

# **MATERIAL SAFETY DATA SHEET**

# **Product Code: MWAM1**

Section	Details
<b>Section 1:</b> Identification of the substance/mixture and of the company undertaking	<b>1.1 Product identifier</b> Product Name: <b>Amnicators</b> ® Product Codes: MWAM1
	<b>1.2 Relevant identified uses of the substance or mixture and uses advised against</b> Intended life cycle stages and user groups <i>PW</i> , <i>SU20</i> , <i>SU24</i>
	Intended use: <i>In-vitro diagnostics under clinical supervision</i> Uses advised against: <i>Void</i>
	1.3 Details of the supplier of the safety data sheet
	Manufacturer: <i>Medical Wire &amp; Equipment</i> <i>Corsham, Wiltshire, SN13 9RT, UK</i> <i>Tel: +44 1225 810361</i>
	Email: sds@mwe.co.uk
	1.4 Emergency Telephone Number
	☎. +44 1225 810361
Section 2: Hazards Identification	<b>2.1 Classification of the substance or mixture</b> 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 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)
	<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: <i>Void</i> Hazard statements: <i>Void</i>
	Other hazards PBT and vPvB assessments: Not applicable



	Froduct Code(s). MWAM		
Section 3: Composition /information on	3.1 Substances		
ingredients	Not applicable		
	3.2 Mixtures		
	Not applicable		
Section 4: First Aid Measures	4.1 Description of first aid measures		
	General information: No special measures required		
	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		
	Aller Swallowing. Seek medical advice		
	<b>4.2 Most important symptoms and effects, both acute and delayed</b> <i>No acute or delayed symptoms expected. No further relevant information</i> <i>available.</i>		
	4.3 Indication of any immediate medical attention and special treatment needed		
	Risk of choking or obstruction if swallowed. No further relevant information available.		
	Information for doctor: Show product label or this Safety Data Sheet		
Section 5: Firefighting measures	5.1 Extinguishing media		
	Suitable extinguishing agents: CO2, extinguishing powder, or water spray. Fight larger fires with water spray or alcohol resistant foam.		
	5.2 Special hazards arising from the substance or mixture No exposure hazards. No toxic gases		
	No further relevant information available		
	5.3 Advice for firefighters		
	Protective equipment: No special measures required		
Section 6: Accidental release measures	6.1 Personal precautions, protective equipment and emergency procedures Not required		
	Not required		
	6.2 Environmental precautions		
	No special measures required		
	6.3 Methods and material for containment and cleaning up No special measures required		
	6.4 Reference to other sections		
	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) Amnicators® Product Code(s): MWAM1

Section 7: Handling & Storage	<b>7.1 Precautions for safe handling</b> No special measures required Information about protection against explosions and fires: <i>No special</i> measures required			
	<b>7.2 Conditions for safe storage, including any incompatibilities</b> Requirements to be met by storerooms and receptacles: <i>No special requirements</i> Information about storage in one common storage facility: <i>Store away from oxidising agents</i>			
	Further information about storage conditions: Store in cool, dry conditions			
	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			
	General information			
	Appearance	Solid		
	Colour	Yellow		
	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	<b>12.1 Toxicity</b> Aquatic toxicity: No further relevant information available <b>12.2 Persistence and degradability</b> No further relevant information available <b>12.3 Bioaccumulative potential</b> No further relevant information available <b>12.4 Mobility in soil</b> No further relevant information available <b>12.5 Results of PBT and vPvB assessment</b> Not applicable <b>12.6 Other adverse effects</b> General notes: Not known to be hazardous to water         No further relevant information available
Section 13: Disposal considerations	<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.
Section 14: Transport information	14.1 UN Number         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>			
	Canada 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 distributorsassumes any liabilities whatsoever for the accuracy or completeness of theinformation contained herein. Final determination of suitability of any materialis the sole responsibility of the user. All materials may present unknownhazards and should be used with caution. Although certain hazards aredescribed herein, we cannot guarantee that these are the only hazards thatexist.Relevant identified uses according toEuropean Chemical Agency (ECHA) : Guidance on Information Requirementsand Chemical Safety Assessment Chapter R.12:Use description. Version 3.0,December 2015, www.echa.europa.eu			
	Code	Name		
	Key Descriptor: Life Cycle Stages			
	PŴ	Widespread use by professional workers		
	Supplementary descriptor: Sectors of use			
	SU4	Manufacture of food products		
	SU20	Health services		
	SU24	Scientific research and 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)