

according to Regulation (EC) No 1907/2006 (REACH)

Trade name: HTRF Insulin High Range kit - 10K pts / 62IN1PEH

Version: KIT, Page 1 of 1, Revision date: 07/09/2023

Cette section présente les différents flacons présents dans le kit. Les fiches de sécurité de tous ces composants sont disponibles dans la langue choisie à la suite du document.

This section shows all the vials in the kit. The Safety Datasheets are available in the selected language in the next part of the document.

Nomenclature of the product

Description	Component	Nb of vials	pH	Color	Physical state
HTRF Diluent 5 (5X) - 100 mL	62DL5DDG	2	7	Colorless	Liquid
HTRF Detect. Buf. 7 - 130 mL		6	7	Colorless	Liquid
HTRF Insulin High Range kit - 10K pts Eu Cryptate antibody		2	-	White	Solid
HTRF Insulin High Range kit - 10K pts XL665 antibody		2	-	Blue	Solid
HTRF Insulin kit - Std	62INSCDA	2	-	White	Solid

according to Regulation (EC) No 1907/2006 (REACH)

Designation / Commercial name : HTRF Diluent 5 (5X) - 100 mL 62DL5DDG

Version: UK, Page 1 of 13, Revision date: 07/09/2023

SECTION 1 : IDENTIFICATION OF THE SUBSTANCE/MIXTURE AND OF THE COMPANY/UNDERTAKING

1.1 Product identifier:

Designation / Commercial name : HTRF Diluent 5 (5X) - 100 mL 62DL5DDG

CAS No.:

Index No:

EC No:

REACH No:

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

Relevant identified uses: Use of the substance or mixture for Laboratory Research use only ;

Uses advised against: Do not use for diagnostics, therapeutics or other clinical uses. ;

1.3 Details of the supplier of the safety data sheet:

Supplier:

Name: CISBIO BIOASSAYS, company of Revvity Group - CBBIOA -

Address: Parc Marcel Boiteux - BP 84175 - 30200 Codolet, France

Phone : +33 4 66 79 67 05 - Fax : +33 4 66 79 67 50

E-Mail (competent person):  codolet.sds@revvity.com

1.4 EMERGENCY TELEPHONE NUMBER:

France - Numéro ORFILA (INRS) : + 33 (0)1 45 42 59 59

Ce numéro permet d'obtenir les coordonnées de tous les centres Anti-poison Français. Ces centres anti-poison et de toxicovigilance fournissent une aide médicale gratuite (hors coût d'appel), 24 heures sur 24 et 7 jours sur 7.

USA & Canada - Phone: 1-888-963-456 (1)

Other countries - Phone: +33 (0) 466 796 737 (2)

<https://www.cisbio.com>

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(1) Available from Monday to Thursday 8:30 am to 5:30pm GMT-5 and Friday: 8:30 am to 3:00pm GMT-5

(2) Available from Monday to Friday 9:00 am to 5:30 pm GMT+2

SECTION 2 : HAZARDS IDENTIFICATION

2.1 Classification of the substance or mixture:

Classification according to Regulation (EC) No 1272/2008 [CLP]	Category code	Hazard statement	Precautionary statement
The substance or mixture is not classified as hazardous under the CLP Regulation (EC) No 1272/2008	None	None	None

2.2 Label elements

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

Product identifier:

Designation / Commercial name : HTRF Diluent 5 (5X) - 100 mL 62DL5DDG

Substances contained in this product:

according to Regulation (EC) No 1907/2006 (REACH)

Designation / Commercial name : HTRF Diluent 5 (5X) - 100 mL 62DL5DDG

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Hazard pictograms

Signal word:

Hazard and precautionary statements:

2.3 Other hazards

The mixture does not contain substances classified as 'Substances of Very High Concern' (SVHC) $\geq 0.1\%$ published by the European Chemicals Agency (ECHA) under article 57 of REACH. The mixture satisfies neither the PBT nor the vPvB criteria for mixtures in accordance with annexe XIII of the REACH regulations EC 1907/2006. ;

Adverse human health effects and symptoms:

according to Regulation (EC) No 1907/2006 (REACH)

Designation / Commercial name : HTRF Diluent 5 (5X) - 100 mL 62DL5DDG

Version: UK, Page 3 of 13, Revision date: 07/09/2023

SECTION 3 : COMPOSITION/INFORMATION ON INGREDIENTS

3.2 Mixtures

Hazardous ingredients:

Substance name	CAS n°	Index n°	EC n°	Classification according Regulation (EC) No. 1272 [CLP]	Concentration (%)	SCL	M-factor
potassium dihydrogenorthophosphate	7778-77-0		231-913-4		< 3%		

Additional information:

Full text of H- and EUH-phrases: see SECTION 16.

SECTION 4 : FIRST AID MEASURES

4.1 Description of first aid measures

General information:Do not leave affected person unattended. ;

Following inhalation:In case of respiratory tract irritation, consult a physician. ;

Following skin contact:After contact with skin, wash immediately with water ;

Following eye contact:After contact with the eyes, rinse with water with the eyelids open for a sufficient length of time, then consult an ophthalmologist immediately. ;

Following ingestion:Do NOT induce vomiting. ;

Self-protection of the first aider:

4.2 Most important symptoms and effects, both acute and delayed

Symptoms:No known symptoms to date. ;

Effects:

4.3 Indication of any immediate medical attention and special treatment needed

Notes for the doctor:

SECTION 5 : FIREFIGHTING MEASURES

5.1 Extinguishing media:

Suitable extinguishing media:This product is not flammable. Use extinguishing agent suitable for type of surrounding fire ;

5.2 Special hazards arising from the substance or mixture

Hazardous combustion products:/

5.3 Advice for fire-fighters

Wear Protective clothing. ;

SECTION 6 : ACCIDENTAL RELEASE MEASURES

6.1 Personal precautions, protective equipment and emergency procedures

Emergency procedures: Provide adequate ventilation. ;

according to Regulation (EC) No 1907/2006 (REACH)

Designation / Commercial name : HTRF Diluent 5 (5X) - 100 mL 62DL5DDG

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6.2 Environmental precautions

Do not allow to enter into surface water or drains. ;

6.3 Methods and material for containment and cleaning up

For cleaning up: Suitable material for taking up: Absorbing material, organic ;

Other information:

6.4 Reference to other sections

Additional information:

SECTION 7 : HANDLING AND STORAGE

7.1 Precautions for safe handling

Protective measures:

Advice on safe handling: Avoid contact with skin, eyes and clothes. ;

Fire preventions:

Do not eat, drink or smoke in areas where reagents are handled. ;

Advice on general occupational hygiene

Handle in accordance with good industrial hygiene and safety practice ;

7.2 Conditions for safe storage, including any incompatibilities

Technical measures and storage conditions:

Requirements for storage rooms and vessels: Keep container tightly closed. ;

Hints on storage assembly:

Materials to avoid:

Further information on storage conditions:

7.3 Specific end uses:

Recommendations on specific end uses: Observe technical data sheet. ;

SECTION 8 : EXPOSURE CONTROLS/PERSONAL PROTECTION

8.1 Control parameters

Preliminary remark:

8.1.1 Occupational exposure limits:

- France

Substance	EC-No.	CAS-No	VLE (mg/m ³)	VLE (ppm)	VME (mg/m ³)	VME (ppm)
7778-77-0 / 231-913-4	231-913-4	7778-77-0				

according to Regulation (EC) No 1907/2006 (REACH)

Designation / Commercial name : HTRF Diluent 5 (5X) - 100 mL 62DL5DDG

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- Spain

Source :	Limites de Exposicion Profesional para Agentes Quimicos en Espana Instituto Nacional de Seguridad e Higiene en el Trabajo June 2015					
Substance	EC-No.	CAS-No	VLA-EC (mg/m3)	VLA-EC (ppm)	VLA-ED (mg/m3)	VLA-ED (ppm)
7778-77-0 / 231-913-4	231-913-4	7778-77-0				

- Germany

Source :	TRGS 900, June 2015, BAuA				
Substance	EC-No.	CAS-No	AGW (mg/m3)	AGW (ppm)	
7778-77-0 / 231-913-4	231-913-4	7778-77-0			

- Italia
- Greece
- UK
- OSHA (USA)

Source :	Occupational Safety and Health Administration (OSHA) Permissible Exposure Limits (PELS) from 29 CFR 1910.1000					
Substance	EC-No.	CAS-No	OSHA Permissible Exposure Limit (PEL) 8-hour TWA (ppm)	OSHA Permissible Exposure Limit (PEL) 8-hour TWA (mg/m3)	OSHA Permissible Exposure Limit (PEL) STEL (ppm)	OSHA Permissible Exposure Limit (PEL) STEL (mg/m3)
7778-77-0 / 231-913-4	231-913-4	7778-77-0				

8.1.2 Biological limit values (Germany):

Source :	List of recommended health-based biological limit values (BLVs) and biological guidance values (BGVs), June 2014				
Substance	EC-No.	CAS-No	BLV (mg/m3)	BLV (ppm)	
7778-77-0 / 231-913-4	231-913-4	7778-77-0			

according to Regulation (EC) No 1907/2006 (REACH)

Designation / Commercial name : HTRF Diluent 5 (5X) - 100 mL 62DL5DDG

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8.1.3 Exposure limits at intended use (Germany):

Source :	TRGS 903, November 2015, BAuA			
Substance	EC-No.	CAS-No	BGW (mg/m3)	BGW (ppm)
7778-77-0 / 231-913-4	231-913-4	7778-77-0		

8.1.4 DNEL/PNEC-values:

- DNEL worker

Source :	GESTIS – substance database								
Substance	EC-No.	CAS-No	Acute – dermal, local effects (mg/kg/day)	Long-term – dermal, local effects (mg/kg/day)	Long-term – dermal, systemic effects (mg/kg/day)	Acute – inhalation, local effects (mg/m3)	Acute – inhalation, systemic effects (mg/m3)	Long-term – inhalation, local effects (mg/m3)	Long-term – inhalation, systemic effects (mg/m3)
7778-77-0 / 231-913-4	231-913-4	7778-77-0					4.07-4.07		

- DNEL consumer

Source :	GESTIS – substance database								
Substance	EC-No.	CAS-No	Acute – dermal, local effects (mg/kg/day)	Long-term – dermal, local effects (mg/kg/day)	Long-term – dermal, systemic effects (mg/kg/day)	Acute – inhalation, local effects (mg/m3)	Acute – inhalation, systemic effects (mg/m3)	Long-term – inhalation, local effects (mg/m3)	Long-term – inhalation, systemic effects (mg/m3)
7778-77-0 / 231-913-4	231-913-4	7778-77-0							

DNEL remark:

- PNEC

Source :	INERIS																
Substance	EC-No.	CAS-No	PNEC AQUATIC									PNEC Sediment					
			freshwater			marine water			intermittent release			freshwater			marine water		
			(mg/L)	(mg/kg)	(ppm)	(mg/L)	(mg/kg)	(ppm)	(mg/L)	(mg/kg)	(ppm)	(mg/L)	(mg/kg)	(ppm)	(mg/L)	(mg/kg)	(ppm)
7778-77-0 / 231-913-4	231-913-4	7778-77-0															

