

EC-Safety Data Sheet

according to Regulation (EC) No. 1907/2006 (REACH)
and Regulation (EU) Nr. 453/2010



1 Commercial product name and supplier

Productname:	Bechtol CLASSIC REF: 534
Application/use:	Desinfection and cleaning of medical devices
Manufacturer:	Alfred Becht GmbH P.O.B 1145, D-77601 Offenburg Carl-Zeiss-Str. 16, D-77656 Offenburg Telephone:+49-0781 – 60586 - 0 Telefax: +49 - 0781 – 60586 – 40
Productmanager:	Patricia Klug klug@becht-online.de, Responsible officer for medical devices
Information department/	Tel.: + 49 781/60586-0
Emergency phone number:	Tel.: + 49 781/60586-0 or +49 174 9879176

2 Hazards identification

Danger description:	Classification in accordance with Regulation (EC) No 1272/2008 on classification, labeling and packaging of substances and mixtures No hazardous ingredients as defined in Directive 67/548/EEC and Regulation (EC) No 1272/2008.
Signalword: Danger	H226 flammable liquid and vapor, Category 3 H302 Harmful if swallowed. Acute toxicity, Category 4 (oral) H314 Causes severe skin burns, Category 1B H400 very toxic to aquatic life, Category 1
	Classification acc. to directive 67/548/EEC: F, R10 Flammable. Xi, R36/38 Irritating to eyes and skin. R67 Vapours may cause drowsiness and dizziness. N, R50 Very toxic to aquatic organisms. R52/53 Harmful to aquatic organisms, may cause long-term adverse effects in the aquatic environment.

3 Composition / Data on components:

Chemical characterization Description: Mixture of substances listed below with non-hazardous additions:				
	REACH-Reg.no.			
	CAS-No.	Design (RL 67/548/EWG)	R-phrases	
Ingredients	EINECS-No.	Design.(EG 1272/2008)	H-phrases	Concentration
Benzalkonium-chloride	68391-01-5 269-919-4	C, N acute Tox. 4, Skin Corr. 1B, Aquatic Acute 1	22-34-50 H302, H314, H400	4 - 9 %
Tridecylamine	01-2119461722-40-0000 86089-17-0 289-185-9	Xn, N Acute Tox. 4, Skin Corr. 1B, Eye Dam. 1 Aquatic Chronic 1	22,37/38, 41, 52/53 H302,H314H 318, H410	5 - 10 %
Propan-1-ol	01-2119486761-29-XXXX 71-23-8 200-746-9	F, Xi Flam. Liq. 2; Eye Dam. 1 STOT SE 3	11-41-67 H225; H318,H336	10 - 15%

Ingredients	REACH-Reg.no. CAS-No. EINECS-No.	Design (RL 67/548/EWG) Design.(EG 1272/2008)	R-phrases H-phrases	Concentration
Lactatic acid 90%, L-(+)-2-Hydroxy- propion acid	79-33-4 201-196-2	Xi Eye Dam. 1, irritant 2	38-41 H318, H315	<1,0
<p>Classification in accordance with Regulation 1272/2008 Harmful if swallowed, acute toxicity: Cat. 4 (oral) Causes severe skin burns and eye damage. Irritating on skin: Cat. 1B, Sensitization of the skin: Cat 1</p> <p>Classification in accordance with Regulation 67/548/EU F, R10 flammable Xi, R36/38 Irritating to eyes and skin R67 Vapours may cause drowsiness and dizziness. N, R50 very toxic for aquatic organisms R52/53 Harmful to aquatic organisms, may cause long-term adverse effects in the aquatic environment.</p> <p>Additional information: Risk assessment, please refer to chapter 16.</p>				

4 First aid measures

General recommendation:	Take off contaminated clothing immediately. In case of health problems seek medical advice.
After inhaling:	Aerosol (droplets): may inflame the mucous membrane in the lungs causing a partial loss of function. This can be stabilized by giving the patient oxygen.
After skin contact:	Wash immediately with plenty of water and soap and eventually applying grease (fat) to the affected area. If skin irritation persists seek medical advice. Remove contaminated clothing immediately.
After eye contact:	Rinse cautiously with water and continue rinsing for min.15 minutes with eyelids open. Remove contact lenses if possible, continue rinsing even when contact with the eye is no longer painful. Seek medical advice immediately, bring the container or label and present it to the medical personnel
After swallowing:	Do not induce vomiting. Drink plenty of water or other liquids. Do not drink fruit juices, the esophagus could be inflamed. Eventually neutralize with active coal or another neutralizing agent.
Advice for medical first aid or special treatment:	-

