

MATERIAL SAFETY DATA SHEET

Sterile Eye Wash

Reviewed 29/12/2012

1. Identification of the Substance/Preparation and the Company

Trade Name: Sterile Eye Wash

Product Code: 2143 500ml Blue Dot Sterile Eye Wash Solution
2144 250ml Blue Dot Sterile Eye Wash Solution
EYE500C 500ml Blue Dot Sterile Eye Wash Solution With Cap

Use of the preparation: A liquid for irrigation and cleansing of the eyes

Company: Crest Medical Ltd
Healthcare Enterprise House
17 Chesford Grange
Woolston
Warrington,
WA1 4RQ, UK

Contact: Tel: +44 (0) 845 230 2092
Fax: +44 (0) 845 230 2091
Email: sales@crestmedical.co.uk
www.crestmedical.co.uk

2. Hazard Identification

This preparation is, according to the conventional method of Directive 1999/45/EC and subsequent amendments, classified as not "Hazardous".

3. Composition/information on ingredients

CAS No: Not applicable, preparation is a mixture.
EINECS No: Not applicable, preparation is a mixture.

Composition: An aqueous solution containing 0.9% w/v sodium chloride EP.

4. First Aid Measures

Based on the composition of this preparation none would be required.

5. Fire Fighting Measures

Only the packaging containing the preparation would burn.

Suitable extinguishing media: Water spray/fog, foam, carbon dioxide and dry powder.

Standard protective equipment should be worn by fire-fighters.

In the event of a large fire toxic fumes containing oxides of carbon may be formed, which would necessitate the use of a self-contained breathing apparatus.

6. Accidental Release Measures

Personal precautions: None required.

Methods for cleaning-up: Mechanically collect any packaging for subsequent disposal and then rinse any spilled preparation to a drain with water.

7. Handling and Storage

Handling: No special measures required.

Storage: Store under normal warehouse conditions.

8. Exposure Controls/Personal Protection

Exposure controls: No assigned values for the ingredients of this preparation.

Personal protection: None required.

9. Physical and Chemical Properties

Appearance: Preparation is a clear colourless liquid

Odour: Preparation is odourless

pH of preparation: 4.5 – 7.0

Boiling point of preparation: ca 100°C

Flash point of preparation: N/A

Flammability: Preparation is non flammable

Solubility: Preparation is completely miscible with water

10. Stability and Reactivity

This preparation is stable under normal conditions of storage/use and no chemical incompatibility is known.

11. Toxicological Information

Based on the ingredients present and their concentrations this preparation is, according to the conventional method of Directive 1999/45 EC and subsequent amendments, classified as not "Dangerous" according to health criteria.

12. Ecological Information

Based on the ingredients present and their concentrations this preparation is, according to the conventional method of Directive 1999/45 EC and subsequent amendments, classified as not "Dangerous" to the environment.

13. Disposal Considerations

Dispose of the packaging according to local and national regulations whilst the preparation can be discharged to any drain.

14. Transport Information

This preparation is classified as not "Hazardous" for transport purposes

ADR – Not regulated

IMDG – Not regulated

IATA – Not regulated

15. Regulatory Information

This preparation is not classified as not "Hazardous" for labeling purposes.

Label for supply:

Active Ingredient 0.9% w/v sodium chloride EP

Directions for Use:

To open: Twist cap smoothly to break seal and remove cap.

How to use: Position container above the eye and gently squeeze so that the fluid flows freely across the eyeball to the outer corner.

Dose: Irrigate and cleanse the eye(s) with as much solution as required.

16. Other Information

This Safety Data Sheet, which takes into consideration the requirements of Directive 1999/45/EC plus subsequent amendments, has been prepared in accordance with Regulation (EC) No 1272/2008 as amended by Regulation (EC) No 453/2010. It is believed to be correct and corresponds to the latest state of scientific/technical knowledge but all data, instructions, recommendations and/or suggestions are made without guarantee.

Technical Data Sheet For The Blue Dot Blanket

Item	Unit	Technical Requirement
Aluminium coated level adhesion		≤20%
Aluminium coated level thickness		≤2.5Ω/□
Aluminium coated level uniformity		±10%
Ingredient		Polyester film
Tensile-strength	/	MD≥170Mpa
		TD≥170Mpa
Elongation at break	/	MD≥90%
		TD≥90%
Thickness	um	12um
Cutting size		Length: 140cm±20mm
		Width: 213cm±20mm
Fold forming size		Length: 8cm
		Width: 11cm
Appearance	--	Appearance should be complete, uniform color, should be straight and smooth, should be neat and clean, no foreign objects

MATERIAL SAFETY DATA SHEET

ACCORDING TO 91/155/EEC AND ISO 9001:2008

Prepared on: Aug 1, 2011

Revised on: Sep 1, 2011

IDENTITY (As Used on Label and list)

Product name: Saline Cleansing Swab (Wipe)

SECTION I —CHEMICAL PRODUCT AND COMPANY IDENTIFICATION

Manufacturer's Name:

NANTONG STRIP MEDICAL SUPPLY CO.,LTD.