Source :	INERIS													
Substance	EC-No.	CAS-No	Others											
			PNEC soil			PNEC sewage treatment plant			PNEC air			PNEC secondary poisoning		
			(mg/L)	(mg/kg)	(ppm)	(mg/L)	(mg/kg)	(ppm)	(mg/L)	(mg/kg)	(ppm)	(mg/L)	(mg/kg)	(ppm)

according to Regulation (EC) No 1907/2006 (REACH)

Designation / Commercial name : HTRF Diluent 5 (5X) - 100 mL 62DL5DDG

Version: UK, Page 7 of 13, Revision date: 07/09/2023

7778-77-0 / 231-913-4	231-913-4	7778-77-0																	
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PNEC remark:

Control parameters remark:

8.2 Exposure controls

8.2.1 Appropriate engineering controls:

8.2.2 Personal protective equipment:

Eye / Face protection: Safety glasses with side-shields ;

Skin protection:Gloves ;

Respiratory protection:Ensure adequate ventilation ;

Thermal hazards:

8.2.3 Environmental exposure controls:

SECTION 9 : PHYSICAL AND CHEMICAL PROPERTIES

9.1 Information on basic physical and chemical properties

Appearance

Physical state	Liquid ;
Colour	Colorless ;
Odour	
Odour threshold (ppm)	

	Value	Concentration (mol/L)	Method	Temperature (°C)	Pressure (kPa)	Remark
pH	7					
Melting point (°C)						
Freezing point (°C)						
Initial boiling point/boiling range (°C)						
Flash point (°C)						
Evaporation rate (kg/m ² /h)						
Flammability (type :) (%)						
Upper/lower flammability or explosive limits	Upper explosive limit (%)					
	Lower explosive limit (%)					
Vapour pressure (kPa)						
Vapour density (g/cm ³)						
Densities	Density (g/cm ³)					
	Relative density (g/cm ³)					
	Bulk density (g/cm ³)					
	Critical density (g/cm ³)					
Solubility (Type :) (g/L)						
Partition coefficient (log Pow) n-octanol/water at pH :						
Auto-ignition temperature (°C)						
Decomposition temperature (°C)						
Decomposition energy : kJ						
Viscosity	Viscosity, dynamic (poiseuille)					
	Viscosity, cinematic (cm ² /s)					
Oxidising properties						

according to Regulation (EC) No 1907/2006 (REACH)

Designation / Commercial name : HTRF Diluent 5 (5X) - 100 mL 62DL5DDG

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Explosive properties						
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9.2 Other information:

No other relevant data available

SECTION 10 : STABILITY AND REACTIVITY

10.1 Reactivity This material is considered to be non-reactive under normal use conditions. ;

10.2 Chemical stability

10.3 Possibility of hazardous reactions

10.4 Conditions to avoid:

10.5 Incompatible materials:

10.6 Hazardous decomposition products:

Does not decompose when used for intended uses. ;

SECTION 11 : TOXICOLOGICAL INFORMATION

Toxicokinetics, metabolism and distribution

11.1 Information on toxicological effects

Substances

- **Acute toxicity**

Animal data:

Acute oral toxicity:

Acute dermal toxicity:

Acute inhalative toxicity:

Practical experience / human evidence:

Assessment / Classification:

General Remark:

- **Skin corrosion/irritation**

Animal data:

In-vitro skin test method:

In-vitro skin test result:

Assessment / Classification:

according to Regulation (EC) No 1907/2006 (REACH)

Designation / Commercial name : HTRF Diluent 5 (5X) - 100 mL 62DL5DDG

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- **Eye damage/irritation**

Animal data:

In vitro eye test method:

In vitro eye test result:

Assessment / Classification:

- **CMR effects (carcinogenicity, mutagenicity and toxicity for reproduction)**
 - Germ cell mutagenicity:

Animal data:

Assessment / Classification:

- Carcinogenicity

Practical experience / human evidence:

Animal data:

Other information:

Assessment / Classification:

- Reproductive toxicity

Practical experience / human evidence:

Animal data:

Other information:

Assessment / Classification:

Overall assessment on CMR properties:

- **Specific target organ toxicity (single exposure)**
 - STOT SE 1 and 2

Animal data:

Other information:

- STOT SE 3

Practical experience / human evidence:

Other information:

Assessment / Classification:

- **Specific target organ toxicity (repeated exposure)**

Practical experience / human evidence:

Animal data:

according to Regulation (EC) No 1907/2006 (REACH)

Designation / Commercial name : HTRF Diluent 5 (5X) - 100 mL 62DL5DDG

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Assessment / Classification:

Other information

- **Aspiration hazard**

Practical experience / human evidence:

Experimental data: viscosity data: see SECTION 9.

Assessment / Classification:

Remark:

11.1.1 Mixtures

No toxicological information is available for the mixture itself

SECTION 12 : ECOLOGICAL INFORMATION

In case that test data regarding one endpoint/differentiation exist for the mixture itself, the classification is carried out according to the substance criteria (excluding biodegradation and bioaccumulation). If no test data exist, the criteria for mixture classification has to be used (calculation method) in this case the toxicological data of the ingredients are shown.

12.1 **Aquatic toxicity:**

Acute (short-term) fish toxicity

Chronic (long-term) fish toxicity

Acute (short-term) toxicity to crustacea

Chronic (long-term) toxicity to crustacea

Acute (short-term) toxicity to algae and cyanobacteria

Toxicity to microorganisms and other aquatic plants / organisms

Assessment / Classification:

12.2 **Persistence and degradability**

Biodegradation:

Abiotic Degradation:

Assessment / Classification:

12.3 **Bioaccumulative potential**

Bioconcentration factor (BCF):

12.4 **Mobility in soil**

according to Regulation (EC) No 1907/2006 (REACH)

Designation / Commercial name : HTRF Diluent 5 (5X) - 100 mL 62DL5DDG

Version: UK, Page 11 of 13, Revision date: 07/09/2023

12.5 Results of PBT and vPvB assessment

12.6 Other adverse effects:

Additional ecotoxicological information:

SECTION 13 : DISPOSAL CONSIDERATIONS

13.1 Waste treatment methods

Waste treatment options:Dispose of waste according to applicable legislation. ;

SECTION 14 : TRANSPORT INFORMATION

ADR/RID/AND/IMDG/IATA

UN No.	
UN Proper shipping name	
Transport hazard class(es)	
Hazard label(s)	
Packing group	

Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code

Land transport (ADR/RID)

Classification code ADR:	Special Provisions for ADR/RID:
Limited quantities for ADR/RID:	Excepted Quantities for ADR/RID:
Packing Instructions for ADR/RID:	Special packing provisions for ADR/RID:
Mixed packing provisions:	
Portable tanks and bulk containers Instructions:	
Portable tanks and bulk containers Special Provisions:	
ADR Tank Code:	ADR Tank special provisions:
Vehicle for tank carriage:	
Special provisions for carriage Packages:	
Special provisions for carriage Bulk:	
Special provisions for carriage for loading, unloading and handling:	
Special Provisions for carriage Operation:	
Hazard identification No:	Transport category (Tunnel restriction code):

Sea transport (IMDG)

Marine Pollutant:	Subsidiary risk(s) for IMDG:
Packing provisions for IMDG:	Limited quantities for IMDG:
Packing instructions for IMDG:	IBC Instructions:
IBC Provisions:	IMO tank instructions:
UN tank instructions:	Tanks and bulk Provisions:
EmS :	Stowage and segregation for IMDG:
Properties and observations:	

Inland waterway transport (ADN)

Classification Code ADN:	Special Provisions ADN:
Limited quantities ADN:	Excepted quantities ADN:

according to Regulation (EC) No 1907/2006 (REACH)

Designation / Commercial name : HTRF Diluent 5 (5X) - 100 mL 62DL5DDG

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Carriage permitted:

Provisions concerning loading and unloading:

Number of blue cones/lights:

Equipment required:

Provisions concerning carriage:

Remark:

Air transport (ICAO-TI / IATA-DGR)

Subsidiary risk for IATA:

Excepted quantity for IATA:

Passenger and Cargo Aircraft Limited Quantities Packing Instructions:

Passenger and Cargo Aircraft Limited Quantities Maximal Net Quantity :

Passenger and Cargo Aircraft Packaging Instructions :

Passenger and Cargo Aircraft Maximal Net Quantity :

Cargo Aircraft only Packaging Instructions :

Cargo Aircraft only Maximal Net Quantity :

ERG code:

Special Provisions for IATA:

SECTION 15 : REGULATORY INFORMATION

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

EU regulations

- Authorisations and/or restrictions on use:

Authorisations:

Restrictions on use:

SVHC :

- Other EU regulations:
- Directive 2010/75/EC on industrial emissions

Not relevant

National regulations

15.2 Chemical Safety Assessment:

For this mixture, no chemical safety assessment has been carried out

SECTION 16 : OTHER INFORMATION

16.1 Indication of changes

Date of the previous version:07/09/2023

Modifications:

16.2 Other informations

16.3 Classification for mixtures and used evaluation method according to regulation (EC) 1207/2008 [CLP]:

See SECTION 2.1 (classification).

according to Regulation (EC) No 1907/2006 (REACH)

Designation / Commercial name : HTRF Diluent 5 (5X) - 100 mL 62DL5DDG

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16.4 Relevant R-, H- and EUH-phrases (number and full text):

according to Regulation (EC) No 1907/2006 (REACH)

Designation / Commercial name : HTRF Insulin kit - Std 62INSCDA

Version: UK, Page 1 of 12, Revision date: 07/09/2023

SECTION 1 : IDENTIFICATION OF THE SUBSTANCE/MIXTURE AND OF THE COMPANY/UNDERTAKING

1.1 Product identifier:

Designation / Commercial name : HTRF Insulin kit - Std 62INSCDA

CAS No.:

Index No:

EC No:

REACH No:

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

Relevant identified uses: Use of the substance or mixture for Laboratory Research use only ;

Uses advised against: Do not use for diagnostics, therapeutics or other clinical uses. ;

1.3 Details of the supplier of the safety data sheet:

Supplier:

Name: CISBIO BIOASSAYS, company of Revvity Group - CBBIOA -

Address: Parc Marcel Boiteux - BP 84175 - 30200 Codolet, France

Phone : +33 4 66 79 67 05 - Fax : +33 4 66 79 67 50

E-Mail (competent person):  codolet.sds@revvity.com

1.4 EMERGENCY TELEPHONE NUMBER:

France - Numéro ORFILA (INRS) : + 33 (0)1 45 42 59 59

Ce numéro permet d'obtenir les coordonnées de tous les centres Anti-poison Français. Ces centres anti-poison et de toxicovigilance fournissent une aide médicale gratuite (hors coût d'appel), 24 heures sur 24 et 7 jours sur 7.

