

Trade name: HTRF cGMP kit - 10K pts / 62GM2PEH

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	pН	Color	Physical state
HTRF Diluent 1 - 20 mL	62DL1DDD	1	7	Colorless	Liquid
HTRF Lysis & Detect. Buf. 2 - 105 mL		1	7	Colorless	Liquid
HTRF cGMP kit - 10K pts d2 reagent		1	-	Blue	Solid
HTRF cGMP kit - Std	62GMPCDA	1	-	White	Solid
HTRF cGMP kit - 10K pts Eu Cryptate antibody		1	-	White	Solid



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

Designation / Commercial name : HTRF Diluent 1 - 20 mL 62DL1DDD 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 1 - 20 mL 62DL1DDD

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 2:00 am to 5:20 pm 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 1 - 20 mL 62DL1DDD

Substances contained in this product:



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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) >= 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
ethanol	64-17-5	603-002-00-5	200-578-6	Flammable liquid - Flam. Liq. 2 - H225	< 1%		

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.;

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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

<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>Technical measures and storage conditions:</u> <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:

France

Source :	Informations rela	formations relatives à la réglementation VME (France) : ED 984, 07.2012											
Substance	EC-No.	CAS-No	VLE (mg/m3)	VME (ppm)									
64-17-5 / 200-578- 6	200-578-6	64-17-5	9500	5000	1900	1000							



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Source :		mites de Exposicion Profesional para Agentes Quimicos en Espana istituto Nacional de Seguridad e Higiene en el Trabajo ine 2015									
Substance	EC-No.	CAS-No	VLA-EC (mg/m3)	VLA-EC (ppm)	VLA-ED (mg/m3)	VLA-ED (ppm)					
64-17-5 / 200-578- 6	200-578-6	64-17-5	1,91	1							

• Germany

Source :	TRGS 900, June 2015, BA	RGS 900, June 2015, BAuA									
Substance	EC-No.	CAS-No	AGW (mg/m3)	AGW (ppm)							
64-17-5 / 200-578-6	200-578-6	64-17-5	960	500							

- Italia
- Greece
- UK
- OSHA (USA)

Source :	Occupational Safe	ccupational 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)						
64-17-5 / 200-578-6	200-578-6	64-17-5	1000	1900								

8.1.2 <u>Biological limit values (Germany):</u>

Source :	List of recommended heal	of recommended health-based biological limit values (BLVs) and biological guidance values (BGVs), June 2014									
Substance	EC-No.	EC-No. CAS-No		BLV (ppm)							
64-17-5 / 200-578-6	200-578-6	64-17-5									

8.1.3 Exposure limits at intended use (Germany):



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V										
Source :	e : TRGS 903, November 2015, BAuA									
Substance	EC-No.	CAS-No	BGW (ppm)							
64-17-5 / 200-578-6	200-578-6	64-17-5								

8.1.4 <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
64-17-5 / 200-578-6	200-578-6	64-17-5					950-950		

• 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
64-17-5 / 200-578-6	200-578-6	64-17-5							

DNEL remark:

• PNEC

Source :	INERIS																
Substance EC-No.			PNEC AQUATIC						PNEC Sediment								
			freshwater			marine water		intermittent release		freshwater		marine water		:er			
	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)
64-17-5 / 200-578-6	200-578-6	64-17-5															

Source :	INERIS													
			Others											
Substance	EC-No.	CAS-No		PNEC soil		PNEC s	ewage trea plant	atment	PNEC air				EC second poisoning	
			(mg/L)	(mg/kg)	(ppm)	(mg/L)	(mg/kg)	(ppm)	(mg/L)	(mg/kg)	(ppm)	(mg/L)	(mg/kg)	(ppm)
64-17-5 / 200-578-6	200-578-6	64-17-5												

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Control parameters remark:

8.2 Exposure controls

- 8.2.1 Appropriate engineering controls:
- 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 <u>Environmental exposure controls:</u>

SECTION 9 : PHYSICAL AND CHEMICAL PROPERTIES

9.1 Information on basic physical and chemical properties

<u>Appearance</u>

Appeurunee	
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/boilir	g range (°C)						
Flash point (°C)							
Evaporation rate (kg/m ² /	h)						
Flammability (type :) (%)							
Upper/lower flammability or explosive limits	Upper explosive limit (%)						
innits	Lower explosive limit (%)						
Vapour pressure (kPa)							
Vapour density (g/cm 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 n-octanol/water at pH :	Pow)						
Auto-ignition temperature	re (°C)						
Decomposition temperature (°C) Decomposition energy : kJ							
Viscosity	Viscosity, dynamic (poiseuille)						
	Viscosity, cinematic (cm ³ /s)				1		
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. ;

SECTION 11: TOXICOLOGICAL INFORMATION

Toxicokinetics, metabolism and distribution

11.1 Information on toxicological effects

Substances

• Acute toxicity

<u>Animal data:</u> 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:

In vitro eye test method:

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

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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:

- 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

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 <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:

Assessment / Classification:

12.3 Bioaccumulative potential

Bioconcentration factor (BCF):

