

1 Identification of substance/mixture and company

1.1 Product identifier

Product form : Mixture
Product name : LEPTIN RIA CT
Catalog # : KIPMR44 REF

1.2 Relevant identified uses of substance or mixture and uses advised against

1.2.1 Relevant identified uses

Industrial/Professional use spec : Use by professionals
Use of the substance/mixture : Tracer, Laboratory reagent, Immunoassays

1.2.2 Uses advised against

No additional information available

1.3 Details of the supplier of the safety data sheet

Supplier/Manufacturer

DIAsource ImmunoAssays S.A.

Rue du Bosquet, 2

B-1348 Louvain-la-Neuve

Belgium

Tel. Nr. +32 (0)10/84.99.11

E-mail: products.support@diasource.be

1.4 Emergency telephone number

DIAsource (only office hours) : +32 (0)10/84.99.23

Centre Anti-Poisons (BE) : 070 245 245

Please refer to your local Anti-Poison Center!

2 Hazards identification

2.1 Classification of the substance or mixture

Classification according to Regulation (EC) No. 1272/2008 [CLP]:

Not classified

Adverse physicochemical, human health and environmental effects:

No additional information available

2.2 Label element

Labelling according to Regulation (EC) No. 1272/2008 [CLP]

EUH phrases : EUH210 - Safety data sheet available on request

2.3 Other hazards

No additional information available

3 Composition/information on ingredients

3.1 Substances

Not applicable

3.2 Mixtures

Name	Product identifier	%	Classification according to Regulation (EC) No. 1272/2008 [CLP]
Albumins, blood serum	(CAS-No.) 9048-46-8 (EC-No.) 232-936-2 (EC Index-No.) -	< 8	Acute Tox. 4 (Oral), H302
Sodium phosphate, dihydrate	(CAS-No.) 10028-24-7 (EC-No.) 231-448-7 (EC Index-No.) -	< 1,5	Eye Irrit. 2, H319

Other hazardous substances: 125J Protein ≤ 110 kBq (of the finished product).

Full text of H-statements: see section16

4 First aid measures

4.1 Description of first aid measures

- First-aid measures general : Never give anything by mouth to an unconscious person. If you feel unwell, seek medical advice (show the label where possible).
- First-aid measures after inhalation : If breathing is difficult, remove victim to fresh air and keep at rest in a position comfortable for breathing. Allow victim to breathe fresh air.
- First-aid measures after skin contact : Remove affected clothing and wash all exposed skin area with mild soap and water, followed by warm water rinse.
- First-aid measures after eye contact : IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.
- First-aid measures after ingestion : Rinse mouth. Get medical advice/attention.

4.2 Most important symptom and effects, both acute and delayed

- Symptoms/injuries : Not expected to present a significant hazard under anticipated conditions of normal use.

4.3 Indication of any immediate medical attention and special treatment needed

No additional information available.

5 Firefighting measures

5.1 Extinguishing media

- Suitable extinguishing media : Foam. Extinguishing powder. Carbon dioxide. Sand. Water spray.
- Unsuitable extinguishing media : Do not use a heavy water stream.

5.2 Special hazards arising from the substance or mixture

- Hazardous decomposition products in case of fire : No additional information available.

5.3 Advice for firefighters

- Firefighting instructions : Use water spray or fog for cooling exposed containers. Prevent fire-fighting water from entering environment.
- Protection during firefighting : Do not enter fire area without proper protective equipment, including respiratory protection.

6 Accidental release measures

6.1 Personal precautions, protective equipment and emergency procedures

- 6.1.1 For non-emergency personnel
Emergency procedures : Evacuate unnecessary personnel.
- 6.1.2 For emergency responders
Protective equipment : Equip cleanup crew with proper protection.
Emergency procedures : Ventilate area.

6.2 Environmental precautions

Avoid release to the environment. Prevent entry to sewers and public waters. Notify authorities if liquid enters sewers or public waters.

6.3 Methods and material for containment and cleaning up

- Methods for cleaning up : Collect spillage. Store away from other materials.

6.4 Reference to other sections

Concerning personal protective equipment to use, see section 8. Concerning disposal elimination after cleaning, see section 13.

7 Handling and storage

7.1 Precautions for safe handling

- Hygiene measures : When using do not eat, drink or smoke. Wash hands and other exposed areas with mild soap and water before eating, drinking or smoking and when leaving work.

7.2 Conditions for safe storage, including any incompatibilities

- Storage conditions : Store in original container. Store in dry, cool, well-ventilated area. Keep container closed when not in use.
- Prohibitions on mixed storage : Keep away from food, drink and animal feedingstuffs.

7.3 Specific end use(s)

Tracer.