USA & Canada - Phone: 1-888-963-456 (1)

Other countries - Phone: +33 (0) 466 796 737 (2)

<https://www.cisbio.com>

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(2) Available from Monday to Friday 9:00 am to 5:30 pm GMT+2

SECTION 2 : HAZARDS IDENTIFICATION

2.1 Classification of the substance or mixture:

Classification according to Regulation (EC) No 1272/2008 [CLP]	Category code	Hazard statement	Precautionary statement
The substance or mixture is not classified as hazardous under the CLP Regulation (EC) No 1272/2008	None	None	None

2.2 Label elements

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

Product identifier:

Designation / Commercial name : HTRF Insulin kit - Std 62INSCDA

Substances contained in this product:

according to Regulation (EC) No 1907/2006 (REACH)

Designation / Commercial name : HTRF Insulin kit - Std 62INSCDA

Version: UK, Page 2 of 12, Revision date: 07/09/2023

Hazard pictograms

Signal word:

Hazard and precautionary statements:

2.3 Other hazards

The mixture does not contain substances classified as 'Substances of Very High Concern' (SVHC) $\geq 0.1\%$ published by the European Chemicals Agency (ECHA) under article 57 of REACH. The mixture satisfies neither the PBT nor the vPvB criteria for mixtures in accordance with annexe XIII of the REACH regulations EC 1907/2006. ;

Adverse human health effects and symptoms:

according to Regulation (EC) No 1907/2006 (REACH)

Designation / Commercial name : HTRF Insulin kit - Std 62INSCDA

Version: UK, Page 3 of 12, Revision date: 07/09/2023

SECTION 3 : COMPOSITION/INFORMATION ON INGREDIENTS

3.2 Mixtures

Hazardous ingredients:

This mixture does not contain any hazardous substances at the concentration limits given in Regulation (EC) No. 1272/2008 and OSHA Hazard Communication Standard 29 CFR 1910.1200.

Additional information:

Full text of H- and EUH-phrases: see SECTION 16.

SECTION 4 : FIRST AID MEASURES

4.1 Description of first aid measures

General information: Do not leave affected person unattended. ; Remove affected person from the danger area and lay down. ;

Following inhalation: In case of respiratory tract irritation, consult a physician. ; Provide fresh air. ;

Following skin contact: After contact with skin, wash immediately with water ; Remove contaminated clothing ;

Following eye contact: After contact with the eyes, rinse with water with the eyelids open for a sufficient length of time, then consult an ophthalmologist immediately. ;

Following ingestion: Do NOT induce vomiting. ; Give nothing to eat or drink. ; If accidentally swallowed rinse the mouth with plenty of water (only if the person is conscious) and obtain immediate medical attention. ;

Self-protection of the first aider:

4.2 Most important symptoms and effects, both acute and delayed

Symptoms: No known symptoms to date. ;

Effects:

4.3 Indication of any immediate medical attention and special treatment needed

Notes for the doctor:

SECTION 5 : FIREFIGHTING MEASURES

5.1 Extinguishing media:

Suitable extinguishing media: This product is not flammable. Use extinguishing agent suitable for type of surrounding fire ;

5.2 Special hazards arising from the substance or mixture

Hazardous combustion products: /

5.3 Advice for fire-fighters

Wear Protective clothing. ;

SECTION 6 : ACCIDENTAL RELEASE MEASURES

6.1 Personal precautions, protective equipment and emergency procedures

Emergency procedures: Provide adequate ventilation. ; Emergency procedures: Remove persons to safety. ; Personal precautions: Use personal protection equipment (see section 8). ;

according to Regulation (EC) No 1907/2006 (REACH)

Designation / Commercial name : HTRF Insulin kit - Std 62INSCDA

Version: UK, Page 4 of 12, Revision date: 07/09/2023

6.2 Environmental precautions

Do not allow to enter into surface water or drains. ; Ensure all waste water is collected and treated via a waste water treatment plant. ;

6.3 Methods and material for containment and cleaning up

For cleaning up: Suitable material for taking up: Absorbing material, organic ;

Other information:

6.4 Reference to other sections

Additional information:

SECTION 7 : HANDLING AND STORAGE

7.1 Precautions for safe handling

Protective measures:

Advice on safe handling: Avoid contact with skin, eyes and clothes. ; Avoid: Eye contact ; Avoid: Generation/formation of aerosols ; Avoid: Skin contact ; Avoid: inhalation ; In the immediate working surroundings there must be: Emergency shower installed ; In the immediate working surroundings there must be: Provide eye shower and label its location conspicuously ; Wash contaminated clothing immediately. ;

Fire preventions:

Do not eat, drink or smoke in areas where reagents are handled. ; Do not pipet by mouth ; Wear suitable one-way gloves at work ;

Advice on general occupational hygiene

Handle in accordance with good industrial hygiene and safety practice ; Observe technical data sheet. ; Remove contaminated, saturated clothing. ; Wash hands before breaks and after work. ;

7.2 Conditions for safe storage, including any incompatibilities

Technical measures and storage conditions:

Requirements for storage rooms and vessels: Keep container tightly closed. ; Keep-store only in original container or in properly labeled containers ;

Hints on storage assembly:

Materials to avoid:

Further information on storage conditions:

7.3 Specific end uses:

Recommendations on specific end uses: Observe technical data sheet. ;

SECTION 8 : EXPOSURE CONTROLS/PERSONAL PROTECTION

8.1 Control parameters

Preliminary remark:

8.1.1 Occupational exposure limits:

- France

according to Regulation (EC) No 1907/2006 (REACH)

Designation / Commercial name : HTRF Insulin kit - Std 62INSCDA

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- Spain
- Germany
- Italia
- Greece
- UK
- OSHA (USA)

8.1.2 Biological limit values (Germany):

8.1.3 Exposure limits at intended use (Germany):

8.1.4 DNEL/PNEC-values:

- DNEL worker
- DNEL consumer

DNEL remark:

- PNEC

PNEC remark:

Control parameters remark:

8.2 Exposure controls

8.2.1 Appropriate engineering controls:

according to Regulation (EC) No 1907/2006 (REACH)

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8.2.2 Personal protective equipment:

Eye / Face protection: Safety glasses with side-shields ;

Skin protection:Gloves ; Laboratory coats ;

Respiratory protection:Ensure adequate ventilation ;

Thermal hazards:

8.2.3 Environmental exposure controls:

SECTION 9 : PHYSICAL AND CHEMICAL PROPERTIES

9.1 Information on basic physical and chemical properties

Appearance

Physical state	Solid ;
Colour	White ;
Odour	
Odour threshold (ppm)	

	Value	Concentration (mol/L)	Method	Temperature (°C)	Pressure (kPa)	Remark
pH						
Melting point (°C)						
Freezing point (°C)						
Initial boiling point/boiling range (°C)						
Flash point (°C)						
Evaporation rate (kg/m ² /h)						
Flammability (type :) (%)						
Upper/lower flammability or explosive limits	Upper explosive limit (%)					
	Lower explosive limit (%)					
Vapour pressure (kPa)						
Vapour density (g/cm ³)						
Densities	Density (g/cm ³)					
	Relative density (g/cm ³)					
	Bulk density (g/cm ³)					
	Critical density (g/cm ³)					
Solubility (Type :) (g/L)						
Partition coefficient (log Pow) n-octanol/water at pH :						
Auto-ignition temperature (°C)						
Decomposition temperature (°C) Decomposition energy : kJ						
Viscosity	Viscosity, dynamic (poiseuille)					
	Viscosity, cinematic (cm ² /s)					
Oxidising properties						
Explosive properties						

9.2 Other information:

No other relevant data available

according to Regulation (EC) No 1907/2006 (REACH)

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SECTION 10 : STABILITY AND REACTIVITY

10.1 Reactivity This material is considered to be non-reactive under normal use conditions. ;

10.2 Chemical stability

10.3 Possibility of hazardous reactions

10.4 Conditions to avoid:

10.5 Incompatible materials:

10.6 Hazardous decomposition products:

Does not decompose when used for intended uses. ; Thermal decomposition can lead to the escape of irritating gases and vapors. ;

SECTION 11 : TOXICOLOGICAL INFORMATION

Toxicokinetics, metabolism and distribution

11.1 Information on toxicological effects

Substances

- **Acute toxicity**

Animal data:

Acute oral toxicity:

Acute dermal toxicity:

Acute inhalative toxicity:

Practical experience / human evidence:

Assessment / Classification:

General Remark:

- **Skin corrosion/irritation**

Animal data:

In-vitro skin test method:

In-vitro skin test result:

Assessment / Classification:

- **Eye damage/irritation**

Animal data:

according to Regulation (EC) No 1907/2006 (REACH)

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In vitro eye test method:

In vitro eye test result:

Assessment / Classification:

- **CMR effects (carcinogenicity, mutagenicity and toxicity for reproduction)**
 - Germ cell mutagenicity:

Animal data:

Assessment / Classification:

- Carcinogenicity

Practical experience / human evidence:

Animal data:

Other information:

Assessment / Classification:

- Reproductive toxicity

Practical experience / human evidence:

Animal data:

Other information:

Assessment / Classification:

Overall assessment on CMR properties:

- **Specific target organ toxicity (single exposure)**
 - STOT SE 1 and 2

Animal data:

Other information:

- STOT SE 3

Practical experience / human evidence:

Other information:

Assessment / Classification:

- **Specific target organ toxicity (repeated exposure)**

Practical experience / human evidence:

Animal data:

Assessment / Classification:

Other information

- **Aspiration hazard**

according to Regulation (EC) No 1907/2006 (REACH)

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Practical experience / human evidence:

Experimental data: viscosity data: see SECTION 9.

Assessment / Classification:

Remark:

11.1.1 Mixtures

No toxicological information is available for the mixture itself

SECTION 12 : ECOLOGICAL INFORMATION

In case that test data regarding one endpoint/differentiation exist for the mixture itself, the classification is carried out according to the substance criteria (excluding biodegradation and bioaccumulation). If no test data exist, the criteria for mixture classification has to be used (calculation method); in this case the toxicological data of the ingredients are shown.

