



SAFETY DATA SHEET

In accordance with Regulation (EC) No 1907/2006 (REACH) and Regulation (EU) 2020/878

Date of issuance: 05.05.2022	Issue: 03/2022
According to Regulation (EU) 1907/2006 (REACH)	Supersedes issue: 02/2018

1. IDENTIFICATION OF THE PREPARATION AND THE COMPANY

- 1.1. Product identifier:** Commercial product name: **QUARTYSEPT**
Medical device class IIa
Unique Formula Identifier (UFI): **QQ30-J00J-J00S-8Q84**
- 1.2. Relevant identified uses of the mixture and uses advised against:** Ready for use solution for fast disinfection of surfaces of non-invasive medical devices
- 1.3. Company identification:** ZHIVAS Ltd, 36, Dondukov Blvd, 1000 Sofia, Bulgaria
Postal address: 14, Assen Yordanov Blvd., Sofia 1592
Telephone/Fax: + 359 2 981 78 23
E- mail: zhivas@techno-link.com,
Internet: www.zhivas.com
+ 359 2 981 78 23 (Zhivas Ltd., Sofia (working hours))
- 1.4. Emergency telephone :**

2. HAZARDS IDENTIFICATION

- 2.1 Classification of the mixture:** The product is classified as hazardous in accordance with the Regulation (EU) 1272/2008 (CLP) (and subsequent amendments).
- Hazard class and hazard category**
Flammable liquid, Category 3, H226
Serious eye damage/ irritation, Category 2, H319
Specific target organ toxicity - single exposure, Category 3, H336
- 2.2 Label elements**
- Hazard-determining components of labelling:**
Propane-2-ol; Ethanol; Benzalkonium chloride
- Pictograms:**



(GHS02) (GHS07)



Signal word: Warning

Hazard statements:

H226 Flammable liquid and vapours.

H319 Causes serious eye irritation.

H336 May cause drowsiness and dizziness.

Precautionary statements:

P102 – Keep out of reach of children

P210 - Keep away from heat/sparks/open flames/hot surfaces. — No smoking.

P305+P351+P338 – IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.

P337+P313. If eye irritation persists: Get medical advice/attention.

P403+P 233 Store in a well-ventilated place.Keep container tightly closed.

2.3. Other hazards

- On the basis of the available data, it does not contain substances with PBT or vPvB properties in a percentage more than 0,1 %.

- Ecotoxicological information: The mixture does not contain components considered to have endocrine disrupting properties under REACH Regulation Article 57(f) or Commission Delegated Regulation (EU) 2017/2100 or Commission Regulation (EU) 2018/605 at levels of 0.1% or higher.

- Toxicological information: The mixture does not contain components that are considered to have endocrine disrupting properties under REACH Regulation , Article 57(f) or Commission Delegated Regulation (EU) 2017/2100, or Commission Regulation (EU) 2018/605 at levels of 0.1% or higher.

3. COMPOSITION/ INFORMATION ON INGREDIENTS

3.2. Mixture

The preparation is a mixture – aqueous solution of alcohols and quaternary ammonium salt

Component	CAS №	EC №	Concentration g/100g	Classification (Reg.(CE) 1272/2008)
Propane-2-ol	67-63-0	200-661-7	20	Flam.Liq.2; H225 Eye Irrit.2; H319 STOT SE 3; H336
Ethanol	64-17-5	200-578-6	10	Flam.Liq. 2; H225 Eye Irrit.2; H319
Benzalkonium chloride	68424-85-1	270-325-2	0.20	Acute Tox. 4; H302 Skin Corr. 1B; H314 Aquatic Acute 1; H400 Aquatic Chronic 1; H 410

For the wording of the listed hazard statements refer to section 16.



4. FIRST AID MEASURES

4.1. Description of first aid measures

- Inhalation:** Take the subject out into fresh air. Maintain normal body temperature. If symptoms persist call a physician.
- Eye contact:** Rinse immediately with plenty of water - also under the eyelids - for 15 - 20 minutes. Consult with an ophthalmologist.
- Skin contact:** Not applicable
- Ingestion:** Rinse the mouth with plenty of water (if only the person is conscious). Do not induce vomiting. If symptoms persist call a physician

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

Principal routes of exposure:

- Eye contact:** Irritating to eyes.
- Skin contact:** May cause irritation by skin contact.
- Ingestion:** Ingestion of this material may cause irritation to mucous membranes, symptoms such as nausea, vomiting, gastric distress
- Inhalation:** Inhalation may cause irritation.

