

17.09.2013

Kit Components

Product code	Description
LDLL-0XXX	CHOLESTEROL LDL SL 2G (Kit) LDLL-0230 / LDLL-0380

Components:

LDLL-5XXX	CHOLESTEROL LDL SL 2G - R1
LDLL-6XXX	CHOLESTEROL LDL SL 2G - R2

1 Identification

- **Product identifier**
- **Trade name:** CHOLESTEROL LDL SL 2G - R1
- **Article number:** LDLL-5XXX
- **Relevant identified uses of the substance or mixture and uses advised against**
- **Application of the substance / the preparation** Reagent for IN VITRO diagnostic
- **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 Directive 67/548/EEC or Directive 1999/45/EC** Not applicable.
- **Information concerning particular hazards for human and environment:**
The product does not have 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.

Label elements

- **Labelling according to EU guidelines:**
Observe the general safety regulations when handling chemicals.
The product is not subject to identification regulations according to directives on hazardous materials.
- **Classification system:**
- **NFPA ratings (scale 0 - 4)**



- **HMIS-ratings (scale 0 - 4)**



3 Composition/information on ingredients

- **Chemical characterization: Mixtures**
- **Description:**
Mixture of substances.
Aqueous solution.
- **Dangerous components:**
Each of the components is present in less than 1% concentration for hazardous components (or 0.1% concentration for potential carcinogens, reproductive toxins, and mutagens).

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; consult doctor in case of complaints.
If required, provide artificial respiration.
- **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.

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Seek advice from a doctor or a poison control center.

· **Information for doctor:**

· *Most important symptoms and effects, both acute and delayed*

Sensitization possible through inhalation.

Prolonged or repeated exposure may cause allergic reactions in certain sensitive individuals.

Allergic symptoms such as:

Skin irritation

Eye irritation

Runny nose

Coughing

Asthma attacks

· *Indication of any immediate medical attention and special treatment needed* Data not available

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

Avoid physical contact with material.

Prevent formation of aerosols.

· **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.

Avoid physical contact with material.

Prevent formation of aerosols.

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:* 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.

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- **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:**

Goggles recommended during refilling.

Use equipment tested and approved under appropriate government standards such as NIOSH (US) or EN166 (EU).

- **Body protection:** Protective work clothing

9 Physical and chemical properties

- **Information on basic physical and chemical properties**

- **General Information**

- **Appearance:**

Form:	Liquid
Color:	Colorless to light yellow
Odor:	Odorless

- **pH-value at 20 °C (68 °F):**

6.3

- **Change in condition**

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

- **Flash point:**

Data not available

- **Flammability (solid, gaseous):**

Not applicable

- **Ignition temperature:**

Data not available

- **Decomposition temperature:**

Data not available

- **Auto igniting:**

Product is not selfigniting.

- **Danger of explosion:**

Product does not present an explosion hazard.

- **Vapor pressure:**

Data not available

- **Density at 20 °C (68 °F):**

1.012 g/cm³ (8.445 lbs/gal)

- **Vapour density**

Data not available

- **Evaporation rate**

Data not available

- **Solubility in / Miscibility with**

Water: Fully miscible.

- **Partition coefficient (n-octanol/water):**

Data not available

- **Viscosity:**

Dynamic: Data not available

- **Other information**

No further relevant information available.

10 Stability and reactivity

- **Reactivity** See § Possibility of hazardous reactions.

- **Chemical stability** Stable under recommended storage conditions.

- **Possibility of hazardous reactions** No dangerous reactions if used according to specifications.

- **Conditions to avoid** No further relevant information available.

- **Incompatible materials:** Unknown

- **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:**

- **Primary irritant effect:**

- **on the skin:** Contact with skin may cause redness, irritation and discomfort.

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- *on the eye*: May cause irritating effect.
- *Inhalation*:
May cause irritating effect.
May be harmful by inhalation.
- *Ingestion*: May be harmful if swallowed.
- *Sensitization*:
Sensitization possible through inhalation.
Prolonged or repeated exposure may cause allergic reactions in certain sensitive individuals.
Allergic symptoms such as:
Skin irritation
Eye irritation
Runny nose
Coughing
Asthma attacks
- **Additional toxicological information**:
The product is not subject to classification according to internally approved calculation methods for preparations:
When used and handled according to specifications, the product does not have any harmful effects according to our experience and the information provided to us.
- *Carcinogenic categories*
- *IARC (International Agency for Research on Cancer)*
No component, contained in this product at concentration equal or greater than 0.1 %, is listed by IARC as a carcinogen.
- *NTP (National Toxicology Program)*
No component, contained in this product at concentration equal or greater than 0.1 %, is listed by NTP as a carcinogen.
- *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 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 · DOT, ADR, ADN, IMDG, IATA	Not applicable -
· UN proper shipping name · DOT, ADR, ADN, IMDG, IATA	-
· Transport hazard class(es) · DOT, ADR, ADN, IMDG, IATA · Class	-
· Packing group · DOT, ADR, IMDG, IATA	-
· Environmental hazards: · Marine pollutant:	No
· Special precautions for user	Not applicable.

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· **Transport in bulk according to Annex II of MARPOL73/78 and the IBC Code** Not applicable.

