

Safety Data Sheet

pH Neutral

Replaces date: 11/11/2015

Revision date: 17/06/2016

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

1.1. Product identifier

Trade name: pH Neutral

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.

Article no

Article no	Description
4750	

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

Recommended uses: Eye wash.
Neutralization of acids and alkali.

1.3. Details of the supplier of the safety data sheet

Manufacturer

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
Homepage: www.plum.dk

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.

Safety Data Sheet

pH Neutral

Replaces date: 11/11/2015

Revision date: 17/06/2016

SECTION 3: Composition/information on ingredients

3.2. Mixtures

Substance	CAS number	EC No	REACH Reg. No.	Concentration	Notes	CLP-classification
AQUA	7732-18-5			> 80%		
Disodium phosphate	7558-79-4	231-448-7		1 - 5%		
Potassium phosphate	7778-77-0			< 1%		

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

SECTION 4: First aid measures

4.1. Description of first aid measures

Inhalation:	The product does not release hazardous vapours.
Ingestion:	Seek medical advice in case of discomfort.
Skin contact:	Seek medical advice in case of persistent discomfort.
Eye contact:	Not applicable.
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.
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5.2. Special hazards arising from the substance or mixture

No hazards.

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

Safety Data Sheet

pH Neutral

Replaces date: 11/11/2015

Revision date: 17/06/2016

6.1. Personal precautions, protective equipment and emergency procedures

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: 5-35 °C.

Risk of infection from reuse of opened bottles.

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 Ensure compliance with local regulations for emissions.

Safety Data Sheet

pH Neutral

Replaces date: 11/11/2015

Revision date: 17/06/2016

controls:

SECTION 9: Physical and chemical properties

9.1. Information on basic physical and chemical properties

Parameter	Value/unit
State	Liquid
Colour	Clear Colourless
Odour	Neutral
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)	7.2 - 7.5	
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

Parameter	Value/unit	Remarks
Density	1040 kg/m ³	

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).

Safety Data Sheet

pH Neutral

Replaces date: 11/11/2015

Revision date: 17/06/2016

10.5. Incompatible materials

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:	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 release hazardous vapours. 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

Safety Data Sheet

pH Neutral

Replaces date: 11/11/2015

Revision date: 17/06/2016

Test data are not available.

12.5. Results of PBT and vPvB assessment

No assessment required, as the product contains inorganic matter only.

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.

Category of waste: 15 01 02 plastic packaging
16 10 02 aqueous liquid wastes other than those mentioned in 16 10 01

SECTION 14: Transport information

14.1. UN-No.:	Not applicable.	14.4. Packing group:	Not applicable.
14.2. UN proper shipping name:	Not applicable.	14.5. Environmental hazards:	Not applicable.
14.3. Transport hazard class(es):	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

Safety Data Sheet

pH Neutral

Replaces date: 11/11/2015

Revision date: 17/06/2016

Other Information: Chemical safety assessment has not been performed.

SECTION 16: Other information

Version history and indication of changes

Version	Revision date	Responsible	Changes
2.0.0	29/01/2015	SKP	453/2010 (UK)
2.1.0	11/11/2015	SKP	2015/830 (UK)
2.2.0	17/06/2016	SKP	1, 6, 16

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: Expiry date for unopened, sealed bottles: At least three years from the manufacturing date. Additional information can be obtained by contacting info@plum.dk or by telephone +45 6471 2112.

Vendor notes:

pH Neutral is used after contact with acids and bases. Recommended rinsing period: two minutes.

For continuous rinsing until seen by a doctor, Plum Eye Wash with 0.9% sodium chloride solution is recommended.

Date: 17/06/2016

SDS is prepared by

Company: Plum A/S

Address: Frederik Plums Vej 2

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E-mail: info@plum.dk

Phone: +45 64712112

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Homepage: www.plum.dk

Document language: GB

Safety Data Sheet

QuickClean

Replaces date: 18/09/2015

Revision date: 11/11/2015

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

1.1. Product identifier

Trade name: QuickClean

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. Exempted from REACH registration according to REACH Annex IV.

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

Recommended uses: Wipe (wash swap) of nonwoven material.

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

The product does not contain any PBT or vPvB substances.