8 Exposure controls/personnel protection

8.1 Control parameters

No additional information available

8.2 Exposure controls

Hand protection	: Wear suitable gloves. Nitrile rubber. The exact break trough time has to be found out by the manufacturer of the protective gloves and has to be observed. Wear protective gloves.
Eye protection	: Safety goggles recommended during refilling.
Skin and body protection	: Protective clothing not absolutely neces.
Respiratory protection	: Not required.

9 Physical and chemical properties

9.1 Information on basic physical and chemical properties

Physical state	: Solid for dilution / liquid
Colour	: No data available
Odor	: Characteristic.
Odour threshold	: No data available
pH	: No data available
Relative evaporation rate (butylacetate=1)	: No data available
Melting point	: No data available
Freezing point	: No data available
Boiling point	: No data available
Flammability	: No data available
Flash point	: No data available
Auto-ignition temperature	: No data available
Decomposition temperature	: No data available
Flammability (solid, gas)	: Non flammable
Vapour pressure	: No data available
Relative vapour density at 20°C	: No data available
Relative density	: No data available
Solubility	: No data available
Log Pow	: No data available
Viscosity, kinematic	: No data available
Viscosity, dynamic	: No data available
Explosive properties	: No data available
Oxidising properties	: No data available
Explosive limits	: No data available

9.2 Other information

No additional information available

10 Stability and reactivity

10.1 Reactivity

No dangerous reactions known.

10.2 Chemical stability

Stable under use and storage conditions as recommended in section 7.

10.3 Possibility of hazardous reactions

No dangerous reactions known under normal conditions of use.

10.4 Conditions to avoid

Direct sunlight. Extremely high or low temperatures.

10.5 Incompatible materials

None known.

10.6 Hazardous decomposition products

No hazardous decomposition products known.

11 Toxicological information

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

Acute toxicity	: Not classified
Skin corrosion/irritation	: Not classified Based on available data, the classification criteria are not met
Serious eye damage/irritation	: Not classified Based on available data, the classification criteria are not met

Respiratory or skin sensitization	: Not classified Based on available data, the classification criteria are not met
Germ cell mutagenicity	: Not classified Based on available data, the classification criteria are not met
Carcinogenicity	: Not classified Based on available data, the classification criteria are not met
Reproductive toxicity	: Not classified Based on available data, the classification criteria are not met
Specific target organ toxicity (single exposure)	: Not classified Based on available data, the classification criteria are not met
Specific target organ toxicity (repeated exposure)	: Not classified Based on available data, the classification criteria are not met
Aspiration hazard	: Not classified Based on available data, the classification criteria are not met
Potential adverse human health effects and Symptoms	: Based on available data, the classification criteria are not met.

12 Ecological information

12.1 Toxicity

No additional information available.

12.2 Persistence and degradability

LEPTIN RIA CT	
Persistence and degradability	Not established.

12.3 Bioaccumulative potential

LEPTIN RIA CT	
Bioaccumulative potential	Not established.

12.4 Mobility in soil

No additional information available.

12.5 Results of PBT and vPvB assessment

No additional information available.

12.6 Endocrine disrupting properties

Other adverse effects	: No other effects known.
	: Do not empty into drains.

13 Disposal considerations

13.1 Waste treatment methods

Waste treatment methods	: Do not empty into drains.
Waste disposal recommendations	: Dispose in a safe manner in accordance with local/national regulations. Maximal amount of radioactivity (≤ 3 Bq/g) for Iod 125 in accordance with the German Radiation Protection Ordinance should be considered.
Ecology - waste materials	: Avoid release to the environment.

14 Transport information

In accordance with ADR / IMDG / IATA - Classification of consignments with an activity limit of $> 1 \cdot 10^6$ Bq (Iod 125).
Consignments with an activity limit of $\leq 1 \cdot 10^6$ Bq (Iod 125) are not classified as dangerous goods and not subject to the provisions of ADR / IMDG / IATA. Within one and the same consignment maximal 9 finished products a $1,1 \cdot 10^5$ Bq can be sent without classification.

14.1 UN number or ID number

UN-No. (ADR)	: 2910
UN-No. (IMDG)	: 2910
UN-No. (IATA)	: 2910

14.2 UN proper shipping name

Proper Shipping Name (ADR)	: RADIOACTIVE MATERIAL, EXCEPTED PACKAGE - LIMITED QUANTITY OF MATERIAL
Proper Shipping Name (IMDG)	: RADIOACTIVE MATERIAL, EXCEPTED PACKAGE - LIMITED QUANTITY OF MATERIAL
Proper Shipping Name (IATA)	: RADIOACTIVE MATERIAL, EXCEPTED PACKAGE - LIMITED QUANTITY OF MATERIAL
Transport document description (ADR)	: UN 2910 RADIOACTIVE MATERIAL, EXCEPTED PACKAGE - LIMITED QUANTITY OF MATERIAL, 7, (E)

