

SAFETY DATA SHEET  
**Amnicator®**

SECTION	DETAILS
SECTION 1 Identification of the Substance/Mixture and of the Company Undertaking	<p>1.1 Product Identifier Product Name: Amnicator® Product Codes: MWAM2, MWAM5</p> <p>1.2 Relevant Identified Uses of the Substance or Mixture and Uses Advised Against Intended Life Cycle Stages and User Groups: PW, SU20, SU24 Intended Use: In-vitro diagnostics under clinical supervision Uses Advised Against: Void</p> <p>1.3 Details of the Supplier of the Safety Data Sheet Manufacturer: Medical Wire &amp; Equipment Co. (Bath) Ltd. Corsham, Wiltshire, SN13 9RT, UK</p> <p>Email: <a href="mailto:sds@mwe.co.uk">sds@mwe.co.uk</a></p> <p>1.4 Emergency Telephone Number +44 (0)1225 810361</p>
SECTION 2 Hazards Identification	<p>2.1 Classification of the Substance or Mixture in an Individual Vial Classification of the Mixture According to Regulation 1272/2008/EC: This product is not classified</p> <p>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).</p> <p>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 European (EU) directives (1999/45/EC and Amendments)</p> <p>2.2 Label Elements The product is not subject to hazard identification regulations according to EU directives. GHS Label Elements: Void Hazard Pictograms: Void Signal Word: Void Hazard Statements: Void</p> <p>2.3 Other Hazards PBT and vPvB Assessments: Not applicable</p>
SECTION 3 Composition /Information on Ingredients	<p>3.1 Substances Not applicable.</p> <p>3.2 Mixtures The mixture is not classified according to Regulation 1272/2008/EC No dangerous components as defined by regulations. Metolose 9004-65-3 Nitrazine Yellow – 5423-07-4</p>
SECTION 4 First Aid Measures	<p>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</p>

	<p>After Skin Contact: Transient contact is harmless, but in case of prolonged contact or irritation wash with water and soap and rinse thoroughly          After Eye Contact: Rinse opened eye for several minutes under running water. If symptoms persist seek medical attention          After Swallowing: If symptoms persist seek medical advice</p> <p>4.2 Most Important Symptoms and Effects, Both Acute and Delayed          No acute or delayed symptoms expected.          No further relevant information available.</p> <p>4.3 Indication of any Immediate Medical Attention and Special Treatment Needed          No further relevant information available.          Information for Doctor: Show product label or this Safety Data Sheet</p>
<p>SECTION 5          Firefighting Measures</p>	<p>5.1 Extinguishing Media          Suitable Extinguishing Agents: CO<sub>2</sub>, extinguishing powder, or water spray. Fight larger fires with water spray or alcohol resistant foam</p> <p>5.2 Special Hazards Arising from the Substance or Mixture          No exposure hazards.          No toxic gases.          No further relevant information available.</p> <p>5.3 Advice for Firefighters          Protective Equipment: No special measures required</p>
<p>SECTION 6          Accidental Release Measures</p>	<p>6.1 Personal Precautions, Protective Equipment and Emergency Procedures          Not required.</p> <p>6.2 Environmental Precautions          No special measures required.          Wipe up with damp sponge or cloth.</p> <p>6.3 Methods and Material for Containment and Cleaning Up          No special measures required.</p> <p>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.</p>
<p>SECTION 7          Handling &amp; Storage</p>	<p>7.1 Precautions for Safe Handling          No special measures required.          Information about Protection Against Explosions and Fires: No special measures required</p> <p>7.2 Conditions for Safe Storage, Including any Incompatibilities          Requirements to be met by storerooms and receptacles: 5 – 25°C          Information about Storage in One Common Storage Facility: Store away from oxidising agents          Further Information about Storage Conditions: Store in cool, dry conditions in well-sealed receptacles</p> <p>7.3 Specific End Uses          No further relevant information available.</p>
<p>SECTION 8          Exposure Controls/ Personal Protection</p>	<p>8.1 Control Parameters          Components with Limit Values that Require Monitoring at the Workplace: The product does not contain any relevant quantities of materials with critical values that have to be monitored at the workplace.</p> <p>8.2 Exposure Controls</p>