SECTION 3: Composition/information on ingredients

3.2. Mixtures

Safety Data Sheet

QuickClean

Replaces date: 18/09/2015

Revision date: 11/11/2015

Contains no substances subject to reporting requirements

Ingredient comments:

Paper:
MG 40 g/m² +/-2%
Adhesive 4 g/m² +/-2%
Al-foil 7 my +/-2%
Surlyn 23/m² +/-2%

Nonwoven:
Weight 28 gr/m²
Fibre: 44 % cellulose
Rayon/polyester 36%

Wash liquid:
Purified Water

SECTION 4: First aid measures

4.1. Description of first aid measures

Inhalation: The product does not release hazardous vapours.

Ingestion: Not applicable.

Skin contact: The product is intended to come into contact with the skin.

Eye contact: 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.

General: When obtaining medical advice, show the safety data sheet or label.

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

None known.

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

Treat symptoms. No special immediate treatment required.

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. Use water or water mist to cool non-ignited stock.

Unsuitable extinguishing media: Do not use water stream, as it may spread the 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

Move containers from danger area if it can be done without risk. Avoid inhalation of vapour and flue gases - seek fresh air.

Safety Data Sheet

QuickClean

Replaces date: 18/09/2015

Revision date: 11/11/2015

SECTION 6: Accidental release measures

6.1. Personal precautions, protective equipment and emergency procedures

For non-emergency personnel: Keep unnecessary personnel away.

For emergency responders: 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

Sweep up/collect spills for possible reuse or transfer to suitable waste containers.

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. Single use.
Shelf life: 5 years from the manufacturing date.

7.2. Conditions for safe storage, including any incompatibilities

Keep in tightly closed original packaging.

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.

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.

Safety Data Sheet

QuickClean

Replaces date: 18/09/2015

Revision date: 11/11/2015

Environmental exposure controls:

Ensure compliance with local regulations for emissions.

SECTION 9: Physical and chemical properties

9.1. Information on basic physical and chemical properties

Parameter	Value/unit
State	Napkin with liquid.
Colour	White
Odour	Neutral
Solubility	Not applicable.
Explosive properties	Non-explosive
Oxidising properties	Non-oxidising.

Parameter	Value/unit	Remarks
pH (solution for use)	7	Value for the cleaning fluid.
pH (concentrate)	No data	
Melting point	0 °C	Value for the cleaning fluid.
Freezing point	0 °C	Value for the cleaning fluid.
Initial boiling point and boiling range	100 °C	Value for the cleaning fluid.
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	1	Value for the cleaning fluid.
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

Keep from drying out.

Safety Data Sheet

QuickClean

Replaces date: 18/09/2015

Revision date: 11/11/2015

10.5. Incompatible materials

None known.

10.6. Hazardous decomposition products

None known.

SECTION 11: Toxicological information

11.1. Information on toxicological effects

Acute toxicity - oral:	The product does not have to be classified.
Acute toxicity - dermal:	The product does not have to be classified.
Acute toxicity - inhalation:	No hazards.
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:	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 release hazardous vapours.
Repeated STOT exposure:	No hazards.
Aspiration hazard:	No hazards.
Other toxicological effects:	None known.

SECTION 12: Ecological information

12.1. Toxicity

The product does not have to be classified.

12.2. Persistence and degradability

Test data are not available.

12.3. Bioaccumulative potential

Test data are not available.

12.4. Mobility in soil

Test data are not available.

Safety Data Sheet

QuickClean

Replaces date: 18/09/2015

Revision date: 11/11/2015

12.5. Results of PBT and vPvB assessment

The product does not contain any PBT or vPvB substances.

12.6. Other adverse effects

None known.

SECTION 13: Disposal considerations

13.1. Waste treatment methods

Contact the local authorities.

Empty, cleansed packaging should be disposed of for recycling.
Avoid unnecessary release to the environment.

Depending on the actual use:

16 01 99 wastes not otherwise specified

18 01 03*wastes whose collection and disposal is subject to special requirements in order to prevent infection

18 01 04 wastes whose collection and disposal is not subject to special requirements in order to prevent infection (for example dressings, plaster casts, linen, disposable clothing, diapers)

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: None.

15.2. Chemical Safety Assessment

Other Information: Chemical safety assessment has not been performed.

