ELITech Clinical Systems SAS

Safety Data Sheet
acc. to OSHA HCS

Printing date 04/28/2014 Reviewed on 04/14/2014

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1 Identification

· **Product identifier**

· ***Trade name:*** **Magnesium Reagent R**

· ***Article number:***
- Envoy Vital Diagnostics article number : 55400
- Eon Vital Diagnostics article number : 77400A

· ***Synonyms***
- Envoy Vital Diagnostics Reagent(s) : ENVOY500 MAGNESIUM R
- Eon Vital Diagnostics Reagent(s) : EON100 MAGNESIUM R

· ***Relevant identified uses of the substance or mixture and uses advised against***

· ***Application of the substance / the mixture***
Reagent for IN VITRO diagnostic
Product included in kit(s) Envoy Vital Diagnosics :
- Reference(s) for kit composed of one reagent : 55400.

Product included in kit(s) Eon Vital Diagnosics :
- Reference(s) for kit composed of one reagent : 77400.

· **Details of the supplier of the safety data sheet**

· ***Manufacturer/Supplier:***
Manufacturer :
ELITech Clinical Systems SAS
Zone Industrielle
61500 Sées • France
Tel : +33 (0)2 33 81 21 00
Fax : +33 (0)2 33 28 77 51
www.elitechgroup.com
MSDS.ECS-SAS@elitechgroup.com

US Supplier:
Vital Diagnostics Inc.
27 Wellington Road
Lincoln, Rhode Island 02865 USA
(401) 642-8400
(855) 354-8324
www.vitaldiagnostics.com

· ***Information department:*** Product safety department
· ***Emergency telephone number:*** Contact your distributor or poison control center in your country.

2 Hazard(s) identification

· **Classification of the substance or mixture**
· ***Classification according to Regulation (EC) No 1272/2008***


GHS05

Eye Dam. 1 H318 Causes serious eye damage.


GHS07

Skin Irrit. 2 H315 Causes skin irritation.

· **Label elements**
· ***Labelling according to Regulation (EC) No 1272/2008*** The product is classified and labeled according to the CLP regulation.
· ***Hazard pictograms***


GHS05

· ***Signal word*** Danger

· ***Hazard-determining components of labeling:***
2-aminoethanol
· ***Hazard statements***
Causes skin irritation.
Causes serious eye damage.
· ***Precautionary statements***
Wear protective gloves / eye protection / face protection.
Wash thoroughly after handling.
IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.

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Immediately call a POISON CENTER or doctor/physician.
Take off contaminated clothing and wash before reuse.
If skin irritation occurs: Get medical advice/attention.
IF ON SKIN: Wash with plenty of soap and water.

3 Composition/information on ingredients

· **Chemical characterization: Mixtures**
· ***Description:***
Mixture of substances.
Aqueous solution.

· ***Dangerous components:***

· *CAS NO. Description*		*%*
141-43-5	2-aminoethanol Skin Corr. 1B, H314; Acute Tox. 4, H302; Acute Tox. 4, H312; Acute Tox. 4, H332	2.5-10%
9002-92-0	dodecan-1-ol, ethoxylated Eye Dam. 1, H318; Acute Tox. 4, H302	< 1.0%

4 First-aid measures

· **Description of first aid measures**
· ***General information:***
Immediately remove any clothing soiled by the product.
Show this safety data sheet to the doctor in attendance.
· ***After inhalation:***
Supply fresh air; consult doctor in case of complaints.
If required, provide artificial respiration.
· ***After skin contact:***
Immediately wash with water and soap and rinse thoroughly.
If skin irritation or rash occurs: Get medical advice/attention.
· ***After eye contact:***
Protect unharmed eye.
Remove contact lenses, if present and easy to do.
Rinse opened eye for several minutes under running water. Then consult a doctor.
· ***After swallowing:***
Never give anything by mouth to an unconscious person.
Do not induce vomiting.
Rinse out mouth and then drink plenty of water.
Seek advice from a doctor or a poison control center.
· ***Information for doctor:***
· ***Most important symptoms and effects, both acute and delayed***
Skin irritation
Eye damage
· ***Indication of any immediate medical attention and special treatment needed*** Treat symptomatically.

