

# **MATERIAL SAFETY DATA SHEET**

## **Product Code: MW148**

Section	Details		
Section 1: Identification of the	1.1 Product identifier		
substance/mixture and of the company	Product Name: Cytotak™Cytology Sampling Brush		
undertaking	Product Codes: MW148		
	1.2 Relevant identified uses of the substance or mixture and uses		
	advised against		
	Intended life cycle stages and user groups		
	<i>PW</i> ,SU4 ,SU20 ,SU24 Intended use: <i>In-vitro diagnostics under clinical supervision</i>		
	Uses advised against: Void		
	1.3 Details of the supplier of the safety data sheet		
	Manufacturer:		
	Medical Wire & Equipment		
	Corsham, Wiltshire, SN13 9RT, UK		
	Tel: +44 1225 810361		
	Email: <i>sds@mwe.co.uk</i>		
	1.4 Emergency Telephone Number		
	☎. +44 1225 810361		
Section 2: Hazards Identification	2.1 Classification of the substance or mixture		
	Classification according to Regulation 1272/2008/EC		
	This product is not classified		
	This product contains no hazardous constituents, or the concentration of all		
	chemical constituents are below the regulatory threshold limits described by		
	European directive 1272/2008/EC and the Occupational Safety Health		
	Administration Hazard Communication Standard 29 CFR 1910.1200 and the		
	Canadian Workplace Hazardous Materials Information System (WHMIS).		
	Information partaining to particular dangars for man and anyironment		
	Information pertaining to particular dangers for man and environment The product presents no hazards to man or the environment as calculated by		
	the procedures of the EU directives (1999/45/EC and Amendments)		
	2.2. Label elemente		
	<b>2.2 Label elements</b> The product is not subject to hazard identification regulations according to EU		
	directives.		
	GHS label elements: <i>Void</i>		
	Hazard pictograms: <i>Void</i>		
	Signal word: Void		
	Hazard statements: <i>Void</i>		
	Other hazards		
	PBT and vPvB assessments: Not applicable		



Section 3: Composition /information on ingredients	3.1 Substances Not applicable		
	<b>3.2 Mixtures</b> Not applicable		
Section 4: First Aid Measures	<b>4.1 Description of first aid measures</b> General information: <i>No special measures required</i>		
	After inhalation: Supply fresh air; seek medical advice in case of complaints After skin contact: Contact is harmless, but in case of irritation wash with water and soap and rinse thoroughly After eye contact: Contact is harmless, but in case of irritation rinse opened eye for several minutes under running water. If symptoms persist seek medical attention. After swallowing: Seek medical advice		
	<b>4.2 Most important symptoms and effects, both acute and delayed</b> No acute or delayed symptoms expected. No further relevant information available.		
	<b>4.3 Indication of any immediate medical attention and special treatment needed</b> <i>Risk of choking or obstruction if swallowed. No further relevant information available.</i>		
	Information for doctor: Show product label or this Safety Data Sheet		
Section 5: Firefighting measures	<b>5.1 Extinguishing media</b> Suitable extinguishing agents: CO2, extinguishing powder, or water spray. Fight larger fires with water spray or alcohol resistant foam.		
	<b>5.2 Special hazards arising from the substance or mixture</b> No exposure hazards. No toxic gases No further relevant information available		
	<b>5.3 Advice for firefighters</b> Protective equipment: <i>No special measures required</i>		
Section 6: Accidental release measures	6.1 Personal precautions, protective equipment and emergency procedures Not required		
	<b>6.2 Environmental precautions</b> No special measures required		
	<b>6.3 Methods and material for containment and cleaning up</b> <i>No special measures required</i>		
	<b>6.4 Reference to other sections</b> No dangerous substances released. See Section 7 for information on safe handling See Section 8 for information on personal protection equipment See Section 13 for disposal information		
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### MATERIAL SAFETY DATA SHEET (Ref: ISO 11014:2009; European Directive 1907/2006/EC) Cytotak™ Cytology Sampling Brush Product Code(s): MW148

