

Safety Data Sheet

QuickCool

Replaces date: 09/03/2015

Revision date: 11/11/2015

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

1.1. Product identifier

Trade name: QuickCool

Other Information: The product is a medical device covered by Council Directive 93/42/EEC on medical devices. Consequently, the product does not require a safety data sheet and therefore this data sheet does not fully meet the statutory requirements for a safety data sheet.

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

Recommended uses: Burn gel for minor burns.

1.3. Details of the supplier of the safety data sheet

Supplier

Company: Plum A/S
Address: Frederik Plums Vej 2
Zip code: 5610 Assens
Country: DENMARK
E-mail: info@plum.dk
Phone: +45 64712112
Fax: +45 64712125

1.4. Emergency Telephone Number

0870 600 6266 (UK only) Only available to health professionals. The emergency telephone is open 24 hours.

SECTION 2: Hazards identification

2.1. Classification of the substance or mixture

CLP-classification: The product shall not be classified as hazardous according to the classification and labeling rules for substance and mixtures.

2.2. Label elements

Supplemental information

According to the classification and labeling of substances and mixtures, the product should not be labeled as hazardous.

2.3. Other hazards

Assessment to determine PBT and vPvB has not been made.

SECTION 3: Composition/information on ingredients

3.2. Mixtures

Substance	CAS number	EC No	REACH Reg. No.	Concentration	Notes	CLP-classification

Safety Data Sheet

QuickCool

Replaces date: 09/03/2015

Revision date: 11/11/2015

AQUA	7732-18-5			90 - 100%		
MELALEUCA OIL (TEA TREE OIL)	68647-73-4			1%		
Emulsifier						
Preservatives						

Please see section 16 for the full text of R-phrases and H-phrases.

SECTION 4: First aid measures

4.1. Description of first aid measures

- Inhalation:** The product does not release hazardous vapours. Seek fresh air.
- Ingestion:** Wash out mouth thoroughly and drink 1-2 glasses of water in small sips. Seek medical advice in case of discomfort.
- Skin contact:** Seek medical advice in case of persistent discomfort.
- Eye contact:** Flush with water (preferably using eye wash equipment) until irritation subsides. Seek medical advice if symptoms persist.
- General:** The product is intended for first aid, and its use should always be followed by a visit to the doctor. If defects or adverse side effects are found during use, please report such defects or side effects to Plum A/S, info@plum.dk by phone +45 6471 2112, so that the necessary remedies can be initiated and the obligation to report serious adverse effects according to Appendix VII item 4 of the Directive can be observed. Serious adverse effects should always be reported to the Board of Health in the state in which the side effect has occurred.

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

No hazards.

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

No special immediate treatment required. Treat symptoms.

SECTION 5: Fire-fighting measures

5.1. Extinguishing media

Suitable extinguishing media: The product is not directly flammable. Choose extinguishing agents based on the surrounding fire.

5.2. Special hazards arising from the substance or mixture

The product is not directly flammable. Avoid inhalation of vapour and fumes - seek fresh air.

5.3. Advice for fire-fighters

If there is a risk of exposure to vapour and flue gases, a self-contained breathing apparatus must be worn.

SECTION 6: Accidental release measures

6.1. Personal precautions, protective equipment and emergency procedures

Safety Data Sheet

QuickCool

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For non-emergency personnel: Keep unnecessary personnel away.

For emergency responders: In addition to the above: No special steps are necessary.

6.2. Environmental precautions

Avoid unnecessary release to the environment.

6.3. Methods and material for containment and cleaning up

Contain and absorb spill with sand or other absorbent material and transfer to suitable waste containers. Wipe up minor spills with a cloth.

6.4. Reference to other sections

See section 8 for type of protective equipment. See section 13 for instructions on disposal.

SECTION 7: Handling and storage

7.1. Precautions for safe handling

To ensure that the product remains sterile, the sealing must not be broken before use.

7.2. Conditions for safe storage, including any incompatibilities

Storage temperature: < 25 °C.
Store frost-free. Do not expose to heat (e.g. sunlight).

7.3. Specific end use(s)

None.

SECTION 8: Exposure controls/personal protection

8.1. Control parameters

Occupational exposure limit: Contains no substances subject to reporting requirements

Legal basis: EH40/2005 Workplace exposure limits incl. supplement from October 2007.

Other Information: The product requires no special exposure control.

8.2. Exposure controls

Appropriate engineering controls: Wear the personal protective equipment specified below.

Personal protective equipment, eye/face protection: Not required.

Personal protective equipment, hand protection: Not required.

Personal protective equipment, skin protection: Not required.

Personal protective equipment, respiratory protection: Not required.

Environmental exposure controls: Ensure compliance with local regulations for emissions.

