

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

1.1. Product identifier

Softa-Man acute

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

Use of the substance/mixture

Hand disinfectant

1.3. Details of the supplier of the safety data sheet

Manufacturer

Company name: B. Braun Medical AG
Street: Seesatz 17
Place: CH-6204 Sempach
Responsible Department: Zentrale Service-Bereiche / Logistik und Supply Chain
Telephone: +49 (0) 5661 / 71-4422
E-Mail: logistics.service@bbraun.com
Responsible for the safety data sheet: sds@gbk-ingelheim.de

Supplier

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

Flammable liquid: Flam. Liq. 2

Serious eye damage/eye irritation: Eye Dam. 1

Specific target organ toxicity - single exposure: STOT SE 3

Hazard Statements:

Highly flammable liquid and vapour.

Causes serious eye damage.

May cause drowsiness or dizziness.

2.2. Label elements

Hazardous components which must be listed on the label

Propan-1-ol

Signal word:

Danger

Pictograms:



Hazard statements

H225 Highly flammable liquid and vapour.

H318 Causes serious eye damage.

H336 May cause drowsiness or dizziness.

Precautionary statements

P210 Keep away from heat, hot surfaces, sparks, open flames and other ignition sources. No smoking.

P260 Do not breathe vapour.

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.

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

P313 Get medical advice/attention.

Additional advice on labelling

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

In accordance with section 1.5.2 of Annex I of the European Regulation (EC) No 1272/2008, following H and P statements may be omitted for containers < 125 ml: H225, H336, P210, P260, P304+P340

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

Vapours may form explosive mixture with air.

SECTION 3: Composition/information on ingredients

3.2. Mixtures

Chemical characterization

Alcoholic solution

Hazardous components

CAS No	Chemical name			Quantity
	EC No	Index No	REACH No	
	Classification according to Regulation (EC) No. 1272/2008 [CLP]			
64-17-5	Ethanol			< 55 %
	200-578-6	603-002-00-5	01-2119457610-43	
	Flam. Liq. 2, Eye Irrit. 2; H225 H319			
71-23-8	Propan-1-ol			< 25 %
	200-746-9	603-003-00-0	01-2119486761-29	
	Flam. Liq. 2, Eye Dam. 1, STOT SE 3; H225 H318 H336			
78-93-3	Butanone			< 5 %
	201-159-0	606-002-00-3	02-2119752535-35	
	Flam. Liq. 2, Eye Irrit. 2, STOT SE 3; H225 H319 H336 EUH066			

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 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.

Do not induce vomiting.

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 drowsiness or dizziness.

Attention. Beware, danger of aspiration.

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

Alcohol-resistant foam, dry chemical, carbon dioxide (CO₂), water-spray.

Unsuitable extinguishing media

Full water jet.

5.2. Special hazards arising from the substance or mixture

Fire may produce:

Carbon monoxide and carbon dioxide

5.3. Advice for firefighters

Use breathing apparatus with independent air supply.

Protective suit.

Additional information

Vapours are heavier than air and spread along ground.

The vapour/air mixture is explosive, even in empty, uncleaned receptacles.

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.

Keep away sources of ignition.

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

Ensure adequate ventilation.

When using do not eat, drink or smoke.

Avoid contact with eyes.

Advice on protection against fire and explosion

Keep product and empty container away from heat and sources of ignition.

Do not smoke - volatile.

Take precautionary measures against static discharges.

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.

Pay attention to anti-explosion rules.

Advice on storage compatibility

Incompatible with:

Oxidizing agents.

Alkaline metals and earth alkaline metals.

Further information on storage conditions

Keep away from food, drink and animal feeding stuffs.

7.3. Specific end use(s)

Hand disinfectant

SECTION 8: Exposure controls/personal protection

8.1. Control parameters

Exposure limits (EH40)

CAS No	Substance	ppm	mg/m ³	fibres/ml	Category	Origin
78-93-3	Butan-2-one (methyl ethyl ketone)	200	600		TWA (8 h)	WEL
		300	899		STEL (15 min)	WEL
64-17-5	Ethanol	1000	1920		TWA (8 h)	WEL
		-	-		STEL (15 min)	WEL
71-23-8	Propan-1-ol	200	500		TWA (8 h)	WEL
		250	625		STEL (15 min)	WEL

Biological Monitoring Guidance Values (EH40)

CAS No	Substance	Parameter	Value	Test material	Sampling time
78-93-3	Butan-2-one	butan-2-one	70 µmol/L	urine	Post shift

8.2. Exposure controls

Appropriate engineering controls

Ensure adequate ventilation, especially in confined areas.

Protective and hygiene measures

Do not inhale vapours.