5 Fire-fighting measures

Suitable extinguishing agents:	Water jet, extinguishing powder, CO ² .
Extinguishing media to avoid:	Water jet
Particular danger	Special hazards caused by the material, its products of combustion or resulting gases: Flammable. Vapors are heavier than the atmosphere. Explosive atmosphere possible even at slightly higher temperature.
Protective equipment:	Enter the danger zone only with a self-contained breathing apparatus. Avoid skin contact by the wearing of tightly closed chemical protection suits and by keeping a safe distance away.
Additional information:	Fire residues and contaminated extinguishing water must be disposed of according to official regulations.

6 Accidental release measures

person related measure:	Do not inhale vapors / aerosols. Avoid contact with eyes and skin.
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environmental protection:	Oxygen mask or self-contained breathing apparatus. Wear impermeable clothing. Take off contaminated clothing and shower. Ensure adequate ventilation. Do not allow undiluted product to reach sewage system or surface water systems. When product comes in contact with water or sewage systems contact proper authorities.
purification/absorption:	Absorb major quantities with liquid-binding material (sand, universal binders, diatomaceous, sawdust). Dispose of the material collected according to official regulations. Ensure adequate ventilation
additional advice:	Information for safe handling, see 7 Information for personal protection, see 8 Information referring to dangerous reactions, see 10 Information for disposal, see 13

7. Handling and storage

7.1 Handling:

Advice for safe contact:	Avoid skin and eye contact. Do not inhale aerosol (droplets). Wear protective clothing, eye protection and gloves. Ensure proper ventilation. Badly ventilated areas may require forced air ventilation. Keep container tightly locked.
Fire and explosion information:	Not required.
Additional information:	If used in an ultrasound device keep lid tightly locked before connecting with circuit. Do not remove lid before disconnecting from circuit.

7.2 Storage:

Requirements for storerooms and containers:	Packing material: plastics
Information about storage in one common facility:	Do not store with medical supplies, foodstuff or animal feed. Keep away from children.
Further information about storage conditions:	Temperature of storage: 0-25°C. Max. storage time: 2,5 years. Do not expose to direct sunshine. Keep container tightly locked.
Storage class:	8A, Combustible corrosive substances

8 Exposure controls and personal protection

8.1 Additional information about design of technical systems:

8.2 Components with critical values (that require monitoring) at the workspace:

AGW (Deutschland):	not determined
AGW (TRGS 900):	not determined
DNEL/DMEL-Value:	not determined
PNEC-Value:	not determined
Remarks:	The substance is not volatile.
Technical protection:	Concentrate and ready-to-use-solution should only be handled at room temperature (< 22°C) in a well-ventilated area to avoid formation of aerosols.
Amine, sum parameter. Measuring for example with a periodic test tube amine-test, quality check.	

8.3 Personal protective equipment

Respiratory protection:	not required by normal handling.
Skin protection:	protective clothing
Material of gloves:	Latex gloves
Protection provided:	<5 minutes are sufficient for one application. For longer applications butyl rubber gloves 0.4mm are recommended. For splash protection Latex and Rubber gloves are recommended
Eye protection:	Goggles or full face protection
Protective clothing:	Impermeable clothing, protective gloves and eyewear / face protection
Hygienic measures:	No drinking, eating or smoking at your workplace, after work hands and face should be washed.
Protective measures:	use only in well ventilated area

