

1 Identification

- **Product identifier**
- **Trade name:** SERUM CONTROL LEVEL 1 (L1)
- **Article number:**
 - Envoy Vital Diagnostics article number : 55131
 - Eon Vital Diagnostics article number : 77131A
- **Synonyms**
 - Envoy Vital Diagnostics Reagent(s) : Envoy 500 Serum Control L1
 - Eon Vital Diagnostics Reagent(s) : Eon Serum Control L1
- **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 Diagnostics :
 - Kit composed of two reagents : 55131
 - Product included in kit(s) Eon Vital Diagnostics :
 - Kit composed of two reagents : 77131
- **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** The product is not classified according to the CLP regulation.
- **Additional information:**
 - Each human donor unit used to manufacture this product was tested by FDA accepted methods and found non-reactive for Hepatite B Surface Antigen (HBsAg), antibody to Hepatitis C (HCV) and antibody to HIV-1/HIV-2. This product may also contain other human source material for which there are no approval tests. In accordance with good laboratory practice, all human source material should be considered potentially infectious and handled with the same precautions used with patient specimens.
- **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:**
 - Human serum
 - Contains compounds of human origin potentially infectious.
- **Dangerous components:** No dangerous component in reportable quantity.

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.
 - If required, provide artificial respiration.
 - Seek immediate medical advice.

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- **After skin contact:**
Immediately rinse with water.
Clean with a disinfectant.
Seek immediate 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.
Seek immediate 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** 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 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**
Handle as potentially infectious.
Wear protective equipment. Keep unprotected persons away.
Ensure adequate ventilation
Avoid physical contact with material.
Avoid formation of dust.
- **Environmental precautions:** Do not allow to enter sewers/ surface or ground water.
- **Methods and material for containment and cleaning up:**
Take up dry.
Pick up mechanically.
Clean the affected area carefully; suitable cleaners are:
Warm water and cleansing agent
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.
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:** Not required.
- **Further information about storage conditions:** Protect the product from light. Avoid exposure to heat.
- **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.

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- **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 are to be adhered to when handling products potentially infectious.
Keep away from foodstuffs, beverages and feed.
Disinfect workplace and hands after work.
Immediately remove all soiled and contaminated clothing.
- **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:	Freeze dried powder
· Color:	Slightly yellow
· Odor:	Odorless
- **pH-value:** Data not available
- **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:** Product does not present an explosion hazard.
- **Vapor pressure:** Not applicable.
- **Density:** Data not available
- **Vapour density** Data not available
- **Evaporation rate** Data not available
- **Solubility in / Miscibility with Water:** Soluble.
- **Partition coefficient (n-octanol/water):** Data not available
- **Viscosity:**
- **Dynamic:** Not applicable.
- **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.

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- **Incompatible materials:** Data not 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:** Data not available
- **Primary irritant effect:**
- **on the skin:**
May cause irritating effect.
May be harmful if absorbed through skin.
- **on the eye:** May cause irritating effect.
- **Inhalation:**
May cause irritating effect.
May be harmful by inhalation.
- **Ingestion:** May be harmful if swallowed.
- **Sensitization:** Data not available
- **Additional toxicological information:**
Each human donor unit used to manufacture this product was tested by FDA accepted methods and found non-reactive for Hepatite B Surface Antigen (HBsAg), antibody to Hepatitis C (HCV) and antibody to HIV-1/HIV-2. This product may also contain other human source material for which there are no approval tests. In accordance with good laboratory practice, all human source material should be considered potentially infectious and handled with the same precautions used with patient specimens.
- **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:** 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 product 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:** Glass bottle

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 | - |

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Trade name: SERUM CONTROL LEVEL 1 (L1)

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· 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):** 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.
- **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 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.
- *** Data compared to the previous version altered.**

