SAFETY DATA SHEET REGULATION (EC) No: 1907/2006 (REACH)

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

1.1. Product identifier:

Product name: Bradoplus hand and skin disinfectant

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

Biocidal product, product type: PT1

Field of application: hand and skin disinfectant for skin disinfection, hygienic hand disinfection and surgical hand disinfection (surgical washing).

For professional use.

Ready-to-use liquid, use as a concentrated, undiluted product.

1.3. Details of the supplier of the safety data sheet

Manufacturer:	Florin Ltd
Address:	17. Kenyérgyári út, Szeged, 6725
Phone Number:	0062 592 100
Fax:	0062 592 145
E-mail:	info@florin.hu

1.4. Emergency telephone number

Health Toxicology Information Service (HTIS)

Address:	2. Nagyvárad tér, Budapest, 1096, Hungary
Telephone:	+36 80 201 199
	+36 1 476 6464

SECTION 2: Hazards identification

2.1. Classification of the substance or mixture

Determination of the product: mixture

Classification according to 1272/2008/EC regulation

Flam. Liq. 2	H225
Aquatic Chronic 3	H412

The full text for all Classification and Hazard Statements is displayed in Section 16.

2.2. Label elements

Hazard pictogram:

Word of caution: Danger

Hazard statements:

H225 Highly flammable liquid and vapour.

H412 Harmful to aquatic life with long lasting effects.

Precautionary statements:

P102 Keep out of reach of children.

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

P233 Keep container tightly closed.

P403+P235 Store in a well-ventilated place. Keep cool.

Additional informations: Do not mix with other cleaning and disinfecting agents!

Biocidal active substances:

Ethanol (96.5%) 72.9% (CAS: 64-17-5)

Biphenyl-2-ol 0.2% (CAS: 90-43-7)

Alkyl (C12-C16) dimethylbenzylammonium chloride 0.1% (CAS: 68424-85-1).

Other Ingredients: C8-C10 Fatty Acid Ethoxylate, Ion Exchanged Water.

Hazardous components which must be listed on the label:

Ethanol, Biphenyl-2-ol, Alkyl (C12-C16) dimethylbenzylammonium chloride.

2.3. Other hazards: PBT or vPvB criteria: Not applicable. None known.

SECTION 3: Composition/information on ingredients

3.2. Mixtures

Ingredients	EU-number	CAS-number	Conc. (%)	Classification 1272/2008/EK	Type
Ethanol	200-578-6	64-17-5	<73	Flam. Liq. 2 H225	(2)
Biphenyl-2-ol	201-993-5	90-43-7	≤0,20	Skin Irrit. 2 H315 Eye Irrit.2 H319 STOT SE 3 H335 Aquatic Acute 1 H400 Aquatic Chronic 1 H410	(1)
Alkyl (C12-C16) dimethylbenzyl ammonium chloride	270-325-2	68424-85-1	≤0,10	Acute Tox. 4, H302 Skin Corr. 1B H314 Aquatic Acute 1 H400 Aquatic Chronic1 H410 (M:10)	(1)

Type:

(1) Material classified according to health or environmental danger

(2) Material has occupational exposure limit

(3) Material meets the PBT criteria according to XIII. Annex of 1907/2006/EC decree

(4) Materials meet the vPvB criteria according to XIII. Annex of 1907/2006/EC decree

(5) Substance subject to authorization Annex XIV to Regulation (EC) No 1907/2006 Annex, or SVHC of particular concern. Occupational exposure limits, if available, are detailed in section 8.

REACH registration number:

Ethanol: 01-2119457610-43-0147

Biphenyl-2-ol: 01-2119511183-53-000

Alkyl (C12-C16) dimethylbenzylammonium chloride: 01-2119970550-39

The full text for all Classification and Hazard Statements is displayed in Section 16.

SECTION 4: First aid measures

4.1. Description of first aid measures

Inhalation: Remove the injured person to fresh air, keep at rest in a position comfortable for breathing, loosen tight clothing. If unconscious, place in recovery position and get medical attention.

Skin contact: Remove contaminated clothing and footwear, wash affected skin area thoroughly with plenty of water. Get medical attention if symptoms occur.

Eye contact: Rinse the eyes with running water for at least 10 minutes, pulling the edges of the eyelids apart and constantly moving the eyeball. If symptoms persist for a long time, consult a specialist.

Ingestion**:** If swallowed, rinse mouth thoroughly, then drink plenty of water and seek medical advice immediately. Do not induce vomiting.

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

No data is available on the product. See Section 11 for information on ingredients.

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

Treat symptomatically. No special treatment.