9 Physical and chemical properties

9.1 Appearance:

Form (condition of aggregation):	fluid
Colour:	clear
Odour:	alcoholic

9.2 Data relevant to product safety:

pH-value at 100 [g/l H ₂ O] and 20°C: [pH]	9-10
Change in condition:	
Boiling point/-range: [°C]	no data available
Flashpoint: [°C]	41°C in accordance with DIN EN ISO 3679
Flammability:	no data available
Ignition temperature: [°C]	no data available
Explosion risk:	no data available
Oxidizing properties:	no data available
Vapor pressure [h-Pa]	0.4 hPh (calculated)
Density: [g/cm ³]	1,005 – 1,015
Dissolubility (+declaration of solvent):	
Dissolubility in water [mg/l]	fully soluble with water
Coefficient n-Octanol/water	no data available
Viscosity:	no data available
Steam pressure: [%]	no data available
Speed of evaporation: [%]	no data available

9.3 Additional information:

10 Stability and reactivity

Conditions to be avoided:	No decomposition by proper storage and handling. Reacts with acid with heat/do not store in direct sunlight. Do not mix with oxidizing materials
Substances to be avoided:	Acids and oxidizing materials. When mixed with concentrated nitric acid, nitrosamine can be created as a dangerous bi-product of decomposition.
Additional information:	No data available

11 Toxicological information

11.1 General recommendation: -

Acute toxicity:

Acute toxicity by oral: LD50 rat (oral) > 1500 mg/kg (computed value)
Acute toxicity by inhalation:
Vapor: the vapor pressure of all the ingredients is so low that no danger exists by inhaling vapors from the concentrate or ready to use solution.
Dangers of aspiration:
Direct inhalation of aerosol droplets should be avoided.
Aerosol will irritate the eyes, airway and mucous membrane of the lungs.
Acute Toxicity by way of skin contact: LD50 rat (dermal) >1400->2800mg/kg
Skin irritation: corrosive (caustic)
Eye irritation: corrosive (caustic)
Sensitization: by skin contact
Toxicity by repeated exposure: not determined
Danger from aspiration: high
By aspiration the product irritates the airway and lungs.
Genotoxicity in vivo: not determined
Carcinogenicity: not determined
Reproductive toxicity: not determined
Teratogenicity: not determined

Additional information:

When the safety precautions are properly followed the product can be used safely.
Primary irritation:
Skin: Irritates skin and mucous membrane.
Eyes: Irritates and can cause irreversible eye damage.
Sensitization: can occur by skin contact.
After analysis in accordance with the current EC regulations for mixtures the product has exhibited the following hazards:
- Causes severe irritation
- Sensitization can occur by skin contact
- Harmful when inhaled, ingested or in contact with skin

12 Ecological information

12.1 Product:

Toxicological information:

Persistence and degradability:
The ingredients of the product are biologically and abiotically degradable.
When properly used the diluted product solution can be disposed of in the local sewage system. Therefore information towards toxicity affecting fish and daphnia is not relevant.
The product is de-toxicated by diluting with normal tap water before it enters the sewage system.
The individual ingredients of the product are biologically degraded in the sewage treatment plant. Disposed of with the sewage sludge or binds with solid sewage particles before entering the on-site pre-flooder.
Effects to sewage treatment facilities:
No negative effects to sewage treatment facilities can be expected when properly diluted mixtures are disposed of in the sewage system.
Results of PBT and vPvB assessment:
The ingredients concur with the current criteria of REACH regulations.
No PBT or vPvB substances.

13 Disposal details

13.1 Product	
Recommendation:	Disposal in accordance with official regulations. Diluted product solution can be disposed of in the local sewage system. EVC Waste Code 07 06 00 (Waste from HZVA pertaining to grease, lubricants, detergents ,disinfectants and toiletries.)
General recommendation:	Disposal according to national regulations

13.2 Uncleaned Packagings	
Recommendation:	Dispose of residual waste. Recycle only after thoroughly cleaning. EVC Waste Code 15 01 10 (Packaging containing hazardous residual waste or that have been contaminated with hazardous residual waste.) Disposal according to national regulations

14 Transport information

14.1 Land transport ADR/RID and GGVSE (cross-border / domestic):	
UN-Number:	
ADR / RID-Class:	1993
GGVSE-Class:	3
Designation of goods::	FLAMMABLE LIQUID N.O.S. (1-PROPANOL)
Packaging Group:	III
Additional information:	274, 601, 640E
Category of tunnel:	D/E

