

SAFETY DATA SHEET

SECTION 1: IDENTIFICATION OF THE MIXTURE AND OF THE COMPANY/UNDERTAKING

1.1. <u>Product identifier:</u> 500ml Blue Dot BUFFER Eye Wash Solution

Article number: 8720

1.2. <u>Relevant identified uses of the mixture and uses advised against:</u> Eye wash. Neutralization of acids and alkali. For consumer use.

The product is used after contact with acids and bases. Recommended rinsing period: two minutes. For continuous rinsing until seen by a doctor, Eye Wash with 0.9% sodium chloride solution is recommended.

The product is a medical device covered by Council Directive 93/42/EEC concerning medical devices. Mixtures qualified as medical devices shall not be subject to Annex IV of Regulation (EC) No 1907/2006 (REACH), the preparation of a safety data sheet for such mixtures is not required. The following information is for reference only to ensure the safe use of the product.

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

Information about the distributor: CREST MEDICAL LTD BLUEDOT HOUSE, 3 CHESFORD GRANGE, WOOLSTON, WARRINGTON, WA14RQ Tel.: 0845 2302092

- 1.3.1.
 Responsible person:
 PAULINE CADDICK

 E-mail:
 Pauline.caddick@crestmedical.co.uk
- 1.4. <u>Emergency telephone number:</u> *Please fill in*

SECTION 2: HAZARDS IDENTIFICATION

2.1. <u>Classification of the mixture:</u>

Classification according to Regulation (EC) No 1272/2008 (CLP):

Not considered as hazardous mixture.

Hazard statements: No hazard statements.

2.2. Label elements:

Hazard statements: No hazard statements.

Precautionary statements: No precautionary statements.

2.3. <u>Other hazards:</u>

The product has no other known specific hazards for human or environment. Results of PBT and vPvB assessment: No data available. Assessment has not been made. Endocrine disrupting property: Based on available data, it does not contain endocrine disruptors.





SECTION 3: COMPOSITION/INFORMATION ON INGREDIENTS

3.1. <u>Substances:</u>

Not applicable.

3.2. <u>Mixtures:</u>

	CAS number	EC number / ECHA list number	REACH registration number	Conc. (%)	Classification according to Regulation (EC) No 1272/2008 (CLP)		
Description					Pictogram, signal word code(s)	Hazard class and category code(s)	Hazard statement code(s)
	-			-			
Water*	7732-18-5	231-791-2	-	> 80	-	not classified	-
Disodium hydrogen-ortho- phosphate*	755 ⁸⁻ 79-4	231-448-7	-	1 - 5	-	not classified	-
Potassium phosphate*	7778-77-0	231-913-4	-	< 1	-	not classified	-

*: Classification specified by the manufacturer; the substance is not listed in Annex VI of the Regulation (EC) No 1272/2008.

For the full text of hazard statements, see Section 16.

SECTION 4: FIRST AID MEASURES

4.1. Description of first aid measures:

General information: 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 sales@chinalongbow.com by phone +86 757 81220959, 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.

INGESTION:

Measures:

- Seek medical advice in case of discomfort.

INHALATION:

Measures:

SKIN CONTACT:

Measures:

- Seek medical advice in case of persistent discomfort.

The product does not release hazardous vapours

EYE CONTACT:

Measures:

Not applicable.

4.2. <u>Most important symptoms and effects, both acute and delayed:</u>

No acute and delayed symptoms and effects known.

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

No special treatment needed; treat symptomatically.

SECTION 5: FIREFIGHTING MEASURES

5.1. <u>Extinguishing media:</u>

- 5.1.1. Suitable extinguishing media: The product is not directly flammable. Choose extinguishing media depending on surrounding fire.
- 5.1.2. Unsuitable extinguishing media: No data available.
- 5.2. <u>Special hazards arising from the substance or mixture:</u> No special hazards.





5.3. <u>Advice for firefighters:</u>

Wear full protective clothing. If there is a risk of exposure to vapour and flue gases, wear self-contained breathing apparatus.

SECTION 6: ACCIDENTAL RELEASE MEASURES

6.1. <u>Personal precautions, protective equipment and emergency procedures:</u>

- 6.1.1. For non-emergency personnel: Allow only well-trained experts wearing suitable
 - Allow only well-trained experts wearing suitable protective clothing to abide in the field of accident.
- 6.1.2. For emergency responders: Keep unnecessary personnel away.
- 6.2. <u>Environmental precautions:</u>
- Avoid unnecessary release to the environment.
- 6.3. <u>Methods and material for containment and cleaning up:</u> Contain and absorb spilled product with sand or other absorbent material and transfer to suitable waste containers. Wipe up minor spills with a cloth.
- 6.4. <u>Reference to other sections:</u> For further and detailed information see Sections 8 and 13.