4.3. Indication of any immediate medical attention and special treatment needed:

In case of eye contact and ingestion with symptoms of irritation, immediately call for medical help. For specialist advice physicians should contact the Poisons Information Service.

5. FIRE-FIGHTING MEASURES

- 5.1. Extinguishing media:** The mixture is flammable. Water spray jet, alcohol resistant foam, CO₂, dry powder
- 5.2. Special hazards, arising from the preparation itself** Vapors are heavier than air and may spread along floors In case of fire, toxic gases may be formed: CO, CO₂.
- In case of burning of the PE package the following toxic gases may be formed: CO, CO₂, light hydrocarbons.
- 5.3. Advice for firefighters** Do not use water for extinguishing, only for cooling of containers. Cool closed containers exposed to fire with water spray.
- Standard protective equipment should be worn by fire-fighters. In the event of a large fire toxic fumes containing oxides of carbon may be formed, which would necessitate the use of a self contained breathing apparatus.

6. ACCIDENTAL RELEASE MEASURES

- 6.1. Personal precautions:** Avoid direct contact with the eyes and skin. Remove all sources of ignition.
- Ensure good ventilation of the workplace.



- 6.2. Environmental precautions:** Should not be released in large quantities in the environment. Avoid subsoil penetration. The small releases can be diluted with plenty of water.
- If the product contaminates the environment inform respective authorities and proceed according to the local legislation
- 6.3. Methods and material for containment and cleaning up:** Absorb by means of suitable inert materials (cloth, fleece, sand, sawdust or soil). The contaminated material should be collected mechanically for subsequent disposal. Wash with water and detergent...
- 6.4. Reference to other sections:** Refer to protective measures, listed in sections 7 and 8

7. HANDLING AND STORAGE

- 7.1. Precautions for safe handling** Follow the operating instructions as specified on the label. Avoid direct contact with the eyes and skin. Do not allow disposal of the preparation into the environment. Do not use near possible sources of ignition
- 7.2. Conditions for safe storage, including any incompatibilities** Store in well closed original package, in dry and well ventilated premises, at temperatures between 0°C and 30°C. Do not expose to direct sunlight, away from food and beverages.
- 7.3. Specific end uses** For professional use only

8. EXPOSURE CONTROLS/ PERSONAL PROTECTION

8.1. Exposure limit values

Limit values for some ingredients in the air of the work environment

Ingredient	CAS Number	EC Number	Exposure 8 hours (Permissible exposure limit)	Exposure 15 min. (Ceiling Limit Value)	Basis
Propane-2-ol (Isopropyl alcohol)	67-63-0	200-661-7	980 mg/m ³ (400 ppm)	1225 mg/m ³ (490 ppm)	Bulgarian legislation
Ethyl alcohol	64-17-5	200-578-6	1000 mg/m ³	500 mg/m ³	

DNEL/DMEL and PNEC values

There are no data available on the preparation itself.

DNEL (The derived no-effect level) Values for Propan-2-ol (CAS 67-63-0)

Limit Value type (End use)	Exposure route	Exposure frequency	Limit value
Consumer	Inhalation	Short-term (acute)	1036 mg/m ³
Consumer	Dermal	Long-term (repeated)	319 mg/kg
Consumer	Inhalation	Long-term (repeated)	89 mg/m ³
Consumer	Oral	Long-term (repeated)	26 mg/kg
Industrial	Dermal	Long-term (repeated)	888 mg/kg
Industrial	Inhalation	Long-term (repeated)	500 mg/m ³

**PNEC (The predicted no-effect concentration) Values for Propan-2-ol (CAS 67-63-0)**

Limit Value type (End use)	Exposure route	Limit value
Industrial	Fresh water (including sewage plant)	140,9 mg/l
Industrial	Marine water	140,9 mg/l
Consumer	Fresh water sediment	552 mg/kg
Consumer	Marine sediment	552 mg/kg
Industrial	Soil	28 mg/kg

8.2. Exposure controls

General protective measures: No further data, see item 7.

