

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

Trade name: HTRF Insulin High Range kit - 500 pts / 62IN1PEG 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	рН	Color	Physical state
HTRF Diluent 5 (5X) - 10 mL	62DL5DDC	1	7	Colorless	Liquid
HTRF Detect. Buf. 7 - 55 mL		1	7	Colorless	Liquid
HTRF Insulin High Range kit - 500 pts Eu Cryptate antibody		1	-	White	Solid
HTRF Insulin High Range kit - 500 pts XL665 antibody		1	-	Blue	Solid
HTRF Insulin kit - Std	62INSCDA	1	-	White	Solid



according to Hazard Communication Standard (HCS) (29 CFR 1910.1200(g))

Designation / Trade name: HTRF Diluent 5 (5X) - 10 mL 62DL5DDC Version: US, 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 / Trade name: HTRF Diluent 5 (5X) - 10 mL 62DL5DDC

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 in accordance with 29 CFR 1910 (OSHA HCS)	Category code	Hazard statement	Precautionary statement
The substance or mixture is not classified as hazardous in accordance with 29 CFR 1910 (OSHA HCS)	None	None	None

2.2 Label elements

Labelling according to Hazard Communication Standard (HCS) (29 CFR 1910.1200(g))

Product identifier:

Designation / Trade name: HTRF Diluent 5 (5X) - 10 mL 62DL5DDC

Substances contained in this product:



Designation / Trade name: HTRF Diluent 5 (5X) - 10 mL 62DL5DDC Version: US, 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) >= 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:

according to Hazard Communication Standard (HCS) (29 CFR 1910.1200(g))

Designation / Trade name: HTRF Diluent 5 (5X) - 10 mL 62DL5DDC Version: US, Page 3 of 12, 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 in accordance with 29 CFR 1910 (OSHA HCS)	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. ; Additional information:

SECTION 6 : ACCIDENTAL RELEASE MEASURES

6.1 Personal precautions, protective equipment and emergency procedures

Emergency procedures: Provide adequate ventilation. ;

according to Hazard Communication Standard (HCS) (29 CFR 1910.1200(g))

Designation / Trade name: HTRF Diluent 5 (5X) - 10 mL 62DL5DDC Version: US, Page 4 of 12, Revision date: 07/09/2023

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

<u>Protective measures:</u> 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. ; <u>Advice on general occupational hygiene</u> : Handle in accordance with good industrial hygiene and safety practice ;

7.2 Conditions for safe storage, including any incompatibilities

<u>Requirements for storage rooms and vessels</u>: Keep container tightly closed. ; <u>Hints on storage assembly:</u> Materials to avoid: <u>Further information on storage conditions:</u>

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:

• OSHA (USA)

Source :	Occupational Safet	cupational 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)							

Designation / Trade name: HTRF Diluent 5 (5X) - 10 mL 62DL5DDC Version: US, Page 5 of 12, Revision date: 07/09/2023

				\sim	
7778-77-0 / 231-913- 4	13-4	7778-77-0			

Source :	RGS 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								

8.1.2 <u>DNEL/PNEC-values:</u>

• DNEL worker

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

• DNEL consumer

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

• PNEC

Source :	INERIS																
		EC-No. CAS-No		PNEC AQUATIC									PNEC Sediment				
Substance	EC-No		freshwater			m	marine water			intermittent release			reshwate	er	ma	arine wat	er
Substance EC-No.			(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	IS												
			Others											
Substance	EC-No.	CAS-No		PNEC soil		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)



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								v	
7778-77-0 / 231-913-4	231-913-4	7778-77-0							

8.2 Exposure controls

8.2.1 <u>Appropriate engineering controls:</u>

Technical measures and appropriate working operations should be given priority over the use of personal protective equipment. See section 7

8.2.2 <u>Personal protective equipment:</u>

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

Skin protection:Gloves;

Respiratory protection:Ensure adequate ventilation ;

Thermal hazards:

8.2.3 Environmental exposure controls:

Consumer exposure control

Measures related to consumer uses of the substance (as such or in mixtures): Measures related to the service life of the substance in articles:

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
рН		7					
Melting point (°C)							
Freezing point (°C)							
Initial boiling point/b	oiling range (°C)						
Flash point (°C)							
Evaporation rate (kg	/m²/h)						
Flammability (type :) (%)						
Upper/lower flammability or explo limits	Upper explosive limit osive (%)						
	Lower explosive limit (%)						
Vapour pressure (kP	a)						
Vapour density (g/cr	1 ³)						
	Density (g/cm ³)						
Densities	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 ³ /s)						
· · · ·	Explosive properties						

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Oxidising properties				•
	()vidising 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

<u>Substances</u>

• 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:

according to Hazard Communication Standard (HCS) (29 CFR 1910.1200(g))

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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 (carcinogenity, mutagenicity and toxicity for reproduction)
 - Germ cell mutagenicity:

Animal data:

Assessment / Classification:

o 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)
 - $\circ~$ STOT SE 1 and 2

Animal data:

Other information:

o STOT SE 3

Practical experience / human evidence:

Other information:

according to Hazard Communication Standard (HCS) (29 CFR 1910.1200(g))

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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 <u>Mixtures</u> 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:



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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. ;

Other disposal recommendations: Additional information:

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 Provision	ins:
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, unloadin	ng and handling:
Special Provisions for carriage Operation:	
Hazard identification No:	Transport category (Tunnel restriction code):

according to Hazard Communication Standard (HCS) (29 CFR 1910.1200(g))

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<u>Sea transport (IMDG)</u>					
Marine Pollutant:					
Packing provisions for IMDG:					
Packing instructions for IMDG:					
IBC Provisions:					
UN tank instructions:					
EmS :					
Properties and observations:					

Subsidiary risk(s) for IMDG: Limited quantities for IMDG: **IBC Instructions:** IMO tank instructions: Tanks and bulk Provisions: Stowage and segregation for IMDG:

Inland waterway transport (ADN)
Classification Code ADN:
Limited quantities ADN:
Carriage permitted:
Provisions concerning loading and unloading:
Provisions concerning carriage:
Remark:

Special Provisions ADN: **Excepted quantities ADN:** Equipment required:

Number of blue cones/lights:

<u>Air transport (ICAO-TI / IATA-DGR)</u>

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

15.2 Chemical Safety Assessment:

For the following substances of this mixture a 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 Abbreviations and acronyms:
- 16.3 Key literature references and sources for data
- 16.4 Classification for mixtures and used evaluation method according to Hazard Communication Standard (HCS) (29 CFR 1910.1200(g):

See SECTION 2.1 (classification).

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



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according to Hazard Communication Standard (HCS) (29 CFR 1910.1200(g))

Designation / Trade name: HTRF Insulin kit - Std 62INSCDA Version: US, Page 1 of 11, Revision date: 07/09/2023

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

REACH No:

1.1 Product identifier:

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

CAS No.: Index No: EC 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 in accordance with 29 CFR 1910 (OSHA HCS)	Category code	Hazard statement	Precautionary statement
The substance or mixture is not classified as hazardous in accordance with 29 CFR 1910 (OSHA HCS)	None	None	None

2.2 Label elements

Labelling according to Hazard Communication Standard (HCS) (29 CFR 1910.1200(g))

Product identifier:

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

Substances contained in this product:

according to Hazard Communication Standard (HCS) (29 CFR 1910.1200(g))

Designation / Trade name: HTRF Insulin kit - Std 62INSCDA Version: US, Page 2 of 11, 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) >= 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:

according to Hazard Communication Standard (HCS) (29 CFR 1910.1200(g))

Designation / Trade name: HTRF Insulin kit - Std 62INSCDA Version: US, Page 3 of 11, 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.