5 Fire-fighting measures

· **Extinguishing media**
· ***Suitable extinguishing agents:***
CO2, extinguishing powder or water spray. Fight larger fires with water spray or alcohol resistant foam.
Use fire fighting measures that suit the environment.
· **Special hazards arising from the substance or mixture**
Formation of hazardous vapours/gases is possible during heating or in case of fire.
Nitrogen oxides (NOx)
Carbon oxides (COx)
· **Advice for firefighters**
· ***Protective equipment:*** As in any fire, wear a respiratory protective device, and full protective gear.
· **Additional information** Non-combustible liquid.

6 Accidental release measures

· **Personal precautions, protective equipment and emergency procedures**
Wear protective clothing.
Ensure adequate ventilation
Avoid physical contact with material.
· **Environmental precautions:** Do not allow to enter sewers/ surface or ground water.
· **Methods and material for containment and cleaning up:**
Absorb with liquid-binding material (sand, diatomite, universal binders, sawdust).
Send for recovery or disposal in suitable receptacles.
Clean the affected area carefully.

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· **Reference to other sections**
See Section 7 for information on safe handling.
See Section 8 for information on personal protection equipment.
See Section 13 for disposal information.

7 Handling and storage

· **Handling:**
· ***Precautions for safe handling***
Ensure good ventilation/exhaustion at the workplace.
Open and handle receptacle with care.
Avoid physical contact with material.
Observe the warnings on the label.
· ***Information about protection against explosions and fires:*** No special measures required.

· **Conditions for safe storage, including any incompatibilities**
· ***Storage:***
· ***Requirements to be met by storerooms and receptacles:*** Unsuitable material for receptacle: copper.
· ***Information about storage in one common storage facility:*** Do not store together with strong acids.
· ***Further information about storage conditions:***
Protect the product from light. Avoid exposure to heat.
Do not freeze.
· ***Recommended storage temperature:*** 2-8 °C
· **Specific end use(s)** No further relevant information available.

8 Exposure controls/personal protection

· **Additional information about design of technical systems:** Eyewash fountain and safety shower in the area of storage and use.

· **Control parameters**

· ***Components with limit values that require monitoring at the workplace:***	
141-43-5 2-aminoethanol	
PEL (USA)	Long-term value: 6 mg/m³, 3 ppm
REL (USA)	Short-term value: 15 mg/m³, 6 ppm Long-term value: 8 mg/m³, 3 ppm
TLV (USA)	Short-term value: 15 mg/m³, 6 ppm Long-term value: 7.5 mg/m³, 3 ppm

· ***Additional information:*** The lists that were valid during the creation were used as basis.

· **Exposure controls**
· ***Personal protective equipment:***
· ***General protective and hygienic measures:***
The usual precautionary measures for handling chemicals should be followed.
Keep away from foodstuffs, beverages and feed.
Immediately remove all soiled and contaminated clothing.
Avoid contact with the eyes and skin.
Wash hands before breaks and at the end of work.
Do not inhale gases / fumes / aerosols.
· ***Breathing equipment:***
Under normal conditions, the use of these products should not require respiratory protection. If overexposure should occur and ventilation is not adequate to maintain airborne concentrations at acceptable levels, the use of respiratory protection should be evaluated by a qualified professional.
Use equipment tested and approved under appropriate government standards such as NIOSH (US) or CEN (EU).
· ***Protection of hands:***


Protective gloves

The glove material has to be impermeable and resistant to the product/ the substance/ the preparation.
Selection of the glove material on consideration of the penetration times, rates of diffusion and the degradation
Use equipment tested and approved under appropriate government standards such as NIOSH (US) or CEN (EU).
· ***Material of gloves***
Natural rubber, NR
Recommended thickness of the material: ≥ 0.6 mm
The selection of the suitable gloves does not only depend on the material, but also on further marks of quality and varies from manufacturer to manufacturer. As the product is a preparation of several substances, the resistance of the glove material can not be calculated in advance and has therefore to be checked prior to the application.
· ***Penetration time of glove material***
Penetration time : > 480 mm
The exact break through time has to be found out by the manufacturer of the protective gloves and has to be observed.