	<p>Engineering Controls: No special measures required</p> <p>8.3 Personal Protective Equipment          Respiratory Protection/Breathing Equipment: Not required          Protection of Hands: Protective gloves (e.g., nitrile or equivalent)          Eye Protection: Safety glasses          Body Protection: Protective work clothing (e.g. lab coat)</p> <p>8.4 General Protective and Hygienic Measures          Observe normal precautions for handling chemicals.</p>																																
<p>SECTION 9          Physical and Chemical Properties</p>	<p>9.1 Information on Basic Physical and Chemical Properties</p> <table border="1" data-bbox="504 636 1232 1303"> <tr> <td colspan="2">General Information</td> </tr> <tr> <td>Appearance</td> <td>Plastic shaft with rayon bud dipped with nitrazine yellow.</td> </tr> <tr> <td>Colour</td> <td>Yellow</td> </tr> <tr> <td>Odour</td> <td>Not applicable</td> </tr> <tr> <td>pH</td> <td>Not applicable</td> </tr> <tr> <td colspan="2">Change in condition</td> </tr> <tr> <td>Melting Point/ Melting Range</td> <td>Not determined</td> </tr> <tr> <td>Boiling Point/ Boiling Range</td> <td>Not determined</td> </tr> <tr> <td>Flash Point</td> <td>Not applicable</td> </tr> <tr> <td>Flammability</td> <td>Non-flammable</td> </tr> <tr> <td>Explosive Properties</td> <td>Product does not present an explosion hazard</td> </tr> <tr> <td>Density</td> <td>Not determined</td> </tr> <tr> <td>Solubility in / Miscibility with Water</td> <td>Soluble</td> </tr> <tr> <td>Auto Ignition Temperature</td> <td>Not determined</td> </tr> <tr> <td>Kinematic Viscosity</td> <td>Not determined</td> </tr> <tr> <td>Relative Vapour Density</td> <td>Not determined</td> </tr> </table> <p>9.2 Other Information          No further relevant information available.</p>	General Information		Appearance	Plastic shaft with rayon bud dipped with nitrazine yellow.	Colour	Yellow	Odour	Not applicable	pH	Not applicable	Change in condition		Melting Point/ Melting Range	Not determined	Boiling Point/ Boiling Range	Not determined	Flash Point	Not applicable	Flammability	Non-flammable	Explosive Properties	Product does not present an explosion hazard	Density	Not determined	Solubility in / Miscibility with Water	Soluble	Auto Ignition Temperature	Not determined	Kinematic Viscosity	Not determined	Relative Vapour Density	Not determined
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<p>SECTION 10          Stability and Reactivity</p>	<p>10.1 Reactivity          No significant reactions known.</p> <p>10.2 Chemical stability          Thermal Decomposition / Conditions to be Avoided: No decomposition if used according to specification</p> <p>10.3 Possibility of Hazardous Reactions          No dangerous reactions known.</p> <p>10.4 Conditions to Avoid          No further relevant information available.</p> <p>10.5 Incompatible Materials          No further relevant information available.</p> <p>10.6 Hazardous Decomposition Products          No dangerous decomposition products known.</p>																																
<p>SECTION 11</p>	<p>11.1 Information on Toxicological Effects          Acute Toxicity: None</p>																																