12.1 Aquatic toxicity:

Acute (short-term) fish toxicity

Chronic (long-term) fish toxicity

Acute (short-term) toxicity to crustacea

Chronic (long-term) toxicity to crustacea

Acute (short-term) toxicity to algae and cyanobacteria

Toxicity to microorganisms and other aquatic plants / organisms

Assessment / Classification:

12.2 Persistence and degradability

Biodegradation:

Abiotic Degradation:

Assessment / Classification:

12.3 Bioaccumulative potential

Bioconcentration factor (BCF):

12.4 Mobility in soil

12.5 Results of PBT and vPvB assessment

12.6 Other adverse effects:

according to Regulation (EC) No 1907/2006 (REACH)

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Additional ecotoxicological information:

SECTION 13 : DISPOSAL CONSIDERATIONS

13.1 Waste treatment methods

Waste treatment options: Dispose of waste according to applicable legislation. ;

SECTION 14 : TRANSPORT INFORMATION

ADR/RID/AND/IMDG/IATA

UN No.	
UN Proper shipping name	
Transport hazard class(es)	
Hazard label(s)	
Packing group	

Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code

Land transport (ADR/RID)

Classification code ADR:	Special Provisions for ADR/RID:
Limited quantities for ADR/RID:	Excepted Quantities for ADR/RID:
Packing Instructions for ADR/RID:	Special packing provisions for ADR/RID:
Mixed packing provisions:	
Portable tanks and bulk containers Instructions:	
Portable tanks and bulk containers Special Provisions:	
ADR Tank Code:	ADR Tank special provisions:
Vehicle for tank carriage:	
Special provisions for carriage Packages:	
Special provisions for carriage Bulk:	
Special provisions for carriage for loading, unloading and handling:	
Special Provisions for carriage Operation:	
Hazard identification No:	Transport category (Tunnel restriction code):

Sea transport (IMDG)

Marine Pollutant:	Subsidiary risk(s) for IMDG:
Packing provisions for IMDG:	Limited quantities for IMDG:
Packing instructions for IMDG:	IBC Instructions:
IBC Provisions:	IMO tank instructions:
UN tank instructions:	Tanks and bulk Provisions:
EmS :	Stowage and segregation for IMDG:
Properties and observations:	

Inland waterway transport (ADN)

Classification Code ADN:	Special Provisions ADN:
Limited quantities ADN:	Excepted quantities ADN:
Carriage permitted:	Equipment required:
Provisions concerning loading and unloading:	Provisions concerning carriage:
Number of blue cones/lights:	Remark:

according to Regulation (EC) No 1907/2006 (REACH)

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Air transport (ICAO-TI / IATA-DGR)

Subsidiary risk for IATA:

Excepted quantity for IATA:

Passenger and Cargo Aircraft Limited Quantities Packing Instructions:

Passenger and Cargo Aircraft Limited Quantities Maximal Net Quantity :

Passenger and Cargo Aircraft Packaging Instructions :

Passenger and Cargo Aircraft Maximal Net Quantity :

Cargo Aircraft only Packaging Instructions :

Cargo Aircraft only Maximal Net Quantity :

ERG code:

Special Provisions for IATA:

SECTION 15 : REGULATORY INFORMATION

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

EU regulations

- Authorisations and/or restrictions on use:

Authorisations:

Restrictions on use:

SVHC :

- Other EU regulations:
- Directive 2010/75/EC on industrial emissions

Not relevant

National regulations

15.2 Chemical Safety Assessment:

For this mixture, no chemical safety assessment has been carried out

SECTION 16 : OTHER INFORMATION

16.1 Indication of changes

Date of the previous version:06/09/2023

Modifications:

16.2 Other informations

16.3 Classification for mixtures and used evaluation method according to regulation (EC) 1207/2008 [CLP]:

See SECTION 2.1 (classification).

16.4 Relevant R-, H- and EUH-phrases (number and full text):

according to Regulation (EC) No 1907/2006 (REACH)

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according to Regulation (EC) No 1907/2006 (REACH)

Designation / Commercial name : HTRF Detect. Buf. 7 - 130 mL

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SECTION 1 : IDENTIFICATION OF THE SUBSTANCE/MIXTURE AND OF THE COMPANY/UNDERTAKING

1.1 Product identifier:

Designation / Commercial name : HTRF Detect. Buf. 7 - 130 mL

CAS No.:

Index No:

EC No:

REACH No:

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

Relevant identified uses: Use of the substance or mixture for Laboratory Research use only ;

Uses advised against: Do not use for diagnostics, therapeutics or other clinical uses. ;

1.3 Details of the supplier of the safety data sheet:

Supplier:

Name: CISBIO BIOASSAYS, company of Revvity Group - CBBIOA -

Address: Parc Marcel Boiteux - BP 84175 - 30200 Codolet, France

Phone : +33 4 66 79 67 05 - Fax : +33 4 66 79 67 50

E-Mail (competent person):  codolet.sds@revvity.com

1.4 EMERGENCY TELEPHONE NUMBER:

France - Numéro ORFILA (INRS) : + 33 (0)1 45 42 59 59

Ce numéro permet d'obtenir les coordonnées de tous les centres Anti-poison Français. Ces centres anti-poison et de toxicovigilance fournissent une aide médicale gratuite (hors coût d'appel), 24 heures sur 24 et 7 jours sur 7.

USA & Canada - Phone: 1-888-963-456 (1)

Other countries - Phone: +33 (0) 466 796 737 (2)

<https://www.cisbio.com>

<https://www.revvity.com>

(1) Available from Monday to Thursday 8:30 am to 5:30pm GMT-5 and Friday: 8:30 am to 3:00pm GMT-5

(2) Available from Monday to Friday 9:00 am to 5:30 pm GMT+2

SECTION 2 : HAZARDS IDENTIFICATION

2.1 Classification of the substance or mixture:

Classification according to Regulation (EC) No 1272/2008 [CLP]	Category code	Hazard statement	Precautionary statement
The substance or mixture is not classified as hazardous under the CLP Regulation (EC) No 1272/2008	None	None	None

2.2 Label elements

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

Product identifier:

Designation / Commercial name : HTRF Detect. Buf. 7 - 130 mL

Substances contained in this product:

according to Regulation (EC) No 1907/2006 (REACH)

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Hazard pictograms

Signal word:

Hazard and precautionary statements:

2.3 Other hazards

The mixture does not contain substances classified as 'Substances of Very High Concern' (SVHC) $\geq 0.1\%$ published by the European Chemicals Agency (ECHA) under article 57 of REACH. The mixture satisfies neither the PBT nor the vPvB criteria for mixtures in accordance with annexe XIII of the REACH regulations EC 1907/2006. ;

Adverse human health effects and symptoms:

according to Regulation (EC) No 1907/2006 (REACH)

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SECTION 3 : COMPOSITION/INFORMATION ON INGREDIENTS

3.2 Mixtures

Hazardous ingredients:

Substance name	CAS n°	Index n°	EC n°	Classification according Regulation (EC) No. 1272 [CLP]	Concentration (%)	SCL	M-factor
potassium fluoride	7789-23-3	009-005-00-2	232-151-5	Acute toxicity - Acute Tox. 3 - H301 - Oral Acute toxicity - Acute Tox. 3 - H311 - Dermal Acute toxicity - Acute Tox. 3 - H331 - Inhalation	< 3%		

Additional information:

Full text of H- and EUH-phrases: see SECTION 16.

SECTION 4 : FIRST AID MEASURES

4.1 Description of first aid measures

General information: Do not leave affected person unattended. ;

Following inhalation: In case of respiratory tract irritation, consult a physician. ;

Following skin contact: After contact with skin, wash immediately with water ;

Following eye contact: After contact with the eyes, rinse with water with the eyelids open for a sufficient length of time, then consult an ophthalmologist immediately. ;

Following ingestion: Do NOT induce vomiting. ;

Self-protection of the first aider:

4.2 Most important symptoms and effects, both acute and delayed

Symptoms: No known symptoms to date. ;

Effects:

4.3 Indication of any immediate medical attention and special treatment needed

Notes for the doctor:

SECTION 5 : FIREFIGHTING MEASURES

5.1 Extinguishing media:

Suitable extinguishing media: This product is not flammable. Use extinguishing agent suitable for type of surrounding fire ;

5.2 Special hazards arising from the substance or mixture

Hazardous combustion products: /

5.3 Advice for fire-fighters

Wear Protective clothing. ;

according to Regulation (EC) No 1907/2006 (REACH)

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SECTION 6 : ACCIDENTAL RELEASE MEASURES

6.1 Personal precautions, protective equipment and emergency procedures

Emergency procedures: Provide adequate ventilation. ;

6.2 Environmental precautions

Do not allow to enter into surface water or drains. ;

6.3 Methods and material for containment and cleaning up

For cleaning up: Suitable material for taking up: Absorbing material, organic ;

Other information:

6.4 Reference to other sections

Additional information:

SECTION 7 : HANDLING AND STORAGE

7.1 Precautions for safe handling

Protective measures:

Advice on safe handling: Avoid contact with skin, eyes and clothes. ;

Fire preventions:

Do not eat, drink or smoke in areas where reagents are handled. ;

Advice on general occupational hygiene

Handle in accordance with good industrial hygiene and safety practice ;

7.2 Conditions for safe storage, including any incompatibilities

Technical measures and storage conditions:

Requirements for storage rooms and vessels: Keep container tightly closed. ;

Hints on storage assembly:

Materials to avoid:

Further information on storage conditions:

7.3 Specific end uses:

Recommendations on specific end uses: Observe technical data sheet. ;

SECTION 8 : EXPOSURE CONTROLS/PERSONAL PROTECTION

8.1 Control parameters

Preliminary remark:

8.1.1 Occupational exposure limits:

- France

according to Regulation (EC) No 1907/2006 (REACH)

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Substance	EC-No.	CAS-No	VLE (mg/m ³)	VLE (ppm)	VME (mg/m ³)	VME (ppm)
7789-23-3 / 232-151-5	232-151-5	7789-23-3			2,5	

- Spain

Source :	Limites de Exposicion Profesional para Agentes Quimicos en Espana Instituto Nacional de Seguridad e Higiene en el Trabajo June 2015					
Substance	EC-No.	CAS-No	VLA-EC (mg/m ³)	VLA-EC (ppm)	VLA-ED (mg/m ³)	VLA-ED (ppm)
7789-23-3 / 232-151-5	232-151-5	7789-23-3				

- Germany

Source :	TRGS 900, June 2015, BAuA				
Substance	EC-No.	CAS-No	AGW (mg/m ³)	AGW (ppm)	
7789-23-3 / 232-151-5	232-151-5	7789-23-3			

- Italia
- Greece
- UK
- OSHA (USA)

Source :	Occupational Safety and Health Administration (OSHA) Permissible Exposure Limits (PELS) from 29 CFR 1910.1000					
Substance	EC-No.	CAS-No	OSHA Permissible Exposure Limit (PEL) 8-hour TWA (ppm)	OSHA Permissible Exposure Limit (PEL) 8-hour TWA (mg/m ³)	OSHA Permissible Exposure Limit (PEL) STEL (ppm)	OSHA Permissible Exposure Limit (PEL) STEL (mg/m ³)
7789-23-3 / 232-151-5	232-151-5	7789-23-3				

8.1.2 Biological limit values (Germany):

according to Regulation (EC) No 1907/2006 (REACH)

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Source :	List of recommended health-based biological limit values (BLVs) and biological guidance values (BGVs), June 2014			
Substance	EC-No.	CAS-No	BLV (mg/m3)	BLV (ppm)
7789-23-3 / 232-151-5	232-151-5	7789-23-3		

8.1.3 Exposure limits at intended use (Germany):

Source :	TRGS 903, November 2015, BAuA			
Substance	EC-No.	CAS-No	BGW (mg/m3)	BGW (ppm)
7789-23-3 / 232-151-5	232-151-5	7789-23-3		

