

24.05.2024	Kit Components		
Product code	Description		
321	LDL colesterolo diretto / LDL direct cholesterol B81180301 - B75182584A - A-R0200001401 - R3330000054 - B74182787		
Components:			
291155	LDL Colesterolo R2		
291154	LDL Colesterolo R1		



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Safety data sheet

according to Regulation (EC) No 1907/2006, Article 31 including amending Regulation EU/2020/878

Printing date 24.05.2024

Version number 1

Revision: 24.05.2024

<pre>1 Identification of the substance/mixture and of the company/ undertaking</pre>
· 1.1 Diagnostic Reagent
· Trade name: LDL Colesterolo R2
 Article number: 291155 CAS Number: 7732-18-5 EC number: 231-791-2 UFI: HTPO-GOST-400Q-POY3 1.2 Relevant identified uses of the substance or mixture and uses advised against Relevant Identified Uses: For laboratory use only Uses advised against: Uses other than those recommended Application of the substance / the mixture Diagnostic reagent
 1.3 Details of the supplier of the safety data sheet Manufacturer/Supplier: Sclavo Diagnostics International Via Po 26-28, Loc. Pian dei Mori CAP: 53018 - SOVICILLE - (SI) ITALY Further information obtainable from: Product safety department. 1.4 Emergency telephone number: +39 0577 390 444 / 445

2 Hazards identification

- 2.1 Classification of the substance or mixture
 Classification according to Regulation (EC) No 1272/2008
- The substance is not allocation according to Regulation (EC) NO 12/2/2008
- The substance is not classified, according to the CLP regulation.
- · 2.2 Label elements
- \cdot Labelling according to Regulation (EC) No 1272/2008 $\ensuremath{\texttt{Void}}$
- · Hazard pictograms Void
- · Signal word Void
- · Hazard statements Void
- · 2.3 Other hazards
- \cdot Results of PBT and vPvB assessment
- **PBT:** Not applicable.
- **vPvB:** Not applicable.

3 Composition/information on ingredients

- · 3.1 Substances
- · CAS No. Description

7732-18-5 water, distilled, conductivity or of similar purity

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Trade name: LDL Colesterolo R2

· Identification number(s)

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• **EC number:** 231-791-2

4 First aid measures

- · 4.1 Description of first aid measures
- · General information: No special measures required.
- After inhalation:
- Supply fresh air; consult doctor in case of complaints.
- After skin contact: Generally the product does not irritate the skin. • After eye contact:
- Rinse opened eye for several minutes under running water.
- After swallowing: If symptoms persist consult doctor.
- 4.2 Most important symptoms and effects, both acute and delayed No further relevant information available.
- \cdot 4.3 Indication of any immediate medical attention and special treatment needed

No further relevant information available.

5 Firefighting measures

- \cdot 5.1 Extinguishing media
- Suitable extinguishing agents:
- Use fire extinguishing methods suitable to surrounding conditions.
- \cdot 5.2 Special hazards arising from the substance or mixture
- No further relevant information available.
- \cdot 5.3 Advice for firefighters
- · Protective equipment: No special measures required.

6 Accidental release measures

- 6.1 Personal precautions, protective equipment and emergency procedures Not required.
- · 6.2 Environmental precautions: Dilute with plenty of water.
- 6.3 Methods and material for containment and cleaning up: Absorb with liquid-binding material (sand, diatomite, acid binders,
- universal binders, sawdust).
 6.4 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

- · 7.1 Precautions for safe handling No special measures required.
- · Information about fire and explosion protection:
- No special measures required.
- · 7.2 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: None.

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Trade name: LDL Colesterolo R2

(Contd. of page 2) · 7.3 Specific end use(s) No further relevant information available. 8 Exposure controls/personal protection · 8.1 Control parameters · Ingredients with limit values that require monitoring at the workplace: Not required. • Additional information: The lists valid during the making were used as basis. · 8.2 Exposure controls · Appropriate engineering controls No further data; see section 7. · Individual protection measures, such as personal protective equipment · General protective and hygienic measures: The usual precautionary measures are to be adhered to when handling chemicals. · Respiratory protection: Not required. · Hand protection 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 · 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. \cdot 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/face protection Goggles recommended during refilling