Address (Number, street, City, State, and ZIP Code):

A Building, 182 Yue Long Nan Road, Nantong, Jiangsu, China(226006)

Emergency Telephone Number: 0086-513-85512391

Fax Number for Information: 0086-513-85089339

SECTION II —COMPOSITION/INFORMATION ON INGREDIENTS

Single or mixture component: Mixture component (Component that is packaged in an inner packet, which is additionally packaged in an outer box)

Substance	CAS NO.
Mixture component:	
Sodium chloride	7647-14-5
Water	7732-18-5

Other ingredients---A proprietary blend of preservatives in an aqueous solution of sodium chloride, which is impregnated onto a polypropylene based non-woven fabric.

SECTION III —HAZARDS IDENTIFICATION

Emergency Overview: This product with no health hazards reported from normal use. The most important hazard is that eye contact will cause irritation.

Human Health

Eye contact: Will cause irritation

Skin contact: Not expected to present an irritation hazard under normal conditions of use.

Inhalation: Not considered to present an inhalation hazard under normal conditions of use.

Ingestion: Not considered to present an ingestion hazard under normal conditions of use.

Note: Read the entire MSDS for a more thorough evaluation of the hazards.

SECTION IV—FIRST AID MEASURES

Eye contact: If the impregnating liquid comes into direct contact with the eyes, not expected to present an irritation hazard under normal conditions of use. If irritation, stop use and rinse with water. If irritation develops seek medical advice.

Inner/outer bags:

Eye contact: There is a risk of eyeball to be scratched. Flush eyes with plenty of clean water. Get medical attention if you feel unwell.

SECTION V—FIRE FIGHTING MEASURES

Suitable extinguishing media are water spray, foam, carbon dioxide and dry powder. Standard protective equipment should be worn by firefighters.

In the event of a large fire toxic fumes containing oxides of carbon may be formed, which would necessitate the use of a self-contained breathing apparatus.

Fire Fighting Procedures:

In the event of a fire, wear full protective clothing and NIOSH-approved self-contained breathing apparatus with full-face piece operated in the pressure demand or other positive pressure mode. Fight fire from the maximum distance. Evacuate area. Extinguish a fire from windward. Prevent inhalation of gas produced.

Specific Hazards:

When involved in a fire, this material may decompose and produce irritating fumes and gas.

SECTION VI—ACCIDENTAL RELEASE MEASURES

Personal Precautions:

Wear appropriate personal protective equipment as specified in Section VIII. Avoid direct contact with skin.

Environmental Precautions:

This material may be non-hazardous in ordinary use and may be discarded in accordance with applicable governmental regulations and take order with the demands of the environmental protection section.

Methods of Clean up:

Sweep all spilled material. Dispose in accordance with applicable state and federal regulations.

SECTION VII—HANDLING AND STORAGE

Handling Precautions:

Do not use this product any place under high temperature.

Storage Precautions:

Keep product in a cool place away from exposure to sunlight. Do not store product any place where becomes high temperature. Do not damage to outer bag.

SECTION VIII—EXPOSURE CONTROLS/PERSONAL PROTECTION

Engineering measure:

Use exhaust ventilation to keep airborne concentration below exposure limit.

Personal protection equipment:

Eye protection: Not required under normal use.

Hand protection: Not required under normal use.

Skin and Body Protection: Not required under normal use.

SECTION IX—PHYSICAL AND CHEMICAL PROPERTIES

Physical state

Appearance: White non-woven fabric impregnated with a colorless liquid.

Odour: Ethereal

Boiling point: ca 85°C

Flammability: flammable

Explosive properties: n/a

Oxidizing properties: n/a

pH of impregnating liquid: n/a

Flash point of Impregnating liquid: No ignition at 140°C

Solubility: complete miscible with water

Auto-ignition: Not applicable to Auto-ignition substance stated in UN recommendations

Self-heating: Not applicable to Auto-ignition substance stated in UN recommendations

Inner bag:

Appearance: While or colored sheet

Melting point: Polyethylene: 115°C or higher Polypropylene: 125°C or higher

Specific gravity: Polyethylene: 0.91 to 0.94 Polypropylene: 0.89

Water solubility: Insoluble

SECTION X—STABILITY AND REACTIVITY

The product is stable under normal conditions but avoid use near possible sources of ignition.

