Safety Data Sheet
acc. to OSHA HCS

Printing date 03/13/2015 Reviewed on 03/12/2015

*

1: Identification

· **Product identifier**

· ***Trade name:*** **CHOLESTEROL LDL 2G CALIBRATOR**

· *Article number:* 55115A / 77115A / LDLL-4XXX
· *Synonyms* ENVOY 500 LDL CAL / EON LDL CAL / CHOLESTEROL LDL 2G CAL
· ***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) :
- Kit composed of one reagent : 55115 / 77115 / LDLL-0041

· **Details of the supplier of the safety data sheet**
· ***Manufacturer/Supplier:***
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

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

· ***Classification according to Directive 67/548/EEC or Directive 1999/45/EC***

Xn; Harmful

R22: Harmful if swallowed.
R32-52/53: Contact with acids liberates very toxic gas. Harmful to aquatic organisms, may cause long-term adverse effects in the aquatic environment.

· *Information concerning particular hazards for human and environment:*
The product has to be labeled due to the calculation procedure of international guidelines.
· *Classification system:*
The classification was made according to the latest editions of international substances lists, and expanded upon from company and literature data.
· ***Additional information:***
Contains compounds of human origin potentially infectious.
All products derived from blood are prepared from the blood of donors tested individually and found to be negative for HbsAg and antibodies to HCV and HIV1/HIV2. Nevertheless is impossible to reach complete information about the possibility of disease transmission, please handle as potentially infectious.

· **Label elements**
· ***Labelling according to Regulation (EC) No 1272/2008*** The product is classified and labeled according to the CLP regulation.
· *Hazard pictograms* -
· *Signal word* -
· *Hazard statements*
Harmful to aquatic life with long lasting effects.
· *Precautionary statements*
Avoid release to the environment.
· ***Additional information:***
Contact with acids liberates very toxic gas.

*

3: Composition/information on ingredients

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

· ***Dangerous components:***

· *CAS NO.*	*Description*	*%*	
26628-22-8	sodium azide	T+ R28; N R50/53 R32 Acute Tox. 2, H300; Aquatic Acute 1, H400; Aquatic Chronic 1, H410	< 0.5%

· ***Additional information:*** Contains compounds of human origin potentially infectious.

4: First-aid measures

· **Description of first aid measures**
· ***General information:***
Show this safety data sheet to the doctor in attendance.

(Contd. on page 2)

Safety Data Sheet
acc. to OSHA HCS

Printing date 03/13/2015 Reviewed on 03/12/2015

Trade name: CHOLESTEROL LDL 2G CALIBRATOR

(Contd. of page 1)

Immediately remove any clothing soiled by the product.
· ***After inhalation:***
Supply fresh air; consult doctor in case of complaints.
If required, provide artificial respiration.
· ***After skin contact:***
Immediately rinse with water.
Clean with a disinfectant.
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. If symptoms appear, seek medical advice.
· ***After swallowing:***
Never give anything by mouth to an unconscious person.
Rinse out mouth.
Seek advice from a doctor or a poison control center.
· ***Information for doctor:***
· *Most important symptoms and effects, both acute and delayed* Data not available
· *Indication of any immediate medical attention and special treatment needed* Data not available

5: Fire-fighting measures

· **Extinguishing media**
· ***Suitable extinguishing agents:***
Use fire fighting measures that suit the environment.
CO2, extinguishing powder or water spray. Fight larger fire with alcohol resistant foam.
· ***For safety reasons unsuitable extinguishing agents:*** Unknown
· **Special hazards arising from the substance or mixture**
Formation of toxic gases is possible during heating or in case of fire.
Carbon oxides (COx)
Nitrogen oxides (NOx)
· **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**
Handle as potentially infectious.
Wear protective clothing.
Ensure adequate ventilation
Avoid formation of dust/spray.
Avoid physical contact with material.
· **Environmental precautions:** Prevent seepage into sewage system, workpits and cellars.
· **Methods and material for containment and cleaning up:**
Pick up mechanically.
Clean the affected area carefully; suitable cleaners are:
Disinfectant.
Send for recovery or disposal in suitable receptacles.
· **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***
Handle as potentially infectious.
Ensure good ventilation/exhaustion at the workplace.
Open and handle receptacle with care.
Avoid physical contact with material.
Prevent formation of dust.
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:* No special requirements.
· *Information about storage in one common storage facility:* Store away from incompatible materials (see section 10).
· *Further information about storage conditions:*
Keep container tightly closed.
Protect the product from light. Avoid exposure to heat.
· *Recommended storage temperature:* 2-8 °C