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 butyl, minimum coat thickness 0,7 mm, permeation resistance (wear duration) approx. 480 minutes, i.e. protective glove <Butoject 898> 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.

Respiratory protection

No personal respiratory protective equipment normally required.

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:	Colourless
Odour:	Alcoholic

Changes in the physical state

Initial boiling point and boiling range:	84 °C	
Flash point:	21 °C	DIN 51755
Lower explosion limits:	2,1	*)
Upper explosion limits:		*)
Ignition temperature:	360 °C	*)
Vapour pressure: (at 20 °C)	59 hPa	**)
Density (at 20 °C):	0,86 g/cm ³	
Water solubility: (at 20 °C)	Miscible	
Solvent content:	< 80 %	

9.2. Other information

No data available.

*) Propan-1-ol

***) Ethanol

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 oxidizing agents.

Reactions with alkali metals.

Reactions with earth alkali metals.

10.4. Conditions to avoid

Vapour/air mixtures are explosive at intensive warming.

Heating can release vapours which can be ignited.

10.5. Incompatible materials

oxidizing agents

Alkaline metals and alkaline earth metals.

10.6. Hazardous decomposition products

Carbon monoxide and carbon dioxide.

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.

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

May cause drowsiness or dizziness. (Propan-1-ol), (Butanone)

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

Ingestion causes irritation of upper respiratory system and gastrointestinal disturbance. Swallowing renders reabsorption possible.

Further information

If appropriately handled and if in accordance with the general hygienic rules, no damages to health have become known.

SECTION 12: Ecological information

12.1. Toxicity

Ecological data are not available.

12.2. Persistence and degradability

Ethanol / Propan-1-ol

Readily biodegradable (to OECD criteria).

12.3. Bioaccumulative potential

No data available.

12.4. Mobility in soil

No data available.

12.5. Results of PBT and vPvB assessment

According to Regulation (EC) No 1907/2006 (REACH) none of the substances, contained in this product are a PBT / vPvB substance.

12.6. Other adverse effects

Low hazard to waters.

Further information

Ecological injuries are not known or expected under normal use.

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

070604 WASTES FROM ORGANIC CHEMICAL PROCESSES; wastes from the MFSU of fats, grease, soaps, detergents, disinfectants and cosmetics; other organic solvents, washing liquids and mother liquors
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.

SECTION 14: Transport information

Land transport (ADR/RID)

14.1. UN number:

UN 1987

14.2. UN proper shipping name:

ALCOHOLS, N.O.S. (Ethanol, Propan-1-ol)

14.3. Transport hazard class(es):

3

14.4. Packing group:

II

Hazard label:

3



Classification code: F1
Limited quantity: 1 L / 30 kg
Excepted quantity: E2
Transport category: 2
Hazard No: 33
Tunnel restriction code: D/E

Inland waterways transport (ADN)

14.1. UN number: UN 1987
14.2. UN proper shipping name: ALCOHOLS, N.O.S. (Ethanol, Propan-1-ol)
14.3. Transport hazard class(es): 3
14.4. Packing group: II
Hazard label: 3



Classification code: F1
Limited quantity: 1 L / 30 kg
Excepted quantity: E2

Marine transport (IMDG)

14.1. UN number: UN 1987
14.2. UN proper shipping name: ALCOHOLS, N.O.S.
14.3. Transport hazard class(es): 3
14.4. Packing group: II
Hazard label: 3



Marine pollutant: No
Limited quantity: 1 L / 30 kg
Excepted quantity: E2
EmS: F-E, S-D

Air transport (ICAO)

14.1. UN number: UN 1987
14.2. UN proper shipping name: (Ethanol, Propan-1-ol, Solution)
14.3. Transport hazard class(es): 3
14.4. Packing group: II
Hazard label: 3



Limited quantity Passenger: 1 L
Passenger LQ: Y341
Excepted quantity: E2

IATA-packing instructions - Passenger: 353
IATA-max. quantity - Passenger: 5 L
IATA-packing instructions - Cargo: 364
IATA-max. quantity - Cargo: 60 L

14.5. Environmental hazards

ENVIRONMENTALLY HAZARDOUS: no

14.6. Special precautions for user

Handle in accordance with good industrial hygiene and safety practice.

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): < 80 %

National regulatory information

Employment restrictions: Observe employment restrictions for young people. Observe employment restrictions for child bearing mothers and nursing.

Water contaminating class (D): 1 - slightly 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)

H225 Highly flammable liquid and vapour.

H318 Causes serious eye damage.

H319 Causes serious eye irritation.

H336 May cause drowsiness or dizziness.

EUH066 Repeated exposure may cause skin dryness or cracking.

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)

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

B. Braun Medical AG

Softa-Man acute

Revision date: 01.06.2015

Revision No: 1,3

Product code: 00056-0230

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