<u>Additional information:</u> 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. ; Additional information:

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). ;

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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 ;

<u>Advice on general occupational hygiene</u>: 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

<u>Requirements for storage rooms and vessels</u>: Keep container tightly closed. ; Keep-store only in original container or in properly labeled containers ; <u>Hints on storage assembly</u>: Materials to avoid: <u>Further information on storage conditions</u>:

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:

• OSHA (USA)

according to Hazard Communication Standard (HCS) (29 CFR 1910.1200(g))

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8.1.2 DNEL/PNEC-values:

- DNEL worker
- DNEL consumer
- PNEC

8.2 Exposure controls

8.2.1 <u>Appropriate engineering controls:</u>

Technical measures and appropriate working operations should be given priority over the use of personal protective equipment. See section 7

8.2.2 <u>Personal protective equipment:</u>

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

Skin protection: Gloves ; Laboratory coats ;

Respiratory protection:Ensure adequate ventilation ;

Thermal hazards:

8.2.3 <u>Environmental exposure controls:</u>

Consumer exposure control

<u>Measures related to consumer uses of the substance (as such or in mixtures):</u> <u>Measures related to the service life of the substance in articles:</u>

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
рН							
Melting point (°C)							
Freezing point (°C)							
Initial boiling point/boiling ra	ange (°C)						
Flash point (°C)							
Evaporation rate (kg/m²/h)							
Flammability (type :) (%)							
Upper/lower flammability or explosive	Upper explosive limit (%)						
limits	Lower explosive limit (%)						
Vapour pressure (kPa)							
Vapour density (g/cm³)							
Density (g/cm³)							



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				V
Densitie	s 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 ter	nperature (°C)			
Decomposition temperature (°C) Decomposition energy : kJ				
Viscosity	Viscosity, dynamic (poiseuille)			
	Viscosity, cinematic (cm ³ /s)			
Explosive properties				
	Oxidising 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. ; 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:

according to Hazard Communication Standard (HCS) (29 CFR 1910.1200(g))

Designation / Trade name: HTRF Insulin kit - Std 62INSCDA Version: US, Page 7 of 11, Revision date: 07/09/2023

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:

In vitro eye test method: In vitro eye test result: Assessment / Classification:

CMR effects (carcinogenity, 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:



Designation / Trade name: HTRF Insulin kit - Std 62INSCDA Version: US, Page 8 of 11, Revision date: 07/09/2023

Specific target organ toxicity (single exposure)

 STOT SE 1 and 2

Animal data:

Other information:

o 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 <u>Mixtures</u> 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

according to Hazard Communication Standard (HCS) (29 CFR 1910.1200(g))

Designation / Trade name: HTRF Insulin kit - Std 62INSCDA Version: US, Page 9 of 11, Revision date: 07/09/2023

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:

Additional ecotoxicological information:

SECTION 13 : DISPOSAL CONSIDERATIONS

13.1 Waste treatment methods

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

Other disposal recommendations: Additional information:

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:Special packing provisions for ADR/RID:Portable tanks and bulk containers Special Provisions:Portable tanks and bulk containers Special Provisions:ADR Tank special provisions:

according to Hazard Communication Standard (HCS) (29 CFR 1910.1200(g))

Designation / Trade name: HTRF Insulin kit - Std 62INSCDA Version: US, Page 10 of 11, Revision date: 07/09/2023

Vehicle for tank carriage: Special provisions for carriage Bulk:	Special provisions for carriage Packages:
Special provisions for carriage bulk.	ading and handling.
Special Provisions for carriage Operation:	
Hazard identification No:	Transport category (Tunnel restriction code):
	Transport category (Tunner 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:	
<u> Air transport (ICAO-TI / IATA-DGR)</u>	
Subsidiary risk for IATA:	Excepted quantity for IATA:
Passenger and Cargo Aircraft Limited Quantitie	s Packing Instructions:
Passenger and Cargo Aircraft Limited Quantitie	s Maximal Net Quantity :
Passenger and Cargo Aircraft Packaging Instruct	tions :
Passenger and Cargo Aircraft Maximal Net Qua	ntity :
Cargo Aircraft only Packaging Instructions :	
Course Alassaft, and Maniaral National Nation	

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

15.2 Chemical Safety Assessment:

For the following substances of this mixture a 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:

according to Hazard Communication Standard (HCS) (29 CFR 1910.1200(g))

Designation / Trade name: HTRF Insulin kit - Std 62INSCDA Version: US, Page 11 of 11, Revision date: 07/09/2023

16.2 Abbreviations and acronyms:

- 16.3 Key literature references and sources for data
- 16.4 Classification for mixtures and used evaluation method according to Hazard Communication Standard (HCS) (29 CFR 1910.1200(g):

See SECTION 2.1 (classification).