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Section 7: Handling & Storage	7.1 Precautions for safe handling No special measures required Information about protection against explosions and fires: No special measures required			
	<b>7.2 Conditions for safe storage, including any incompatibilities</b> Requirements to be met by storerooms and receptacles: <i>No special</i> <i>requirements</i>			
	Information about storage in one common storage facility: <i>Store away from oxidising agents</i> Further information about storage conditions: <i>Store in cool, dry conditions</i>			
	7.3 Specific end uses No further relevant information available			
Section 8: Exposure controls/ personal protection	<b>8.1 Control parameters</b> Components with limit values that require monitoring at the workplace: <i>The product does not contain any relevant quantities of materials with critical values that have to be monitored at the workplace.</i>			
	8.2 Exposure controls Engineering controls: <i>No special measures required</i>			
	Personal Protective Equipment Respiratory protection/breathing equipment: <i>Not required</i> Protection of hands: <i>Not required</i> Eye protection: <i>Not required</i> Body protection: <i>Not required</i>			
Section 9: Physical and chemical properties	9.1 Information on basic physical and chemical properties			
proportioo	General information			
		Solid		
	Appearance			
	Colour	According to specification		
	Odour	Characteristic		
	Change in condition			
	Melting point/ Melting range	Not determined		
	Boiling point/ Boiling range	Not determined		
	Flash point	Not applicable		
	Explosive properties	Product does not present an explosion hazard		
	Density	Not determined		
	Solubility in / Miscibility with water	Insoluble		
	<b>9.2 Other information</b> No further relevant information available			
Section 10: Stability and reactivity	10.1 Reactivity         No significant reactions known         10.2 Chemical stability         Thermal decomposition / conditions to be avoided: No decomposition if used according to specification         10.3 Possibility of hazardous reactions         No dangerous reactions known         10.4 Conditions to avoid         No further relevant information available         10.5 Incompatible materials         No further relevant information available         10.6 Hazardous decomposition products         No dangerous decomposition products known			

Please note that as medical devices the products referred to on this document have no legal requirement for a Safety Data Sheet. The product is not classified according to the Globally Harmonised System (GHS). This Safety Data Sheet has been compiled for the convenience of the user, providing information compliant with the GHS according to the format of the regulations indicated. (Ref. Regulation 1907/2006/EC Article 2 (6), Regulation 1272/2008 EC Article 1.(5(a)), & OSHA HCS )



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Section 11: Toxicological information	<ul> <li>11.1 Information on toxicological effects <ul> <li>Acute toxicity:</li> <li>Primary irritant effect:</li> <li>On the skin: none</li> <li>On the eye: none</li> <li>Respiratory or skin senitisation: No sensitising effects known</li> <li>Additional information:</li> <li>When used and handled in accordance with specification, the product has no harmful effects according to the information available to us and to our experience with the product.</li> <li>The product is not subject to classification according to the calculation method of the General EU Classification Guidelines for Preparations as issued in the latest version.</li> <li>The product is not subject to OSHA classification according to internally approved calculation methods for preparations</li> </ul> </li> </ul>
Section 12: Ecological Information	12.1 Toxicity         Aquatic toxicity: No further relevant information available         12.2 Persistence and degradability         No further relevant information available         12.3 Bioaccumulative potential         No further relevant information available         12.4 Mobility in soil         No further relevant information available         12.5 Results of PBT and vPvB assessment         Not applicable         12.6 Other adverse effects         General notes: Not known to be hazardous to water         No further relevant information available
Section 13: Disposal considerations           Section 13: Transport information	<b>13.1 Waste treatment methods</b> Recommendation         Must adhere to national and local regulations.         Smaller quantities can be disposed of with solid waste.         US: Disposal must be made according to the regulations found in 40 CFR 261         This product is not considered a RCRA hazardous waste         Uncleaned packagings:         Recommendation: Must adhere to national and local regulations.         Recommended cleansing agent: water, if necessary with cleansing agents. <b>14.1 UN Number</b> Not regulated*
	14.2 UN proper shipping name         Not regulated*         14.3 Transport hazard classes         Not regulated*         14.4 Packing group         Not regulated*         14.5 Environmental hazards         Not regulated*         14.6 Special precautions for user         Not applicable         14.7 Transport in bulk according to Annex II of MARPOL 73/78 and the         IBC Code         Not applicable         * DOT, ADR, ADN, IMDG, IATA as appropriate



