03.02.2014 **Kit Components**

Product code	Description
55425	**ENVOY 500 TOTAL PROTEIN REAGENT KIT**

Components:

55425	Envoy 500 Total Protein Reagent

VITAL DIAGNOSTICS
An ELITech Group company

Safety Data Sheet
acc. to OSHA HCS

Printing date 02/03/2014 Reviewed on 01/21/2014

1 Identification

· **Product identifier**

· ***Trade name:*** **Envoy 500 Total Protein Reagent**

· ***Article number:*** 55425
· ***Relevant identified uses of the substance or mixture and uses advised against***
· ***Application of the substance / the mixture*** Reagent for IN VITRO diagnostic

· **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

Met. Corr.1 H290 May be corrosive to metals.


GHS07

Skin Irrit. 2 H315 Causes skin irritation.
Eye Irrit. 2 H319 Causes serious eye irritation.

Aquatic Chronic 3 H412 Harmful to aquatic life with long lasting effects.

· **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*** Warning
· ***Hazard statements***
May be corrosive to metals.
Causes skin irritation.
Causes serious eye irritation.
Harmful to aquatic life with long lasting effects.
· ***Precautionary statements***
Wear protective gloves/protective clothing/eye protection/face protection.
Avoid release to the environment.
IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.
If eye irritation persists: Get medical advice/attention.
Absorb spillage to prevent material damage.

(Contd. on page 2)

Safety Data Sheet
acc. to OSHA HCS

Printing date 02/03/2014 Reviewed on 01/21/2014

Trade name: Envoy 500 Total Protein Reagent

(Contd. of page 1)

3 Composition/information on ingredients

· **Chemical characterization: Mixtures**
· ***Description:***
Mixture of the substances listed below with nonhazardous additions.
Aqueous solution.

· ***Dangerous components:***

· CAS NO.	Description	%
1310-73-2	sodium hydroxide Met. Corr.1, H290; Skin Corr. 1A, H314	≤ 2.5%
7758-99-8	copper (II) sulfate Aquatic Acute 1, H400; Aquatic Chronic 1, H410; Acute Tox. 4, H302; Skin Irrit. 2, H315; Eye Irrit. 2, H319	< 0.5%

· ***Additional information:*** For the wording of the listed risk phrases refer to section 16.

4 First-aid measures

· **Description of first aid measures**
· ***General information:***
Show this safety data sheet to the doctor in attendance.
Immediately remove any clothing soiled by the product.
· ***After inhalation:***
Supply fresh air; consult doctor in case of complaints.
In case of unconsciousness place patient stably in side position for transportation.
If required, provide artificial respiration.
· ***After skin contact:***
Immediately wash with water and soap and rinse thoroughly.
If symptoms appear, seek medical advice.
· ***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:***
Rinse out mouth.
Do not induce vomiting.
Immediately call a doctor.
· ***Information for doctor:***
· ***Most important symptoms and effects, both acute and delayed*** Irritation and corrosion. Danger to the sight.
· ***Indication of any immediate medical attention and special treatment needed***
The first aid procedure should be established in consultation with the doctor.

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 toxic gases is possible during heating or in case of fire.
· **Advice for firefighters**
· ***Protective equipment:*** As in any fire, wear a respiratory protective device, and full protective gear.

6 Accidental release measures

· **Personal precautions, protective equipment and emergency procedures**
Wear protective equipment. Keep unprotected persons away.
Ensure adequate ventilation
Avoid physical contact with material.
· **Environmental precautions:**
Dilute with plenty of water.
Prevent seepage into sewage system, workpits and cellars.
· **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.
· **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.