9 Physical and chemical properties

 9.1 Information on basic physical and chemical properties General Information 		
Physical state Fluid		
· Colour:	Yellowish	
· Odour:	Odourless	
· Odour threshold:	Not determined.	
 Melting point/freezing point: 	0 °C	
• Boiling point or initial boiling	J	
point and boiling range	100 °C (7732-18-5 water, distilled,	
	conductivity or of similar purity)	
· Flammability	Not applicable.	
• Lower and upper explosion limit		
· Lower:	Not determined.	
· Upper:	Not determined.	
· Flash point:	Not applicable.	
• Decomposition temperature:	Not determined.	
· pH	Not determined.	
• Viscosity:		
 Kinematic viscosity 	Not determined.	
• Dynamic at 20 °C:	0.952 mPas	
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Trade name: LDL Colesterolo R2

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· Solubility	
· water:	Fully miscible.
· Partition coefficient n-octanol/	
water (log value)	Not determined.
• Vapour pressure at 20 °C:	23 hPa (7732-18-5 water, distilled,
	conductivity or of similar purity)
• Density and/or relative density	
· Density at 20 °C:	1 g/cm³
· Relative density	Not determined.
· Vapour density	Not determined.
• 9.2 Other information	
· Appearance:	
· Form:	Fluid
• Important information on	
protection of health and	
environment, and on safety.	
• Ignition temperature:	Not determined.
• Explosive properties:	Product does not present an explosion
	hazard.
• Solvent content:	
· Water:	99.8 %
· VOC (EC)	0.00 %
• Solids content:	0.0 %
• Molecular weight	18.02 g/mol
· Change in condition	_
• Evaporation rate	Not determined.
 Information with regard to 	
physical hazard classes	
· Explosives	Void
\cdot Flammable gases	Void
· Aerosols	Void
· Oxidising gases	Void
· Gases under pressure	Void
· Flammable liquids	Void
· Flammable solids	Void
· Self-reactive substances and	
mixtures	Void
· Pyrophoric liquids	Void
· Pyrophoric solids	Void
· Self-heating substances and	
mixtures	Void
· Substances and mixtures, which	
emit flammable gases in contact	
with water	Void
· Oxidising liquids	Void
• Oxidising solids	Void
-	
· Organic peroxides	Void
· Corrosive to metals	Void
• Desensitised explosives	Void

10 Stability and reactivity

· 10.1 Reactivity No further relevant information available.

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- · 10.2 Chemical stability
- · Thermal decomposition / conditions to be avoided:
 - No decomposition if used according to specifications.
- \cdot 10.3 Possibility of hazardous reactions No dangerous reactions known.
- 10.4 Conditions to avoid No further relevant information available.
- \cdot 10.5 Incompatible materials: No further relevant information available.
- \cdot 10.6 Hazardous decomposition products:

No dangerous decomposition products known.

11 Toxicological information

•	11.1 Information on hazard classes as defined in Regulation (EC) No 1272/2008
•	Acute toxicity
	Based on available data, the classification criteria are not met.
•	Skin corrosion/irritation
	Based on available data, the classification criteria are not met.
•	Serious eye damage/irritation
	Based on available data, the classification criteria are not met.
·	Respiratory or skin sensitisation
	Based on available data, the classification criteria are not met.
٠	Germ cell mutagenicity
	Based on available data, the classification criteria are not met.
•	Carcinogenicity
	Based on available data, the classification criteria are not met.
•	Reproductive toxicity
	Based on available data, the classification criteria are not met.
•	STOT-single exposure
	Based on available data, the classification criteria are not met.
•	STOT-repeated exposure
	Based on available data, the classification criteria are not met.
•	Aspiration hazard
	Based on available data, the classification criteria are not met.
	11.2 Information on other hazards
•	Endocrine disrupting properties
	The product contains substances, which affect the thyroid system and
	other hormonal systems.
	None of the ingredients is listed.

12 Ecological information

•	12.1 Toxicity
•	Aquatic toxicity: No further relevant information available.
•	12.2 Persistence and degradability
	No further relevant information available.
•	12.3 Bioaccumulative potential
	No further relevant information available.
•	12.4 Mobility in soil No further relevant information available.
•	12.5 Results of PBT and vPvB assessment
•	PBT: Not applicable.
•	vPvB: Not applicable.
•	12.6 Endocrine disrupting properties
	The product does not contain substances with endocrine disrupting
	properties.
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Trade name: LDL Colesterolo R2

- · 12.7 Other adverse effects
- · Additional ecological information:
- · General notes: Not hazardous for water.

13 Disposal considerations

- · 13.1 Waste treatment methods
- · Recommendation

Smaller quantities can be disposed of with household waste.