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



IEV

according to Hazard Communication Standard (HCS) (29 CFR 1910.1200(g))

Designation / Trade name: HTRF Detect. Buf. 7 - 55 mL Version: US, Page 1 of 12, Revision date: 07/09/2023

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

Product identifier: 1.1

Designation / Trade name: HTRF Detect. Buf. 7 - 55 mL REACH No:

CAS No.: Index No: EC 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. ;

Details of the supplier of the safety data sheet: 1.3

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 in accordance with 29 CFR 1910 (OSHA HCS)	Category code	Hazard statement	Precautionary statement
The substance or mixture is not classified as hazardous in accordance with 29 CFR 1910 (OSHA HCS)	None	None	None

2.2 Label elements

Labelling according to Hazard Communication Standard (HCS) (29 CFR 1910.1200(g))

Product identifier:

Designation / Trade name: HTRF Detect. Buf. 7 - 55 mL

Substances contained in this product:

according to Hazard Communication Standard (HCS) (29 CFR 1910.1200(g))

Designation / Trade name: HTRF Detect. Buf. 7 - 55 mL Version: US, 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) >= 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:

according to Hazard Communication Standard (HCS) (29 CFR 1910.1200(g))

Designation / Trade name: HTRF Detect. Buf. 7 - 55 mL Version: US, Page 3 of 12, 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 in accordance with 29 CFR 1910 (OSHA HCS)	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. ; Additional information:

according to Hazard Communication Standard (HCS) (29 CFR 1910.1200(g))

Designation / Trade name: HTRF Detect. Buf. 7 - 55 mL Version: US, Page 4 of 12, Revision date: 07/09/2023

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

<u>Protective measures:</u> 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. ; <u>Advice on general occupational hygiene</u>: Handle in accordance with good industrial hygiene and safety practice ;

7.2 Conditions for safe storage, including any incompatibilities

<u>Requirements for storage rooms and vessels</u>: Keep container tightly closed. ; <u>Hints on storage assembly:</u> Materials to avoid: <u>Further information on storage conditions:</u>

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:

• OSHA (USA)



Designation / Trade name: HTRF Detect. Buf. 7 - 55 mL Version: US, Page 5 of 12, Revision date: 07/09/2023

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)				
7789-23-3 / 232-151- 5	232-151-5	7789-23-3								

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

8.1.2 <u>DNEL/PNEC-values:</u>

• DNEL worker

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

• DNEL consumer

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

• PNEC

Source :	INERIS																
				PNEC AQUATIC							PNEC Sediment						
Substance EC	EC No	EC-No. CAS-No	freshwater			m	arine wat	er	interr	intermittent release		f	reshwate	er	ma	arine wat	er
Substance	EC-NO.		(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



Designation / Trade name: HTRF Detect. Buf. 7 - 55 mL Version: US, Page 6 of 12, Revision date: 07/09/2023

	EC-No. CAS-No		Others											
Substance		CAS-No	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												

8.2 Exposure controls

8.2.1 <u>Appropriate engineering controls:</u>

Technical measures and appropriate working operations should be given priority over the use of personal protective equipment. See section 7

8.2.2 <u>Personal protective equipment:</u>

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

Skin protection:Gloves ;

Respiratory protection:Ensure adequate ventilation ;

Thermal hazards:

8.2.3 Environmental exposure controls:

Consumer exposure control

Measures related to consumer uses of the substance (as such or in mixtures):

Measures related to the service life of the substance in articles:

SECTION 9 : PHYSICAL AND CHEMICAL PROPERTIES

9.1 Information on basic physical and chemical properties

Appearance

<u>, ippearance</u>	
Physical state	Liquid ;
Colour	Colorless ;
Odour	
Odour threshold (ppm)	

		1	1		1		
		Value	Concentration	Method	Temperature (°C)	Pressure (kPa)	Remark
			(mol/L)				
pН		7					
Melting point (°C)							
Freezing point (°C)							
Initial boiling point/boiling	range (°C)						
Flash point (°C)							
Evaporation rate (kg/m²/h)							
Flammability (type :) (%)							
Upper/lower flammability or explosive limits	Upper explosive limit (%)						
mmus	Lower explosive limit (%)						
Vapour pressure (kPa)							
Vapour density (g/cm ³)							
	Density (g/cm³)						
Densities	Relative density (g/cm ³)						
	Bulk density (g/cm ³)						
	Critical density (g/cm ³)						
Solubility (Type:) (g/L)							
Partition coefficient (log Po n-octanol/water at pH :	w)						
Auto-ignition temperature	(°C)						



