

SECTION 1 - IDENTIFICATION OF THE SUBSTANCE/MIXTURE AND OF THE COMPANY/UNDERTAKING

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|--|---|
| Product identifier | MAS® Urinalysis - Liquid Assayed Urinalysis Control |
| Synonyms | 024222 MAS® Urinalysis Control Level 1 (High Abnormal) (4 x 15 mL) 024225 MAS® Urinalysis Control Level 1 (High Abnormal) (4 x 60 mL) 024223 MAS® Urinalysis Control Level 2 (Low Abnormal) (4 x 15 mL) 024226 MAS® Urinalysis Control Level 2 (Low Abnormal) (4 x 60 mL) 024224 MAS® Urinalysis Control Level 3 (Normal) (4 x 15 mL) 024227 MAS® Urinalysis Control Level 3 (Normal) (4 x 60 mL) UA-S1 MAS® Urinalysis Control sample pack (3 x 15 mL) |
| Trade names | MAS® Urinalysis - Liquid Assayed Urinalysis Control |
| Chemical family | Mixture |
| Relevant identified uses of the substance or mixture and uses advised against | Diagnostic Kit. |
| Note | The pharmacological, toxicological, and ecological properties of this product/mixture have not been fully characterized. This data sheet will be updated as more data become available. |
| Issue Date | 02/11/13 |

SECTION 2 - HAZARDS IDENTIFICATION

Classification of the substance or mixture

Regulation (EC) 1272/2008 [GHS] Mixture not yet fully tested.

Directive 67/548/EEC or 1999/45/EC Mixture not yet fully tested.

Label elements

SECTION 2 - HAZARDS IDENTIFICATION ...continued

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| CLP/GHS hazard pictogram | None required |
| CLP/GHS signal word | Warning |
| CLP/GHS hazard statements | None required |
| CLP/GHS precautionary statements | None required |
| EU symbol/indication of danger | None required |
| Risk (R) Phrase(s) | None required |
| Safety Advice | None required |
| Other hazards | No data were available for the mixture. This product contains human urine and should be treated/handled as a potential biohazard. All such human urine has been derived from donors tested individually and shown by FDA approved methods to be free from antibodies to Human Immune Deficiency Virus and Hepatitis B and C. As no test method can offer complete assurance that these or other infectious agents are not present, this product should be handled using standard biosafety precautions. |
| US Signal word | Caution |
| US Hazard overview | Mixture not yet fully tested. This product contains human urine and should be treated/handled as a potential biohazard. |
| Note | This product/mixture does not meet criteria for classification according to Directive 1999/45/EC and Regulation EC No 1272/2008 (EU CLP). Nevertheless, it should be regarded as dangerous/hazardous as it is potentially biohazardous. The pharmacological, toxicological, and ecological properties of this mixture have not been fully characterized. See Section 16 for full text of EU and GHS classifications. The GHS classifications are based on Regulation (EC) 1272/2008. The EU symbol/indicator of danger, R Phrases and Safety Advice are based on Directive 1999/45/EC. |

SECTION 3 - COMPOSITION/INFORMATION ON INGREDIENTS

| <u>Ingredient</u> | <u>CAS #</u> | <u>EINECS/ELIN CS#</u> | <u>Amount</u> | <u>EU Classification</u> | <u>GHS Classification</u> |
|-------------------|--------------|------------------------|---------------|--------------------------|---------------------------|
| Urine (Human) | N/A | N/A | 65-75% | Not classified | Not classified |

SECTION 3 - COMPOSITION/INFORMATION ON INGREDIENTS ...continued

Note The ingredient(s) listed above are considered hazardous. Human urine is listed because it is a potential biohazard. The remaining components are non-hazardous and/or present at amounts below reportable limits. Product also contains trace (0.05%-0.06%) amounts of thioglycolic acid. See Section 16 for full text of EU and GHS classifications. The EU classification is based on Directive 67/548/EEC and the GHS classification is based on Regulation (EC) 1272/2008.