14.3 Seagoing vessel transport IMDG/GGVSea	
UN-Number:	1993
IMDG/GGVSea:	3
Designation of goods:	FLAMMABLE LIQUID N.O.S. (1-PROPANOL)
EmS-No.:	F-E, S-E; Staukategorie A
Class:	3
Packaging Group:	III
marine pollutant:	-

14.4 Carriage By Air ICAO-TI und IATA-DGR	
UN -Nummer:	1993
ICAO/IATA-Nummer:	-
Designation of goods:	FLAMMABLE LIQUID N.O.S. (1-PROPANOL)
Packaging group:	III

14.5 Additional information:

15 Regulatory information

15.1 Labeled in accordance with EC regulations	
	This product is classified and labeled in accordance regulation (EC) Nr. 1272/2008
	Elements of labeling and preventive declarations:



Hazard pictogram:

Signal word: Danger

Hazards

H226 flammable liquid and vapor
H302 harmful if swallowed
H314 causes severe skin burns and eye damage.
H400 very toxic to aquatic life.

Precautions:

P260 Do not breathe vapours/spray.
P264 Wash hands thoroughly after handling.
P270 Do not eat, drink or smoke when using this product.
P273 Avoid release to the environment.
P280 Wear protective gloves/protective clothing/eye protection/face protection.
P303+P352+353 IF ON SKIN (or hair): Remove/Take off immediately all contaminated clothing. Rinse skin with water/shower.
P363 Wash contaminated clothing before reuse.
P305+353+338 IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.
P301+P330+P331 IF SWALLOWED: rinse mouth. Do NOT induce vomiting.
P312 feelings of nausea. Contact POISON INFORMATION CENTER or contact a physician
P304+P340 IF INHALED: provide victim with fresh air and place in a position that provides ease in breathing
P102 Keep out of reach of children.
P235+P410 Keep cool. Protect from sunlight.
P405 Store under lock and key.

- National regulations

Ingredients are specified in MAK-List 2007 appendix 4 and AGW (Arbeitsplatzgrenzwerte) specified in TRGS 900:2006
Statutory order on hazardous incidents: product does not fall under this regulation
Water Hazard Class: 2 (self-rating)

Safety regulations:

Employment restrictions: For pregnant women and persons under 18: yes
Chemical Prohibition Ordinance: yes

Classification according to medical device directive 93/43/EU, class IIb, UMDNS-No. 17-920

Hazard statements which are referred to in part 2 and 3 according to regulation (EC) Nr. 1272/2008

H225 Highly flammable liquid and vapour., Cat. 2
H302 harmful if swallowed, acute toxicity: Cat 4 (oral)
H312 Harmful in contact with skin. Acute Toxicity: Cat 4 (dermal)
H314 Causes severe skin burns and eye damage. Corrosive to skin: Cat 1B
H315 causes skin irritation, Cat. 2
H318 causes severe eye damage, Cat. 1
H336 vapors may cause drowsiness or dizziness., Cat. 3
H400 very toxic for aquatic life, acute aquatic toxicity: Cat 1
H410 Harmful to aquatic life with long lasting effects. Chronically hazardous to water: Cat 3

According to Regulation 67/548/EU

R11 highly flammable
R22 harmful if swallowed
R34 causes burns
R38 irritating to skin
R37/38 irritating to respiratory system and skin
R41 Gefahr ernster Augenschäden

R50 very toxic for aquatic life

R52/53 Harmful to aquatic organisms, may cause long-term adverse effects in the aquatic environment.

R67 vapors may cause drowsiness or dizziness.

Related EC-Directives:

Dangerous Preparation Directive (1999/45/EC), latest amendment by the directive (EC) No. 1907/2006

Dangerous substance directive (67/548/EEC), latest amendment by the directive 2009/2/EC

REACH Directive (EC) No. 1907/2006, latest amendment by the directive (EC) No. 552/2009

Directive (EC) No. 1272/2008 (CLP-(EC-GHS-) Directive)

16 Other data

These data are based on our present knowledge. However, they shall not constitute a guarantee for any specific product features and shall not establish a legally valid contractual relationship.

Legend: n.a. = non applicable
 * = modifications to last version