

SAFETY DATA SHEET

Safety data sheet according to (EC) No. 1907/2006 & 2020/878.

SECTION 1: Identification of the substance/mixture and of the company/undertaking**1.1. Product identifier:**

RONDELL

This safety data sheet covers the following products:

RONDELL BLUE & RONDELL RED

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

Plaque disclosing agent.

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

Directa AB

Box 723

Tel. +46 850650575

SE-194 27 Upplands Väsby

Responsible person for the safety data sheet (e-mail): info@directadental.com

1.4. Emergency telephone number:

NHS (England or Wales): Dial 111 or 0845 4647 NHS 24 (Scotland): Dial 111

National Poisons Information Centre (Ireland): +353 (1) 809 2166 (8.00 a.m. to 10.00 p.m. 7 days a week).

Healthcare Professionals: +353 (1) 809 2566 (24-hour service)

SECTION 2: Hazards identification**2.1. Classification of the substance or mixture:**

CLP (1272/2008): None.

2.2. Label elements:

EUH208: Contains peppermint oil. May produce an allergic reaction.

EUH210: Safety data sheet available on request.

2.3. Other hazards:

PBT/vPvB: The ingredients are not considered PBT/vPvB according to criteria in Regulation 2023/707.

Endocrine disrupting properties: The substances are not identified as having endocrine disrupting properties in accordance with the criteria set out in Regulation 2023/707.

SECTION 3: Composition/information on ingredients**3.2. Mixtures:** Aqueous solution

% w/w	Substance name	CAS No.	EC No.	Index No.	REACH reg. No.	Classification	Note
<50	Glycerol	56-81-5	200-289-5	-	01-2119471987-18	None	1
<5	Ethanol	64-17-5	200-578-6	603-002-00-5	01-2119457610-43	Flam. Liq. 2;H225 Eye Irrit. 2;H319	2,3
<2.5	Erythrosine	16423-68-0	240-474-8	-	01-2120115909-50	Aquatic Chronic 2;H411	-
<0.2	Peppermint oil	8006-90-4	282-015-4	-	01-2119974601-36	Skin Sens. 1;H317 Skin Irrit. 2;H315 Eye Irrit. 2;H319 Aquatic Chronic 3;H412	-

1) The substance has an occupational exposure limit.

2) SCL (Specific Concentration limits) for classification: Eye Irrit. 2;H319: C ≥ 50% (REACH registrant).

3) The substance is an organic solvent.

Wording of hazard statements - see section 16.

SECTION 4: First aid measures**4.1. Description of first aid measures:**

Inhalation: Remove to fresh air. Keep at rest. In case of discomfort: Seek medical advice.

Skin contact: Remove all contaminated clothing. Wash skin with plenty of water and soap. If irritation persists: Seek medical advice.

Eye contact: Immediately flush with water or physiological salt water, holding eye lids open, remember to remove contact lenses, if any. If irritation persists: seek medical advice.

Ingestion: Rinse mouth and drink plenty of water. In case of discomfort: Seek medical advice.

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

May cause an allergic skin reaction. May cause slight eye irritation.

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

Show this safety data sheet to a physician or emergency ward.

SECTION 5: Firefighting measures

5.1. Extinguishing media:

Not combustible. Use suitable extinguishing media for fighting surrounding fire.

5.2. Special hazards arising from the substance or mixture:

Do not inhale smoke fumes. In case of fire, the product may form hazardous decomposition products: Oxides of carbon.

5.3. Advice for firefighters:

When extinguishing surrounding fires use breathing apparatus with an independent source of air.

SECTION 6: Accidental release measures

6.1. Personal precautions, protective equipment and emergency procedures:

Use personal protective equipment - see section 8.

6.2. Environmental precautions:

Do not empty into drains – see section 12. Inform appropriate authorities in accordance with local regulations.

6.3. Methods and material for containment and cleaning up:

Pick up and place in a suitable container. Clean with water. Further handling of spillage – see section 13.

6.4. Reference to other sections:

See above.

SECTION 7: Handling and storage

7.1. Precautions for safe handling:

Avoid contact with eyes. After use wash with soap and plenty of water.

7.2. Conditions for safe storage, including any incompatibilities:

Store in tightly closed original packaging at room temperature in a well-ventilated place.

7.3. Specific end use(s):

See section 1.

