

1: Identification

- **Product identifier**
- **Trade name:** CHOLESTEROL HDL SL REAGENT 1
- **Article number:** 77301A / 79301A / HDLL-0850R1 / HDLL-5XXX.
- **Synonyms**
EON 100 HDL CHOLESTEROL R1 / EON 300 HDL CHOLESTEROL R1 / HDL CHOLESTEROL ENVOY R1 / CHOLESTEROL HDL SL 2G R1.
- **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 two reagents : 77301 / 79301 / 55301 / HDLL-0230.
- **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** The product is not classified according to the CLP regulation.

- **Label elements**
- **Labelling according to Regulation (EC) No 1272/2008 -**
- **Hazard pictograms -**
- **Signal word -**
- **Hazard statements -**

3: Composition/information on ingredients

- **Chemical characterization: Mixtures**
- **Description:**
Mixture of substances.
Aqueous solution.
- **Dangerous components:** No dangerous component in reportable quantity.

4: First-aid measures

- **Description of first aid measures**
- **General information:** Show this safety data sheet to the doctor in attendance.
- **After inhalation:**
Supply fresh air.
Move out of dangerous area.
If required, provide artificial respiration.
If symptoms appear, seek medical advice.
- **After skin contact:**
Rinse with water.
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

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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 clothing.
Ensure adequate ventilation
Prevent formation of aerosols.
Avoid physical contact with material.
- **Environmental precautions:** 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).
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.

7: Handling and storage

- **Handling:**
- **Precautions for safe handling**
Ensure good ventilation/exhaustion at the workplace.
Open and handle receptacle with care.
Prevent formation of aerosols.
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:** Store in a cool location.
· **Information about storage in one common storage facility:** Store away from incompatible materials (see section 10).
· **Further information about storage conditions:** Protect the product from light. Avoid exposure to heat.
· **Recommended storage temperature:** 2-8 °C
- **Specific end use(s)** Data not available.

8: Exposure controls/personal protection

- **Additional information about design of technical systems:** No further data; see item 7.
- **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.
- **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.
Wash hands before breaks and at the end of 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).

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- **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:**
Goggles recommended during refilling.
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:	Slightly yellow
Odor:	Odorless
Odour threshold:	Data not available

· **pH-value at 20 °C (68 °F):** 6

· Change in condition

Melting point/Melting range:	Not applicable
Boiling point/Boiling range:	Data not available
Solidification point:	Not determined

· **Flash point:** Data not available

· **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:** Product does not present an explosion hazard.

· **Vapor pressure:** Data not available

· Density:

Relative density at 20 °C (68 °F)	1.002 g/cm ³ (8.362 lbs/gal)
Vapour density	Data not available
Evaporation rate	Not determined

· 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.
- **Possibility of hazardous reactions** No dangerous reactions if used according to specifications.
- **Conditions to avoid** No further relevant information available.
- **Incompatible materials:** Strong oxidizing agents, acids, bases.
- **Hazardous decomposition products:** None expected under normal condition of use.
- **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:** Data not available

· Primary irritant effect:

· **on the skin:** May cause irritating effect.

· **on the eye:** May cause irritating effect.

· Inhalation:

May be harmful by inhalation.

May cause irritating effect.

· **Ingestion:** May be harmful if swallowed.

· **Sensitization:** Data not available

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- **Additional toxicological information:**
- *Carcinogenic categories*
- *IARC (International Agency for Research on Cancer)* Available information lists no component.
- *NTP (National Toxicology Program)* Available information lists no component.

12: Ecological information

- **Toxicity**
- *Aquatic toxicity:* At present there are no ecotoxicological assessments.
- **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:**
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.
- **Primary packaging:** Plastic vial (composed of polyethylene high density)

14: Transport information

· UN-Number	Not applicable
· <i>DOT, ADR, ADN, IMDG, IATA</i>	-
· UN proper shipping name	
· <i>DOT, ADR, ADN, IMDG, IATA</i>	-
· Transport hazard class(es)	
· <i>DOT, ADR, ADN, IMDG, IATA</i>	
· <i>Class</i>	-
· Packing group	
· <i>DOT, ADR, IMDG, IATA</i>	-
· Environmental hazards:	
· <i>Marine pollutant:</i>	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):* 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* Available information lists none.

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- **MA-RTK** Available information lists none.
- **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.

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.

- **Department issuing MSDS:** Product safety department
- **Contact:** Product safety department
- **Abbreviations and acronyms:**
 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)
 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.