SECTION 4 - FIRST AID MEASURES

Description of first aid measures

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| Immediate Medical Attention Needed | No. If exposed or concerned: Get medical advice/attention. |
| Eye Contact | If easy to do, remove contact lenses, if worn. Immediately flush eyes with copious quantities of water for at least 15 minutes. If irritation occurs or persists, notify medical personnel and supervisor. |
| Skin Contact | Wash exposed area with soap and water and remove contaminated clothing/shoes. If irritation occurs or persists, notify medical personnel and supervisor. |
| Inhalation | Immediately move exposed subject to fresh air. If not breathing, give artificial respiration. If breathing is labored, administer oxygen. Immediately notify medical personnel and supervisor. |
| Ingestion | If swallowed, call a physician immediately. Do not induce vomiting unless directed by medical personnel. Do not give anything to drink unless directed by medical personnel. Never give anything by mouth to an unconscious person. Notify medical personnel and supervisor. |
| Protection of first aid responders | See Section 8 for Exposure Controls/Personal Protection recommendations. |
| Most important symptoms and effects, both acute and delayed | See Sections 2 and 11 |
| Indication of immediate medical attention and special treatment needed, if necessary | Medical conditions aggravated by exposure: None known or reported. Treat symptomatically and supportively. |

SECTION 5 - FIREFIGHTING MEASURES

Extinguishing media Use water spray (fog), foam, dry powder, or carbon dioxide, as appropriate for surrounding fire and materials.

SECTION 5 - FIREFIGHTING MEASURES ...continued

Specific hazards arising from the substance or mixture No information identified. May emit toxic fumes of carbon monoxide and carbon dioxide.

Flammability/Explosivity No explosivity or flammability data identified. As product is an aqueous solution, it is not expected to be flammable or explosive.

Advice for firefighters In case of fire in the surroundings: use the appropriate extinguishing agent. Wear full protective clothing and an approved, positive pressure, self-contained breathing apparatus. Decontaminate all equipment after use.

SECTION 6 - ACCIDENTAL RELEASE MEASURES

Personal precautions, protective equipment and emergency procedures If product is released or spilled, take proper precautions to minimize exposure by using appropriate personal protective equipment (see Section 8). Area should be adequately ventilated.

Environmental precautions Do not empty into drains. Avoid release to the environment.

Methods and material for containment and cleaning up For small spills, soak up material with absorbent, e.g., paper towels. For large spills, cordon off spill area to minimize the spreading of spilled material. Soak up material with absorbent. Disinfect the area twice with an appropriate solvent, such as 5% chlorine bleach solution.

Reference to other sections See Sections 8 and 13 for more information.

SECTION 7 - HANDLING AND STORAGE

Precautions for safe handling This material should be handled at the Biosafety Level 2 (BSL2) consistent with the U.S. Department of Health and Human Services, the U.S. Public Health Service, Centers for Disease Control (CDC), and National Institute of Health (NIH) Guidelines "Biosafety in Microbiological and Biomedical Laboratories" (December 2009, HHS Publication No. (CDC) 21-1112).

Avoid contact with eyes, skin and other mucous membranes. Wash thoroughly after handling. Avoid breathing vapor/mist/spray.

Conditions for safe storage including any incompatibilities Store at 2-8 °C in a well-ventilated area, away from incompatible materials. Keep container upright and tightly closed. Do not freeze.

Bacterial contamination produces an increase in turbidity and/or a characteristic odor. Discard vial if evidence of microbial contamination is observed.

Specific end use(s) No information identified.

SECTION 8 - EXPOSURE CONTROLS/PERSONAL PROTECTION

Control

Parameters/Occupational

Exposure Limit Values

| <u>Compound</u> | <u>Issuer</u> | <u>Type</u> | <u>OEL</u> |
|-----------------|---------------|-------------|------------|
|-----------------|---------------|-------------|------------|

| | | | |
|---------------|----|----|----|
| Urine (Human) | -- | -- | -- |
|---------------|----|----|----|

Exposure/Engineering controls

None normally required. When practicable, handle material in enclosed or contained processes or in processes with effective local exhaust ventilation.

Respiratory protection

When possible, handle material in enclosed processes or containers. If it is properly handled with effective ventilation or containment, respiratory protection should not be needed.

Hand protection

Wear nitrile or other impervious gloves if skin contact is possible. When the material is dissolved or suspended in an organic solvent, wear gloves that provide protection against the solvent.

Skin protection

Wear appropriate gloves, lab coat, or other protective overgarment if skin contact is likely. Base the choice of skin protection on the job activity, potential for skin contact and solvents and reagents in use.