Designation / Trade name: HTRF Detect. Buf. 7 - 55 mL Version: US, Page 7 of 12, Revision date: 07/09/2023

					V
Decomposition temperature (°C) Decomposition energy: kJ					
Viscosity	Viscosity, dynamic (poiseuille)				
	Viscosity, cinematic (cm ³ /s)				
Explosive properties					
	Oxidising 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				

according to Hazard Communication Standard (HCS) (29 CFR 1910.1200(g))

Designation / Trade name: HTRF Detect. Buf. 7 - 55 mL Version: US, Page 8 of 12, Revision date: 07/09/2023

Acute inhalative toxicity:

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 (carcinogenity, mutagenicity and toxicity for reproduction)

• Germ cell mutagenicity:

Animal data:

Assessment / Classification:

o Carcinogenicity

Practical experience / human evidence: Animal data:

Other information: Assessment / Classification:

o Reproductive toxicity

Practical experience / human evidence: Animal data:

Other information:

according to Hazard Communication Standard (HCS) (29 CFR 1910.1200(g))

Designation / Trade name: HTRF Detect. Buf. 7 - 55 mL Version: US, Page 9 of 12, Revision date: 07/09/2023

Assessment / Classification:

Overall assessment on CMR properties:

- Specific target organ toxicity (single exposure)
 - \circ $\,$ STOT SE 1 and 2 $\,$

Animal data:

Other information:

o 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 <u>Mixtures</u> 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

according to Hazard Communication Standard (HCS) (29 CFR 1910.1200(g))

Designation / Trade name: HTRF Detect. Buf. 7 - 55 mL Version: US, Page 10 of 12, Revision date: 07/09/2023

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:

Additional ecotoxicological information:

SECTION 13 : DISPOSAL CONSIDERATIONS

13.1 Waste treatment methods

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

Other disposal recommendations: Additional information:

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: Limited quantities for ADR/RID:

Special Provisions for ADR/RID: Excepted Quantities for ADR/RID:

according to Hazard Communication Standard (HCS) (29 CFR 1910.1200(g))

Designation / Trade name: HTRF Detect. Buf. 7 - 55 mL Version: US, Page 11 of 12, Revision date: 07/09/2023

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 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: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:For IMDG:

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:Provisions concerning carriage:Number of blue cones/lights:Remark:Equipment required:

Air transport (ICAO-TI / IATA-DGR)Subsidiary risk 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

15.2 Chemical Safety Assessment:

For the following substances of this mixture a 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:

according to Hazard Communication Standard (HCS) (29 CFR 1910.1200(g))

Designation / Trade name: HTRF Detect. Buf. 7 - 55 mL Version: US, Page 12 of 12, Revision date: 07/09/2023

16.2 Abbreviations and acronyms:

16.3 Key literature references and sources for data

16.4 Classification for mixtures and used evaluation method according to Hazard Communication Standard (HCS) (29 CFR 1910.1200(g):

See SECTION 2.1 (classification).

16.5 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



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according to Hazard Communication Standard (HCS) (29 CFR 1910.1200(g))

Designation / Trade name: HTRF Insulin High Range kit - 500 pts Eu Cryptate antibody Version: US, Page 1 of 11, Revision date: 07/09/2023

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

1.1 Product identifier:

Designation / Trade name:HTRF Insulin High Range kit - 500 pts Eu Cryptate antibodyCAS 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 in accordance with 29 CFR 1910 (OSHA HCS)	Category code	Hazard statement	Precautionary statement
The substance or mixture is not classified as hazardous in accordance with 29 CFR 1910 (OSHA HCS)	None	None	None

2.2 Label elements

Labelling according to Hazard Communication Standard (HCS) (29 CFR 1910.1200(g))

Product identifier:

Designation / Trade name: HTRF Insulin High Range kit - 500 pts Eu Cryptate antibody

Substances contained in this product:





according to Hazard Communication Standard (HCS) (29 CFR 1910.1200(g))

Designation / Trade name: HTRF Insulin High Range kit - 500 pts Eu Cryptate antibody Version: US, Page 2 of 11, 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) >= 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:

according to Hazard Communication Standard (HCS) (29 CFR 1910.1200(g))

Designation / Trade name: HTRF Insulin High Range kit - 500 pts Eu Cryptate antibody Version: US, Page 3 of 11, 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.