Stability: Stable under ambient conditions.

Conditions to avoid: Forbid the use in the circumstance with high oxygen concentration.

Hazardous decomposition products: None

Inner bag:

Flash point: Polyethylene: 450°C or higher Polypropylene: 400°C or higher

Water reactivity: None

Oxidization: None

Self-reactivity/Explosive: None

Stability/Reactivity: Stable and non-reactive under ambient storage and handling conditions

Outer bag:

Inflammation point: 340 to 400°C

Flash point: 400 to 500°C

Water reactivity: None

Oxidization: None

Self-reactivity/Explosive: None

Stability/Reactivity: Stable and non-reactive under ambient storage and handling conditions

SECTION XI—TOXICOLOGICAL INFORMATION

Mixture component:

Acute toxicity: None known about oral/dermal toxicity

Inner /Outer bag:

Skin corrosion: None

Irritation: Physical irritation to eyes.

Sensitization: None

Acute toxicity: None known about oral toxicity

Carcinogenicity: None

SECTION XII—ECOLOGICAL INFORMATION

Environmental Toxicity:

On the basis of available information, this product is not expected to produce any

significant adverse environmental effects when recommended use instructions are followed.

Mixture components:

Mobility: None known

Persistence/degradability: None known

Bioaccumulative potential: None known

Inner/Outer bags:

Degradability: Non-degradable for long time

SECTION XIII DISPOSAL CONSIDERATIONS

Waste disposal Methods:

Used or unused product should be disposed of in accordance with Local LAWS and Regulations.

Empty Container Warnings:

Empty containers may contain product residue, follow SDS and label warnings even after they have been emptied.

SECTION XIV TRANSPORT INFORMATION

US Department of Transportation Classification:

The product is not a DOT controlled material (United States).

International Air Transportation Association Classification:

This product is not classified as a hazardous material for transport under IATA regulations.

International Maritime Organization – IMDG:

This product is not classified as a hazardous material for transport under MIDG regulations.

UN, IMO, ADR/RID, ICAO Code:

This product is not classified as a hazardous material for conveyance under these codes.

Specific precautionary transport measures: Avoid wetting and violent handling. Ensure to avoid falling, drop, and damage and prevent load collapse during transport.

SECTION XV—REGULATORY INFORMATION

EC label: N/A

Contains: N/A

Other regulation: N/A

For details regulations you should contact the appropriate agency in your country.

SECTION XVI—OTHER INFORMATION

This data is offered in good faith as typical values and not as a product specification. The information in this data sheet was compiled from information supplied by the vendors of the components of this compound. No warranty, either expressed or implied is hereby made. The recommended industrial hygiene and safe handling procedures are believed to be generally applicable. However, each user should review these recommendations in the specific context of the intended use and determine whether they are appropriate.

30FMD120 } We do not have MSDS for these products.
 30FLG180 }
 30FBOT16 }
 30BCE16 }

CREST MEDICAL LIMITED

TECHNICAL FILE PART A			DOCUMENT REFERENCE: APPII.TXT		
PRODUCT RANGE: STERILE FIRST AID DRESSINGS					
APPROVED:			AUTHORISED:		
DATE:			DATE:		
ISSUE:	7	8	9		
DATE:	16/03/10	08/04/14	23/09/15		

APPENDIX II

EC DECLARATION OF CONFORMITY

Crest Medical Limited
 3, Chesford Grange,
 Woolston,
 Warrington,
 Cheshire.
 WA1 4RQ

declares that the medical device range described in Appendix V

STERILE FIRST AID DRESSINGS

is in conformity with the essential requirements and provisions of the Medical Device Directive 93/42/EEC and Statutory Instrument (SI) No. 2936 – 2008 that transposes the Directives into UK National Law,

is manufactured under the harmonised standard EN ISO 13485 and

is subject to the procedure set out in Annex VII plus Annex V (sterility aspects) of Directive 93/42/EEC under the supervision of Intertek AMTAC Certification services, Notified Body Number 0473.

Classification: Class 1 Sterile – Rationale Annex IX (93/42/EEC) – Rule 4 "All non-invasive devices which come into contact with injured skin are in class 1 if they are intended to be used as a mechanical barrier or absorption of exudates.