SECTION 5: Firefighting measures

5.1. Extinguishing media

Suitable extinguishing media: water spray, dry powder, alcohol-resistant foam, CO_2.

Unsuitable extinguishing media: strong jet water

5.2. Special hazards arising from the substance or mixture

Special hazards arising from the substance or mixture:

Fire or heating may increase the pressure and cause the container to rupture.

Ethanol vapors mix well with air and may form an explosive mixture, exploding on ignition of an air source containing 3.3 to 19% by volume of ethanol vapor.

After dilution with a significant amount of water, the preparation loses its flammability.

Decomposition products may include the following materials: carbon dioxide, carbon monoxide.

5.3. Advice for firefighters

Protective measures: In the event of a large fire, wear protective clothing and self-contained breathing apparatus in a closed or poorly ventilated area.

Water spray or water mist may be used to cool containers exposed to fire.

SECTION 6: Accidental release measures

6.1. Personal precautions, protective equipment and emergency procedures

Only emergency personnel can be on site, other people must be removed.

Personal precautions: Ensure adequate ventilation.

Open flames, sources of ignition and sparks must be removed.

6.2. Environmental precautions

Do not allow product or unused product or packing material to reach ground water, water course or sewage system.

6.3. Methods and material for containment and cleaning up

Absorb large spills or spillage with inert absorbent material (sand, ground) and collect in closed, labeled container, kept away from heat and sources of ignition. Contaminated material must be disposed of in accordance with regulations.

6.4. Reference to other sections

Personal protection: Check SECTION 8.

SECTION 7: Handling and storage

7.1. Precautions for safe handling

Keep away from heat, sources of ignition. Avoid contact with eyes. Do not eat, drink or smoke during use. Do not mix with other cleaning and disinfecting agents.

7.2. Conditions for safe storage, including any incompatibilities

Store in the original, intact, unopened container, dry, cool but frost-free, well-ventilated place away from open flames and sources of ignition. Store as described storage conditions.

7.3. Specific end use(s).

The uses specified in 1.2. section, hand disinfection.

SECTION 8: Exposure controls/personal protection

8.1. Control parameters

Name of ingredient	Exposure threshold limit According to 5/2020. (II. 6.) ITM regulations
Ethanol	TWA value: 1900 mg/m^3 STEL-value: 3800 mg/m^3

8.2. Exposure controls

Personal protective equipment: No personal protective equipment required when the product is used properly and for its intended purpose.

General protective and hygiene measures: Avoid contact with eyes, ingestion and inhalation of vapors. Do not eat, drink or smoke when using the appliance. Do not touch electrical equipment until your hands are completely dry.

SECTION 9: Physical and chemical properties

9.1. Information on basic physical and chemical properties

a) Appearance:	colorless, clear liquid
b) Odour:	Scented: slightly fragrant Without scent: alcoholic odor
c) Odour threshold:	Not applicable
d) pH:	6,5-8,0
e) Melting point/freezing point:	Not applicable
f) Initial boiling point and boiling range:	not specified for the mixture
g) Flash point:	23°C
h) Evaporation rate:	not specified for the mixture
i) Flammability (solid, gas):	not flammable
j) Upper/lower flammability	

or explosive limits:	Not applicable
k) Vapour pressure:	No data available
l) Vapour density:	No data available
m) Relative density:	0,86-0,875 g/cm^3
n) Solubility(ies):	Soluble with water in any concentration.
o) Partition coefficient n-octanol/water:	No data available
p) Auto-ignition temperature:	not self-igniting
q) Decomposition temperature:	not specified for the mixture
r) Viscosity:	not specified for the mixture
s) Explosive properties:	not explosive
t) Oxidising properties:	does not show oxidizing properties

9.2. Other informations

No further information is available.

SECTION 10: Stability and reactivity

10.1. Reactivity

No specific data are available on the reactivity of this product or its ingredients.

10.2. Chemical stability

The product is stable at the required storage temperature under normal working conditions.

10.3. Possibility of hazardous reactions

Under normal conditions of storage and use, hazardous reactions will not occur.

10.4. Conditions to avoid

Sunlight, radiant heat, heating, ignition source, sparks, open flame.

10.5. Incompatible materials

Other cleaning and disinfecting agents.

10.6. Hazardous decomposition products

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

SECTION 11: Toxicological information

Targeted toxicological studies have not been performed on the product. The human health assessment was made solely on the basis of its composition, the toxicological data for each component, the concentrations and classifications given in section 3, and the concentration limits of Regulation (EC) No 1272/2008.
The product is physically hazardous, flammable.

11.1. Information on toxicological effects

a) Acute toxicity: not specified for the mixture.