<p>Toxicological Information</p>	<p>Primary Irritant Effect: None          On the Skin: None          On the Eye: None          Respiratory or Skin Sensitisation: No sensitising effects known</p> <p>11.2 Additional Information          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.          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.          The product is not subject to OSHA classification according to internally approved calculation methods for preparations.</p> <p>11.3 Carcinogenic Categories          IARC (International Agency for Research on Cancer): None of the ingredients are listed          NTP (National Toxicology Program) Report on Carcinogens: None of the ingredients are listed          Germ Cell Mutagenicity: No data available          Carcinogenicity: No data available          Reproductive Toxicity: No Data available          Specific Target Organ Toxicity- Single Exposure: No data available          Specific Target Organ Toxicity- Repeated Exposure: No data available          Aspiration Hazard: No data available          Endocrine Disrupting Properties: No data available</p>
<p>SECTION 12          Ecological Information</p>	<p>12.1 Toxicity          Aquatic Toxicity: No further relevant information available</p> <p>12.2 Persistence and Degradability          Not applicable.</p> <p>12.3 Bioaccumulative Potential          Not applicable.</p> <p>12.4 Mobility in Soil          Not applicable.</p> <p>12.5 Results of PBT and vPvB Assessment          Not applicable.</p> <p>12.6 Other Adverse Effects          The ecological effects have not been thoroughly investigated, but currently none have been identified.          General Notes: Not known to be hazardous to water          No further relevant information available.</p> <p>12.7 Endocrine Disrupting Properties          No data available.</p>
<p>SECTION 13          Disposal Considerations</p>	<p>13.1 Waste Treatment Methods          Recommendation: Must adhere to national and local regulations. Smaller quantities can be disposed of with solid waste.</p> <p>13.2 United States (US)          Disposal must be made according to the regulations found in 40 CFR 261.          This product is not considered a RCRA hazardous waste.</p> <p>13.3 Uncleaned Packaging          Recommendation: Must adhere to national and local regulations.          Recommended Cleansing Agent: Water, if necessary, with cleansing agents.</p>

<p>SECTION 14 Transport Information</p>	<p>14.1 UN Number Not regulated*.</p> <p>14.2 UN Proper Shipping Name Not regulated*.</p> <p>14.3 Transport Hazard Classes Not regulated*.</p> <p>14.4 Packing Group Not regulated*.</p> <p>14.5 Environmental Hazards Not regulated*.</p> <p>14.6 Special Precautions for User Not applicable.</p> <p>14.7 Transport in Bulk According to Annex II of MARPOL 73/78 and the IBC Code Not applicable.</p> <p>* DOT, ADR, ADN, IMDG, IATA as appropriate (see abbreviation list)</p>
<p>SECTION 15 Regulatory Information</p>	<p>15.1 Safety, Health and Environmental Regulations/Legislation Specific for the Substance or Mixture</p> <p>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.</p> <p>US SARA 313 &amp; 355 are sections of 40 CFR Protection of Environment: The concentration of all chemical constituents are below the regulatory threshold limits TSCA (Toxic Substances Control Act): All ingredients listed in TSCA Inventory. California Proposition 65 - Chemicals known to the state to cause cancer, reproductive toxicity for males or females, or developmental toxicity: None of the ingredients are listed. NTP (National Toxicology Program) Report on Carcinogens: None of the ingredients are listed TLV (Threshold Limit Value according to American Conference of Governmental Industrial Hygienists): None of the ingredients are listed</p> <p>Canada Canadian Substance Listing Canadian Domestic Substance List (DSL): All ingredients listed Canadian Ingredient Disclosure List (limit 0.1%): No ingredients listed Canadian Ingredient Disclosure List (limit 1%): No ingredients listed</p> <p>15.2 Chemical Safety Assessment A Chemical Safety Assessment has not been carried out.</p>
<p>SECTION 16 Other Information</p>	<p>16.1 To the best of our knowledge, the information contained herein is accurate. However, neither Medical Wire &amp; Equipment Co. (Bath) Ltd. 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.</p> <p>16.2 Relevant Identified Uses European Chemical Agency (ECHA): Guidance on Information Requirements and Chemical Safety Assessment Chapter R.12: Use description. Version 3.0, December 2015, <a href="http://www.echa.europa.eu">www.echa.europa.eu</a></p>

	<p>16.3 Key Descriptor: Life Cycle stages PW: Widespread use by professional workers</p> <p>16.4 Supplementary Descriptor: Sectors of Use SU4: Manufacture of food products SU20: Health services SU24: Scientific research and development</p>
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## References

This 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 Commission regulation (EU) 2020/878 of 18 June 2020 Amending Annex II.
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: Reglement Concernant le Transport International Ferroviaire des Marchandises 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)

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)