SECTION 16: Other information

Version history and indication of changes

Safety Data Sheet

QuickClean

Replaces date: 18/09/2015

Revision date: 11/11/2015

Version	Revision date	Responsible	Changes
1.0.0	18/09/2015	SKP	453/2010 (UK)
1.1.0	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 (unopened).
Additional information can be obtained by contacting info@plum.dk or by telephone +45 6471 2112.

Date:

11/11/2015

Product type:

MDD Class I, Sterile. Rule 1.

SDS is prepared by

Company:

Plum A/S

Address:

Frederik Plums Vej 2

Zip code:

5610 Assens

Country:

DENMARK

E-mail:

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Document language:

GB

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
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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

Replaces date: 09/03/2015

Revision date: 11/11/2015

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

Revision date: 11/11/2015

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

Replaces date: 09/03/2015

Revision date: 11/11/2015

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

QuickCool

Replaces date: 09/03/2015

Revision date: 11/11/2015

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

Replaces date: 09/03/2015

Revision date: 11/11/2015

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.

Date:

11/11/2015

SDS is prepared by

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

Document language:

GB

Safety Data Sheet

QuickRinse

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: QuickRinse

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: Eye wash.

1.3. Details of the supplier of the safety data sheet

Manufacturer

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

The product does not contain any PBT or vPvB substances.

SECTION 3: Composition/information on ingredients

3.2. Mixtures

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

QuickRinse

Replaces date: 09/03/2015

Revision date: 11/11/2015

AQUA	7732-18-5			99.1 %		
SODIUM CHLORIDE	7647-14-5			0.9 %		

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.
Ingestion:	Seek medical advice in case of discomfort.
Skin contact:	Seek medical advice in case of persistent discomfort.
Eye contact:	Not applicable.
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.
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5.2. Special hazards arising from the substance or mixture

No hazards.

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

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

Safety Data Sheet

QuickRinse

Replaces date: 09/03/2015

Revision date: 11/11/2015

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: 5-35 °C.
Risk of infection by recycling used ampoules.

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.

SECTION 9: Physical and chemical properties

Safety Data Sheet

QuickRinse

Replaces date: 09/03/2015

Revision date: 11/11/2015

9.1. Information on basic physical and chemical properties

Parameter	Value/unit
State	Liquid
Colour	Clear Colourless
Odour	Neutral
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)	5 - 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

Parameter	Value/unit	Remarks
Density	1002,5kg/m ³	

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

None known.

Safety Data Sheet

QuickRinse

Replaces date: 09/03/2015

Revision date: 11/11/2015

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:	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 release hazardous vapours. 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.

12.5. Results of PBT and vPvB assessment

Safety Data Sheet

QuickRinse

Replaces date: 09/03/2015

Revision date: 11/11/2015

No assessment required, as the product contains inorganic matter only.

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.

15 01 02 plastic packaging

16 10 02 aqueous liquid wastes other than those mentioned in 16 10 01

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.

SECTION 16: Other information

Version history and indication of changes

Safety Data Sheet

QuickRinse

Replaces date: 09/03/2015

Revision date: 11/11/2015

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 for unopened, sealed ampoules: 5 years from the manufacturing date.
Additional information can be obtained by contacting info@plum.dk or by telephone +45 6471 2112.

Vendor notes:

QuickRinse is intended as an eye wash. If you require larger quantities of rinsing fluid we recommend Plum Eye Wash.

Plum Eye Wash is recommended for rinsing foreign bodies (such as dust, dirt, metal and wood splinters) and chemicals (such as solvents and oil) from the eyes.

After contact with acids or bases, pH Neutral is recommended with a rinsing period of at least two minutes. Continue rinsing with Plum Eye Wash until seen by a doctor.

Twist the ampoule to open and press lightly the ampoule.

Date:

11/11/2015

SDS is prepared by

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

Document language:

GB

Safety Data Sheet

QuickStop

Replaces date: 18/09/2015

Revision date: 11/11/2015

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

1.1. Product identifier

Trade name: QuickStop

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.

Article no

Article no	Description
QuickStop	Gauze 7.5 * 12 cm with elastic bandage 6 cm * 2 m.

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

Recommended uses: First-aid for dressing wounds.

1.3. Details of the supplier of the safety data sheet

Manufacturer

Company: AKLA AB
Address: Enhagsslingan
 Täby, Box 534
Zip code: SE-182 15 Danderyd
Country: SWEDEN

Distributor

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

Safety Data Sheet

QuickStop

Replaces date: 18/09/2015

Revision date: 11/11/2015

Supplemental information

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

2.3. Other hazards

The product does not contain any PBT or vPvB substances.

