

SAFETY DATA SHEET

According to EU Directive 91/151/EEC as amended by Directive 2001/58/EC

Date of issue: March 2015.

1. Identification of the substance and of the company	
1.1 Product Identifier/Trade name	PAD Plus Normal solution
1.2. Relevant Identified Use(s) and uses advised against.	Only for use in dentistry to treat bacterial infections in the mouth when activated with red light at 635nm during a PAD procedure. Advised against all other uses.
1.3 Details of Manufacturer/supplier.	Denfotex Research Ltd., Floor 5, Henriette Raphael House, Kings College London, Guys Hospital Campus, London, SE11UL, United Kingdom.
1.4 Emergency telephone and contact information.	Tel: +44 (0) 7802439204 Email: david.clements@denfotexresearch.com
2. Hazards identification	
2.1 Classification of substance	Not a hazardous substance or mixture according to Regulation no. 1272/2008. This substance is not classified as dangerous according to directive 67/548/EEC.
2.2. Label elements	As required by Medical Device Directive
2.3 Other hazard information	
Ingestion	Supplied in syringes containing 1.2ml of solution with ingestion of 28L necessary to reach NOAEL equivalent to 23,333 syringes.
Skin contact	Will stain skin pale blue which can be washed-off with soap and water.
Eye contact	Flush out solution with water and seek medical advice.
Inhalation	No vapour is released from solution so there is no inhalation.
Environment: vPvB/PBT	No known effect
Additional information	No other risks known.
3. Information on ingredients	
3.1 Substances	Tolonium chloride, buffer, sterile water
3.2 Mixtures	Not a mixture
Other information	
Description:	Pale blue liquid
Hazardous components:	NONE
CAS Number	92-31-9
REACH Number	A registration number is not available as the substance or its uses are exempted from

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	registration, the annual tonnage does not require registration or the registration is envisaged for a later registration deadline.
Synonyms	Toluidine Blue O Methylene Blue T50 or Textra Blutene chloride Basic Blue 17
Formula Molecular Weight EC-No. :	C ₁₅ H ₁₆ ClN ₃ S 305.83 g/mol 202-146-2
4. First Aid Measures	
4.1 Description of First Aid measures	
Ingestion	Swallow 1L of water. Rinse mouth and wash around lips to remove pale blue stain.
Skin	Wash- off with soap and water to remove pale blue stain.
Eyes	Flush out solution with water until clear and seek medical advice.
Inhalation	No vapour is released from solution so there is no inhalation
4.2 Most important symptoms and effects, both acute and delayed	
Ingestion	Urine and faeces will be coloured pale blue which will dissipate after ingestion of 1L of water.
Skin	Wash- off with soap and water to remove pale blue stain.
Eyes	Flush out solution with water until clear and seek medical advice.
Inhalation	No vapour is released from solution so there is no inhalation
4.3 Indication of immediate medical attention and special treatment	Seek medical attention (i) if ingestion is at or exceeds NOAEL of 28L and (ii) after flushing out solution from eyes.
5. Fire Fighting Measures	
5.1 Extinguishing media	
Small fires	Not relevant as solution is (99+%) water.
Large fires	Not relevant as solution is (99+%) water.
5.2 Special hazards arising from substance	None.

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5.3. Special protective actions for fire-fighters	None
6. Accidental release measures	
6.1 Personal precautions, protective equipment and emergency procedures	Avoid ingestion and contact with eyes. For personal protection see section 8.
6.2. Environmental precautions	Do not let product enter drains.
6.3 Methods and materials for containment and cleaning up	Cover spillage with sand or other suitable material to absorb solution. Sweep up and shovel. Keep in suitable, closed containers for disposal
7. Handling & storage	
7.1 Precautions for safe handling	Handle with gloves. Gloves must be inspected prior to use. Use proper glove removal technique (without touching glove's outer surface) to avoid skin contact with product. Dispose of contaminated gloves after use in accordance with applicable laws and good working practices. Wash and dry hands. The selected protective gloves have to satisfy the specifications of EU Directive 89/686/EEC and the standard EN 374 derived from it. Wear suitable eye protection/goggles to prevent solution entering eyes.
7.2 Conditions for safe storage, including any incompatibilities	Store in cool place. Keep container tightly closed in a dry and well-ventilated place at 10-20°C in dark away from foodstuffs.
7.3 Specific End Uses:	Used in dentistry. Clinician will usually have no more than 50 x 1.2ml syringes and spillage can be dealt with by surgery staff.
8. Exposure controls and personal protection	
8.1 Control parameters	Solution contains no substances with occupational exposure limit values.
8.2 Exposure Controls	In case of spillage of solution refer to 6.3 and 7.1 .
8.3 Additional information	Exclude light. Keep at or below 20°C
9. Physical and chemical properties	
9.1 Information on basic physical and chemical properties	
Appearance/Form:	Liquid
Colour:	Pale blue
Odour/odour threshold	None/none.