8.1.4 DNEL/PNEC-values:

- DNEL worker

Source :	GESTIS – substance database								
Substance	EC-No.	CAS-No	Acute – dermal, local effects (mg/kg/day)	Long-term – dermal, local effects (mg/kg/day)	Long-term – dermal, systemic effects (mg/kg/day)	Acute – inhalation, local effects (mg/m3)	Acute – inhalation, systemic effects (mg/m3)	Long-term – inhalation, local effects (mg/m3)	Long-term – inhalation, systemic effects (mg/m3)
7789-23-3 / 232-151-5	232-151-5	7789-23-3				3-3	3-3		

- DNEL consumer

Source :	GESTIS – substance database								
Substance	EC-No.	CAS-No	Acute – dermal, local effects (mg/kg/day)	Long-term – dermal, local effects (mg/kg/day)	Long-term – dermal, systemic effects (mg/kg/day)	Acute – inhalation, local effects (mg/m3)	Acute – inhalation, systemic effects (mg/m3)	Long-term – inhalation, local effects (mg/m3)	Long-term – inhalation, systemic effects (mg/m3)
7789-23-3 / 232-151-5	232-151-5	7789-23-3							

DNEL remark:

- PNEC

Source :	INERIS																			
Substance	EC-No.	CAS-No	PNEC AQUATIC									PNEC Sediment								
			freshwater			marine water			intermittent release			freshwater			marine water					
			(mg/L)	(mg/kg)	(ppm)	(mg/L)	(mg/kg)	(ppm)	(mg/L)	(mg/kg)	(ppm)	(mg/L)	(mg/kg)	(ppm)	(mg/L)	(mg/kg)	(ppm)			
7789-23-3 / 232-151-5	232-151-5	7789-23-3																		

Source :	INERIS
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according to Regulation (EC) No 1907/2006 (REACH)

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Substance	EC-No.	CAS-No	Others											
			PNEC soil			PNEC sewage treatment plant			PNEC air			PNEC secondary poisoning		
			(mg/L)	(mg/kg)	(ppm)	(mg/L)	(mg/kg)	(ppm)	(mg/L)	(mg/kg)	(ppm)	(mg/L)	(mg/kg)	(ppm)
7789-23-3 / 232-151-5	232-151-5	7789-23-3												

PNEC remark:

Control parameters remark:

8.2 Exposure controls

8.2.1 Appropriate engineering controls:

8.2.2 Personal protective equipment:

Eye / Face protection: Safety glasses with side-shields ;

Skin protection: Gloves ;

Respiratory protection: Ensure adequate ventilation ;

Thermal hazards:

8.2.3 Environmental exposure controls:

SECTION 9 : PHYSICAL AND CHEMICAL PROPERTIES

9.1 Information on basic physical and chemical properties

Appearance

Physical state	Liquid ;
Colour	Colorless ;
Odour	
Odour threshold (ppm)	

	Value	Concentration (mol/L)	Method	Temperature (°C)	Pressure (kPa)	Remark
pH	7					
Melting point (°C)						
Freezing point (°C)						
Initial boiling point/boiling range (°C)						
Flash point (°C)						
Evaporation rate (kg/m ² /h)						
Flammability (type :) (%)						
Upper/lower flammability or explosive limits	Upper explosive limit (%)					
	Lower explosive limit (%)					
Vapour pressure (kPa)						
Vapour density (g/cm ³)						
Densities	Density (g/cm ³)					
	Relative density (g/cm ³)					
	Bulk density (g/cm ³)					
	Critical density (g/cm ³)					
Solubility (Type :) (g/L)						
Partition coefficient (log Pow) n-octanol/water at pH :						
Auto-ignition temperature (°C)						

according to Regulation (EC) No 1907/2006 (REACH)

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Decomposition temperature (°C)						
Decomposition energy : kJ						
Viscosity	Viscosity, dynamic (poiseuille)					
	Viscosity, cinematic (cm ² /s)					
Oxidising properties						
Explosive properties						

9.2 Other information:

No other relevant data available

SECTION 10 : STABILITY AND REACTIVITY

10.1 Reactivity This material is considered to be non-reactive under normal use conditions. ;

10.2 Chemical stability

10.3 Possibility of hazardous reactions

10.4 Conditions to avoid:

10.5 Incompatible materials:

10.6 Hazardous decomposition products:

Does not decompose when used for intended uses. ;

SECTION 11 : TOXICOLOGICAL INFORMATION

Toxicokinetics, metabolism and distribution

11.1 Information on toxicological effects

Substances

- **Acute toxicity**

Animal data:

Acute oral toxicity:

Substance name	LD50 (mg/kg)	Species	Method	Symptoms / delayed effects	Remark
7789-23-3 / 232-151-5	245-245	Rat			

Acute dermal toxicity:

Substance name	LD50 (mg/kg)	Species	Method	Remark
7789-23-3 / 232-151-5				

Acute inhalative toxicity:

according to Regulation (EC) No 1907/2006 (REACH)

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Substance name	C(E)L50 (mg/L)	Exposure time	Species	Method	Remark
7789-23-3 / 232-151-5					

Practical experience / human evidence:

Assessment / Classification:

General Remark:

- **Skin corrosion/irritation**

Animal data:

In-vitro skin test method:

In-vitro skin test result:

Assessment / Classification:

- **Eye damage/irritation**

Animal data:

In vitro eye test method:

In vitro eye test result:

Assessment / Classification:

- **CMR effects (carcinogenicity, mutagenicity and toxicity for reproduction)**
 - Germ cell mutagenicity:

Animal data:

Assessment / Classification:

- Carcinogenicity

Practical experience / human evidence:

Animal data:

Other information:

Assessment / Classification:

- Reproductive toxicity

Practical experience / human evidence:

Animal data:

Other information:

Assessment / Classification:

Overall assessment on CMR properties:

- **Specific target organ toxicity (single exposure)**
 - STOT SE 1 and 2

according to Regulation (EC) No 1907/2006 (REACH)

Designation / Commercial name : HTRF Detect. Buf. 7 - 130 mL

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Animal data:

Other information:

- STOT SE 3

Practical experience / human evidence:

Other information:

Assessment / Classification:

- **Specific target organ toxicity (repeated exposure)**

Practical experience / human evidence:

Animal data:

Assessment / Classification:

Other information

- **Aspiration hazard**

Practical experience / human evidence:

Experimental data: viscosity data: see SECTION 9.

Assessment / Classification:

Remark:

11.1.1 Mixtures

No toxicological information is available for the mixture itself

SECTION 12 : ECOLOGICAL INFORMATION

In case that test data regarding one endpoint/differentiation exist for the mixture itself, the classification is carried out according to the substance criteria (excluding biodegradation and bioaccumulation). If no test data exist, the criteria for mixture classification has to be used (calculation method) in this case the toxicological data of the ingredients are shown.

12.1 **Aquatic toxicity:**

Acute (short-term) fish toxicity

Chronic (long-term) fish toxicity

Acute (short-term) toxicity to crustacea

Chronic (long-term) toxicity to crustacea

Acute (short-term) toxicity to algae and cyanobacteria

Toxicity to microorganisms and other aquatic plants / organisms

Assessment / Classification:

according to Regulation (EC) No 1907/2006 (REACH)

Designation / Commercial name : HTRF Detect. Buf. 7 - 130 mL

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12.2 Persistence and degradability

Biodegradation:

Abiotic Degradation:

Assessment / Classification:

12.3 Bioaccumulative potential

Bioconcentration factor (BCF):

12.4 Mobility in soil

12.5 Results of PBT and vPvB assessment

12.6 Other adverse effects:

Additional ecotoxicological information:

SECTION 13 : DISPOSAL CONSIDERATIONS

13.1 Waste treatment methods

Waste treatment options: Dispose of waste according to applicable legislation. ;

SECTION 14 : TRANSPORT INFORMATION

ADR/RID/AND/IMDG/IATA

UN No.	
UN Proper shipping name	
Transport hazard class(es)	
Hazard label(s)	
Packing group	

Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code

Land transport (ADR/RID)

Classification code ADR:

Special Provisions for ADR/RID:

Limited quantities for ADR/RID:

Excepted Quantities for ADR/RID:

Packing Instructions for ADR/RID:

Special packing provisions for ADR/RID:

Mixed packing provisions:

Portable tanks and bulk containers Instructions:

Portable tanks and bulk containers Special Provisions:

ADR Tank Code:

ADR Tank special provisions:

Vehicle for tank carriage:

Special provisions for carriage Packages:

Special provisions for carriage Bulk:

according to Regulation (EC) No 1907/2006 (REACH)

Designation / Commercial name : HTRF Detect. Buf. 7 - 130 mL

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Special provisions for carriage for loading, unloading and handling:

Special Provisions for carriage Operation:

Hazard identification No:

Transport category (Tunnel restriction code):

Sea transport (IMDG)

Marine Pollutant:

Subsidiary risk(s) for IMDG:

Packing provisions for IMDG:

Limited quantities for IMDG:

Packing instructions for IMDG:

IBC Instructions:

IBC Provisions:

IMO tank instructions:

UN tank instructions:

Tanks and bulk Provisions:

EmS :

Stowage and segregation for IMDG:

Properties and observations:

Inland waterway transport (ADN)

Classification Code ADN:

Special Provisions ADN:

Limited quantities ADN:

Excepted quantities ADN:

Carriage permitted:

Equipment required:

Provisions concerning loading and unloading:

Provisions concerning carriage:

Number of blue cones/lights:

Remark:

Air transport (ICAO-TI / IATA-DGR)

Subsidiary risk for IATA:

Excepted quantity for IATA:

Passenger and Cargo Aircraft Limited Quantities Packing Instructions:

Passenger and Cargo Aircraft Limited Quantities Maximal Net Quantity :

Passenger and Cargo Aircraft Packaging Instructions :

Passenger and Cargo Aircraft Maximal Net Quantity :

Cargo Aircraft only Packaging Instructions :

Cargo Aircraft only Maximal Net Quantity :

ERG code:

Special Provisions for IATA:

SECTION 15 : REGULATORY INFORMATION

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

EU regulations

- Authorisations and/or restrictions on use:

Authorisations:

Restrictions on use: 7789-23-3 / 232-151-5

SVHC :

- Other EU regulations:
- Directive 2010/75/EC on industrial emissions

Not relevant

National regulations

according to Regulation (EC) No 1907/2006 (REACH)

Designation / Commercial name : HTRF Detect. Buf. 7 - 130 mL

Version: UK, Page 13 of 13, Revision date: 07/09/2023

15.2 Chemical Safety Assessment:

For this mixture, no chemical safety assessment has been carried out

SECTION 16 : OTHER INFORMATION

16.1 Indication of changes

Date of the previous version:06/09/2023

Modifications:

16.2 Other informations

16.3 Classification for mixtures and used evaluation method according to regulation (EC) 1207/2008 [CLP]:

See SECTION 2.1 (classification).