SECTION 3: Composition/information on ingredients

3.2. Mixtures

Contains no substances subject to reporting requirements

Ingredient comments:

Bandage:
Polyamid 60%
Viscose 40%

Nonwoven cellosoft, large dressing:
Viscose 70%
Polyethylene 30%

Nonwoven cellosoft, small bandage: 3-layer combination of:
100% LDPE-HDPE 30g/m², micro perforated.
100% Viscose 200 g/m² +/- 10%
100% LDPE-HDPE 30g/m², micro perforated.

SECTION 4: First aid measures

4.1. Description of first aid measures

Inhalation: The product does not release hazardous vapours.

Ingestion: Not applicable.

Skin contact: The product is intended to come into contact with the skin.

Eye contact: 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.

General: When obtaining medical advice, show the safety data sheet or label.

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

None known.

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

Treat symptoms. No special immediate treatment required.

SECTION 5: Fire-fighting measures

5.1. Extinguishing media

Suitable extinguishing media: Extinguish with powder, foam, carbon dioxide or water mist. Use water or water mist to cool non-ignited stock.

Unsuitable extinguishing Do not use water stream, as it may spread the fire.

Safety Data Sheet

QuickStop

Replaces date: 18/09/2015

Revision date: 11/11/2015

media:

5.2. Special hazards arising from the substance or mixture

The product decomposes when combusted and the following toxic gases can be formed: Carbon monoxide and carbon dioxide.

5.3. Advice for fire-fighters

Move containers from danger area if it can be done without risk. Avoid inhalation of vapour and flue gases - seek fresh air.

SECTION 6: Accidental release measures

6.1. Personal precautions, protective equipment and emergency procedures

For non-emergency personnel: Keep unnecessary personnel away.

For emergency responders: 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

Sweep up/collect spills for possible reuse or transfer to suitable waste containers.

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. Single use.
Shelf life: 5 years from the manufacturing date.

7.2. Conditions for safe storage, including any incompatibilities

Keep in tightly closed original packaging.

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.

8.2. Exposure controls

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

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

Safety Data Sheet

QuickStop

Replaces date: 18/09/2015

Revision date: 11/11/2015

Personal protective equipment, Not required.
hand protection:

Personal protective equipment, Not required.
skin protection:

Personal protective equipment, Not required.
respiratory protection:

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

SECTION 9: Physical and chemical properties

9.1. Information on basic physical and chemical properties

Parameter	Value/unit
State	Solid substance
Colour	White
Odour	Neutral
Solubility	Not applicable.
Explosive properties	Non-explosive
Oxidising properties	Non-oxidising.

Parameter	Value/unit	Remarks
pH (solution for use)	7	Value for the cleaning fluid.
pH (concentrate)	No data	
Melting point	0 °C	Value for the cleaning fluid.
Freezing point	0 °C	Value for the cleaning fluid.
Initial boiling point and boiling range	100 °C	Value for the cleaning fluid.
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	1	Value for the cleaning fluid.
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.

Safety Data Sheet

QuickStop

Replaces date: 18/09/2015

Revision date: 11/11/2015

10.3. Possibility of hazardous reactions

No risk of hazardous reactions.

10.4. Conditions to avoid

Keep from drying out.

10.5. Incompatible materials

None known.

10.6. Hazardous decomposition products

None known.

SECTION 11: Toxicological information

11.1. Information on toxicological effects

Acute toxicity - oral:	The product does not have to be classified.
Acute toxicity - dermal:	The product does not have to be classified.
Acute toxicity - inhalation:	No hazards.
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:	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 release hazardous vapours.
Repeated STOT exposure:	No hazards.
Aspiration hazard:	No hazards.
Other toxicological effects:	None known.

SECTION 12: Ecological information

12.1. Toxicity

The product does not have to be classified.

12.2. Persistence and degradability

Test data are not available.

Safety Data Sheet

QuickStop

Replaces date: 18/09/2015

Revision date: 11/11/2015

12.3. Bioaccumulative potential

Test data are not available.

12.4. Mobility in soil

Test data are not available.

12.5. Results of PBT and vPvB assessment

The product does not contain any PBT or vPvB substances.