(Contd. on page 3)

Safety Data Sheet
acc. to OSHA HCS

Printing date 03/13/2015 Reviewed on 03/12/2015

Trade name: CHOLESTEROL LDL 2G CALIBRATOR

(Contd. of page 2)

· **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:***	
26628-22-8 sodium azide (<0.5%)	
REL (USA)	Ceiling limit value: 0.3** mg/m³, 0.1* ppm *as HN3; **as NaN3; Skin
TLV (USA)	Ceiling limit value: 0.29** mg/m³, 0.11* ppm *as HN3 vapor **as NaN3

· *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 are to be adhered to when handling products potentially infectious.
The usual precautionary measures for handling chemicals should be followed.
Immediately remove all soiled and contaminated clothing.
Keep away from foodstuffs, beverages and feed.
Wash hands before breaks and at the end of work.
Disinfect workplace and hands after work.
The type of protective equipment must be selected according to the concentration and amount of the dangerous substance at the specific workplace.
· *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.
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:	Lyophilised material
Color:	Yellowish
· *Odor:*	Odorless
· ***pH-value:***	Not applicable
· ***Change in condition***	
Melting point/Melting range:	Data not available
Boiling point/Boiling range:	Not applicable
· ***Flash point:***	Not applicable
· ***Flammability (solid, gaseous):***	Data not available
· ***Ignition temperature:***	Data not available
· *Decomposition temperature:*	Data not available
· ***Auto igniting:***	Product is not selfigniting.
· ***Danger of explosion:***	Data not available

(Contd. on page 4)

Safety Data Sheet
acc. to OSHA HCS

Printing date 03/13/2015 Reviewed on 03/12/2015

Trade name: CHOLESTEROL LDL 2G CALIBRATOR

(Contd. of page 3)

· ***Explosion limits:***	
Lower:	Data not available
Upper:	Data not available
· ***Vapor pressure:***	Not applicable.
· ***Density:***	Data not available
· *Vapour density*	Not applicable
· *Evaporation rate*	Not applicable
· ***Solubility in / Miscibility with***	
Water:	Soluble.
· ***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:*** No decomposition if used according to specifications.
· **Possibility of hazardous reactions**
Contact with acids liberates very toxic gas.
Sodium azide, containded in the product, can react with copper and lead plumbing to form explosive metal azides. If discharge in the canalisations, rinse with plenty of water.
· **Conditions to avoid** No further relevant information available.
· **Incompatible materials:**
Acids.
Sodium azide (26628-22-8) : incompatible with acids, and some metals; forms explosion-sensitive compounds.
· **Hazardous decomposition products:**
Formation of toxic gases is possible during heating or in case of fire.
Carbon oxides (COx)
Nitrogen oxides (NOx)
· **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:

ATE (Acute Toxicity Estimates)		
Oral	LD50	9000 mg/kg (mouse)
Dermal	LD50	6667 mg/kg (rabbit)

26628-22-8 sodium azide		
Oral	LD50	27 mg/kg (mouse)
Dermal	LD50	20 mg/kg (rabbit)
Inhalative	LC50	37 mg/m3 (rat)