SECTION 7: HANDLING AND STORAGE

- 7.1. Precautions for safe handling: Observe conventional hygiene precautions. Technical measures: To ensure that the product remains sterile, the sealing must not be broken before use. Precautions against fire and explosion: No special measures required.
 7.2. Conditions for safe storage, including any incompatibilities: Technical measures and storage condition: Risk of infection from reuse of opened bottles. Storage temperature: 5-35 °C. Incompatible materials: See Section 10.5 Packaging material: No special prescriptions.
- 7.3. <u>Specific end use(s):</u>

No specific instructions available.

SECTION 8: EXPOSURE CONTROLS/PERSONAL PROTECTION

8.1. <u>Control parameters:</u>

Occupational exposure limit values (Commission Directive (EC) No 2000/39 of 8 June 2000): The components of the mixture are not regulated with exposure limit value.

DNEL values		Oral exposure		Dermal exposure		Inhalative exposure	
		Short term (acute)	Long term (chronic)	Short term (acute)	Long term (chronic)	Short term (acute)	Long term (chronic)
Consumar	Local	no data	no data	no data	no data	no data	no data
Consumer	Systemic	no data	no data	no data	no data	no data	no data
Worker	Local	no data	no data	no data	no data	no data	no data
worker	Systemic	no data	no data	no data	no data	no data	no data





PNEC values		
Compartment	Value	Note(s)
Freshwater	no data	no notes
Marine water	no data	no notes
Freshwater sediment	no data	no notes
Marine water sediment	no data	no notes
Sewage Treatment Plant (STP)	no data	no notes
Intermittent release	no data	no notes
Secondary poisoning	no data	no notes
Soil	no data	no notes

8.2. Exposure controls:

3.

In case of a hazardous material with no controlled concentration limit it is the employer's duty to keep concentration levels down to a minimum achievable by existing scientific and technological means, where the hazardous substance poses no harm to workers.

8.2.1. Appropriate engineering controls:

In pursuance of work is proper foresight needed to avoid leaking onto clothes and floors and to avoid contact with eyes and skin. 8.2.2. Individual protection measures, such as personal protective equipment:

- Wear the personal protective equipment specified below.
 - 1. Eye/face protection: Not required.
 - 2. Skin protection:
 - a. Hand protection: Not required.
 - b. Other: Not required.
 - Respiratory protection: Not required.
 - 4. Thermal hazards: No thermal hazards known.

8.2.3. Environmental exposure controls:

Ensure compliance with local regulations for emissions.

The requirements detailed in Section 8 assume skilled work under normal conditions and usage of the product for appropriate aims. If conditions differ from normal or work is carried out under extreme conditions, an expert's advice is necessary before deciding upon further protective measures.

SECTION 9: PHYSICAL AND CHEMICAL PROPERTIES

9.1. Information on basic physical and chemical properties:

	Parameter	Value / Test method / Remarks
1.	Physical state	liquid
2.	Colour	clear, colourless
3.	Odour	neutral
4.	Melting point/freezing point	no data*
5.	Boiling point or initial boiling point and boiling range	100 °C
6.	Flammability	no data*
7.	Lower and upper explosion limit	no data*
8.	Flash point	no data*
9.	Auto-ignition temperature	no data*
10.	Decomposition temperature	no data*
11.	рН	7.2 - 7.5 (concentrate)
12.	Kinematic viscosity	no data*
13.	Solubility in water	Soluble in water
	in other solvents	no data*
14.	Partition coefficient n-octanol/water (log value)	no data*
15.	Vapour pressure	no data*
16.	Density and/or relative density	1040 kg/m³
17.	Relative vapour density	no data*
18.	Particle characteristics	no data*





9.2. <u>Other information:</u>

9.2.1. Information with regard to physical hazard classes: Explosive properties: non-explosive.

9.2.2. Other safety characteristics:

No other characteristics available.

*: The manufacturer did not carry out any tests on this parameter for the product or the results of the tests are not available at the time of publication of the data sheet, or the property is not applicable for the product.