<u>Additional information:</u> 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. ; Additional information:

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 Hazard Communication Standard (HCS) (29 CFR 1910.1200(g))

Designation / Trade name: HTRF Insulin High Range kit - 500 pts Eu Cryptate antibody Version: US, Page 4 of 11, 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 ;

<u>Advice on general occupational hygiene</u>: 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

<u>Requirements for storage rooms and vessels</u>: Keep container tightly closed. ; Keep-store only in original container or in properly labeled containers ; <u>Hints on storage assembly</u>: Materials to avoid: <u>Further information on storage conditions</u>:

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:

• OSHA (USA)

according to Hazard Communication Standard (HCS) (29 CFR 1910.1200(g))

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8.1.2 DNEL/PNEC-values:

- DNEL worker
- DNEL consumer
- PNEC

8.2 Exposure controls

8.2.1 <u>Appropriate engineering controls:</u>

Technical measures and appropriate working operations should be given priority over the use of personal protective equipment. See section 7

8.2.2 <u>Personal protective equipment:</u>

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

Skin protection: Gloves ; Laboratory coats ;

Respiratory protection:Ensure adequate ventilation ;

Thermal hazards:

8.2.3 <u>Environmental exposure controls:</u>

Consumer exposure control

<u>Measures related to consumer uses of the substance (as such or in mixtures):</u> <u>Measures related to the service life of the substance in articles:</u>

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
рН							
Melting point (°C)							
Freezing point (°C)							
Initial boiling point/boiling ra	ange (°C)						
Flash point (°C)							
Evaporation rate (kg/m ² /h)	Evaporation rate (kg/m²/h)						
Flammability (type :) (%)							
Upper/lower flammability or explosive limits	Upper explosive limit (%)						
Lower explosive limit (%)							
Vapour pressure (kPa)							
Vapour density (g/cm ³)	Vapour density (g/cm³)						
	Density (g/cm³)						



according to Hazard Communication Standard (HCS) (29 CFR 1910.1200(g))

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				V
Densities	Relative density (g/cm ³)			
	Bulk density (g/cm ³)			
	Critical density (g/cm ³)			
Solubility (Type:)(g/L)			
Partition coefficient n-octanol/water at p				
Auto-ignition temperature (°C)				
Decomposition temp Decomposition ener				
Viscosity	Viscosity, dynamic (poiseuille)			
	Viscosity, cinematic (cm ³ /s)			
	Explosive properties			
	Oxidising 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. ; 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:

according to Hazard Communication Standard (HCS) (29 CFR 1910.1200(g))

Designation / Trade name: HTRF Insulin High Range kit - 500 pts Eu Cryptate antibody Version: US, Page 7 of 11, Revision date: 07/09/2023

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:

In vitro eye test method: In vitro eye test result: Assessment / Classification:

CMR effects (carcinogenity, 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:

according to Hazard Communication Standard (HCS) (29 CFR 1910.1200(g))

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Specific target organ toxicity (single exposure)

 STOT SE 1 and 2

Animal data:

Other information:

o 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 <u>Mixtures</u> 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

according to Hazard Communication Standard (HCS) (29 CFR 1910.1200(g))

Designation / Trade name: HTRF Insulin High Range kit - 500 pts Eu Cryptate antibody Version: US, Page 9 of 11, Revision date: 07/09/2023

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:

Additional ecotoxicological information:

SECTION 13 : DISPOSAL CONSIDERATIONS

13.1 Waste treatment methods

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

Other disposal recommendations: Additional information:

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:Special packing provisions for ADR/RID:Portable tanks and bulk containers Special Provisions:Portable tanks and bulk containers Special Provisions:ADR Tank special provisions:

according to Hazard Communication Standard (HCS) (29 CFR 1910.1200(g))