- Uncleaned packaging:
- Recommendation: Disposal must be made according to official regulations.
 Recommended cleansing agents:
 - Water, if necessary together with cleansing agents.

14 Transport information

\cdot 14.1 UN number or ID number	
· ADR, IMDG, IATA	not regulated
/ - /	
\cdot 14.2 UN proper shipping name	
· ADR, IMDG, IATA	not regulated
11DIX, 111DO, 11111	not regulated
 14.3 Transport hazard class(es) 	
· ADR, ADN, IMDG, IATA	
· Class	not regulated
· 14.4 Packing group	
· ADR, IMDG, IATA	not regulated
• 14.5 Environmental hazards:	Not applicable.
• 14.6 Special precautions for user	Not applicable.
· 14.7 Maritime transport in bulk	
according to IMO instruments	Not applicable.
· UN "Model Regulation":	not regulated

15 Regulatory information

• 15.1 Safety, health and environmental regulations/legislation specific for the substance or mixture

· Directive 2012/18/EU

· Named dangerous substances - ANNEX I Substance is not listed.

 DIRECTIVE 2011/65/EU on the restriction of the use of certain hazardous substances in electrical and electronic equipment - Annex II

None of the ingredients is listed.

- · REGULATION (EU) 2019/1148
- Annex I RESTRICTED EXPLOSIVES PRECURSORS (Upper limit value for the purpose of licensing under Article 5(3))
- None of the ingredients is listed.

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Trade name: LDL Colesterolo R2

· Annex II - REPORTABLE EXPLOSIVES PRECURSORS

None of the ingredients is listed.

· Regulation (EC) No 273/2004 on drug precursors

None of the ingredients is listed.

• Regulation (EC) No 111/2005 laying down rules for the monitoring of trade between the Community and third countries in drug precursors None of the ingredients is listed.

15.2 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. This Safety Data Sheets is in compliance with Regulation (EC) No 1907/2006, Article 31 as amended by Regulation (EU) 2020/878.

· Department issuing SDS: Product safety department.

- · Contact: -
- Date of previous version: 22.03.2024

 Abbreviations and acronyms:
 ADR: Accord relatif au transport international des marchandises dangereuses par route (European Agreement Concerning the International Carriage of Dangerous Goods by Road) IMDG: International Maritime Code for Dangerous Goods
 IATA: International Air Transport Association GHS: Globally Harmonised System of Classification and Labelling of Chemicals EINECS: European Inventory of Existing Commercial Chemical Substances CAS: Chemical Abstracts Service (division of the American Chemical Society) VOC: Volatile Organic Compounds (USA, EU) PBT: Persistent, Bioaccumulative and Toxic vPvB: very Persistent and very Bioaccumulative

 * Data compared to the previous version altered.



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Safety data sheet

according to Regulation (EC) No 1907/2006, Article 31 including amending Regulation EU/2020/878

Printing date 24.05.2024

Version number 1

Revision: 24.05.2024

1 Identification of the substance/mixture and of the company/ undertaking
· 1.1 Diagnostic Reagent
· Trade name: LDL Colesterolo R1
 Article number: 291154 CAS Number: 7732-18-5 EC number: 231-791-2 UFI: MRP0-003D-U006-1PD1 1.2 Relevant identified uses of the substance or mixture and uses advised against Relevant Identified Uses: For laboratory use only Uses advised against: Uses other than those recommended Application of the substance / the mixture Diagnostic reagent
 1.3 Details of the supplier of the safety data sheet Manufacturer/Supplier: Sclavo Diagnostics International Via Po 26-28, Loc. Pian dei Mori CAP: 53018 - SOVICILLE - (SI) ITALY
 Further information obtainable from: Product safety department. 1.4 Emergency telephone number: +39 0577 390 444 / 445
2 Hazards identification · 2.1 Classification of the substance or mixture · Classification according to Regulation (EC) No 1272/2008

- The substance is not classified, according to the CLP regulation.
- · 2.2 Label elements
- \cdot Labelling according to Regulation (EC) No 1272/2008 Void
- · Hazard pictograms Void
- · Signal word Void
- · Hazard statements Void
- \cdot Additional information:
- Safety data sheet available on request.
- \cdot 2.3 Other hazards
- \cdot Results of PBT and vPvB assessment
- **PBT:** Not applicable.
- **vPvB:** Not applicable.