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

—USA—

1: Identification

- **Product identifier**
- **Trade name:** CHOLESTEROL HDL SL REAGENT 2
- **Article number:** 77301B / 79301B / HDLL-0850R2 / HDLL-6XXX.
- **Synonyms**
EON 100 HDL CHOLESTEROL R2 / EON 300 HDL CHOLESTEROL R2 / HDL CHOLESTEROL ENVOY R2 / CHOLESTEROL HDL SL 2G R2.
- **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 two reagents : 77301 / 79301 / 55301 / HDLL-0230.
- **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** The product is not classified according to the CLP regulation.

- **Label elements**
- **Labelling according to Regulation (EC) No 1272/2008 -**
- **Hazard pictograms -**
- **Signal word -**
- **Hazard statements -**

3: Composition/information on ingredients

- **Chemical characterization: Mixtures**
- **Description:**
Mixture of substances.
Aqueous solution.
- **Dangerous components:** No dangerous component in reportable quantity.

4: First-aid measures

- **Description of first aid measures**
- **General information:** Show this safety data sheet to the doctor in attendance.
- **After inhalation:**
Supply fresh air.
Move out of dangerous area.
If required, provide artificial respiration.
If symptoms appear, seek medical advice.
- **After skin contact:**
Rinse with water.
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

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Trade name: CHOLESTEROL HDL SL REAGENT 2

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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** No further relevant information available.
- **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 clothing.
Ensure adequate ventilation
Prevent formation of aerosols.
Avoid physical contact with material.
- **Environmental precautions:** 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).
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.

7: Handling and storage

- **Handling:**
- **Precautions for safe handling**
Ensure good ventilation/exhaustion at the workplace.
Open and handle receptacle with care.
Prevent formation of aerosols.
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:** Store in a cool location.
· **Information about storage in one common storage facility:** Store away from incompatible materials (see section 10).
· **Further information about storage conditions:** Protect the product from light. Avoid exposure to heat.
· **Recommended storage temperature:** 2-8 °C
- **Specific end use(s)** Data not available.

8: Exposure controls/personal protection

- **Additional information about design of technical systems:** No further data; see item 7.
- **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.
- **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.
Wash hands before breaks and at the end of 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).

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Trade name: CHOLESTEROL HDL SL REAGENT 2

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- **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:**
Goggles recommended during refilling.
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:

· <i>Form:</i>	Liquid
· <i>Color:</i>	Light brown
· <i>Odor:</i>	Odorless
· <i>Odour threshold:</i>	Data not available

· **pH-value at 20 °C (68 °F):** 6

· Change in condition

· <i>Melting point/Melting range:</i>	Not applicable
· <i>Boiling point/Boiling range:</i>	Data not available
· <i>Solidification point:</i>	Not determined

· **Flash point:** Data not available

· **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:** Product does not present an explosion hazard.

· **Vapor pressure:** Data not available

· Density:

· <i>Relative density at 20 °C (68 °F)</i>	1.004 g/cm ³ (8.378 lbs/gal)
· <i>Vapour density</i>	Data not available
· <i>Evaporation rate</i>	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.
- **Possibility of hazardous reactions** No dangerous reactions if used according to specifications.
- **Conditions to avoid** No further relevant information available.
- **Incompatible materials:** No further relevant information available.
- **Hazardous decomposition products:** None expected under normal condition of use.
- **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:

Data not available

· *LD/LC50 values that are relevant for classification:* Data not available

· Primary irritant effect:

· *on the skin:* May cause irritating effect.

· *on the eye:* May cause irritating effect.

· Inhalation:

May be harmful by inhalation.

May cause irritating effect.

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- *Ingestion*: 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.

12: Ecological information

- **Toxicity**
- *Aquatic toxicity*: At present there are no ecotoxicological assessments.
- **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**:
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.
- **Primary packaging**: Plastic vial (composed of polyethylene high density)

14: Transport information

· UN-Number	Not applicable
· <i>DOT, ADR, ADN, IMDG, IATA</i>	-
· UN proper shipping name	
· <i>DOT, ADR, ADN, IMDG, IATA</i>	-
· Transport hazard class(es)	
· <i>DOT, ADR, ADN, IMDG, IATA</i>	
· <i>Class</i>	-
· Packing group	
· <i>DOT, ADR, IMDG, IATA</i>	-
· Environmental hazards :	
· <i>Marine pollutant</i> :	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)*: 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.

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- **U. S. State Regulations:**
- **PA-RTK** Available information lists none.
- **NJ-RTK** Available information lists none.
- **MA-RTK** Available information lists none.
- **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.

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.

- **Department issuing MSDS:** Product safety department
- **Contact:** Product safety department
- **Abbreviations and acronyms:**
 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)
 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.

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

USA