Hygiene measures: General and local ventilation is recommended in order to control limit values of both alcohols in the air of the workplace.

Respiratory protection: In case of exceeding the limit values for work environment – use filter respiratory devices.

Hand protection: Not applicable

Eye protection: Avoid contact with eyes. Use tight goggles by prolonged manipulation.

Body protection: Protective clothing. Wash off any dirt that gets onto skin with lots of water.

9. CHEMICAL AND PHYSICAL PROPERTIES**9.1. Information on basic physical and chemical properties**

Physical state:	Transparent Liquid
Colour:	Colorless
Odour:	Specific of alcohols
Odour threshold	Not applicable
pH (as supplied)	5.0 – 8.0 (20° C)
Boiling point	No data
Flash point	37°C
Flamability	Flammable
Explosive properties	Product is not explosive
Oxidizing properties	No
Density , 20 °C	0,940 - 0,960 g/cm ³
Solubility in organic solvents	Soluble
Solubility in water	Fully miscible
Partition coefficient	Not applicable
Viscosity	Not applicable
Vapour density	No data

9.2. Other information – none**10. STABILITY AND REACTIVITY**



10.1. Reactivity	Flammable. No dangerous reaction known under conditions of normal use.
10.2. Chemical stability	Stable under recommended storage and handling conditions (see section 7).
10.3. Possibility of hazardous reactions	Vapors may form explosive mixtures with air Reaction with oxidizing agents Exothermic reaction with strong acids.
10.4. Conditions to avoid:	High temperatures over 30°C, sources of heat and direct sunlight
10.5. Incompatible materials:	Strong oxidizers and acids.
10.6. Hazardous decomposition products:	Not expected, if followed the instructions for use. By burning toxic gases are released: CO, CO ₂ , nitrous fumes.

11. TOXICOLOGICAL INFORMATION

11.1. Information on toxicological effects

Acute toxicity

Acute oral toxicity	LD50 oral, rat > 2000 mg/kg body weight.
Acute inhalation toxicity	Dose: > 20 mg/l, 4h
Acute dermal toxicity	No information available.

11.2. Additional information:

The mixture does not contain components considered to have endocrine disrupting properties under REACH , Article 57(e) or Commission Delegated Regulation (EU) 2017/2100 or Commission Regulation (EU) 2018/605 at levels of 0.1% or higher.

12. ECOLOGICAL INFORMATION

12.1 Ecotoxicity:

Classified under the conventional method as: No hazardous for the environment

Toxicity of the active ingredients.

Aquatic toxicity		Ethanol	Propan-2-ol
Acute (short-term) fish toxicity			
Parameter:		LC50	
Species:		Pimephales promelas (fathead minnow)	
Effective dose:		11000 mg/l	9640
Exposure time:		96 h	96 h
Acute (short-term) daphnia magna toxicity			
Parameter:		EC50	
Species:		Daphnia magna (Big water flea)	
Effective dose:		9268 mg/l	13299 mg/l
Exposure time:		48 h	48 h

12.2 Persistence and degradability:

No information available

12.3 Bioaccumulative potential:

No information available



12.4 Mobility in soil:

No information available

12.5 Results of PBT and vPvB assessment:

Unknown to product

12.6 Endocrine disrupting properties:

The mixture does not contain components that are considered to have endocrine disrupting properties under REACH Regulation Article 57(e) or Commission Delegated Regulation (EU) 2017/2100 or Commission Regulation (EU) 2018/605 at levels of 0.1% or higher.

12.7 Other adverse effects:

No other adverse environmental impacts are expected (such as ozone destruction, potential for photochemical ozone creation, potential for global warming).

13. DISPOSAL CONSIDERATIONS

13.1 Waste treatment methods

Disposal should be in accordance with the local, state or national legislation
Contain, absorb and transfer to disposable container.
Dilute with plenty of water. Clean thoroughly.
Must not be disposed together with household garbage. Do not discharge into drains or the environment; dispose to an authorized waste collection point.

European waste catalogue

18 01 06* - chemicals consisting of or containing dangerous substances

15 01 10* - packing containing dangerous substances

13.2 Contaminated packaging

Empty packaging should be taken to an approved waste handling site for recycling or disposal.