Safety Data Sheet

QuickCool

Replaces date: 09/03/2015

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SECTION 9: Physical and chemical properties

9.1. Information on basic physical and chemical properties

Parameter	Value/unit
State	Gel
Colour	Clear
Odour	Characteristic
Solubility	Soluble in the following: Water.
Explosive properties	Non-explosive
Oxidising properties	N/A

Parameter	Value/unit	Remarks
pH (solution for use)	No data	
pH (concentrate)	4 - 7	
Melting point	No data	
Freezing point	No data	
Initial boiling point and boiling range	100 °C	
Flash Point	No data	
Evaporation rate	No data	
Flammability (solid, gas)	No data	
Flammability limits	No data	
Explosion limits	No data	
Vapour pressure	No data	
Vapour density	No data	
Relative density	No data	
Partition coefficient n-octanol/water	No data	
Auto-ignition temperature	No data	
Decomposition temperature	No data	
Viscosity	No data	
Odour threshold	No data	

9.2 Other information

Other Information: None.

SECTION 10: Stability and reactivity

10.1. Reactivity

Not reactive.

10.2. Chemical stability

The product is stable when used in accordance with the supplier's directions.

10.3. Possibility of hazardous reactions

No risk of hazardous reactions.

10.4. Conditions to avoid

Do not expose to heat (e.g. sunlight).

10.5. Incompatible materials

Safety Data Sheet

QuickCool

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None known.

10.6. Hazardous decomposition products

None known.

SECTION 11: Toxicological information

11.1. Information on toxicological effects

Acute toxicity - oral:	Ingestion of large quantities may cause discomfort. The product does not have to be classified.
Acute toxicity - dermal:	The product does not have to be classified.
Acute toxicity - inhalation:	The product does not have to be classified.
Skin corrosion/irritation:	The product does not have to be classified.
Serious eye damage/eye irritation:	The product does not have to be classified.
Respiratory sensitisation or skin sensitisation:	Sensitive people may experience allergic reactions. The product does not have to be classified.
Germ cell mutagenicity:	The product does not have to be classified.
Carcinogenic properties:	The product does not have to be classified.
Reproductive toxicity:	The product does not have to be classified.
Single STOT exposure:	The product does not have to be classified.
Repeated STOT exposure:	The product does not have to be classified.
Aspiration hazard:	The product does not have to be classified.

SECTION 12: Ecological information

12.1. Toxicity

The product does not have to be classified.

12.2. Persistence and degradability

Expected to be biodegradable.

12.3. Bioaccumulative potential

No bioaccumulation expected.

12.4. Mobility in soil

Test data are not available.

Safety Data Sheet

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12.5. Results of PBT and vPvB assessment

No assessment has been made.

12.6. Other adverse effects

None known.

SECTION 13: Disposal considerations

13.1. Waste treatment methods

Contact the local authorities.

Absorbent/cloth contaminated with the product: EWC code: 15 02 03 Absorbents, filter materials, wiping cloths and protective clothing other than those mentioned in 15 02 02.

Empty, cleansed packaging should be disposed of for recycling.

07 06 99 wastes not otherwise specified

SECTION 14: Transport information

14.1. UN-No.: Not applicable.

14.2. UN proper shipping name: Not applicable.

14.3. Transport hazard class(es): Not applicable.

14.4. Packing group: Not applicable.

14.5. Environmental hazards: Not applicable.

14.6. Special precautions for user

None.

14.7. Transport in bulk according to Annex II of MARPOL73/78 and the IBC code

Not applicable.

SECTION 15: Regulatory information

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

Special Provisions: The product is covered by Council Directive 93/42/EEC on medical devices. Consequently, the product is not covered by Regulation (EC) no 1272/2008 of the European Parliament and the Council on classification, labelling and packaging of substances and mixtures. cf. Article 1 (5d). Regulation 1907/2006 EC of the European Parliament and Council on registration, evaluation, authorisation and restriction of chemicals (REACH) states in Article 2 (6c) that section IV regarding requirements for safety data sheets does not apply to medical equipment. Consequently, there is no requirement stating that the product mentioned above should be provided with a safety data sheet to meet the requirements of the above regulation.

15.2. Chemical Safety Assessment

Other Information: Chemical safety assessment has not been performed.

Safety Data Sheet

QuickCool

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SECTION 16: Other information

Version history and indication of changes

Version	Revision date	Responsible	Changes
2.0.0	09/03/2015	SKP	453/2010 (UK)
2.1.0	11/11/2015	SKP	2015/830 (UK)

Abbreviations: DNEL: Derived No Effect Level PNEC: Predicted No Effect Concentration PBT: Persistent, Bioaccumulative and Toxic vPvB: Very Persistent and Very Bioaccumulative STOT: Specific Target Organ Toxicity

Other Information: Shelf life: 5 years from the manufacturing date.
Additional information can be obtained by contacting info@plum.dk or by telephone +45 6471 2112.

Vendor notes: QuickCool is used for cooling and relief of minor burns.
Apply a thick layer of the product and do not cover with an airtight material.

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SDS is prepared by

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