16.4 Relevant R-, H- and EUH-phrases (number and full text):

Code	Hazard statments
H301	Toxic if swallowed
H311	Toxic in contact with skin
H331	Toxic if inhaled

according to Regulation (EC) No 1907/2006 (REACH)

Designation / Commercial name : HTRF Insulin High Range kit - 10K pts Eu Cryptate antibody

Version: UK, Page 1 of 12, Revision date: 07/09/2023

SECTION 1 : IDENTIFICATION OF THE SUBSTANCE/MIXTURE AND OF THE COMPANY/UNDERTAKING

1.1 Product identifier:

Designation / Commercial name : HTRF Insulin High Range kit - 10K pts Eu Cryptate antibody

CAS No.:

Index No:

EC No:

REACH No:

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

Relevant identified uses: Use of the substance or mixture for Laboratory Research use only ;

Uses advised against: Do not use for diagnostics, therapeutics or other clinical uses. ;

1.3 Details of the supplier of the safety data sheet:

Supplier:

Name: CISBIO BIOASSAYS, company of Revvity Group - CBBIOA -

Address: Parc Marcel Boiteux - BP 84175 - 30200 Codolet, France

Phone : +33 4 66 79 67 05 - Fax : +33 4 66 79 67 50

E-Mail (competent person):  codolet.sds@revvity.com

1.4 EMERGENCY TELEPHONE NUMBER:

France - Numéro ORFILA (INRS) : + 33 (0)1 45 42 59 59

Ce numéro permet d'obtenir les coordonnées de tous les centres Anti-poison Français. Ces centres anti-poison et de toxicovigilance fournissent une aide médicale gratuite (hors coût d'appel), 24 heures sur 24 et 7 jours sur 7.

USA & Canada - Phone: 1-888-963-456 (1)

Other countries - Phone: +33 (0) 466 796 737 (2)

<https://www.cisbio.com>

<https://www.revvity.com>

(1) Available from Monday to Thursday 8:30 am to 5:30pm GMT-5 and Friday: 8:30 am to 3:00pm GMT-5

(2) Available from Monday to Friday 9:00 am to 5:30 pm GMT+2

SECTION 2 : HAZARDS IDENTIFICATION

2.1 Classification of the substance or mixture:

Classification according to Regulation (EC) No 1272/2008 [CLP]	Category code	Hazard statement	Precautionary statement
The substance or mixture is not classified as hazardous under the CLP Regulation (EC) No 1272/2008	None	None	None

2.2 Label elements

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

Product identifier:

Designation / Commercial name : HTRF Insulin High Range kit - 10K pts Eu Cryptate antibody

Substances contained in this product:

according to Regulation (EC) No 1907/2006 (REACH)

Designation / Commercial name : HTRF Insulin High Range kit - 10K pts Eu Cryptate antibody

Version: UK, Page 2 of 12, Revision date: 07/09/2023

Hazard pictograms

Signal word:

Hazard and precautionary statements:

2.3 Other hazards

The mixture does not contain substances classified as 'Substances of Very High Concern' (SVHC) $\geq 0.1\%$ published by the European Chemicals Agency (ECHA) under article 57 of REACH. The mixture satisfies neither the PBT nor the vPvB criteria for mixtures in accordance with annexe XIII of the REACH regulations EC 1907/2006. ;

Adverse human health effects and symptoms:

according to Regulation (EC) No 1907/2006 (REACH)

Designation / Commercial name : HTRF Insulin High Range kit - 10K pts Eu Cryptate antibody

Version: UK, Page 3 of 12, Revision date: 07/09/2023

SECTION 3 : COMPOSITION/INFORMATION ON INGREDIENTS

3.2 Mixtures

Hazardous ingredients:

This mixture does not contain any hazardous substances at the concentration limits given in Regulation (EC) No. 1272/2008 and OSHA Hazard Communication Standard 29 CFR 1910.1200.

Additional information:

Full text of H- and EUH-phrases: see SECTION 16.

SECTION 4 : FIRST AID MEASURES

4.1 Description of first aid measures

General information: Do not leave affected person unattended. ; Remove affected person from the danger area and lay down. ;

Following inhalation: In case of respiratory tract irritation, consult a physician. ; Provide fresh air. ;

Following skin contact: After contact with skin, wash immediately with water ; Remove contaminated clothing ;

Following eye contact: After contact with the eyes, rinse with water with the eyelids open for a sufficient length of time, then consult an ophthalmologist immediately. ;

Following ingestion: Do NOT induce vomiting. ; Give nothing to eat or drink. ; If accidentally swallowed rinse the mouth with plenty of water (only if the person is conscious) and obtain immediate medical attention. ;

Self-protection of the first aider:

4.2 Most important symptoms and effects, both acute and delayed

Symptoms: No known symptoms to date. ;

Effects:

4.3 Indication of any immediate medical attention and special treatment needed

Notes for the doctor:

SECTION 5 : FIREFIGHTING MEASURES

5.1 Extinguishing media:

Suitable extinguishing media: This product is not flammable. Use extinguishing agent suitable for type of surrounding fire ;

5.2 Special hazards arising from the substance or mixture

Hazardous combustion products: /

5.3 Advice for fire-fighters

Wear Protective clothing. ;

SECTION 6 : ACCIDENTAL RELEASE MEASURES

6.1 Personal precautions, protective equipment and emergency procedures

Emergency procedures: Provide adequate ventilation. ; Emergency procedures: Remove persons to safety. ; Personal precautions: Use personal protection equipment (see section 8). ;

according to Regulation (EC) No 1907/2006 (REACH)

Designation / Commercial name : HTRF Insulin High Range kit - 10K pts Eu Cryptate antibody

Version: UK, Page 4 of 12, Revision date: 07/09/2023

6.2 Environmental precautions

Do not allow to enter into surface water or drains. ; Ensure all waste water is collected and treated via a waste water treatment plant. ;

6.3 Methods and material for containment and cleaning up

For cleaning up: Suitable material for taking up: Absorbing material, organic ;

Other information:

6.4 Reference to other sections

Additional information:

SECTION 7 : HANDLING AND STORAGE

7.1 Precautions for safe handling

Protective measures:

Advice on safe handling: Avoid contact with skin, eyes and clothes. ; Avoid: Eye contact ; Avoid: Generation/formation of aerosols ; Avoid: Skin contact ; Avoid: inhalation ; In the immediate working surroundings there must be: Emergency shower installed ; In the immediate working surroundings there must be: Provide eye shower and label its location conspicuously ; Wash contaminated clothing immediately. ;

Fire preventions:

Do not eat, drink or smoke in areas where reagents are handled. ; Do not pipet by mouth ; Wear suitable one-way gloves at work ;

Advice on general occupational hygiene

Handle in accordance with good industrial hygiene and safety practice ; Observe technical data sheet. ; Remove contaminated, saturated clothing. ; Wash hands before breaks and after work. ;

7.2 Conditions for safe storage, including any incompatibilities

Technical measures and storage conditions:

Requirements for storage rooms and vessels: Keep container tightly closed. ; Keep-store only in original container or in properly labeled containers ;

Hints on storage assembly:

Materials to avoid:

Further information on storage conditions:

7.3 Specific end uses:

Recommendations on specific end uses: Observe technical data sheet. ;

SECTION 8 : EXPOSURE CONTROLS/PERSONAL PROTECTION

8.1 Control parameters

Preliminary remark:

8.1.1 Occupational exposure limits:

- France

according to Regulation (EC) No 1907/2006 (REACH)

Designation / Commercial name : HTRF Insulin High Range kit - 10K pts Eu Cryptate antibody

Version: UK, Page 5 of 12, Revision date: 07/09/2023

- Spain
- Germany
- Italia
- Greece
- UK
- OSHA (USA)

8.1.2 Biological limit values (Germany):

8.1.3 Exposure limits at intended use (Germany):

8.1.4 DNEL/PNEC-values:

- DNEL worker
- DNEL consumer

DNEL remark:

- PNEC

PNEC remark:

Control parameters remark:

8.2 Exposure controls

8.2.1 Appropriate engineering controls:

according to Regulation (EC) No 1907/2006 (REACH)

Designation / Commercial name : HTRF Insulin High Range kit - 10K pts Eu Cryptate antibody

Version: UK, Page 6 of 12, Revision date: 07/09/2023

8.2.2 Personal protective equipment:

Eye / Face protection: Safety glasses with side-shields ;

Skin protection: Gloves ; Laboratory coats ;

Respiratory protection: Ensure adequate ventilation ;

Thermal hazards:

8.2.3 Environmental exposure controls:

SECTION 9 : PHYSICAL AND CHEMICAL PROPERTIES

9.1 Information on basic physical and chemical properties

Appearance

Physical state	Solid ;
Colour	White ;
Odour	
Odour threshold (ppm)	

	Value	Concentration (mol/L)	Method	Temperature (°C)	Pressure (kPa)	Remark
pH						
Melting point (°C)						
Freezing point (°C)						
Initial boiling point/boiling range (°C)						
Flash point (°C)						
Evaporation rate (kg/m ² /h)						
Flammability (type :) (%)						
Upper/lower flammability or explosive limits	Upper explosive limit (%)					
	Lower explosive limit (%)					
Vapour pressure (kPa)						
Vapour density (g/cm ³)						
Densities	Density (g/cm ³)					
	Relative density (g/cm ³)					
	Bulk density (g/cm ³)					
	Critical density (g/cm ³)					
Solubility (Type :) (g/L)						
Partition coefficient (log Pow) n-octanol/water at pH :						
Auto-ignition temperature (°C)						
Decomposition temperature (°C) Decomposition energy : kJ						
Viscosity	Viscosity, dynamic (poiseuille)					
	Viscosity, cinematic (cm ² /s)					
Oxidising properties						
Explosive properties						

9.2 Other information:

No other relevant data available

according to Regulation (EC) No 1907/2006 (REACH)

Designation / Commercial name : HTRF Insulin High Range kit - 10K pts Eu Cryptate antibody

Version: UK, Page 7 of 12, Revision date: 07/09/2023

SECTION 10 : STABILITY AND REACTIVITY

10.1 Reactivity This material is considered to be non-reactive under normal use conditions. ;

10.2 Chemical stability

10.3 Possibility of hazardous reactions

10.4 Conditions to avoid:

10.5 Incompatible materials:

10.6 Hazardous decomposition products:

Does not decompose when used for intended uses. ; Thermal decomposition can lead to the escape of irritating gases and vapors. ;

SECTION 11 : TOXICOLOGICAL INFORMATION

Toxicokinetics, metabolism and distribution

11.1 Information on toxicological effects

Substances

- **Acute toxicity**

Animal data:

Acute oral toxicity:

Acute dermal toxicity:

Acute inhalative toxicity:

Practical experience / human evidence:

Assessment / Classification:

General Remark:

- **Skin corrosion/irritation**

Animal data:

In-vitro skin test method:

In-vitro skin test result:

Assessment / Classification:

- **Eye damage/irritation**

Animal data:

according to Regulation (EC) No 1907/2006 (REACH)

Designation / Commercial name : HTRF Insulin High Range kit - 10K pts Eu Cryptate antibody

Version: UK, Page 8 of 12, Revision date: 07/09/2023

In vitro eye test method:

In vitro eye test result:

Assessment / Classification:

- **CMR effects (carcinogenicity, mutagenicity and toxicity for reproduction)**
 - Germ cell mutagenicity:

Animal data:

Assessment / Classification:

- Carcinogenicity

Practical experience / human evidence:

Animal data:

Other information:

Assessment / Classification:

- Reproductive toxicity

Practical experience / human evidence:

Animal data:

Other information:

Assessment / Classification:

Overall assessment on CMR properties:

- **Specific target organ toxicity (single exposure)**
 - STOT SE 1 and 2

Animal data:

Other information:

- STOT SE 3

Practical experience / human evidence:

Other information:

Assessment / Classification:

- **Specific target organ toxicity (repeated exposure)**

Practical experience / human evidence:

Animal data:

Assessment / Classification:

Other information

- **Aspiration hazard**

according to Regulation (EC) No 1907/2006 (REACH)

Designation / Commercial name : HTRF Insulin High Range kit - 10K pts Eu Cryptate antibody

Version: UK, Page 9 of 12, Revision date: 07/09/2023

Practical experience / human evidence:

Experimental data: viscosity data: see SECTION 9.