(Contd. on page 3)

Safety Data Sheet
acc. to OSHA HCS

Printing date 02/03/2014 Reviewed on 01/21/2014

Trade name: Envoy 500 Total Protein Reagent

(Contd. of page 2)

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:*** Provide alkali-resistant floor.
· ***Information about storage in one common storage facility:*** Do not store together with acids.
· ***Further information about storage conditions:***
Keep receptacle tightly sealed.
Protect the product from light. Avoid exposure to heat.
· ***Recommended storage temperature:*** 2-25 °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:***	
1310-73-2 sodium hydroxide	
PEL (USA)	Long-term value: 2 mg/m³
REL (USA)	Ceiling limit value: 2 mg/m³
TLV (USA)	Ceiling limit value: 2 mg/m³

· ***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.
Wash hands before breaks and at the end of work.
Avoid contact with the eyes and skin.
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:***
The glove material has to be impermeable and resistant to the product/ the substance/ the preparation.
Due to missing tests no recommendation to the glove material can be given for the product/ the preparation/ the chemical mixture.
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***
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*** The exact break through time has to be found out by the manufacturer of the protective gloves and has to be observed.
· ***Eye protection:***
Safety glasses
Use equipment tested and approved under appropriate government standards such as NIOSH (US) or CEN (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:***	uncharacteristic
· ***pH-value:***	>12
· ***Change in condition***	
Melting point/Melting range:	Not applicable

(Contd. on page 4)

Safety Data Sheet
acc. to OSHA HCS

Printing date 02/03/2014 Reviewed on 01/21/2014

Trade name: Envoy 500 Total Protein Reagent

(Contd. of page 3)

Boiling point/Boiling range:	Undetermined.
Solidification point:	Not determined
· ***Flash point:***	Not applicable.
· ***Flammability (solid, gaseous):***	Not determined
· ***Ignition temperature:***	Not determined
· ***Decomposition temperature:***	Not determined
· ***Auto igniting:***	Product is not selfigniting.
· ***Danger of explosion:***	Product does not present an explosion hazard.
· ***Vapor pressure:***	Not determined
· ***Density at 20 °C (68 °F):***	1.022 g/cm³ (8.529 lbs/gal)
· ***Vapour density***	Not determined
· ***Evaporation rate***	Not determined
· ***Solubility in / Miscibility with Water:***	Fully miscible.
· ***Partition coefficient (n-octanol/water):***	Not determined
· ***Viscosity:***	
Dynamic:	Not determined
· **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:*** No decomposition if used according to specifications.
· **Possibility of hazardous reactions** Reacts with acids.
· **Conditions to avoid** No further relevant information available.
· **Incompatible materials:**
Strong oxidizing agents, strong acids
Metals.
· **Hazardous decomposition products:**
Dangerous decomposition products may be formed.
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:***		
1310-73-2 sodium hydroxide		
Oral	LD50	2000 mg/kg (rat)
7758-99-8 copper (II) sulfate		
Oral	LD50	960 mg/kg (rat)
	LDL0	1088 mg/kg (human)
Dermal	LD50	> 2000 mg/kg (rat)

· ***Primary irritant effect:***
· ***on the skin:*** Strong caustic effect on skin and mucous membranes.
· ***on the eye:*** Strong caustic effect.
· ***Inhalation:*** May cause irritation of mucous membranes.
· ***Ingestion:*** May cause burns.
· ***Sensitization:*** No sensitizing effects known.
· ***Additional toxicological information:***
Swallowing will lead to a strong caustic effect on mouth and throat and to the danger of perforation of esophagus and stomach.

· ***Carcinogenic categories***
· ***IARC (International Agency for Research on Cancer)*** None of the ingredient is listed.
· ***NTP (National Toxicology Program)*** None of the ingredient is listed.
· ***CMR effects***
· ***Mutagenicity:*** Data not available
· ***Reproductive Effects:*** Data not available
· ***Effects on development:*** Data not available
· ***Target organs:*** Data not available

(Contd. on page 5)

Safety Data Sheet
acc. to OSHA HCS

Printing date 02/03/2014 Reviewed on 01/21/2014

Trade name: Envoy 500 Total Protein Reagent

(Contd. of page 4)