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· ***Eye protection:***



Tightly sealed goggles

Use equipment tested and approved under appropriate government standards such as NIOSH (US) or EN166 (EU).
· ***Body protection:*** Protective work clothing

9 Physical and chemical properties

· **Information on basic physical and chemical properties**	
· ***General Information***	
· ***Appearance:***	
Form:	Fluid
Color:	Blue
· ***Odor:***	Odorless
· ***pH-value at 25 °C (77 °F):***	11
· ***Change in condition***	
Melting point/Melting range:	Not applicable
Boiling point/Boiling range:	~ 100 °C (~ 212 °F)
Solidification point:	~ 0 °C (~ 32 °F)
· ***Flash point:***	Not applicable.
· ***Flammability (solid, gaseous):***	Not applicable.
· ***Ignition temperature:***	Data not available
· ***Decomposition temperature:***	Data not available
· ***Auto igniting:***	Product is not selfigniting.
· ***Danger of explosion:***	Product does not present an explosion hazard.
· ***Vapor pressure:***	Data not available
· ***Density at 20 °C (68 °F):***	1.002 g/cm³ (8.362 lbs/gal)
· ***Vapour density***	Data not available
· ***Evaporation rate***	Data not available
· ***Solubility in / Miscibility with***	
Water:	Fully miscible.
· ***Partition coefficient (n-octanol/water):***	Data not available
· ***Viscosity:***	
Dynamic:	Data not available
· **Other information**	No further relevant information available.

10 Stability and reactivity

· **Reactivity** See § Possibility of hazardous reactions.
· **Chemical stability** Stable under recommended storage conditions.
· ***Thermal decomposition / conditions to be avoided:*** Data not available
· **Possibility of hazardous reactions** No dangerous reactions known.
· **Conditions to avoid** Avoid high temperature.
· **Incompatible materials:**
Strong acids.
Copper
· **Hazardous decomposition products:**
Formation of hazardous vapours/gases is possible during heating or in case of fire.
Nitrogen oxides (NOx)
Carbon oxides (COx)
· **Additional information:** Stable at the recommended storage temperature and if protected from light. Avoid exposure to heat.

11 Toxicological information

· **Information on toxicological effects**
· ***Acute toxicity:***
LD/LC50 values that are relevant for classification:

141-43-5 2-aminoethanol		
Oral	LD50	2050 mg/kg (rat)
Dermal	LD50	1000 mg/kg (rabbit)

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9002-92-0 dodecan-1-ol, ethoxylated		
Oral	LD50	1000 mg/kg (rat)

· ***Primary irritant effect:***
· ***on the skin:*** Irritant to skin.
· ***on the eye:*** Causes serious eye damage.
· ***Inhalation:***
May cause irritation of mucous membranes.
May be harmful by inhalation.
· ***Ingestion:***
May cause burns.
May be harmful if swallowed.
· ***Sensitization:*** Data not available
· ***Additional toxicological information:*** Data not available

· ***Carcinogenic categories***
· ***IARC (International Agency for Research on Cancer)*** Available information lists no component.
· ***NTP (National Toxicology Program)*** Available information lists no component.
· ***CMR effects***
· ***Carcinogenic effects:*** Data not available
· ***Mutagenicity:*** Data not available
· ***Reproductive Effects:*** Data not available
· ***Effects on development:*** Data not available

12 Ecological information

· **Toxicity**
· ***Aquatic toxicity:***
Information on components:

9002-92-0 dodecan-1-ol, ethoxylated	
EC50	1-10 mg/l (Daphnia)

· **Persistence and degradability** Data not available
· **Behavior in environmental systems:**
· ***Bioaccumulative potential*** Data not available
· ***Mobility in soil*** Data not available
· **Ecotoxical effects:**
· ***Remark:*** In case of spills of large quantities: Harmful effects on water organisms by modification of pH-value.
· **Additional ecological information:**
· ***General notes:***
At present there are no ecotoxicological assessments.
Water hazard class 1 (Self-assessment): slightly hazardous for water
Do not allow undiluted product or large quantities of it to reach ground water, water course or sewage system.
Disposal procedures have to be respected, see Section 13.
· **Other adverse effects** No further relevant information available.