Designation / Trade name: HTRF Insulin High Range kit - 500 pts Eu Cryptate antibody Version: US, Page 10 of 11, Revision date: 07/09/2023

Vehicle for tank carriage: Special provisions for carriage Bulk:	Special provisions for carriage Packages:
Special provisions for carriage for loading, u	inloading and handling:
Special Provisions for carriage Operation:	
Hazard identification No:	Transport category (Tunnel restriction code):
<u>Sea transport (IMDG)</u>	
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 unloadin	ıg:
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 Quan	tities Packing Instructions:
Passenger and Cargo Aircraft Limited Quan	tities Maximal Net Quantity :
Passenger and Cargo Aircraft Packaging Inst	tructions :
Passenger and Cargo Aircraft Maximal Net	Quantity :
Cargo Aircraft only Packaging Instructions :	
Cargo Aircraft only Maximal Not Ouantity	

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

15.2 Chemical Safety Assessment:

For the following substances of this mixture a 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:

according to Hazard Communication Standard (HCS) (29 CFR 1910.1200(g))

Designation / Trade name: HTRF Insulin High Range kit - 500 pts Eu Cryptate antibody Version: US, Page 11 of 11, Revision date: 07/09/2023

16.2 Abbreviations and acronyms:

- 16.3 Key literature references and sources for data
- 16.4 Classification for mixtures and used evaluation method according to Hazard Communication Standard (HCS) (29 CFR 1910.1200(g):

See SECTION 2.1 (classification).

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



according to Hazard Communication Standard (HCS) (29 CFR 1910.1200(g))

Designation / Trade name: HTRF Insulin High Range kit - 500 pts XL665 antibody Version: US, Page 1 of 11, Revision date: 07/09/2023

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

1.1 Product identifier:

Designation / Trade name:HTRF Insulin High Range kit - 500 pts XL665 antibodyCAS No.:Index No:EC No:REACH 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 in accordance with 29 CFR 1910 (OSHA HCS)	Category code	Hazard statement	Precautionary statement
The substance or mixture is not classified as hazardous in accordance with 29 CFR 1910 (OSHA HCS)	None	None	None

2.2 Label elements

Labelling according to Hazard Communication Standard (HCS) (29 CFR 1910.1200(g))

Product identifier:

Designation / Trade name: HTRF Insulin High Range kit - 500 pts XL665 antibody

Substances contained in this product:





according to Hazard Communication Standard (HCS) (29 CFR 1910.1200(g))

Designation / Trade name: HTRF Insulin High Range kit - 500 pts XL665 antibody Version: US, Page 2 of 11, 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) >= 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:

according to Hazard Communication Standard (HCS) (29 CFR 1910.1200(g))

Designation / Trade name: HTRF Insulin High Range kit - 500 pts XL665 antibody Version: US, Page 3 of 11, 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.

<u>Additional information:</u> 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. ; Additional information:

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 Hazard Communication Standard (HCS) (29 CFR 1910.1200(g))

Designation / Trade name: HTRF Insulin High Range kit - 500 pts XL665 antibody Version: US, Page 4 of 11, 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 ;

<u>Advice on general occupational hygiene</u>: 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

<u>Requirements for storage rooms and vessels</u>: Keep container tightly closed. ; Keep-store only in original container or in properly labeled containers ; <u>Hints on storage assembly</u>: Materials to avoid: <u>Further information on storage conditions</u>:

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:

• OSHA (USA)

according to Hazard Communication Standard (HCS) (29 CFR 1910.1200(g))

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8.1.2 DNEL/PNEC-values:

- DNEL worker
- DNEL consumer
- PNEC

8.2 Exposure controls

8.2.1 <u>Appropriate engineering controls:</u>

Technical measures and appropriate working operations should be given priority over the use of personal protective equipment. See section 7

8.2.2 <u>Personal protective equipment:</u>

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

Skin protection: Gloves ; Laboratory coats ;

Respiratory protection:Ensure adequate ventilation ;

Thermal hazards:

8.2.3 <u>Environmental exposure controls:</u>

Consumer exposure control

<u>Measures related to consumer uses of the substance (as such or in mixtures):</u> <u>Measures related to the service life of the substance in articles:</u>