SECTION 8: Exposure controls/personal protection

8.1. Control parameters:

Occupational exposure limits, UK (EH40/ed.2020):

Substance	8-hour TWA	15-min STEL	Comments
Glycerol, mist	10 mg/m ³	-	-
Ethanol	1000 ppm = 1920 mg/m ³	-	-

Occupational exposure limit values, Ireland (2024):

Substance	8-hour TWA	15-min STEL	Notes
Ethanol	-	1000 ppm	-

DNEL/PNEC: No CSR.

8.2. Exposure controls:

Appropriate engineering controls: Ensure adequate ventilation.

Personal protective equipment:

Respiratory protection: Not relevant during intended use.

Skin protection: In case of prolonged use: Wear protective gloves of nitrile rubber (0.35 mm) (EN 374). Data about the breakthrough time of the ingredients are not available. Replacing the glove after use is therefore recommended.

Eye protection: Not relevant during intended use.

Environmental exposure controls: None particular.

SECTION 9: Physical and chemical properties

9.1. Information on basic physical and chemical properties:

Physical state:	Liquid on pads (rondells)
Colour:	Red or blue
Odour:	Peppermint
Melting point/freezing point (°C):	< 0
Boiling point or initial boiling point and boiling range (°C):	> 100
Flammability (solid, gas):	Not determined
Lower and upper explosion limit (vol-%):	Not determined
Flash point (°C):	> 100
Auto-ignition temperature (°C):	Not determined
Decomposition temperature (°C):	Not determined

SECTION 9: Physical and chemical properties (continued)

pH:	7-8
Kinematic viscosity:	Not determined
Solubility:	Completely soluble in water
Partition coefficient n-octanol/water (log value):	Not relevant - mixture (see section 12)
Vapour pressure:	Not determined
Density and/or relative density (g/cm ³):	1.124
Relative vapour density:	Not determined
Particle characteristics:	Not determined
9.2. Other information:	Not determined

SECTION 10: Stability and reactivity

10.1. Reactivity:

No available information.

10.2. Chemical stability:

Stable under normal conditions (3 years) - see section 7.

10.3. Possibility of hazardous reactions:

No available information.

10.4. Conditions to avoid:

No available information.

10.5. Incompatible materials:

No available information.

10.6. Hazardous decomposition products:

When heated to high temperatures (decomposition) toxic fumes are emitted: Oxides of carbon.

SECTION 11: Toxicological information

11.1. Information on hazard classes as defined in Regulation (EC) No 1272/2008:

Acute toxicity: Based on available data, the classification criteria are not met.

Skin corrosion/irritation: Based on available data, the classification criteria are not met.

Serious eye damage/irritation: Based on available data, the classification criteria are not met.

Respiratory or skin sensitization: Based on available data, the classification criteria are not met.

Germ cell mutagenicity: Based on available data, the classification criteria are not met.

Carcinogenicity: Based on available data, the classification criteria are not met.

Reproductive toxicity: Based on available data, the classification criteria are not met.

STOT-single exposure: Based on available data, the classification criteria are not met.

STOT-repeated exposure: Based on available data, the classification criteria are not met.

Aspiration hazard: Based on available data, the classification criteria are not met.

Hazard class	Data	Test	Data source
Acute toxicity:			
Inhalation	LC ₅₀ (rat) = 117-125 mg/l/4H (Ethanol)	OECD 403	ECHA
Dermal	LD ₅₀ (rabbit) > 20000 mg/kg (Ethanol)	No data	IUCLID
Oral	LD ₅₀ (rat) = 2426 mg/kg (Peppermint oil)	No data	ECHA
	LD ₅₀ (rat) = 12600 mg/kg (Glycerol)	No data	Supplier
	LD ₅₀ (rat): 1840-7100 mg/kg (Erythrosine)	No data	Supplier
	LD ₅₀ (rat) = 7060 mg/kg (Ethanol)	No data	Supplier
Corrosion/irritation:	Irritates skin, rabbit (Peppermint oil)	OECD 404, 405	ECHA
	Moderate eye irritation, no skin irritation, rabbit (Ethanol)	OECD 404, 405	ECHA
Sensitization:	Skin sensitisation, guinea pig (Peppermint oil)	OECD 429	ECHA
	No skin sensitization, guinea pig (Ethanol)	GPMT, etc.	ECHA
CMR:	No CMR effects (Peppermint oil)	-	-
	Data on mutagenicity is inconclusive (Ethanol)	Miscellaneous	IUCLID

Information on likely routes of exposure: Ingestion.