Warrington 23/09/15

Alastair Maxwell
 Managing Director

30 BNWT96 - We do not have MSDS for this product.

CREST MEDICAL LIMITED

TECHNICAL FILE PART A			DOCUMENT REFERENCE: APPII.TXT		
PRODUCT RANGE: BLUE DOT TRIANGULAR BANDAGES					
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DATE:	16/03/10	13/03/14	15/06/15		

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is subject to the procedure set out in Annex VII of Directive 93/42/EEC

Classification: Class 1: Non-Sterile – Rationale Annex IX (93/42/EEC) – Rule 1 "All non invasive devices are in class I unless one of the rules set out hereafter applies". No other rules apply.

Warrington 15/06/15

Alastair Maxwell
Managing Director

30 BMT025 - We do not have MSDS for this product.
2044425 + 204443



Crest Medical
suppliers to the medical industry

TECHNICAL FILE PART A			DOCUMENT REFERENCE: APPII.TXT		
PRODUCT RANGE: ADHESIVE TAPES					
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Warrington 08/0915

Alastair Maxwell
Managing Director



30 BDC075 - We donot have MSDS for this product.
30 BDC010

CREST MEDICAL LTD.

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Classification: Class 1: Non-Sterile – Rational Annex IX (93/42/EEC)- Rule 1 - Non-invasive device.

Warrington 1/10/15

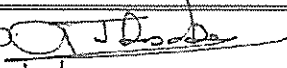
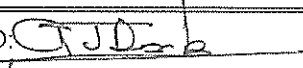
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Alastair Maxwell
Managing Director

30PEWP10

Blue Dot Assorted WashProof Plasters

We do not have MSDS for this product

CREST MEDICAL LIMITED.

TECHNICAL FILE PART A			DOCUMENT REFERENCE: APPII.TXT		
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Warrington 24/08/15


Alastair Maxwell
Managing Director

Technical Data Sheet For 30REVA01

Item	Technical Requirement
Material of film	ethylene-vinyl acetate copolymer
Thickness of film	0.11mm(±10%)
Size of film	20*20cm(±1cm)
Material of filter	polypropylene
Size for inlet port of filter	1.5cm(±0.2cm)
Diameter of outlet for filter	3.6cm*1.55cm
Appearance	Appearance should be complete, uniform color, should be neat and clean, no foreign objects

30FMD120 } We do not have MSDS for these products.
 30FLG180 }
 30FBOT16 }
 30BCE16 }

CREST MEDICAL LIMITED

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Classification: Class 1 Sterile – Rationale Annex IX (93/42/EEC) – Rule 4 "All non-invasive devices which come into contact with injured skin are in class 1 if they are intended to be used as a mechanical barrier or absorption of exudates.

Warrington 23/09/15

Alastair Maxwell
 Managing Director

30 BNWT96 - We do not have MSDS for this product.

CREST MEDICAL LIMITED

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Classification: Class 1: Non-Sterile – Rationale Annex IX (93/42/EEC) – Rule 1 "All non invasive devices are in class I unless one of the rules set out hereafter applies". No other rules apply.

Warrington 15/06/15

Alastair Maxwell
Managing Director

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Warrington 08/0915

Alastair Maxwell
Managing Director



30 BDC075 - We donot have MSDS for this product.
30 BDC010

CREST MEDICAL LTD.

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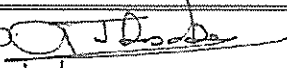
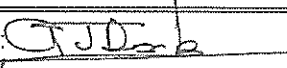
Classification: Class 1: Non-Sterile – Rational Annex IX (93/42/EEC)- Rule 1 - Non-invasive device.

Warrington 1/10/15

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Alastair Maxwell
Managing Director

30PEWP10 Blue Dot Assorted WashProof Plasters
We do not have MSDS for this product

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Warrington 24/08/15


Alastair Maxwell
Managing Director

Technical Data Sheet For 30REVA01

Item	Technical Requirement
Material of film	ethylene-vinyl acetate copolymer
Thickness of film	0.11mm(±10%)
Size of film	20*20cm(±1cm)
Material of filter	polypropylene
Size for inlet port of filter	1.5cm(±0.2cm)
Diameter of outlet for filter	3.6cm*1.55cm
Appearance	Appearance should be complete, uniform color, should be neat and clean, no foreign objects

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WA1 4RQ

declares that the medical device range described in Appendix V

BLUE DOT TRIANGULAR BANDAGE

is in conformity with the essential requirements and provisions of the Medical Device Directive 93/42/EEC and Statutory Instrument (SI) No. 2936 (2008) that transposes the Directive into UK National Law,

is manufactured under the harmonised standard EN ISO 13485 and

is subject to the procedure set out in Annex VII of Directive 93/42/EEC

Classification: Class 1: Non-Sterile – Rationale Annex IX (93/42/EEC) – Rule 1 "All non invasive devices are in class I unless one of the rules set out hereafter applies". No other rules apply.