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)*
No component, contained in this product at concentration equal or grater than 0.1 %, is listed by ACGIH as a carcinogen.
- *NIOSH-Ca (National Institute for Occupational Safety and Health)*
No component, contained in this product at concentration equal or grater than 0.1 %, is listed by NIOSH as a carcinogen.
- *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.
- **Product related hazard informations:**
Observe the general safety regulations when handling chemicals.
The product is not subject to identification regulations according to directives on hazardous materials.
- **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 preparation is a component of an FDA-regulated IN VITRO diagnostic medical device.

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

— USA —

Safety Data Sheet

acc. to OSHA HCS

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1 Identification

- **Product identifier**
- **Trade name:** CHOLESTEROL LDL SL 2G - R2
- **Article number:** LDLL-6XXX
- **Relevant identified uses of the substance or mixture and uses advised against**
- **Application of the substance / the preparation** Reagent for IN VITRO diagnostic
- **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

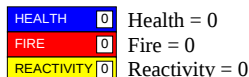
- **Classification of the substance or mixture**
- **Classification according to Directive 67/548/EEC or Directive 1999/45/EC** Not applicable.
- **Information concerning particular hazards for human and environment:**
The product does not have to be labeled due to the calculation procedure of international guidelines.
- **Classification system:**
The classification was made according to the latest editions of international substances lists, and expanded upon from company and literature data.

Label elements

- **Labelling according to EU guidelines:**
Observe the general safety regulations when handling chemicals.
The product is not subject to identification regulations according to directives on hazardous materials.
- **Classification system:**
- **NFPA ratings (scale 0 - 4)**



- **HMIS-ratings (scale 0 - 4)**



3 Composition/information on ingredients

- **Chemical characterization: Mixtures**
- **Description:**
Mixture of substances.
Aqueous solution.
- **Dangerous components:**
Each of the components is present in less than 1% concentration for hazardous components (or 0.1% concentration for potential carcinogens, reproductive toxins, and mutagens).

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; consult doctor in case of complaints.
If required, provide artificial respiration.
- **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.

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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:**

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

Avoid physical contact with material.

Prevent formation of aerosols.

- **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.

Avoid physical contact with material.

Prevent formation of aerosols.

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:* 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:**

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

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Trade name: CHOLESTEROL LDL SL 2G - R2

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

9 Physical and chemical properties

· Information on basic physical and chemical properties

· General Information

· Appearance:

Form:	Fluid
Color:	Colourless to light brown.
Odor:	Odorless

· **pH-value at 20 °C (68 °F):** 6.3

· Change in condition

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

· **Flash point:** Data not available

· **Flammability (solid, gaseous):** Not applicable

· **Ignition temperature:** Data not available

· **Decomposition temperature:** Data not available

· **Auto igniting:** Product is not selfigniting.

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

· **Vapor pressure:** Data not available

· **Density at 20 °C (68 °F):** 1 g/cm³ (8.345 lbs/gal)

· **Vapour density** Data not available

· **Evaporation rate** Data not available

· Solubility in / Miscibility with

Water: Fully miscible.

· **Partition coefficient (n-octanol/water):** Data not available

· Viscosity:

Dynamic: Data not available

· **Other information** No further relevant information available.

10 Stability and reactivity

- **Reactivity** See § Possibility of hazardous reactions.
- **Chemical stability** Stable under recommended storage conditions.
- **Possibility of hazardous reactions** No dangerous reactions if used according to specifications.
- **Conditions to avoid** No further relevant information available.
- **Incompatible materials:** Unknown
- **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:

· Primary irritant effect:

· **on the skin:** Contact with skin may cause redness, irritation and discomfort.

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

· **Inhalation:** May cause irritating effect.

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

· **Sensitization:** No sensitizing effects known.

· Additional toxicological information:

The product is not subject to classification according to internally approved calculation methods for preparations:

When used and handled according to specifications, the product does not have any harmful effects according to our experience and the information provided to us.

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Trade name: CHOLESTEROL LDL SL 2G - R2

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- *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.
- *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 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
· DOT, ADR, ADN, IMDG, IATA	-
· UN proper shipping name	
· DOT, ADR, ADN, IMDG, IATA	-
· Transport hazard class(es)	
· DOT, ADR, ADN, IMDG, IATA	
· Class	-
· Packing group	
· DOT, ADR, IMDG, IATA	-
· Environmental hazards:	
· Marine pollutant:	No
· Special precautions for user	Not applicable.
· Transport in bulk according to Annex II of MARPOL73/78 and the IBC Code	Not applicable.

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)*
No component, contained in this product at concentration equal or grater than 0.1 %, is listed by ACGIH as a carcinogen.

(Contd. on page 5)

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Trade name: CHOLESTEROL LDL SL 2G - R2

(Contd. of page 4)

- *NIOSH-Ca (National Institute for Occupational Safety and Health)*
No component, contained in this product at concentration equal or grater than 0.1 %, is listed by NIOSH as a carcinogen.
- *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.
- **Product related hazard informations:**
Observe the general safety regulations when handling chemicals.
The product is not subject to identification regulations according to directives on hazardous materials.
- **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 preparation is a component of an FDA-regulated IN VITRO diagnostic medical device.

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

— USA —