· *Primary irritant effect:*
· *on the skin:*
Contact with skin may cause redness, irritation and discomfort.
May be harmful if absorbed through skin.
· *on the eye:* May cause irritating effect.
· *Inhalation:*
May be harmful by inhalation.
May cause irritating effect.
· *Ingestion:* Harmful if swallowed.
· *Sensitization:* Data not available
· ***Additional toxicological information:***
All products derived from blood are prepared from the blood of donors tested individually and found to be negative for HbsAg and antibodies to HCV and HIV1/HIV2. Nevertheless is impossible to reach complete information about the possibility of disease transmission, please handle as potentially infectious.
· *Carcinogenic categories*
· *IARC (International Agency for Research on Cancer)*
No component, contained in this product at concentration equal or grater than 0.1 %, is listed by IARC as a carcinogen.
· *NTP (National Toxicology Program)*
No component, contained in this product at concentration equal or grater than 0.1 %, is listed by NTP as a carcinogen.
· *CMR effects*
· *Carcinogenic effects:* Data not available
· *Mutagenicity:* Data not available

(Contd. on page 5)

Safety Data Sheet
acc. to OSHA HCS

Printing date 03/13/2015 Reviewed on 03/12/2015

Trade name: CHOLESTEROL LDL 2G CALIBRATOR

(Contd. of page 4)

· *Reproductive Effects:* Data not available
· *Effects on development:* Data not available
· *Target organs:*
Sodium azide (26628-22-8) :
Cardiovascular system.
Central nervous system.

*
12: Ecological information

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

26628-22-8 sodium azide	
EC50/48h	4.2 mg/l (Daphnia)
LC50/96h	0.68 mg/l (Lepomis macrochirus)

· **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.
Harmful to aquatic life with long lasting effects.
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.

*
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.
· ***Recommended cleansing agent:***
Sodium azide, containded in the product, can react with copper and lead plumbing to form explosive metal azides. If discharge in the canalisations, rinse with plenty of water.
· ***Primary packaging:*** Glass bottle

*
14: Transport information

· **UN-Number**	Not applicable
· ***DOT, ADR, ADN, IMDG, IATA***	-
· **UN proper shipping name**	
· ***DOT, ADN, IMDG, IATA***	-
· ***ADR***	-
· **Transport hazard class(es)**	
· ***DOT, ADR, ADN, IMDG, IATA***	
· *Class*	-
· **Packing group**	
· ***DOT, ADR, IMDG, IATA***	-
· **Environmental hazards:**	
· ***Marine pollutant:***	No
· **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):*	
26628-22-8	sodium azide

· *Section 313 (Specific toxic chemical listings):* Not regulated.

(Contd. on page 6)

Safety Data Sheet
acc. to OSHA HCS

Printing date 03/13/2015 Reviewed on 03/12/2015

Trade name: CHOLESTEROL LDL 2G CALIBRATOR

(Contd. of page 5)

· ***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)*		
26628-22-8	sodium azide	A4

· *NIOSH-Ca (National Institute for Occupational Safety and Health)* Available information lists none.
· *OSHA-Ca (Occupational Safety & Health Administration)*
No component, contained in this product at concentration equal or grater than 0.1 %, is listed by OSHA as a carcinogen.
· **U. S. State Regulations:**

· ***PA-RTK***	
26628-22-8	sodium azide

· ***NJ-RTK***	
26628-22-8	sodium azide

· ***MA-RTK***	
26628-22-8	sodium azide

· ***RI-RTK***	
26628-22-8	sodium azide

· **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.

*
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*
H300 Fatal if swallowed.
H400 Very toxic to aquatic life.
H410 Very toxic to aquatic life with long lasting effects.

R28 Very toxic if swallowed.
R32 Contact with acids liberates very toxic gas.
R50/53 Very toxic to aquatic organisms, may cause long-term adverse effects in the aquatic environment.

· **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 Harmonised 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. 2: Acute toxicity, Hazard Category 2
Aquatic Acute 1: Hazardous to the aquatic environment - AcuteHazard, Category 1
Aquatic Chronic 1: Hazardous to the aquatic environment - Chronic Hazard, Category 1
Aquatic Chronic 3: Hazardous to the aquatic environment - Chronic Hazard, Category 3

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