12 Ecological information

· **Toxicity**

· *Aquatic toxicity:*	
1310-73-2 sodium hydroxide	
EC50/48h	76 mg/l (Daphnia)
LC50/96h	45.4 mg/l (Onchorhyncus mykiss)
7758-99-8 copper (II) sulfate	
EC50/48h	0.02 mg/l (Daphnia)
LC50/96h	0.11 mg/l (Onchorhyncus mykiss)

· **Persistence and degradability** Data not available
· **Behavior in environmental systems:**
· ***Bioaccumulative potential*** Data not available
· ***Mobility in soil*** Data not available
· **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.
Rinse off of bigger amounts into drains or the aquatic environment may lead to increased pH-values. A high pH-value harms aquatic organisms.
Disposal procedures have to be respected, see Section 13.
· **Other adverse effects** No further relevant information available.

13 Disposal considerations

· **Waste treatment methods**
· ***Recommendation:***
Must not be disposed of together with household garbage. Do not allow product to reach sewage system.
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**	
· ***DOT, ADR, IMDG, IATA***	UN1824
· **UN proper shipping name**	
· ***DOT***	Sodium hydroxide solution
· ***ADR***	1824 Sodium hydroxide solution
· ***IMDG, IATA***	SODIUM HYDROXIDE SOLUTION
· **Transport hazard class(es)**	
· ***DOT***	
· ***Class***	8 Corrosive substances.
· ***Label***	8
· ***ADR, IMDG, IATA***	
· ***Class***	8 Corrosive substances
· ***Label***	8
· **Packing group**	
· ***DOT, ADR, IMDG, IATA***	III
· **Environmental hazards:**	
· ***Marine pollutant:***	No
· **Special precautions for user**	Warning: Corrosive substances
· ***Danger code (Kemler):***	80
· ***EMS Number:***	F-A,S-B

(Contd. on page 6)

Safety Data Sheet
acc. to OSHA HCS

Printing date 02/03/2014 Reviewed on 01/21/2014

Trade name: Envoy 500 Total Protein Reagent

(Contd. of page 5)

· ***Segregation groups***	Alkalis
· **Transport in bulk according to Annex II of MARPOL73/78 and the IBC Code**	Not applicable.
· **UN "Model Regulation":**	UN1824, Sodium hydroxide solution, 8, III

15 Regulatory information

· ***SARA***
· ***Section 302/304 (40CFR355.30 / 40CFR355.40):*** None of the ingredients is listed.
· ***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:*** None of the ingredients is listed.
· ***Chemicals known to cause reproductive toxicity for females:*** None of the ingredients is listed.
· ***Chemicals known to cause reproductive toxicity for males:*** None of the ingredients is listed.
· ***Chemicals known to cause developmental toxicity:*** None of the ingredient is listed.

· ***Carcinogenic categories***
· ***EPA (Environmental Protection Agency)*** None of the ingredient is listed.
· ***TLV (Threshold Limit Value established by ACGIH)*** None of the ingredient is listed.
· ***NIOSH-Ca (National Institute for Occupational Safety and Health)*** None of the ingredient is listed.
· ***OSHA-Ca (Occupational Safety & Health Administration)*** None of the ingredient is listed.
· **U. S. State Regulations:**

· ***PA-RTK***	
1310-73-2	sodium hydroxide

· ***NJ-RTK***	
1310-73-2	sodium hydroxide

· ***MA-RTK***	
1310-73-2	sodium hydroxide

· ***RI-RTK***	
1310-73-2	sodium hydroxide

· **US Federal Regulation** This preparation is a component of an FDA-regulated IN VITRO diagnostic medical device.

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

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***
H290 May be corrosive to metals.
H302 Harmful if swallowed.
H314 Causes severe skin burns and eye damage.
H315 Causes skin irritation.
H319 Causes serious eye irritation.
H400 Very toxic to aquatic life.
H410 Very toxic to aquatic life with long lasting effects.

· **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)
LC50: Lethal concentration, 50 percent
LD50: Lethal dose, 50 percent
NOEC : No Observed Effect Concentration
EC50: Effective concentration, 50 percent
IC50 : Inhibitory concentration, 50 percent.