Assessment / Classification:

Remark:

11.1.1 Mixtures

No toxicological information is available for the mixture itself

SECTION 12 : ECOLOGICAL INFORMATION

In case that test data regarding one endpoint/differentiation exist for the mixture itself, the classification is carried out according to the substance criteria (excluding biodegradation and bioaccumulation). If no test data exist, the criteria for mixture classification has to be used (calculation method); in this case the toxicological data of the ingredients are shown.

12.1 *Aquatic toxicity:*

Acute (short-term) fish toxicity

Chronic (long-term) fish toxicity

Acute (short-term) toxicity to crustacea

Chronic (long-term) toxicity to crustacea

Acute (short-term) toxicity to algae and cyanobacteria

Toxicity to microorganisms and other aquatic plants / organisms

Assessment / Classification:

12.2 *Persistence and degradability*

Biodegradation:

Abiotic Degradation:

Assessment / Classification:

12.3 *Bioaccumulative potential*

Bioconcentration factor (BCF):

12.4 *Mobility in soil*

12.5 *Results of PBT and vPvB assessment*

12.6 *Other adverse effects:*

according to Regulation (EC) No 1907/2006 (REACH)

Designation / Commercial name : HTRF Insulin High Range kit - 10K pts Eu Cryptate antibody

Version: UK, Page 10 of 12, Revision date: 07/09/2023

Additional ecotoxicological information:

SECTION 13 : DISPOSAL CONSIDERATIONS

13.1 Waste treatment methods

Waste treatment options:Dispose of waste according to applicable legislation. ;

SECTION 14 : TRANSPORT INFORMATION

ADR/RID/AND/IMDG/IATA

UN No.	
UN Proper shipping name	
Transport hazard class(es)	
Hazard label(s)	
Packing group	

Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code

Land transport (ADR/RID)

Classification code ADR:	Special Provisions for ADR/RID:
Limited quantities for ADR/RID:	Excepted Quantities for ADR/RID:
Packing Instructions for ADR/RID:	Special packing provisions for ADR/RID:
Mixed packing provisions:	
Portable tanks and bulk containers Instructions:	
Portable tanks and bulk containers Special Provisions:	
ADR Tank Code:	ADR Tank special provisions:
Vehicle for tank carriage:	
Special provisions for carriage Packages:	
Special provisions for carriage Bulk:	
Special provisions for carriage for loading, unloading and handling:	
Special Provisions for carriage Operation:	
Hazard identification No:	Transport category (Tunnel restriction code):

Sea transport (IMDG)

Marine Pollutant:	Subsidiary risk(s) for IMDG:
Packing provisions for IMDG:	Limited quantities for IMDG:
Packing instructions for IMDG:	IBC Instructions:
IBC Provisions:	IMO tank instructions:
UN tank instructions:	Tanks and bulk Provisions:
EmS :	Stowage and segregation for IMDG:
Properties and observations:	

Inland waterway transport (ADN)

Classification Code ADN:	Special Provisions ADN:
Limited quantities ADN:	Excepted quantities ADN:
Carriage permitted:	Equipment required:
Provisions concerning loading and unloading:	Provisions concerning carriage:
Number of blue cones/lights:	Remark:

according to Regulation (EC) No 1907/2006 (REACH)

Designation / Commercial name : HTRF Insulin High Range kit - 10K pts Eu Cryptate antibody

Version: UK, Page 11 of 12, Revision date: 07/09/2023

Air transport (ICAO-TI / IATA-DGR)

Subsidiary risk for IATA:

Excepted quantity for IATA:

Passenger and Cargo Aircraft Limited Quantities Packing Instructions:

Passenger and Cargo Aircraft Limited Quantities Maximal Net Quantity :

Passenger and Cargo Aircraft Packaging Instructions :

Passenger and Cargo Aircraft Maximal Net Quantity :

Cargo Aircraft only Packaging Instructions :

Cargo Aircraft only Maximal Net Quantity :

ERG code:

Special Provisions for IATA:

SECTION 15 : REGULATORY INFORMATION

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

EU regulations

- Authorisations and/or restrictions on use:

Authorisations:

Restrictions on use:

SVHC :

- Other EU regulations:
- Directive 2010/75/EC on industrial emissions

Not relevant

National regulations

15.2 Chemical Safety Assessment:

For this mixture, no chemical safety assessment has been carried out

SECTION 16 : OTHER INFORMATION

16.1 Indication of changes

Date of the previous version:06/09/2023

Modifications:

16.2 Other informations

16.3 Classification for mixtures and used evaluation method according to regulation (EC) 1207/2008 [CLP]:

See SECTION 2.1 (classification).

16.4 Relevant R-, H- and EUH-phrases (number and full text):

according to Regulation (EC) No 1907/2006 (REACH)

Designation / Commercial name : HTRF Insulin High Range kit - 10K pts Eu Cryptate antibody

Version: UK, Page 12 of 12, Revision date: 07/09/2023

according to Regulation (EC) No 1907/2006 (REACH)

Designation / Commercial name : HTRF Insulin High Range kit - 10K pts XL665 antibody

Version: UK, Page 1 of 12, Revision date: 07/09/2023

SECTION 1 : IDENTIFICATION OF THE SUBSTANCE/MIXTURE AND OF THE COMPANY/UNDERTAKING

1.1 Product identifier:

Designation / Commercial name : HTRF Insulin High Range kit - 10K pts XL665 antibody

CAS No.: Index No: EC No: REACH No:

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

Relevant identified uses: Use of the substance or mixture for Laboratory Research use only ;

Uses advised against: Do not use for diagnostics, therapeutics or other clinical uses. ;

1.3 Details of the supplier of the safety data sheet:

Supplier:

Name: CISBIO BIOASSAYS, company of Revvity Group - CBBIOA -

Address: Parc Marcel Boiteux - BP 84175 - 30200 Codolet, France

Phone : +33 4 66 79 67 05 - Fax : +33 4 66 79 67 50

E-Mail (competent person):  codolet.sds@revvity.com

1.4 EMERGENCY TELEPHONE NUMBER:

France - Numéro ORFILA (INRS) : + 33 (0)1 45 42 59 59

Ce numéro permet d'obtenir les coordonnées de tous les centres Anti-poison Français. Ces centres anti-poison et de toxicovigilance fournissent une aide médicale gratuite (hors coût d'appel), 24 heures sur 24 et 7 jours sur 7.

USA & Canada - Phone: 1-888-963-456 (1)

Other countries - Phone: +33 (0) 466 796 737 (2)

<https://www.cisbio.com>

<https://www.revvity.com>

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(2) Available from Monday to Friday 9:00 am to 5:30 pm GMT+2

SECTION 2 : HAZARDS IDENTIFICATION

2.1 Classification of the substance or mixture:

Classification according to Regulation (EC) No 1272/2008 [CLP]	Category code	Hazard statement	Precautionary statement
The substance or mixture is not classified as hazardous under the CLP Regulation (EC) No 1272/2008	None	None	None

2.2 Label elements

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

Product identifier:

Designation / Commercial name : HTRF Insulin High Range kit - 10K pts XL665 antibody

Substances contained in this product:

according to Regulation (EC) No 1907/2006 (REACH)

Designation / Commercial name : HTRF Insulin High Range kit - 10K pts XL665 antibody

Version: UK, Page 2 of 12, Revision date: 07/09/2023

Hazard pictograms

Signal word:

Hazard and precautionary statements:

2.3 Other hazards

The mixture does not contain substances classified as 'Substances of Very High Concern' (SVHC) $\geq 0.1\%$ published by the European Chemicals Agency (ECHA) under article 57 of REACH. The mixture satisfies neither the PBT nor the vPvB criteria for mixtures in accordance with annexe XIII of the REACH regulations EC 1907/2006. ;

Adverse human health effects and symptoms:

according to Regulation (EC) No 1907/2006 (REACH)

Designation / Commercial name : HTRF Insulin High Range kit - 10K pts XL665 antibody

Version: UK, Page 3 of 12, Revision date: 07/09/2023

SECTION 3 : COMPOSITION/INFORMATION ON INGREDIENTS

3.2 Mixtures

Hazardous ingredients:

This mixture does not contain any hazardous substances at the concentration limits given in Regulation (EC) No. 1272/2008 and OSHA Hazard Communication Standard 29 CFR 1910.1200.

Additional information:

Full text of H- and EUH-phrases: see SECTION 16.