Substance(s):

Ingredients	Information
Biphenyl-2-ol	Acute toxicity: 2761mg/kg (calculated) LD_{50} (oral, rat): 2733 mg/kg LD_{50} (skin, rat): > 5000 mg/kg LC_{50} (inhalation, rat): > 0,036 mg/m^3 4h

Ingredients	Information
Alkyl (C12-C16) dimethylbenzylammonium chloride	LD_{50} (oral, rat): 795 mg/kg – OECD 401 LD_{50} (skin, rabbit): 3412 mg/kg ATE_{oral}: 1590 mg/kg

b) Skin corrosion / irritation: not specified for the mixture.
Substance(s):

Ingredients	Information
Biphenyl-2-ol	Skin: moderately irritating (rabbit)
Alkyl (C12-C16) dimethylbenzylammonium chloride	Harmful in contact with skin, corrosive to the skin.

c) Serious eye damage / eye irritation: not specified for the mixture.
Substance(s):

Ingredients	Information
Ethanol	Contact with eyes may result in irritation and redness
Biphenyl-2-ol	Contact with eyes may result in serious eye damage.
Alkyl (C12-C16) dimethylbenzylammonium chloride	Eyes: severely irritating (rabbit)

d) Respiratory or skin sensitization: no special information available.

e) Germ cell mutagenicity: no special information available.

f) Carcinogenicity: no specific information available

g) Reproductive toxicity: not specified for the mixture.
Substance(s):

Ingredients	Information
Biphenyl-2-ol	NOAEL (rat, developmental toxicity): 250 mg/kg – OECD 414

h) Specific target organ toxicity - single exposure (STOT): no specific information available

i) Specific target organ toxicity - repeated exposure (STOT): not specified for the mixture.
Substance(s):

Ingredients	Information
Biphenyl-2-ol	LOAEL (male, rat, 2years): 200mg/kg – OECD 453 LOAEL (female, rat, 2years): 647mg/kg – OECD 453 NOAEL (rat, 21days): ≥1000mg/kg – OECD 410

j) Aspiration hazard: no special information available

SECTION 12: Ecological information

Ecological studies have not been performed on the product. It has been assessed solely on the basis of its composition, the data for each component, the concentrations and classifications given in section 3, and the concentration limits of Regulation (EC) No 1272/2008.
The product is classified as Chronic Aquatic Toxicity, Aquatic Chronic 3.

12.1. Toxicity: not specified for the mixture.

Substance(s):

Ingredients	Information
Biphenyl-2-ol	LC_{50} (fish, 96hours): 4,5 mg/l EC_{50} (Daphnia, 48hours): 2,7 mg/l EC_{50} (alga, 72hours): 3,57 mg/l NOEC (alga, 72hours): 0,468 mg/l Chronic NOEC (fish, 21days): 0,036mg/l Chronic NOEC (Daphnia magna, 21days): 0,009mg/l
Alkyl (C12-C16) dimethylbenzylammonium chloride	Acute LC_{50} (hal, 96 hours): 0,515 mg/l Acute LC_{50} (Daphnia magna, 48 hours): 0,016 mg/l Acute EC_{50} (alga, 96 hours): 0,03 mg/kg Chronic NOEC (hal, 28 days): 0,0322 mg/l Chronic NOEC (Daphnia magna, 21 days): 0,0125 mg/l Chronic LOEC (alga, 96 hours):0,0025 mg/l

12.2. Persistence and degradability: not specified for the mixture.

Substance(s):

Ingredients	Information
Biphenyl-2-ol	Readily biodegradable
Alkyl (C12-C16) dimethylbenzylammonium chloride	Readily biodegradable

12.3. Bioaccumulative potential: not specified for the mixture.

Substance(s):

Ingredients	Information
Biphenyl-2-ol	Log Pow: 3,18 – OECD 107
Alkyl (C12-C16) dimethylbenzylammonium chloride	Log Pow 0,004

12.4. Mobility in soil: not specified for the mixture.

Substance(s):

Ingredients	Information
Biphenyl-2-ol	Log Koc: 2,4-2,6

12.5. Results of PBT and vPvB assessment:

Not applicable.

12.6. Other adverse effects:

No known significant effects or critical hazards.

SECTION 13: Disposal considerations

13.1. Waste treatment methods

Dispose of waste / uncleaned packaging in accordance with applicable legislation.

