	552 mg/kg dwt	
PNEC sediment (marine water)	552 mg/kg dwt	

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Propan-2-ol (67-63-0)	
PNEC (Soil)	
PNEC soil	28 mg/kg dwt

#### 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:

Not required for normal conditions of use

#### 8.2.2.2. Skin protection

Skin and body protection:

Not required for normal conditions of use

#### Hand protection:

Not required for normal conditions of use

#### 8.2.2.3. Respiratory protection

#### **Respiratory protection:**

No personal breathing protective equipment is normally required

# 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	: Colourless.
Appearance	: Liquid on inert carrier.
Odour	: alcohol-like.
Odour threshold	: Not available
Melting point	: Not available
Freezing point	: Not available
Boiling point	: Not available
Flammability (solid, gas)	: Highly flammable liquid and vapour
Explosive properties	: Product is not explosive. Explosive vapour/air mixtures may be formed.
Lower explosive limit (LEL)	: 2 vol %
Upper explosive limit (UEL)	: 12 vol %
Flash point	: 18 °C DIN 51755
Auto-ignition temperature	: Not available
Decomposition temperature	: Not available

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### 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 Additional information : 60 - 80 %
: Informations concern to liquid phase.

# **SECTION 10: Stability and reactivity**

#### 10.1. Reactivity

Highly flammable liquid and vapour.

#### 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

Avoid contact with hot surfaces. Heat. No flames, no sparks. Eliminate all sources of ignition.

#### 10.5. Incompatible materials

Oxidizing agent. Acids. Alkaline metals and alkaline earth metals.

### 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) Acute toxicity (dermal) Acute toxicity (inhalation)	<ul> <li>Not classified (Based on available data, the classification criteria are not met)</li> <li>Not classified (Based on available data, the classification criteria are not met)</li> <li>Not classified (Based on available data, the classification criteria are not met)</li> </ul>
Propan-2-ol (67-63-0)	
LD50 oral rat	5840 mg/kg
LD50 dermal rabbit	13900 mg/kg
LC50 Inhalation - Rat	> 25 mg/l 4 h
Skin corrosion/irritation	: Not classified (Based on available data, the classification criteria are not met)
Serious eye damage/irritation	: Causes serious eye irritation.
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)

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Carcinogenicity Reproductive toxicity STOT-single exposure STOT-repeated exposure Aspiration hazard	<ul> <li>Not classified (Based on available data, the classification criteria are not met)</li> <li>Not classified (Based on available data, the classification criteria are not met)</li> <li>May cause drowsiness or dizziness.</li> <li>Not classified (Based on available data, the classification criteria are not met)</li> <li>Not classified (Based on available data, the classification criteria are not met)</li> </ul>
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	: The product is not considered harmful to aquatic organisms nor to cause long-term adverse effects in the environment.
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)	: Not classified (Based on available data, the classification criteria are not met)
Propan-2-ol (67-63-0)	
LC50 fish 1	9640 mg/l Pimephales promelas, 96 h
EC50 Daphnia 1	10000 mg/l Daphnia magna, 48 h
EC50 72h - Algae [1]	1800 mg/l Desmodesmus subspicatus, 72 h

# 12.2. Persistence and degradability

No additional information available

### 12.3. Bioaccumulative potential

Propan-2-ol (67-63-0)	
Log Pow	0.05

## 12.4. Mobility in soil

No additional information available

### 12.5. Results of PBT and vPvB assessment

Softa Swabs	
This substance/mixture does not meet the PBT criteria of REACH regulation, annex XIII	
This substance/mixture does not meet the vPvB criteria of REACH regulation, annex XIII	

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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

No additional information available

SECTION 13: Disposal consideration	s
13.1. Waste treatment methods	
Waste treatment methods Product/Packaging disposal recommendations	<ul> <li>Dispose of contents/container in accordance with licensed collector's sorting instructions.</li> <li>Empty containers should be taken for local recycling, recovery or waste disposal.</li> <li>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.</li> </ul>
Additional information European List of Waste (LoW. EC 2000/532)	<ul> <li>Flammable vapours may accumulate in the container.</li> <li>18 01 06* - chemicals consisting of or containing dangerous substances</li> </ul>

# **SECTION 14: Transport information**

In accordance with ADR / IME	DG / IATA / ADN / RID			
ADR	IMDG	ΙΑΤΑ	ADN	RID
14.1. UN number or ID number				
Not regulated for transport				
14.2. UN proper shippin	g 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 informatic	on available			

### 14.6. Special precautions for user

# **Overland transport**

Not regulated

Transport by sea Not regulated

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#### Air transport Not regulated

# Inland waterway transport

Not regulated

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Rail transport		
Not regulated		
Other applicable information	Special provision 216: Product is not subject to ADR/RID/ADN and IMDG Code. Special provision A46: Product is not subject to IATA-DGR.	
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

: 60 - 80 %

### 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)

### Seveso Directive (Disaster Risk Reduction)

Seveso III Part I (Categories of dangerous substances)	s) Qualifying quantity (tonnes)	
	Lower-tier	Upper-tier
P5c FLAMMABLE LIQUIDS Flammable liquids, Categories 2 or 3 not covered by P5a and P5b	5000	50000

### 15.1.2. National regulations

No additional information available

### 15.2. Chemical safety assessment

No chemical safety assessment has been carried out

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# **SECTION 16: Other information**

# Indication of changes:

Transport information.

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			
ΙΑΤΑ	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			
NOAEL	No-Observed Adverse Effect Level			
NOEC	No-Observed Effect Concentration			
OECD	Organisation for Economic Co-operation and Development			
OEL	Occupational Exposure Limit			
РВТ	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			

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Abbreviations and acronyms:			
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:			
Eye Irrit. 2	Serious eye damage/eye irritation, Category 2		
Flam. Liq. 2	Flammable liquids, Category 2		
H225	Highly flammable liquid and vapour.		
H319	Causes serious eye irritation.		
H336	May cause drowsiness or dizziness.		
STOT SE 3	Specific target organ toxicity – Single exposure, Category 3, Narcosis		

Classification and procedure used to derive the classification for mixtures according to Regulation (EC) 1272/2008 [CLP]:				
Flam. Liq. 2	H225	Expert judgement		
Eye Irrit. 2	H319	Calculation method		
STOT SE 3	H336	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.