1 Identification

- **Product identifier**
- **Trade name:** SERUM CONTROL LEVEL 2 (L2)
- **Article number:**
 - Envoy Vital Diagnostics article number : 55131
 - Eon Vital Diagnostics article number : 77131B
- **Synonyms**
 - Envoy Vital Diagnostics Reagent(s) : Envoy 500 Serum control L2
 - Eon Vital Diagnostics Reagent(s) : Eon Serum control L2
- **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 Diagnostics :
 - Kit composed of two reagents : 55131
 - Product included in kit(s) Eon Vital Diagnostics :
 - Kit composed of two reagents : 77131
- **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** The product is not classified according to the CLP regulation.
- **Additional information:**
 - Each human donor unit used to manufacture this product was tested by FDA accepted methods and found non-reactive for Hepatite B Surface Antigen (HBsAg), antibody to Hepatitis C (HCV) and antibody to HIV-1/HIV-2. This product may also contain other human source material for which there are no approval tests. In accordance with good laboratory practice, all human source material should be considered potentially infectious and handled with the same precautions used with patient specimens.
- **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:**
 - Human serum
 - Contains compounds of human origin potentially infectious.
- **Dangerous components:** No dangerous component in reportable quantity.

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.
 - If required, provide artificial respiration.
 - Seek immediate medical advice.

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Trade name: SERUM CONTROL LEVEL 2 (L2)

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- **After skin contact:**
Immediately rinse with water.
Clean with a disinfectant.
Seek immediate 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.
Seek immediate 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** 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 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**
Handle as potentially infectious.
Wear protective equipment. Keep unprotected persons away.
Ensure adequate ventilation
Avoid physical contact with material.
Avoid formation of dust.
- **Environmental precautions:** Do not allow to enter sewers/ surface or ground water.
- **Methods and material for containment and cleaning up:**
Take up dry.
Pick up mechanically.
Clean the affected area carefully; suitable cleaners are:
Warm water and cleansing agent
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.
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:** Not required.
- **Further information about storage conditions:** Protect the product from light. Avoid exposure to heat.
- **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.

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Trade name: SERUM CONTROL LEVEL 2 (L2)

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- **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 are to be adhered to when handling products potentially infectious.
Keep away from foodstuffs, beverages and feed.
Disinfect workplace and hands after work.
Immediately remove all soiled and contaminated clothing.
- **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 protective gloves 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:	Freeze dried powder
· Color:	Slightly yellow
· Odor:	Odorless
- **pH-value:** Data not available
- **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:** Product does not present an explosion hazard.
- **Vapor pressure:** Not applicable.
- **Density:** Data not available
- **Vapour density** Data not available
- **Evaporation rate** Data not available
- **Solubility in / Miscibility with Water:** Soluble.
- **Partition coefficient (n-octanol/water):** Data not available
- **Viscosity:**
- **Dynamic:** Not applicable.
- **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.

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Trade name: SERUM CONTROL LEVEL 2 (L2)

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- **Incompatible materials:** Data not 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:** Data not available
- **Primary irritant effect:**
- **on the skin:**
May cause irritating effect.
May be harmful if absorbed through skin.
- **on the eye:** May cause irritating effect.
- **Inhalation:**
May cause irritating effect.
May be harmful by inhalation.
- **Ingestion:** May be harmful if swallowed.
- **Sensitization:** Data not available
- **Additional toxicological information:**
Each human donor unit used to manufacture this product was tested by FDA accepted methods and found non-reactive for Hepatite B Surface Antigen (HBsAg), antibody to Hepatitis C (HCV) and antibody to HIV-1/HIV-2. This product may also contain other human source material for which there are no approval tests. In accordance with good laboratory practice, all human source material should be considered potentially infectious and handled with the same precautions used with patient specimens.
- **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:** 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 product 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:** Glass bottle

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 | - |

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Trade name: SERUM CONTROL LEVEL 2 (L2)

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· 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):** 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.
- **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 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.
- *** Data compared to the previous version altered.**