14. TRANSPORT INFORMATION

Land transport (ADR/RID)

14.1. UN number: 1993

14.2. Proper shipping name: FLAMMABLE LIQUID, N.O.S. (Ethanol, Isopropanol)

14.3. Class: 3

14.4. Packing group: III



14.5. Environmentally hazardous: no

14.6. Special precautions for use: no

For limited quantities up to 5 L

Inland waterway transport (ADN)
Not relevant.

Air transport (IATA)

14.1. UN number: UN 1993

14.2. Proper shipping name: FLAMMABLE LIQUID, N.O.S. (Ethanol, Isopropanol)

14.3. Class: 3

14.4. Packing group: III

14.5. Environmentally hazardous:

14.6. Special precautions for use: no



Sea transport (IMDG)



ZHIVAS Ltd.

- 14.1. UN number: UN 1993
- 14.2. Proper shipping name: FLAMMABLE LIQUID, N.O.S. (Ethanol, Isopropanol)
- 14.3. Class: 3
- 14.4. Packing group: III

- 14.5. Environmentally hazardous: -
- 14.6. Special precautions for use: no
- 14.7. Transport in bulk: not relevant.



For limited quantities up to 5 L

15. REGULATORY INFORMATION

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

REGULATION (EC) No 1907/2006 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 18 December 2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH), establishing a European Chemicals Agency, amending Directive 1999/45/EC and repealing Council Regulation (EEC) No 793/93 and Commission Regulation (EC) No 1488/94 as well as Council Directive 76/769/EEC and Commission Directives 91/155/EEC, 93/67/EEC, 93/105/EC and 2000/21/EC

REGULATION (EC) No 1272/2008 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 16 December 2008 on classification, labelling and packaging of substances and mixtures, amending and repealing Directives 67/548/EEC and 1999/45/EC, and amending Regulation (EC) No 1907/2006;

REGULATION (EU) 2020/878. amending the annex II of Regulation(EC) 1907/2006 of the European Parliament and of the Council on the Registration, Evaluation, Authorization and Restriction of Chemicals (REACH);

REGULATION (EC) No 648/2004 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 31 March 2004 on detergents;

DIRECTIVE 1999/45/EC OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 31 May 1999 concerning the approximation of the laws, regulations and administrative provisions of the Member States relating to the classification, packaging and labelling of dangerous preparations;

ESIS : European chemical Substances Information System;

COMMISSION DIRECTIVE 2001/60/EC of 7 August 2001 adapting to technical progress Directive 1999/45/EC of the European Parliament and of the Council concerning the approximation of the laws, regulations and administrative provisions of the Member States relating to the classification, packaging and labelling of dangerous preparations;

Council Directive 91/689/EEC of 12 December 1991 on hazardous waste;

European Parliament and Council Directive 94/62/EC of 20 December 1994 on packaging and packaging waste;

DIRECTIVE 2008/112/EC OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 16 December 2008 amending Council Directives 76/768/EEC, 88/378/EEC, 1999/13/EC and Directives 2000/53/EC, 2002/96/EC and 2004/42/EC of the European Parliament and of the Council in order to adapt them to Regulation (EC) No 1272/2008 on classification, labelling and packaging of substances and mixtures.

15.2. Chemical safety assessment

For this mixture a chemical safety assessment has not been carried out.



16. OTHER INFORMATION

The information given corresponds to the current state of our knowledge and experience of the product, and is not exhaustive. This applies to product, which conforms to the specification unless otherwise stated. In this case of combinations and mixtures one must make sure, that no new dangers can arise.

In any case the user is not exempt from observing all legal, administrative and regulatory procedures, relating to the product, personal hygiene and protection of human welfare and the environment.

Section 1.1: Added Unique Formula Identifier (UFI)

SDS updated according to the requirements of Regulation (EU) 2020/878

Hazard statements (GHS):

- H226 Flammable liquid and vapors.
- H319 Causes serious eye irritation.
- H336 May cause drowsiness and dizziness.
- H302 Harmful if swallowed
- H314 Causes severe skin burns and eye damage
- H400 Very toxic to aquatic life