SECTION 10: STABILITY AND REACTIVITY

- 10.1. <u>Reactivity:</u> Not reactive.
 10.2. <u>Chemical stability:</u> The product is stable when used in accordance with the supplier's directions.
 10.3. <u>Possibility of hazardous reactions:</u> No risk of hazardous reactions.
- 10.4.Conditions to avoid:
Do not expose to heat (e.g. sunlight).
- 10.5.
 Incompatible materials: No incompatible materials known.
- 10.6.Hazardous decomposition products:
No hazardous decomposition products known.

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 sensitisation: 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.

11.1.1. Summaries of the information derived from the test conducted:

No data available.

11.1.2. Relevant toxicological properties:

- Acute toxicity: Oral: Ingestion of large quantities may cause discomfort. The product does not have to be classified. Dermal: The product does not have to be classified. Inhalation: The product does not have to be classified. STOT-single exposure: The product does not release hazardous vapours. The product does not have to be classified. **Information on likely routes of exposure:** Ingestion, inhalation, skin contact, eye contact. **Symptoms related to the physical, chemical and toxicological characteristics:** No data available.
- **11.1.5.** Delayed and immediate effects as well as chronic effects from short and long-term exposure: No data available.
- **11.1.6.** Interactive effects: No data available.

11.1.3.

11.1.4.

11.1.7. Absence of specific data: No information.





11.2. Information on other hazards:

Endocrine disrupting properties: Endocrine disrupting property: Based on available data, it does not contain endocrine disruptors. **Other information:** No data available.

SECTION 12: ECOLOGICAL INFORMATION

12.1.	<u>Toxicity:</u>
	The mixture is not classified as hazardous for the environment.
12.2.	Persistence and degradability:
	Expected to be biodegradable.
12.3.	Bioaccumulative potential:
	No bioaccumulation expected.
12.4.	Mobility in soil:
-	No data available.
12.5.	Results of PBT and vPvB assessment:
-	No assessment required, as the product contains inorganic matter only.
12.6.	Endocrine disrupting properties:
	Endocrine disrupting property: Based on available data, it does not contain endocrine disruptors.
12.7.	Other adverse effects:
-	No data available.

SECTION 13: DISPOSAL CONSIDERATIONS

13.1.	Waste treatme	nt methods:				
	Disposal according to the local regulations.					
13.1.1.	Information regarding the disposal of the product:					
	Dispose of in accordance with applicable regulations. Contact the local authorities.					
	List of Waste Code:					
	16 10 02	aqueous liquid wastes other than those mentioned in 16 10 01				
	Absorbent/cloth contaminated with the product:					
	15 02 03	absorbents, filter materials, wiping cloths and protective clothing other than those mentioned in 15 02 02				
13.1.2.	Information regarding the disposal of the packaging:					
-	Dispose of in accordance with applicable regulations.					
	Empty, cleansed packaging should be disposed of for recycling.					
	List of Waste Code:					
	15 01 02	plastic packaging				
13.1.3.	Physical/chemical properties that may affect waste treatment options shall be specified:					
	No data available.					
13.1.4.	Sewage disposal:					
• •	No data available.					
13.1.5.	Special precautions for any recommended waste treatment:					

No data available.

SECTION 14: TRANSPORT INFORMATION

ADR/RID; ADN; IMDG; IATA: Not subject to the conventions of carriage of dangerous goods.

14.1.	UN	number	or ID	number:

- No UN Number.
- **14.2.** <u>UN proper shipping name:</u> No proper shipping name.
- 14.3.Transport hazard class(es):No transport hazard classes.
- 14.4. <u>Packing group:</u> No packing group.
- 14.5. <u>Environmental hazards:</u> No relevant information available.





14.6. <u>Special precautions for user:</u>

 No relevant information available.
 14.7. <u>Maritime transport in bulk according to IMO instruments:</u> Not applicable.

SECTION 15: REGULATORY INFORMATION

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

REGULATION (EC) No 1907/2006 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 18 December 2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH), establishing a European Chemicals Agency, amending Directive (EC) No 1999/45 and repealing Council Regulation (EC) No 793/93 and Commission Regulation (EC) No 1488/94 as well as Council Directive (EEC) No 76/769 and Commission Directives (EEC) No 91/155, (EEC) No 93/67, (EC) No 93/105 and (EC) No 2000/21

REGULATION (EC) No 1272/2008 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 16 December 2008 on classification, labelling and packaging of substances and mixtures, amending and repealing Directives (EEC) No 67/548 and (EC) No 1999/45, and amending Regulation (EC) No 1907/2006

COMMISSION REGULATION (EU) 2020/878 of 18 June 2020 amending Annex II to Regulation (EC) No 1907/2006 of the European Parliament and of the Council concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH)

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. <u>Chemical safety assessment:</u> Chemical safety assessment has not been carried out.

