MATERIAL SAFETY DATA SHEET Redcap Phosphate Buffered Solution

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

1.1. Product identifier Trade name: Redcap

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. Neutralization of acids and alkali.

1.3. Details of the supplier of the safety data sheet

Company: Reliance Medical LTD

Address: West Ave, Talke, Stoke-On-Trent, Staffordshire, ST7 1TL, United Kingdom.

1.4. Emergency Telephone Number: 08456 448808

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

Substance	CAS Number	EC No	REACH Reg No	Concentration	Notes	CLP Class
AQUA	7732-18-5			> 80%		
Sodium	7558-79-4	231-448-7		1 - 5%		
Phosphate						
Dibasic						
Potassium	7778-77-0			< 1%		
Phosphate						

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.

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

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 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	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	100 °C	
range		
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- octonol/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/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

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.

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.

14.2. 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

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

For further information, please contact Reliance Medical LTD.

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