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Trade name: LDL Colesterolo R1

4 First aid measures

- · 4.1 Description of first aid measures
- After inhalation:
- Supply fresh air; consult doctor in case of complaints.
- \cdot After skin contact: Generally the product does not irritate the skin.
- After eye contact:
- Rinse opened eye for several minutes under running water.
- · After swallowing: If symptoms persist consult doctor.
- 4.2 Most important symptoms and effects, both acute and delayed No further relevant information available.
- \cdot 4.3 Indication of any immediate medical attention and special treatment needed

No further relevant information available.

5 Firefighting measures

- 5.1 Extinguishing media
- \cdot Suitable extinguishing agents:
- Use fire extinguishing methods suitable to surrounding conditions.
- \cdot 5.2 Special hazards arising from the substance or mixture
- No further relevant information available.
- · 5.3 Advice for firefighters
- · Protective equipment: No special measures required.

6 Accidental release measures

- · 6.1 Personal precautions, protective equipment and emergency procedures Not required.
- · 6.2 Environmental precautions: Dilute with plenty of water.
- \cdot 6.3 Methods and material for containment and cleaning up:

Absorb with liquid-binding material (sand, diatomite, acid binders, universal binders, sawdust).

6.4 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.

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Trade name: LDL Colesterolo R1

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7 Handling and storage

• 7.1 Precautions for safe handling

No special precautions are necessary if used correctly.

- Information about fire and explosion protection:
- No special measures required.
- \cdot 7.2 Conditions for safe storage, including any incompatibilities
- Storage:
- \cdot Requirements to be met by storerooms and receptacles:
 - No special requirements.
- · Information about storage in one common storage facility: Not required.
- \cdot Further information about storage conditions: None.
- · 7.3 Specific end use(s) No further relevant information available.

8 Exposure controls/personal protection

- 8.1 Control parameters
 Ingredients with limit values that require monitoring at the workplace: Not required.
 Additional information:
- The lists valid during the making were used as basis.
- · 8.2 Exposure controls
- · Appropriate engineering controls No further data; see section 7.
- Individual protection measures, such as personal protective equipment
 General protective and hygienic measures:

Wash hands before breaks and at the end of work.

· Respiratory protection: Not required.

Hand protection

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

- 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.
- 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.
- \cdot Eye/face protection Goggles recommended during refilling

9 Physical and chemical properties

- \cdot 9.1 Information on basic physical and chemical properties
- · General Information
- · Physical state
- Colour:
- Odour:Odour threshold:

Fluid Yellowish Odourless Not determined.

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Trade name: LDL Colesterolo R1

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0 °C
100 °C (7732-18-5 water, distilled,
conductivity or of similar purity)
Not applicable.
Not determined.
Not determined.
Not applicable.
Not determined.
Not determined.
Not determined.
0.952 mPas
Fully miscible.
, ruiry misciple.
Not determined.
23 hPa (7732-18-5 water, distilled,
conductivity or of similar purity)
1
$1 g/cm^3$
Not determined.
Not determined.
Fluid
Not determined.
Product does not present an explosio.
hazard.
98.1 %
0.00 %
1.0 %
18.02 g/mol
Not determined.
Void
Void
Void Void

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Trade name: LDL Colesterolo R1

		(Contd. of page 4)
· Self-heating substances and		
mixtures	Void	
· Substances and mixtures, whi	ich	
emit flammable gases in cont	tact	
with water	Void	
• Oxidising liquids	Void	
• Oxidising solids	Void	
· Organic peroxides	Void	
· Corrosive to metals	Void	
• Desensitised explosives	Void	

10 Stability and reactivity

- · 10.1 Reactivity No further relevant information available.
- · 10.2 Chemical stability
- · Thermal decomposition / conditions to be avoided:
- No decomposition if used according to specifications.
- · 10.3 Possibility of hazardous reactions No dangerous reactions known.
- 10.4 Conditions to avoid No further relevant information available.
- · 10.5 Incompatible materials: No further relevant information available.
- · 10.6 Hazardous decomposition products:
- No dangerous decomposition products known.

11 Toxicological information

 11.1 Information on hazard classes as defined in Regulation (EC) No 1272/2008
 Acute toxicity

Based on available data, the classification criteria are not met.