SECTION 16: OTHER INFORMATION

Information regarding the revision of the safety data sheet: No information.

Literature references / data sources:

Safety data sheet issued by the manufacturer (15.08.2018, English).

Methods used for the classification according to Regulation (EC) No 1272/2008:

Based on the calculation method carried out on the basis of the known hazards of the components, not considered as a hazardous mixture.

Relevant hazard statements (code and full text) of Sections 2 and 3: No relevant statements.

Training advice: No data available.





Full text of the abbreviations in the safety data sheet: ADN: The European Agreement concerning the International Carriage of Dangerous Goods by Inland Waterways. ADR: The European Agreement concerning the International Carriage of Dangerous Goods by Road. ATE: Acute Toxicity Estimate. AOX: Adsorbable organic halides. BCF: Bioconcentration factor. BOD: Biological Oxygen Demand. CAS number: Chemical Abstract Service number. CLP: Regulation (EC) No 1272/2008 on classification, labelling and packaging of substances and mixtures. CMR effects: Carcinogenic, mutagenic, reprotoxic effects. COD: Chemical Oxygen Demand. CSA: Chemical Safety Assessment. CSR: Chemical Safety Report. DNEL: Derived-No-Effect-Level. ECHA: European Chemical Agency. EC: European Community. EC number: EINECS and ELINCS numbers (see also EINECS and ELINCS). EEC: European Economic Community. EEA: European Economic Area (EU + Iceland, Liechtenstein and Norway). EINECS: European Inventory of Existing Commercial Chemical Substances. ELINCS: European List of Notified Chemical Substances. EN: European Norm. EU: European Union. EWC: European Waste Catalogue (replaced by LoW - see below). GHS: Globally Harmonized System of Classification and Labelling of Chemicals. IATA: International Air Transport Association. ICAO-TI: Technical Instructions for the Safe Transport of Dangerous Goods by Air. IMDG: International Maritime Dangerous Goods. IMO: International Maritime Organization. IMSBC: International Maritime Solid Bulk Cargoes. IUCLID: International Uniform Chemical Information Database. IUPAC: International Union of Pure and Applied Chemistry. Kow: n-Octanol - Water Partition Coefficient. LC50: Lethal concentration resulting in 50 % mortality. LD50: Lethal dose resulting in 50 % mortality (median lethal dose). LoW: List of Waste. LOEC: Lowest Observed Effect Concentration. LOEL: Lowest Observed Effect Level. NOEC: No Observed Effect Concentration. NOEL: No Observed Effect Level. NOAEC: No Observed Adverse Effect Concentration. NOAEL: No Observed Adverse Effect Level. OECD: Organization for Economic Cooperation and Development. OSHA: Occupational Safety and Health Administration. PBT: Persistent, Bioaccumulative and Toxic. PNEC: Predicted No Effect Concentration. QSAR: Quantitative Structure Activity Relationship. REACH: Regulation 1907/2006/EC concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals. RID: Regulations Concerning the International Transport of Dangerous Goods by Rail. SCBA: Self Contained Breathing Apparatus. SDS: Safety Data Sheet. STOT: Specific Target Organ Toxicity. SVHC: Substances of Very High Concern. UN: United Nations. UVCB: Chemical Substances of Unknown or Variable Composition, Complex Reaction Products and Biological Materials. VOC: Volatile Organic Compound. vPvB: very Persistent and very Bioaccumulative.





This safety data sheet had been prepared on the basis of information provided by the manufacturer/supplier and conform to the relevant regulations.

The information, data and recommendations contained herein are provided in good faith, obtained from reliable sources and believed to be true and accurate as of the date issued; however, no representation is made as to the comprehensiveness of the information.

The SDS shall be used only as a guide for handling the product; in the course of handling and using the product other considerations may arise or be required.

Users are cautioned to determine the appropriateness and applicability of the above information to their particular circumstances and purposes and assume all risk associated with the use of this product.

It is the responsibility of the user to fully comply with local, national and international regulations concerning the use of this product.

Safety data sheet was prepared by: MSDS-Europe International branch of ToxInfo Kft.



Professional help regarding the explanation of the safety data sheet: +36 70 335 8480; info@msds-europe.com www.msds-europe.com