SECTION 14: Transport information

14.1. UN-number	1170
14.2. UN proper shipping name	Ethanol solution
14.3. Transport hazard class(es)	3
14.4. Packing group	II.
14.5. Environmental hazards	none
14.6. Special precautions for user	none

14.7. Transport in bulk according to
Annex II of Marpol and the IBC Code not applicable

SECTION 15: Regulatory information

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

Considered European Union laws and regulations:

- Regulation (EC) No 1272/2008 on Classification, Labeling and Packaging of substances and mixtures (CLP Regulation)
- Regulation (EC) No 1907/2006 on the Registration, Evaluation, Authorization and Restriction of Chemicals (REACH)
- REGULATION 2015/830 of 28 May 2015 amending Regulation (EC) No 1907/2006 of the European Parliament and of the Council on the Registration, Evaluation, Authorization and Restriction of Chemicals (REACH) (Text with EEA relevance)
- Regulation (EU) 528/2012 on the marketing and use of biocidal products

Related Hungarian laws and regulations:

- 2000. year XXV. Act on Chemical Safety
- Decree 44/2000 (XII.27.) EüM on the detailed rules of certain procedures and activities related to dangerous substances and dangerous preparations
- 5/2020. (II. 6.) ITM Decree on the protection of the health and safety of workers exposed to chemical pathogens
- CLXXXV of 2012. Act on Waste Management
- Decree 72/2013 VM KöM on the list of wastes
- 225/2015 Government Decree on the conditions for carrying out activities related to hazardous waste
- 2015 LXXXIX. Act promulgating the consolidated text of Annexes A and B of the European Agreement concerning the International Carriage of Dangerous Goods by Road (ADR), as amended and supplemented in 2011

15.2. Chemical safety assessment: No chemical safety report was prepared for the mixture.

SECTION 16: Other information

Abbreviations used in he safety data sheet:

ADR:	European Agreement concerning the International Carriage of Dangerous Goods by Road
ATE	Acute toxicity estimate
CAS:	Chemical Abstracts Service
COD:	Chemical Oxygen Demand
EC_{50}:	Half maximal effective concentration The concentration of a drug, antibody or toxicant which induces a response halfway between the baseline and maximum after a specified exposure time
HTIS:	Health Toxicology Information Service
LC_{50}:	Lethal Concentration for the 50 % of living organism.
LD_{50}:	Lethal Dose the amount of a material, given all at once, which causes the death of 50% (one half) of a group of test animals
LOAEL	Lowest Observed Adverse Effect Level
Log Kow:	Octanol-water partition coefficient
	The level of exposure to a substance above which humans should not be exposed,
NOAEL:	No-Observed-Adverse-Effect Level
NOEL:	No Observed Effect Level Concentration
NOEC:	No Observed Effect Concentration
OECD	Organisation for Economic Cooperation and Development

PBT: Persistent, Bioaccumulative, Toxic
PNEC: Predicted No Effect Concentration
The concentration of a chemical which marks the limit at which below no adverse effects of exposure in an ecosystem are measured
REACH: Registration, Evaluation, Authorisation and Restriction of Chemicals
TWA: Time weighted Average
the average exposure to a contaminant to which workers may be exposed without adverse effect over a period such as in an 8-hour day or 40-hour week (an average work shift).
STEL: Short-Term Exposure Limit
limit value above which exposure to a chemical substance should not occur and usually relates to a 15 minute reference period.
UN: four-digit numbers that identify hazardous materials, and articles (such as explosives, flammable liquids, oxidizers, toxic liquids, etc.) in the framework of international transport. Given by the United Nations
vPvB: very Persistent, very Bioaccumulative

Full text of classifications:

Acute Tox.	Acute toxicity
Aquatic Acute	Hazardous to the aquatic environment
Aquatic Chronic	Hazardous to the aquatic environment
Eye Irrit	Serious eye irritation
Flam. Liq.	Flammable liquid
Skin Irrit.	Skin irritation
Skin Corr.	Skin corrosion
STOT SE	Specific target organ toxicity — single exposure

Full text of H-statements:

H225	Highly flammable liquid and vapour.
H226	Flammable liquid and vapour.
H302	Harmful if swallowed.
H314	Causes severe skin burns and eye damage.
H315	Causes skin irritation.
H319	Causes serious eye irritation.
H335	May cause respiratory irritation.
H400	Very toxic to aquatic life
H410	Very toxic to aquatic life with long lasting effects.
H412	Harmful to aquatic life with long lasting effects.

Information for readers:
The information provided in this Material Safety Data Sheet is correct to the best of our knowledge, information and belief at the date of its publication. The safety data sheet describes the product in terms of safety requirements. The information given is designed only as guidance for safe handling, use, processing, storage, transportation, disposal and release and is not to be considered a warranty or quality specification.

Changes to the previous release during the revision: 1.4., 9.1., 16. sections and 10.3., 12.3., 12.5., 12.6. section titles were affected.

End of safety data sheet