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13 Disposal considerations

· **Waste treatment methods**
· ***Recommendation:*** Disposal must be made according to official regulations.

· **Uncleaned packagings:**
· ***Recommendation:*** Disposal must be made according to official regulations.
· ***Primary packaging:*** Plastic vial (composed of polyethylene high density).

14 Transport information

· **UN-Number**	Not applicable
· ***DOT, ADR, ADN, IMDG, IATA***	-
· **UN proper shipping name**	
· ***DOT, ADR, ADN, IMDG, IATA***	-
· **Transport hazard class(es)**	
· ***DOT, ADR, ADN, IMDG, IATA***	
· ***Class***	-
· **Packing group**	
· ***DOT, ADR, IMDG, IATA***	-
· **Environmental hazards:**	
· ***Marine pollutant:***	No

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· **Special precautions for user**	Not applicable.
· **Transport in bulk according to Annex II of MARPOL73/78 and the IBC Code**	Not applicable.
· **UN "Model Regulation":**	-

15 Regulatory information

· ***SARA***
· ***Section 302/304 (40CFR355.30 / 40CFR355.40):*** Available information lists none.
· ***Section 313 (Specific toxic chemical listings):*** Not regulated.
· ***TSCA (Toxic Substances Control Act):*** This product is regulated by the Food and Drug Administration; it is exempt from requirements of TSCA.
· ***Proposition 65***
· ***Chemicals known to cause cancer:*** Available information lists none.
· ***Chemicals known to cause reproductive toxicity for females:*** Available information lists none.
· ***Chemicals known to cause reproductive toxicity for males:*** Available information lists none.
· ***Chemicals known to cause developmental toxicity:*** Available information lists none.

· ***Carcinogenic categories***
· ***EPA (Environmental Protection Agency)*** Available information lists none.
· ***TLV (Threshold Limit Value established by ACGIH)*** Available information lists none.
· ***NIOSH-Ca (National Institute for Occupational Safety and Health)*** Available information lists none.
· ***OSHA-Ca (Occupational Safety & Health Administration)*** Available information lists none.
· **U. S. State Regulations:**
· ***PA-RTK*** Available information lists none.

· ***NJ-RTK***	
141-43-5	2-aminoethanol

· ***MA-RTK***	
141-43-5	2-aminoethanol

· ***RI-RTK*** Available information lists none.
· **US Federal Regulation** This mixture is a component of an FDA-regulated IN VITRO diagnostic medical device.

· **Chemical safety assessment:** A Chemical Safety Assessment has not been carried out.

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16 Other information

This information is based on our present knowledge. However, this shall not constitute a guarantee for any specific product features and shall not establish a legally valid contractual relationship.

· ***Relevant phrases***
H302 Harmful if swallowed.
H312 Harmful in contact with skin.
H314 Causes severe skin burns and eye damage.
H332 Harmful if inhaled.

· **Department issuing MSDS:** Product safety department
· **Contact:** Product safety department
· ***Abbreviations and acronyms:***
SVHC : Substances of Very High Concern
ADR: Accord européen sur le transport des marchandises dangereuses par Route (European Agreement concerning the International Carriage of Dangerous Goods by Road)
IMDG: International Maritime Code for Dangerous Goods
DOT: US Department of Transportation
IATA: International Air Transport Association
GHS: Globally Harmonized System of Classification and Labelling of Chemicals
ACGIH: American Conference of Governmental Industrial Hygienists
EINECS: European Inventory of Existing Commercial Chemical Substances
ELINCS: European List of Notified Chemical Substances
CAS: Chemical Abstracts Service (division of the American Chemical Society)
NOEC : No Observed Effect Concentration
EC50: Effective concentration, 50 percent
IC50 : Inhibitory concentration, 50 percent.
Acute Tox. 4: Acute toxicity, Hazard Category 4
Skin Corr. 1B: Skin corrosion/irritation, Hazard Category 1B
Skin Irrit. 2: Skin corrosion/irritation, Hazard Category 2
Eye Dam. 1: Serious eye damage/eye irritation, Hazard Category 1

· **** Data compared to the previous version altered.***