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Section 15: Regulatory information	15.1 Safety, health and environmental regulations/legislation specific for the substance or mixture			
	EU			
	Labelling according to Regulation (EC) No 1272/2008 not required. Labelling is according to European In Vitro Diagnostic Medical Devices Directive 98/79/EC			
	US SARA 313 & 355 are sections of 40 CFR Protection of Environment <i>No ingredients listed</i> TSCA (Toxic Substances Control Act) <i>No ingredients listed.</i> California Proposition 65 Chemicals known to the state to cause cancer, reproductive toxicity for males or females, or developmental toxicity <i>No ingredients listed.</i> NTP (National Toxicology Program) Report on Carcinogens <i>No ingredients listed</i> TLV (Threshold Limit Value according to American Conference of Governmental Industrial Hygienists) <i>No ingredients listed</i> <i>Canada</i> Canadian Substance Listing			
	Canadian Domestic Substance List (DSL): <i>All ingredients listed</i> Canadian Ingredient Disclosure List (limit 0.1%): <i>No ingredients listed</i> Canadian Ingredient Disclosure List (limit 1%): <i>No ingredients listed</i>			
	<b>15.2 Chemical safety assessment</b> A Chemical Safety Assessment has not been carried out.			
Section 16: Other information	To the best of our knowledge, the information contained herein is accurate. However, neither Medical Wire & Equipment nor any of its distributors assumes any liabilities whatsoever for the accuracy or completeness of the information contained herein. Final determination of suitability of any material is the sole responsibility of the user. All materials may present unknown hazards and should be used with caution. Although certain hazards are described herein, we cannot guarantee that these are the only hazards that exist. <i>Relevant identified uses according to</i> European Chemical Agency (ECHA) : Guidance on Information Requirements and Chemical Safety Assessment Chapter R.12:Use description. Version 3.0, December 2015, www.echa.europa.eu			
	Code	Name		
	Key Descriptor: Life Cycle Stages			
	PW	Widespread use by professional workers		
	Supplementary descriptor: Sectors of use			
	SU4	Manufacture of food products		
	SU20	Health services Scientific research and		
	SU24	development		



#### References

This Material Safety Data Sheet has been prepared in accordance with the requirements of the following regulations 1. ISO 11014:2009 Safety data sheet for chemical products

- 2. European Regulation 1907/2006/EC as amended by Regulation (EC) 1272/2008 and Regulation (EU) 2015/830
- 3. For UK: Statutory Instrument 2008 No. 2852 The REACH Enforcement Regulations 2008
- 4. For US: Occupational Safety Health Administration Hazard Communication Standard 29 CFR 1910.1200
- 5. For Canada: Workplace Hazardous Information System
- 6. For Australia: Work Health and Safety Act 2011(the WHS Act)
- 7. Globally Harmonized System of Classification and Labelling of Chemicals (United Nations)

#### Abbreviations

ADR: European Agreement concerning the International Carriage of Dangerous Goods By Road (1957, amended 1975) ADN: Agreement concerning the International Carriage of Dangerous Goods By Inland Waterways (Version as revised 1 January, 2007)

RID: *Reglemant concernant le transport international ferroviaire des merchandises dangereuses*, concerns the international transport of goods by rail, and forms part of COTIF, the Convention concerning International Carriage by Rail (Version with effect from 1 January, 2009).

IMDG: International Maritime Dangerous Goods Code (2006 edition, ISBN 978-92-8001-4214-3)

ICAO: International Civil Aviation Organisation (2007-2008 Edition)

IATA: International Air Transport Association

GHS: Globally Harmonized System of Classification and Labelling of Chemicals (GHS) (6<sup>th</sup> Revised Edition) United Nations 2015 (ISBN 978-92-1-117087-0)