· LD/LC50 values relevant for classification:

ATE (Acute Toxicity Estimates)

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Oral LD50 50,000 mg/kg
· Skin corrosion/irritation
 Based on available data, the classification criteria are not met.
· Serious eye damage/irritation
 Based on available data, the classification criteria are not met.
· Respiratory or skin sensitisation
 Based on available data, the classification criteria are not met.
· Germ cell mutagenicity
 Based on available data, the classification criteria are not met.

    Carcinogenicity

 Based on available data, the classification criteria are not met.
· Reproductive toxicity
 Based on available data, the classification criteria are not met.
· STOT-single exposure
 Based on available data, the classification criteria are not met.
· STOT-repeated exposure
 Based on available data, the classification criteria are not met.
· Aspiration hazard
 Based on available data, the classification criteria are not met.
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Trade name: LDL Colesterolo R1

- 11.2 Information on other hazards
 Endocrine disrupting properties
 The product contains substances, which affect the thyroid system and other hormonal systems.
 - None of the ingredients is listed.

12 Ecological information

- · 12.1 Toxicity
- · Aquatic toxicity: No further relevant information available.
- · 12.2 Persistence and degradability
- No further relevant information available.
- · 12.3 Bioaccumulative potential
- No further relevant information available.
- 12.4 Mobility in soil No further relevant information available.
- \cdot 12.5 Results of PBT and vPvB assessment
- **PBT:** Not applicable.
- **vPvB:** Not applicable.
- · 12.6 Endocrine disrupting properties
- The product does not contain substances with endocrine disrupting properties.
- · 12.7 Other adverse effects
- · Additional ecological information:
- · General notes: Not hazardous for water.

13 Disposal considerations

- · 13.1 Waste treatment methods
- **Recommendation** Must not be disposed together with household garbage. Do not allow product to reach sewage system.
- Uncleaned packaging:
- · Recommendation:
- Disposal must be made according to official regulations.
- · Recommended cleansing agents:
- Water, if necessary together with cleansing agents.

14 Transport information

 14.1 UN number or ID number ADR, IMDG, IATA 	not regulated
· 14.2 UN proper shipping name · ADR, IMDG, IATA	not regulated
\cdot 14.3 Transport hazard class(es)	
· ADR, ADN, IMDG, IATA · Class	not regulated
 14.4 Packing group ADR, IMDG, IATA 	not regulated
· 14.5 Environmental hazards:	Not applicable.
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Trade name: LDL Colesterolo R1

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• 14.6 Special precautions for user Not applicable.	
14.7 Maritime transport in bulk	

not regulated

according to IMO instruments Not applicable.

• UN "Model Regulation":

15 Regulatory information

- 15.1 Safety, health and environmental regulations/legislation specific for the substance or mixture
- · Directive 2012/18/EU
- · Named dangerous substances ANNEX I Substance is not listed.
- DIRECTIVE 2011/65/EU on the restriction of the use of certain hazardous substances in electrical and electronic equipment - Annex II

None of the ingredients is listed.

· REGULATION (EU) 2019/1148

• Annex I - RESTRICTED EXPLOSIVES PRECURSORS (Upper limit value for the purpose of licensing under Article 5(3))

None of the ingredients is listed.

· Annex II - REPORTABLE EXPLOSIVES PRECURSORS

None of the ingredients is listed.

· Regulation (EC) No 273/2004 on drug precursors

None of the ingredients is listed.

 Regulation (EC) No 111/2005 laying down rules for the monitoring of trade between the Community and third countries in drug precursors

None of the ingredients is listed.

• 15.2 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. This Safety Data Sheets is in compliance with Regulation (EC) No 1907/2006, Article 31 as amended by Regulation (EU) 2020/878.

• Relevant phrases H302 Harmful if swallowed.

- · Department issuing SDS: Product safety department.
- · Contact: -
- Date of previous version: 22.03.2024

 Abbreviations and acronyms: ADR: Accord relatif au transport international des marchandises dangereuses par route (European Agreement Concerning the International Carriage of Dangerous Goods by Road) IMDG: International Maritime Code for Dangerous Goods IATA: International Air Transport Association GHS: Globally Harmonised System of Classification and Labelling of Chemicals 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) VOC: Volatile Organic Compounds (USA, EU) LC50: Lethal concentration, 50 percent

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Trade name: LDL Colesterolo R1

LD50: Lethal dose, 50 percent PBT: Persistent, Bioaccumulative and Toxic vPvB: very Persistent and very Bioaccumulative ATE: Acute toxicity estimate values Acute Tox. 4: Acute toxicity - Category 4 • *** Data compared to the previous version altered**.