SECTION 4 : FIRST AID MEASURES

4.1 Description of first aid measures

General information: Do not leave affected person unattended. ; Remove affected person from the danger area and lay down. ;

Following inhalation: In case of respiratory tract irritation, consult a physician. ; Provide fresh air. ;

Following skin contact: After contact with skin, wash immediately with water ; Remove contaminated clothing ;

Following eye contact: After contact with the eyes, rinse with water with the eyelids open for a sufficient length of time, then consult an ophthalmologist immediately. ;

Following ingestion: Do NOT induce vomiting. ; Give nothing to eat or drink. ; If accidentally swallowed rinse the mouth with plenty of water (only if the person is conscious) and obtain immediate medical attention. ;

Self-protection of the first aider:

4.2 Most important symptoms and effects, both acute and delayed

Symptoms: No known symptoms to date. ;

Effects:

4.3 Indication of any immediate medical attention and special treatment needed

Notes for the doctor:

SECTION 5 : FIREFIGHTING MEASURES

5.1 Extinguishing media:

Suitable extinguishing media: This product is not flammable. Use extinguishing agent suitable for type of surrounding fire ;

5.2 Special hazards arising from the substance or mixture

Hazardous combustion products: /

5.3 Advice for fire-fighters

Wear Protective clothing. ;

SECTION 6 : ACCIDENTAL RELEASE MEASURES

6.1 Personal precautions, protective equipment and emergency procedures

Emergency procedures: Provide adequate ventilation. ; Emergency procedures: Remove persons to safety. ; Personal precautions: Use personal protection equipment (see section 8). ;

according to Regulation (EC) No 1907/2006 (REACH)

Designation / Commercial name : HTRF Insulin High Range kit - 10K pts XL665 antibody

Version: UK, Page 4 of 12, Revision date: 07/09/2023

6.2 Environmental precautions

Do not allow to enter into surface water or drains. ; Ensure all waste water is collected and treated via a waste water treatment plant. ;

6.3 Methods and material for containment and cleaning up

For cleaning up: Suitable material for taking up: Absorbing material, organic ;

Other information:

6.4 Reference to other sections

Additional information:

SECTION 7 : HANDLING AND STORAGE

7.1 Precautions for safe handling

Protective measures:

Advice on safe handling: Avoid contact with skin, eyes and clothes. ; Avoid: Eye contact ; Avoid: Generation/formation of aerosols ; Avoid: Skin contact ; Avoid: inhalation ; In the immediate working surroundings there must be: Emergency shower installed ; In the immediate working surroundings there must be: Provide eye shower and label its location conspicuously ; Wash contaminated clothing immediately. ;

Fire preventions:

Do not eat, drink or smoke in areas where reagents are handled. ; Do not pipet by mouth ; Wear suitable one-way gloves at work ;

Advice on general occupational hygiene

Handle in accordance with good industrial hygiene and safety practice ; Observe technical data sheet. ; Remove contaminated, saturated clothing. ; Wash hands before breaks and after work. ;

7.2 Conditions for safe storage, including any incompatibilities

Technical measures and storage conditions:

Requirements for storage rooms and vessels: Keep container tightly closed. ; Keep-store only in original container or in properly labeled containers ;

Hints on storage assembly:

Materials to avoid:

Further information on storage conditions:

7.3 Specific end uses:

Recommendations on specific end uses: Observe technical data sheet. ;

SECTION 8 : EXPOSURE CONTROLS/PERSONAL PROTECTION

8.1 Control parameters

Preliminary remark:

8.1.1 Occupational exposure limits:

- France

according to Regulation (EC) No 1907/2006 (REACH)

Designation / Commercial name : HTRF Insulin High Range kit - 10K pts XL665 antibody

Version: UK, Page 5 of 12, Revision date: 07/09/2023

- Spain
- Germany
- Italia
- Greece
- UK
- OSHA (USA)

8.1.2 Biological limit values (Germany):

8.1.3 Exposure limits at intended use (Germany):

8.1.4 DNEL/PNEC-values:

- DNEL worker
- DNEL consumer

DNEL remark:

- PNEC

PNEC remark:

Control parameters remark:

8.2 Exposure controls

8.2.1 Appropriate engineering controls:

according to Regulation (EC) No 1907/2006 (REACH)

Designation / Commercial name : HTRF Insulin High Range kit - 10K pts XL665 antibody

Version: UK, Page 6 of 12, Revision date: 07/09/2023

8.2.2 Personal protective equipment:

Eye / Face protection: Safety glasses with side-shields ;

Skin protection: Gloves ; Laboratory coats ;

Respiratory protection: Ensure adequate ventilation ;

Thermal hazards:

8.2.3 Environmental exposure controls:

SECTION 9 : PHYSICAL AND CHEMICAL PROPERTIES

9.1 Information on basic physical and chemical properties

Appearance

Physical state	Solid ;
Colour	Blue ;
Odour	
Odour threshold (ppm)	

	Value	Concentration (mol/L)	Method	Temperature (°C)	Pressure (kPa)	Remark
pH						
Melting point (°C)						
Freezing point (°C)						
Initial boiling point/boiling range (°C)						
Flash point (°C)						
Evaporation rate (kg/m ² /h)						
Flammability (type :) (%)						
Upper/lower flammability or explosive limits	Upper explosive limit (%)					
	Lower explosive limit (%)					
Vapour pressure (kPa)						
Vapour density (g/cm ³)						
Densities	Density (g/cm ³)					
	Relative density (g/cm ³)					
	Bulk density (g/cm ³)					
	Critical density (g/cm ³)					
Solubility (Type :) (g/L)						
Partition coefficient (log Pow) n-octanol/water at pH :						
Auto-ignition temperature (°C)						
Decomposition temperature (°C) Decomposition energy : kJ						
Viscosity	Viscosity, dynamic (poiseuille)					
	Viscosity, cinematic (cm ² /s)					
Oxidising properties						
Explosive properties						

9.2 Other information:

No other relevant data available

according to Regulation (EC) No 1907/2006 (REACH)

Designation / Commercial name : HTRF Insulin High Range kit - 10K pts XL665 antibody

Version: UK, Page 7 of 12, Revision date: 07/09/2023

SECTION 10 : STABILITY AND REACTIVITY

10.1 Reactivity This material is considered to be non-reactive under normal use conditions. ;

10.2 Chemical stability

10.3 Possibility of hazardous reactions

10.4 Conditions to avoid:

10.5 Incompatible materials:

10.6 Hazardous decomposition products:

Does not decompose when used for intended uses. ; Thermal decomposition can lead to the escape of irritating gases and vapors. ;

SECTION 11 : TOXICOLOGICAL INFORMATION

Toxicokinetics, metabolism and distribution

11.1 Information on toxicological effects

Substances

- **Acute toxicity**

Animal data:

Acute oral toxicity:

Acute dermal toxicity:

Acute inhalative toxicity:

Practical experience / human evidence:

Assessment / Classification:

General Remark:

- **Skin corrosion/irritation**

Animal data:

In-vitro skin test method:

In-vitro skin test result:

Assessment / Classification:

- **Eye damage/irritation**

Animal data:

according to Regulation (EC) No 1907/2006 (REACH)

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In vitro eye test method:

In vitro eye test result:

Assessment / Classification:

- **CMR effects (carcinogenicity, mutagenicity and toxicity for reproduction)**
 - Germ cell mutagenicity:

Animal data:

Assessment / Classification:

- Carcinogenicity

Practical experience / human evidence:

Animal data:

Other information:

Assessment / Classification:

- Reproductive toxicity

Practical experience / human evidence:

Animal data:

Other information:

Assessment / Classification:

Overall assessment on CMR properties:

- **Specific target organ toxicity (single exposure)**
 - STOT SE 1 and 2

Animal data:

Other information:

- STOT SE 3

Practical experience / human evidence:

Other information:

Assessment / Classification:

- **Specific target organ toxicity (repeated exposure)**

Practical experience / human evidence:

Animal data:

Assessment / Classification:

Other information

- **Aspiration hazard**

according to Regulation (EC) No 1907/2006 (REACH)

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Practical experience / human evidence:

Experimental data: viscosity data: see SECTION 9.

Assessment / Classification:

Remark:

11.1.1 Mixtures

No toxicological information is available for the mixture itself

SECTION 12 : ECOLOGICAL INFORMATION

In case that test data regarding one endpoint/differentiation exist for the mixture itself, the classification is carried out according to the substance criteria (excluding biodegradation and bioaccumulation). If no test data exist, the criteria for mixture classification has to be used (calculation method); in this case the toxicological data of the ingredients are shown.

12.1 Aquatic toxicity:

Acute (short-term) fish toxicity

Chronic (long-term) fish toxicity

Acute (short-term) toxicity to crustacea

Chronic (long-term) toxicity to crustacea

Acute (short-term) toxicity to algae and cyanobacteria

Toxicity to microorganisms and other aquatic plants / organisms

Assessment / Classification:

12.2 Persistence and degradability

Biodegradation:

Abiotic Degradation:

Assessment / Classification:

12.3 Bioaccumulative potential

Bioconcentration factor (BCF):

12.4 Mobility in soil

12.5 Results of PBT and vPvB assessment

12.6 Other adverse effects:

according to Regulation (EC) No 1907/2006 (REACH)

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Additional ecotoxicological information:

SECTION 13 : DISPOSAL CONSIDERATIONS

13.1 Waste treatment methods

Waste treatment options:Dispose of waste according to applicable legislation. ;

SECTION 14 : TRANSPORT INFORMATION

ADR/RID/AND/IMDG/IATA

UN No.	
UN Proper shipping name	
Transport hazard class(es)	
Hazard label(s)	
Packing group	

Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code

Land transport (ADR/RID)

Classification code ADR:	Special Provisions for ADR/RID:
Limited quantities for ADR/RID:	Excepted Quantities for ADR/RID:
Packing Instructions for ADR/RID:	Special packing provisions for ADR/RID:
Mixed packing provisions:	
Portable tanks and bulk containers Instructions:	
Portable tanks and bulk containers Special Provisions:	
ADR Tank Code:	ADR Tank special provisions:
Vehicle for tank carriage:	
Special provisions for carriage Packages:	
Special provisions for carriage Bulk:	
Special provisions for carriage for loading, unloading and handling:	
Special Provisions for carriage Operation:	
Hazard identification No:	Transport category (Tunnel restriction code):

Sea transport (IMDG)

Marine Pollutant:	Subsidiary risk(s) for IMDG:
Packing provisions for IMDG:	Limited quantities for IMDG:
Packing instructions for IMDG:	IBC Instructions:
IBC Provisions:	IMO tank instructions:
UN tank instructions:	Tanks and bulk Provisions:
EmS :	Stowage and segregation for IMDG:
Properties and observations:	

Inland waterway transport (ADN)

Classification Code ADN:	Special Provisions ADN:
Limited quantities ADN:	Excepted quantities ADN:
Carriage permitted:	Equipment required:
Provisions concerning loading and unloading:	Provisions concerning carriage:
Number of blue cones/lights:	Remark:

according to Regulation (EC) No 1907/2006 (REACH)

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Air transport (ICAO-TI / IATA-DGR)

Subsidiary risk for IATA:

Excepted quantity for IATA:

Passenger and Cargo Aircraft Limited Quantities Packing Instructions:

Passenger and Cargo Aircraft Limited Quantities Maximal Net Quantity :

Passenger and Cargo Aircraft Packaging Instructions :

Passenger and Cargo Aircraft Maximal Net Quantity :

Cargo Aircraft only Packaging Instructions :

Cargo Aircraft only Maximal Net Quantity :

ERG code:

Special Provisions for IATA:

SECTION 15 : REGULATORY INFORMATION

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

EU regulations

- Authorisations and/or restrictions on use:

Authorisations:

Restrictions on use:

SVHC :

- Other EU regulations:
- Directive 2010/75/EC on industrial emissions

Not relevant

National regulations

15.2 Chemical Safety Assessment:

For this mixture, no chemical safety assessment has been carried out

SECTION 16 : OTHER INFORMATION

16.1 Indication of changes

Date of the previous version:06/09/2023

Modifications:

16.2 Other informations

16.3 Classification for mixtures and used evaluation method according to regulation (EC) 1207/2008 [CLP]:

See SECTION 2.1 (classification).

16.4 Relevant R-, H- and EUH-phrases (number and full text):

according to Regulation (EC) No 1907/2006 (REACH)

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