Warrington 15/06/15

Alastair Maxwell
Managing Director

30 BMT025 - We do not have MSDS for this product.
2044425 + 204443



Crest Medical
suppliers to the medical industry

TECHNICAL FILE PART A			DOCUMENT REFERENCE: APPII.TXT		
PRODUCT RANGE: ADHESIVE TAPES					
APPROVED:			AUTHORISED:		
DATE: 8/9/2015			DATE: 8/9/2015		
ISSUE:	2	3	4	5	
DATE:	24/09/07	16/03/10	20/03/14	08/09/15	

APPENDIX II

EC DECLARATION OF CONFORMITY

Crest Medical Limited
3, Chesford Grange,
Woolston,
Warrington,
Cheshire.
WA1 4RQ

declares that the medical device range described in Appendix V

ADHESIVE TAPES

is in conformity with the essential requirements and provisions of the Medical Device Directive 93/42/EEC and Statutory Instrument (SI) No. 2936 (2008) that transposes the Directive into UK National Law,

is manufactured under the harmonised standard EN ISO 13485 and

is subject to the procedure set out in Annex VII of Directive 93/42/EEC.

Classification: Class 1 Non-Sterile – Rationale Annex IX, (93/42/EEC) – Rule 1 "All non-invasive devices which do not come into contact with injured skin are in class I unless one of the rules set out hereafter applies". No other rules apply.

Warrington 08/0915

Alastair Maxwell
Managing Director



30 BDC075 - We donot have MSDS for this product.
30 BDC010

CREST MEDICAL LTD.

TECHNICAL FILE PART A			DOCUMENT REFERENCE: APPII.TXT		
PRODUCT RANGE: CREST MEDICAL NON STERILE BANDAGES					
APPROVED:			AUTHORISED:		
DATE:			DATE:		
ISSUE:	6	7	8		
DATE:	30/04/13	14/04/14	1/10/15		

APPENDIX II

EC DECLARATION OF CONFORMITY

Crest Medical Limited
3, Chesford Grange,
Woolston,
Warrington,
Cheshire.
WA1 4RQ
United Kingdom

declares that the medical device range described in Appendix V

NON STERILE BANDAGES

is in conformity with the essential requirements and provisions of the Medical Device Directive 93/42/EEC and Statutory Instrument (SI) No. 2936 (2008) that transposes the Directive into the UK National Law,

is manufactured under the harmonised standard EN ISO 13485 and

is subject to the procedure set out in Annex VII of Directive 93/42/EEC.

Classification: Class 1: Non-Sterile – Rational Annex IX (93/42/EEC)- Rule 1 - Non-invasive device.

Warrington 1/10/15



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Alastair Maxwell
Managing Director

30PEWP10

Blue Dot Assorted WashProof Plasters

We do not have MSDS for this product

CREST MEDICAL LIMITED.

TECHNICAL FILE PART A		DOCUMENT REFERENCE: APPII.TXT			
PRODUCT RANGE: STERILE ADHESIVE PLASTERS					
APPROVED: 		AUTHORISED: 			
DATE: 24/8/2015		DATE: 24/8/2015			
ISSUE:	1	2	3		
DATE:	29/03/11	21/05/13	24/08/15		

APPENDIX II

EC DECLARATION OF CONFORMITY

Crest Medical Limited
3, Chesford Grange,
Woolston,
Warrington,
Cheshire.
WA1 4RQ

declares that the medical device range described in Appendix V

BLUE DOT STERILE ADHESIVE PLASTERS

is in conformity with the essential requirements and provisions of the Medical Device Directive 93/42/EEC and Statutory Instrument (SI) No.2936 (2008) that transposes the Directive into UK National Law

is manufactured under the national standard BS EN ISO 13485 transposing the harmonised standard EN ISO 13485 and

is subject to the procedure set out in Annex VII plus Annex V (sterility aspects) of Directive 93/42/EEC

Warrington 24/08/15


Alastair Maxwell
Managing Director

Technical Data Sheet For 30REVA01

Item	Technical Requirement
Material of film	ethylene-vinyl acetate copolymer
Thickness of film	0.11mm(±10%)
Size of film	20*20cm(±1cm)
Material of filter	polypropylene
Size for inlet port of filter	1.5cm(±0.2cm)
Diameter of outlet for filter	3.6cm*1.55cm
Appearance	Appearance should be complete, uniform color, should be neat and clean, no foreign objects