Eye/face protection

Wear safety glasses with side shields, chemical splash goggles, or full face shield, if necessary. Base the choice of protection on the job activity and potential for contact with eyes or face. An emergency eye wash station should be available.

Environmental Exposure Controls

Avoid release to the environment and operate within closed systems wherever practicable.

Other protective measures

Wash hands in the event of contact with this product/mixture, especially before eating, drinking or smoking. Protective equipment is not to be worn outside the work area (e.g., in common areas or out-of-doors). Decontaminate all protective equipment following use.

SECTION 9 - PHYSICAL AND CHEMICAL PROPERTIES

Information on basic physical and chemical properties

Appearance

Clear liquid

Color

Colorless

Odor

No information identified.

Odor threshold

No information identified.

pH

5-8

Melting point/freezing point

No information identified.

SECTION 9 - PHYSICAL AND CHEMICAL PROPERTIES ...continued

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|---|----------------------------|
| Initial boiling point and boiling range | No information identified. |
| Flash point | No information identified. |
| Evaporation rate | No information identified. |
| Flammability (solid, gas) | No information identified. |
| Upper/lower flammability or explosive limits | No information identified. |
| Vapor pressure | No information identified. |
| Vapor density | No information identified. |
| Relative density | No information identified. |
| Water solubility | Miscible with water |
| Solvent solubility | No information identified. |
| Partition coefficient (n-octanol/water) | No information identified. |
| Auto-ignition temperature | No information identified. |
| Decomposition temperature | No information identified. |
| Viscosity | No information identified. |
| Explosive properties | No information identified. |
| Oxidizing properties | No information identified. |
| Other information | |
| Molecular weight | Not applicable (Mixture) |
| Molecular formula | Not applicable (Mixture) |

SECTION 10 - STABILITY AND REACTIVITY

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| Reactivity | No information identified. |
| Chemical stability | Stable when stored as recommended. |
| Possibility of hazardous reactions | Not expected to occur. |
| Conditions to avoid | Avoid temperatures $\geq 25^{\circ}$ C. Do not freeze. |

SECTION 10 - STABILITY AND REACTIVITY ...continued

Incompatible materials No information identified.

Hazardous decomposition products No information identified.

SECTION 11 - TOXICOLOGICAL INFORMATION**Information on toxicological effects**

Route of entry May be absorbed by inhalation, skin contact and ingestion.

Acute toxicity

| <u>Compound</u> | <u>Type</u> | <u>Route</u> | <u>Species</u> | <u>Dose</u> |
|-----------------|-------------|--------------|----------------|-------------|
| Urine (Human) | -- | -- | -- | -- |

Irritation/Corrosion No studies identified.

Sensitization No studies identified.

STOT-single exposure No studies identified.

STOT-repeated exposure/Repeat-dose toxicity No studies identified.

Reproductive toxicity No studies identified.

Developmental toxicity No studies identified.

Genotoxicity No studies identified.

Carcinogenicity No studies identified. None of the components of this mixture present at levels greater than or equal to 0.1% are listed by NTP, IARC, ACGIH or OSHA as a carcinogen.

Aspiration hazard No data available.

Human health data See "Section 2 - Other Hazards"

Additional information The toxicological properties of this mixture have not been fully characterized.

SECTION 12 - ECOLOGICAL INFORMATION**Toxicity**

| <u>Compound</u> | <u>Type</u> | <u>Species</u> | <u>Concentration</u> |
|-----------------|-------------|----------------|----------------------|
| Urine (Human) | -- | -- | -- |

SECTION 12 - ECOLOGICAL INFORMATION ...continued

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|---|--|
| Persistence and Degradability | No data available. |
| Bioaccumulative potential | No data available. |
| Mobility in soil | No data available. |
| Results of PBT and vPvB assessment | Not performed. |
| Other adverse effects | No data available. |
| Note | The environmental characteristics of this product/mixture have not been fully investigated. Releases to the environment should be avoided. |

SECTION 13 - DISPOSAL CONSIDERATIONS

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| Waste treatment methods | Used product should be disposed of according to local, state, and federal regulations. Do not send down the drain or flush down the toilet. All wastes containing the material should be properly labeled. Dispose of wastes in accordance to prescribed federal, state, and local guidelines, e.g., appropriately permitted chemical waste incinerator. Rinse waters resulting from spill cleanups should be discharged in an environmentally safe manner, e.g., appropriately permitted municipal or on-site wastewater treatment facility. |
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SECTION 14 - TRANSPORT INFORMATION