SECTION 11: Toxicological information (continued)

Symptoms:

Inhalation: Not relevant during intended use.
 Skin: May cause slight irritation.
 Eyes: May cause weak irritation with redness.
 Ingestion: Ingestion of large amounts may lead to irritation of the gastrointestinal tract with nausea and diarrhoea.
 Chronic effects: Peppermint oil may produce an allergic reaction. Prolonged or frequent exposure to vapours of volatile organic compounds may result in damage to the liver, kidneys, blood or central nervous system (including brain damage).

11.2. Information on other hazards: None known.

SECTION 12: Ecological information

12.1. Toxicity:

Aquatic	Data	Test (Media)	Data source
Fish	LC ₅₀ (Fish, 96h) = 3.4 mg/l (Peppermint oil) LC ₅₀ (Pimephales promelas, 96h) = 15300 mg/l (Ethanol)	QSAR No info (FW)	ECHA IUCLID
Daphnia	EC ₅₀ (Daphnia magna, 48h) = 2.7 mg/l (Peppermint oil) EC ₅₀ (Daphnia magna, 48h): 9268-14221 mg/l (Ethanol) EC ₅₀ (Daphnia sp., 48h) = 8.1 mg/l (Erythrosine)	QSAR No info (FW) No info (FW)	ECHA IUCLID ECHA
Algae	EC ₅₀ (Algae, 72h) = 2.61 mg/l (Peppermint oil) EC ₅₀ (Chlorella vulgaris, 72h) = 275 mg/l (Ethanol) EC ₁₀ (Chlorella vulgaris) = 11.5 mg/l (Ethanol)	QSAR OECD 201 (FW) OECD 201 (FW)	ECHA IUCLID IUCLID

12.2. Persistence and degradability:

Peppermint oil is readily degradable (OECD 301).

Ethanol is rapidly degradable (OECD 301 D).

12.3. Bioaccumulative potential:

Ethanol: Log K_{ow} <1 (no bioaccumulative potential).

12.4. Mobility in soil:

Ethanol: K_{oc} < 5 (very large mobility expected in soil).

12.5. Results of PBT and vPvB assessment:

The ingredients are not considered PBT/vPvB according to criteria in Regulation 2023/707.

12.6. Endocrine disrupting properties:

The product does not contain any substance identified as having endocrine disrupting properties.

12.7. Other adverse effects:

None known.

SECTION 13: Disposal considerations

13.1. Waste treatment methods:

Disposal should be according to local, state or national legislation. Dispose of through authority facilities or pass to chemical disposal company.

EWC-Code: 18 01 07 (residues)

SECTION 14: Transport information

Not dangerous goods (ADR/RID/IMDG/IATA).

14.1. UN number or ID number: None.

14.2. UN proper shipping name: None.

14.3. Transport hazard class(es): None.

14.4. Packing group: None.

14.5. Environmental hazards: None.

14.6. Special precautions for user: None.

14.7. Maritime transport in bulk according to IMO instruments: Not relevant.

SECTION 15: Regulatory information

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

None.

15.2. Chemical safety assessment:

No CSR.

SECTION 16: Other information

Hazard statements mentioned in section 3:

H225: Highly flammable liquid and vapour.
H315: Causes skin irritation.
H317: May cause an allergic skin reaction.
H319: Causes serious eye irritation.
H411: Toxic to aquatic life with long lasting effects.
H412: Harmful to aquatic life with long lasting effects.

Abbreviations:

CMR = Carcinogenicity, mutagenicity and reproductive toxicity.

CSR = Chemical Safety Report

DNEL = Derived No-Effect Level

EC₅₀ = Effect Concentration 50 %

FW = Fresh Water

LC₅₀ = Lethal Concentration 50 %

LD₅₀ = Lethal Dose 50 %

PBT = Persistent, Bioaccumulative, Toxic

PNEC = Predicted No-Effect Concentration

vPvB = very Persistent, very Bioaccumulative

Literature:

ECHA = European Chemical Agency Registration dossier.

IUCLID = International Uniform Chemical Information Database.

Supplier's safety data sheet.

Training advice:

No special training is required. However, the user should be well instructed in the execution of the task, be familiar with this Safety Data Sheet and have normal training in the use of personal protective equipment.

Changes since the previous edition:

Not relevant

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