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
рН							
Melting point (°C)							
Freezing point (°C)							
Initial boiling point/boiling r	ange (°C)						
Flash point (°C)							
Evaporation rate (kg/m ² /h)							
Flammability (type :) (%)							
Upper/lower flammability or explosive	Upper explosive limit (%)						
limits Lower explosive limit (%)							
Vapour pressure (kPa)							
Vapour density (g/cm ³)	Vapour density (g/cm³)						
	Density (g/cm³)						



according to Hazard Communication Standard (HCS) (29 CFR 1910.1200(g))

Designation / Trade name: HTRF Insulin High Range kit - 500 pts XL665 antibody Version: US, Page 6 of 11, Revision date: 07/09/2023

				V
Densities	Relative density (g/cm ³)			
	Bulk density (g/cm ³)			
	Critical density (g/cm ³)			
Solubility (Type :) (g/L)			
Partition coefficien n-octanol/water a				
Auto-ignition tem	perature (°C)			
Decomposition te Decomposition en				
Viscosity	Viscosity, dynamic (poiseuille)			
Ē	Viscosity, cinematic (cm ³ /s)			
	Explosive properties			
	Oxidising 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. ; 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:

according to Hazard Communication Standard (HCS) (29 CFR 1910.1200(g))

Designation / Trade name: HTRF Insulin High Range kit - 500 pts XL665 antibody Version: US, Page 7 of 11, Revision date: 07/09/2023

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:

In vitro eye test method: In vitro eye test result: Assessment / Classification:

CMR effects (carcinogenity, 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:

according to Hazard Communication Standard (HCS) (29 CFR 1910.1200(g))

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Specific target organ toxicity (single exposure)

 STOT SE 1 and 2

Animal data:

Other information:

o 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 <u>Mixtures</u> 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

according to Hazard Communication Standard (HCS) (29 CFR 1910.1200(g))

Designation / Trade name: HTRF Insulin High Range kit - 500 pts XL665 antibody Version: US, Page 9 of 11, Revision date: 07/09/2023

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:

Additional ecotoxicological information:

SECTION 13 : DISPOSAL CONSIDERATIONS

13.1 Waste treatment methods

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

Other disposal recommendations: Additional information:

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:Special packing provisions for ADR/RID:Portable tanks and bulk containers Special Provisions:Portable tanks and bulk containers Special Provisions:ADR Tank special provisions:

according to Hazard Communication Standard (HCS) (29 CFR 1910.1200(g))

Designation / Trade name: HTRF Insulin High Range kit - 500 pts XL665 antibody Version: US, Page 10 of 11, Revision date: 07/09/2023

Vehicle for tank carriage: Special provisions for carriage Bulk:	Special provisions for carriage Packages:
Special provisions for carriage for loading, unload	ing 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:	
<u>Air transport (ICAO-TI / IATA-DGR)</u>	
Subsidiary risk for IATA:	Excepted quantity for IATA:
Passenger and Cargo Aircraft Limited Quantities F	
Passenger and Cargo Aircraft Limited Quantities	-
Passenger and Cargo Aircraft Packaging Instruction	•
Passenger and Cargo Aircraft Maximal Net Quant	
Cargo Aircraft only Packaging Instructions :	,
Cargo Aircraft only Maximal Net Quantity :	
,	

SECTION 15 : REGULATORY INFORMATION

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

Special Provisions for IATA:

15.2 Chemical Safety Assessment:

For the following substances of this mixture a chemical safety assessment has been carried out :

SECTION 16 : OTHER INFORMATION

16.1 Indication of changes

ERG code:

Date of the previous version:06/09/2023 Modifications:

according to Hazard Communication Standard (HCS) (29 CFR 1910.1200(g))

Designation / Trade name: HTRF Insulin High Range kit - 500 pts XL665 antibody Version: US, Page 11 of 11, Revision date: 07/09/2023

16.2 Abbreviations and acronyms:

- 16.3 Key literature references and sources for data
- 16.4 Classification for mixtures and used evaluation method according to Hazard Communication Standard (HCS) (29 CFR 1910.1200(g):

See SECTION 2.1 (classification).

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