12.6. Other adverse effects

None known.

SECTION 13: Disposal considerations

13.1. Waste treatment methods

Contact the local authorities.

Empty, cleansed packaging should be disposed of for recycling.
Avoid unnecessary release to the environment.

Depending on the actual use:

16 01 99 wastes not otherwise specified

18 01 03*wastes whose collection and disposal is subject to special requirements in order to prevent infection

18 01 04 wastes whose collection and disposal is not subject to special requirements in order to prevent infection (for example dressings, plaster casts, linen, disposable clothing, diapers)

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: None.

Safety Data Sheet

QuickStop

Replaces date: 18/09/2015

Revision date: 11/11/2015

15.2. Chemical Safety Assessment

Other Information: Chemical safety assessment has not been performed.

SECTION 16: Other information

Version history and indication of changes

Version	Revision date	Responsible	Changes
1.0.0	18/09/2015	SKP	453/2010 (UK)
1.1.0	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 (unopened).
 Additional information can be obtained by contacting info@plum.dk or by telephone +45 6471 2112.

Date: 11/11/2015

Product type: MDD Class I, Annex 7, Steril, Rule 4 mechanical barrier.

SDS is prepared by

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
Document language: GB

Safety Data Sheet

Plum Eye Wash

Replaces date: 02/02/2015

Revision date: 11/11/2015

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

1.1. Product identifier

Trade name: Plum Eye Wash

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.

Article no

Article no	Description
4600	

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

Recommended uses: Eye wash.
Rinsing of foreign bodies and chemicals from the eyes.

1.3. Details of the supplier of the safety data sheet

Manufacturer

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.

Safety Data Sheet

Plum Eye Wash

Replaces date: 02/02/2015

Revision date: 11/11/2015

SECTION 3: Composition/information on ingredients

3.2. Mixtures

Substance	CAS number	EC No	REACH Reg. No.	Concentration	Notes	CLP-classification
AQUA	7732-18-5			99.1 %		
SODIUM CHLORIDE	7647-14-5			0.9 %		

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.
Ingestion:	Seek medical advice in case of discomfort.
Skin contact:	Seek medical advice in case of persistent discomfort.
Eye contact:	Not applicable.
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

No hazards.

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

Plum Eye Wash

Replaces date: 02/02/2015

Revision date: 11/11/2015

For non-emergency personnel: Keep unnecessary personnel away.

For emergency responders: In addition to the above: Normal protective clothing equivalent to EN 469 is recommended.

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: 5-35 °C.

Risk of infection from reuse of opened bottles.

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

Plum Eye Wash

Replaces date: 02/02/2015

Revision date: 11/11/2015

SECTION 9: Physical and chemical properties

9.1. Information on basic physical and chemical properties

Parameter	Value/unit
State	Liquid
Colour	Clear Colourless
Odour	Neutral
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)	5 - 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

Parameter	Value/unit	Remarks
Density	1002,5kg/m³	

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

Plum Eye Wash

Replaces date: 02/02/2015

Revision date: 11/11/2015

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:	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 release hazardous vapours. 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

Plum Eye Wash

Replaces date: 02/02/2015

Revision date: 11/11/2015

12.5. Results of PBT and vPvB assessment

No assessment required, as the product contains inorganic matter only.

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.

15 01 02 plastic packaging

16 10 02 aqueous liquid wastes other than those mentioned in 16 10 01

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

Plum Eye Wash

Replaces date: 02/02/2015

Revision date: 11/11/2015

SECTION 16: Other information

Version history and indication of changes

Version	Revision date	Responsible	Changes
2.0.0	02/02/2015	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:

Expiry date for unopened, sealed bottles: At least three years from the manufacturing date. Additional information can be obtained by contacting info@plum.dk or by telephone +45 6471 2112.

Vendor notes:

Plum Eye Wash is recommended for rinsing foreign bodies (such as dust, dirt, metal and wood splinters) and chemicals (such as solvents and oil) from the eyes.

After contact with acids or bases, pH Neutral is recommended with a rinsing period of at least two minutes. Continue rinsing with Plum Eye Wash until seen by a doctor.

Turn the lid to break the seal and open the bottle. Press the bottle lightly so that the liquid will hit the eye in a soft squirt. Never press too hard.

Date:

11/11/2015

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