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Change in condition	Becomes paler on exposure to light or heat
Melting point/melting range	Solution so not applicable
Boiling point/boiling range:	100°C
Freezing point	0°C
Evaporation rate	As water leaving blue stain
Flash point	Not applicable
Auto ignition temperature	Not applicable
Explosive properties	Not applicable
Upper/lower flammability	Not applicable
Oxidising properties	Not applicable
Decomposition temperature	Not applicable
Density:	1.0g/cm ³
Vapour pressure:	2.8 KN.m ⁻² at 23°C
Viscosity:	1mPa
pH	5.0 to 5.5
Solubility in/miscibility with water:	Aqueous solution 20mg/L: Miscible
Content of solvents	None
Organic content:	<0.03%
Water content:	99.6%
Other information	None
10. Stability and reactivity	
10.1 Reactivity	None
10.2 Chemical stability	Stable in dark and 0°C to 20°C
10.3 Possibility of hazardous reactions	None
10.4 Conditions to avoid:	Avoid heat, light
10.5 Incompatible materials	None
10.6 Hazardous decomposition products:	None
Other information	Avoid contacting solution with bleach, carboxylic acids, chelating agents which will render solution ineffective
11. Toxicological information	
11.1 Information on toxicological effect	
Acute toxicity:	None until NOAEL of 28L ingested.
Skin corrosion/irritation	Prolonged contact may cause irritation especially if

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	exposed to light
Serious eye damage/irritation	Irritant
Respiratory/skin sensitisation:	May cause sensitisation in susceptible individuals
Germ cell mutagenicity	No known mutagenicity below NOAEL of 28L
Carcinogenicity	No known mutagenicity below NOAEL of 28L
Reproductive toxicity	No known mutagenicity below NOAEL of 28L
STOT – single exposure	No known effect below NOAEL of 28L
STOT – repeated exposure	No known effect below NOAEL of 28L
Aspiration hazard	None
12. Ecological information	
12.1 Toxicity	No known data
12.2 Persistence and degradability	Diluted and degrades with water
12.3 Bioaccumulative potential	No data.
12.4 Mobility in soil	No data.
12.5 Results of PBT and vPvB assessment	Not applicable to medical device.
12.6 Other adverse effects	None known.
13. Disposal instructions	
13.1 Waste treatment methods	Use proper landfill disposal or incineration in accordance with local regulations
14. Transport information	No special precautions
14.1 UN Number	ADR/RID: Not applicable IMDG: Not applicable IATA: Not applicable
14.2 UN Proper Shipping Name	ADR/RID: Not dangerous goods. IMDG: Not dangerous goods. IATA: Not dangerous goods
14.3 Transport Hazard Classes	ADR/RID: Not applicable. IMDG: Not applicable IATA: Not applicable
14.4 Packing group	ADR/RID: Not applicable. IMDG: Not applicable IATA: Not applicable
14.5 Environmental hazards	ADR/RID: Not applicable. IMDG: Not applicable IATA: Not applicable
14.6 Special precautions for user	Follow instructions in Directions For Use

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14.7 Transport in bulk	Not applicable
15. Regulatory information	
15.1 Safety, health and environmental regulations/legislation specific for substance	This safety datasheet complies with the requirements of Regulation (EC) No. 1907/2006
Chemical safety assessment	Contains no known hazard.
16. Other information	The above information is based on our present day knowledge and relates solely to the safety requirements of the product. It does not constitute a guarantee for any specific property users of the product should satisfy themselves that the information is sufficient for their specific circumstances of use