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| Transport | Based on the available data, this product/mixture is not regulated as a hazardous material/dangerous good under EU ADR/RID, US DOT, Canada TDG, IATA, or IMDG. |
| UN number | None assigned. |
| UN proper shipping name | None assigned. |
| Transport hazard classes and packing group | None assigned. |
| Environmental hazards | Based on the available data, this product/mixture is not regulated as an environmental hazard or a marine pollutant. |
| Special precautions for users | Mixture not fully tested - avoid exposure. |

SECTION 14 - TRANSPORT INFORMATION ...continued

Transport in bulk according to Annex II of MARPOL73/78 and the IBC Code Not applicable.

SECTION 15 - REGULATORY INFORMATION

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| Safety, health and environmental regulations/legislation specific for the substance or mixture | This SDS complies with the requirements under US, EU and GHS (EU CLP - Regulation EC No 1272/2008) guidelines. Consult your local or regional authorities for more information. |
| Chemical safety assessment | Not conducted. |
| OSHA Hazardous | Caution. Mixture not fully tested. Product contains human urine and should be treated/handled as a potential biohazard. |
| WHMIS classification | Not required. Drugs are not subject to WHMIS. This product/mixture has been classified in accordance with the hazard criteria of the Controlled Products Regulations and the SDS contains all of the information required by those regulations. |
| TSCA status | Not listed |
| SARA section 313 | Not listed. |
| California proposition 65 | Not listed. |

SECTION 16 - OTHER INFORMATION

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|---|---|
| Full text of R phrases and EU Classifications | Not applicable. |
| Full text of H phrases, P phrases and GHS classification | Not applicable. |
| Sources of data | Information from published literature and internal company data. |
| Abbreviations | ACGIH - American Conference of Governmental Industrial Hygienists ADR/RID - European Agreement Concerning the International Carriage of Dangerous Goods by Road/Rail AIHA - American Industrial Hygiene Association CAS# - Chemical Abstract Services Number DNEL - Derived No Effect Level DOT - Department of Transportation EINECS - European Inventory of New and Existing Chemical Substances ELINCS - European List of Notified Chemical Substances EU - European Union GHS - Globally Harmonized System of Classification and Labelling of Chemicals IARC - International Agency for Research on Cancer IDLH - Immediately Dangerous to Life or Health IATA- International Air |

SECTION 16 - OTHER INFORMATION ...continued

Abbreviations ...continued Transport Association IMDG - International Maritime Dangerous Goods LOEL - Lowest Observed Effect Level LOAEL - Lowest Observed Adverse Effect Level NIOSH - The National Institute for Occupational Safety and Health NOEL - No Observed Effect Level NOAEL - No Observed Adverse Effect Level NTP - National Toxicology Program OEL - Occupational Exposure Limit OSHA - Occupational Safety and Health Administration PBT - Persistent, Bioaccumulative and Toxic PNEC - Predicted No Effect Concentration SARA - Superfund Amendments and Reauthorization Act STEL - Short Term Exposure Limit TDG - Transport Dangerous Goods TSCA - Toxic Substances Control Act TWA - Time Weighted Average WHMIS - Workplace Hazardous Materials Information System

Revisions This is the forth version of this SDS.

Disclaimer The above information is based on data available to us and is believed to be correct. Since the information may be applied under conditions beyond our control and with which we may be unfamiliar, we do not assume any responsibility for the results of its use and all persons receiving it must make their own determination of the effects, properties and protections which pertain to their particular conditions. No representation, warranty, or guarantee, express or implied (including a warranty of fitness or merchantability for a particular purpose), is made with respect to the materials, the accuracy of this information, the results to be obtained from the use thereof, or the hazards connected with the use of the material. Caution should be used in the handling and use of the material because it is a pharmaceutical/diagnostic product. The above information is offered in good faith and with the belief that it is accurate. As of the date of issuance, we are providing all information relevant to the foreseeable handling of the material. However, in the event of an adverse incident associated with this product, this Safety Data Sheet is not, and is not intended to be, a substitute for consultation with appropriately trained personnel.