14.3 Transport hazard class(es)

Transport hazard class(es) (ADR)	: 7
Transport hazard class(es) (IMDG)	: 7
Subsidiary risk (IMDG)	: SP290
Transport hazard class(es) (IATA)	: 7

14.4 Packing group

Packing group (ADR)	: Not applicable
Packing group (IMDG)	: Not applicable
Packing group (IATA)	: Not applicable

14.5 Environmental hazards

Dangerous for the environment	: No
Marine pollutant	: No
Other information	: No supplementary information available

14.6 Special precautions for user

14.6.1 Overland transport

Special provisions (ADR)	: 290, 325
Transport category (ADR)	: 4
Tunnel restriction code (ADR)	: E
Limited quantities (ADR)	: 0
Excepted quantities (ADR)	: E0

14.6.2 Transport by sea

Special provisions (ADR)	: 290, 325
Limited quantities (IMDG)	: 0
Excepted quantities (IMDG)	: E0
Packing instructions (IMDG)	: 4.1.9
EmS-No. (Fire)	: F-I
EmS-No. (Spillage)	: S-S
Stowage category (IMDG)	: A

14.6.3 Air transport

CAO packing instructions (IATA)	: See 10.3
PCA Limited quantities (IATA)	: Forbidden
Special provisions (IATA)	: A23, A130
ERG code (IATA)	: 7L

14.7 Maritime transport in bulk according to IMO instruments

Not applicable

15 Regulatory information

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

15.1.1 EU-Regulations

No REACH Annex XVII restrictions.

Contains no substance on the REACH candidate list.

15.1.2 National regulations

Water hazard class (WGK)	: 1 - low hazard to waters
WGK remark	: Classification based on the components in compliance with Verwaltungsvorschrift wassergefährdender Stoffe (VwVwS)
Storage class (LGK)	: LGK 13 - Non-combustible solids

15.2 Chemical safety assessment

No chemical safety assessment has been carried out for the substance or the mixture by the supplier.

16 Other information

Data sources	: REGULATION (EC) No 1272/2008 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 16 December 2008 on classification, labelling and packaging of substances and mixtures, amending and repealing Directives 67/548/EEC and 1999/45/EC, and amending Regulation (EC) No 1907/2006.
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Change compared to the previous version : -

Abbreviations and acronyms:

ADR	European Agreement concerning the International Carriage of Dangerous Goods by Road
AGS	Ausschuss für Gefahrstoffe
CLP	Regulation (EC) No 1272/2008 on classification, labelling and packaging of substances and mixtures
DFG	Senatskommission zur Prüfung gesundheitsschädlicher Arbeitsstoffe der DFG (MAK-Kommission)
DMEL	Derived Minimal Effect Level
DNEL	Derived No-Effect Level
EC50	The effective concentration of substance that causes 50% of the maximum response (Median Effective Concentration)
ErC50	The concentration of a substance which results in 50% reduction in growth rate of the test population relative to the control within 72 hours exposure
IATA	International Air Transport Association
IC50	The inhibition concentration of a substance that causes a 50% inhibition of growth of the test population relative to the control within a designated period
IMDG	"International Maritime Dangerous Goods Code" for the transport of dangerous goods by sea
LC50	Lethal Concentration to 50 % of a test population (Median Lethal Concentration)
LD50	Lethal Dose to 50% of a test population (Median Lethal Dose)
LOAEL	Lowest Observed Adverse Effect Level
NIOSH	National Institute for Occupational Safety and Health of USA
NOAEC/L	No Observed Adverse Effect Concentration/Level
NOEC/L	No Observed Effect Concentration/Level
OECD	Organisation for Economic Cooperation and Development
OSHA	Occupational Safety and Health Administration of USA
PBT	Persistent, Bioaccumulative and Toxic substance
PNEC	Predicted No-Effect Concentration
REACH	Regulation (EC) No 1907/2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals
RID	Règlement international concernant le transport des marchandises dangereuses par chemin de fer (Regulations Concerning the International Transport of Dangerous Goods by Rail)
SDS	Safety Data Sheet
STP	Sewage Treatment Plant
TRGS	Technische Regeln für Gefahrstoffe
TWA	Time weighted average, long term exposure limit (8 hour reference period).
UFI	Unique Formula Identifier
vPvB	Very Persistent and Very Bioaccumulative

Full text of H- and EUH-phrases:

Acute Tox. 4 (Oral)	Acute toxicity, Category 4 (Oral)
Eye Irrit. 2	Serious eye damage/eye irritation, Category 2
H302	Harmful if swallowed
H319	Causes serious eye irritation.

SDS EU (REACH Annex II)

This information is based on our current knowledge and is intended to describe the product for the purposes of health, safety and environmental requirements only. It should not therefore be construed as guaranteeing any specific property of the product.