12.4 Mobility in soil

12.5 Results of PBT and vPvB assessment

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

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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: Limited quantities for ADR/RID: Packing Instructions for ADR/RID: Mixed packing provisions:	Special Provisions for ADR/RID: Excepted Quantities for ADR/RID: Special packing provisions for ADR/RID:
Portable tanks and bulk containers Instructions: Portable tanks and bulk containers Special Provisio	nc.
ADR Tank Code: Vehicle for tank carriage:	ADR Tank special provisions:
Special provisions for carriage Packages: Special provisions for carriage Bulk:	
Special provisions for carriage for loading, unloadir Special Provisions for carriage Operation:	ng and handling:
Hazard identification No:	Transport category (Tunnel restriction code):
Sea transport (IMDG)Marine Pollutant:Packing provisions for IMDG:Packing instructions for IMDG:IBC Provisions:UN tank instructions:EmS :StowagProperties and observations:	Subsidiary risk(s) for IMDG: Limited quantities for IMDG: IBC Instructions: IMO tank instructions: Tanks and bulk Provisions: re and segregation for IMDG:
Inland waterway transport (ADN) Classification Code ADN: Limited quantities ADN: Carriage permitted: Provisions concerning loading and unloading: Number of blue cones/lights:	Special Provisions ADN: Excepted quantities ADN: Equipment required: Provisions concerning carriage: 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 :Passenger and Cargo Aircraft Maximal Net Quantity :Cargo Aircraft only Packaging Instructions :Passenger and Cargo Aircraft Maximal Net Quantity :Cargo Aircraft only Maximal Net Quantity :Cargo Aircraft only Packaging Instructions :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: 64-17-5 / 200-578-6 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):

Code	Hazard statments
H225	Highly flammable liquid and vapour



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

Designation / Commercial name : HTRF cGMP kit - Std 62GMPCDA 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 cGMP kit - Std 62GMPCDA

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 cGMP kit - Std 62GMPCDA

Substances contained in this product:



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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) >= 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:

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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.;

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 ;

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

<u>Technical measures and storage conditions:</u> <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:

• France



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- Spain
- Germany
- Italia
- Greece
- UK
- OSHA (USA)
- 8.1.2 <u>Biological limit values (Germany):</u>
- 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 <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>

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	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/cm³)							
	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 P n-octanol/water at pH :	ow)						
Auto-ignition temperature	(°C)						
Decomposition temperature (°C) Decomposition energy : kJ							
Viscosity	Viscosity, dynamic (poiseuille)						
	Viscosity, cinematic (cm ³ /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 cGMP kit - Std 62GMPCDA 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 cGMP kit - Std 62GMPCDA 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 (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:

- 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

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

Designation / Commercial name : HTRF cGMP kit - Std 62GMPCDA 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 <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:

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. ;

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

SECTION 14 : TRANSPORT INFORMATION

ADR/RID/AND/IMDG/IATA

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

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 Provi	sions:
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, unloa	ding 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 : Stow	vage 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 :ERG code:Special Provisions for IATA:

SECTION 15 : REGULATORY INFORMATION

15.1 Safety, health and environmental regulations/legislation specific for the substance or mixture <u>EU regulations</u>

• 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):



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

Designation / Commercial name : HTRF Lysis & Detect. Buf. 2 - 105 mL Version: UK, Page 1 of 15, 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 Lysis & Detect. Buf. 2 - 105 mLCAS 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
Acute toxicity - Acute Tox. 4 - H332 - Inhalation	Acute Tox. 4	H332	P261 P271 P304 + P340 P312
Hazardous to the aquatic environment - Aquatic Chronic 3 - H412	Aquatic Chronic 3	H412	P273 P501

2.2 Label elements

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

Product identifier:

Designation / Commercial name : HTRF Lysis & Detect. Buf. 2 - 105 mL

Substances contained in this product:

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

Designation / Commercial name : HTRF Lysis & Detect. Buf. 2 - 105 mL Version: UK, Page 2 of 15, Revision date: 07/09/2023

Substance name	CAS n°	Index n°	EC n°		
potassium fluoride	7789-23-3	009-005-00-2	232-151-5		
Poly(oxy-1,2-ethanediyl), α -[4-(1,1,3,3-tetramethylbutyl)phenyl]- ω -hydroxy-	9002-93-1				

Hazard pictograms GHS07-exclam



Signal word: Warning

Hazard and precautionary statements:

Code	Hazard statments
H332	Harmful if inhaled
H412	Harmful to aquatic life with long lasting effects
P261	Avoid breathing dust/fume/gas/mist/vapours/spray.
P271	Use only outdoors or in a well-ventilated area.
P273	Avoid release to the environment.
P304 + P340	IF INHALED: Remove person to fresh air and keep comfortable for breathing.
P312	Call a POISON CENTRE/doctor/ if you feel unwell.
P501	Dispose of contents/container to

2.3 Other hazards

The mixture contains substances classified as 'Substances of Very High Concern' (SVHC) published by the European CHemicals Agency (ECHA) under article 57 of REACH at levels of 0.1% or higher. This substance or mixture contains no components considered to be either persistent, bioaccumulative and toxic (PBT), or very persistent and very bioaccumulative (vPvB) at levels of 0.1% or higher ;

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	< 10%		
Poly(oxy-1,2-ethanediyl), α-[4-(1,1,3,3- tetramethylbutyl)phenyl]- ω-hydroxy-	9002-93-1			Acute toxicity - Acute Tox. 4 - H302 - Oral Hazardous to the aquatic environment - Aquatic Acute 1 - H400 Hazardous to the aquatic environment - Aquatic Chronic 1 - H410 Serious eye damage/eye irritation - Eye Dam. 1 - H318 Skin corrosion/irritation - Skin Irrit. 2 - H315	< 1%		
potassium dihydrogenorthophosphate	7778-77-0		231-913-4		< 1%		

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:

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

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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.;

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>Technical measures and storage conditions:</u> <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. ;

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SECTION 8 : EXPOSURE CONTROLS/PERSONAL PROTECTION

8.1 Control parameters

Preliminary remark:

8.1.1 Occupational exposure limits:

• France

Source :	Informations rel	ormations relatives à la réglementation VME (France) : ED 984, 07.2012											
Substance	EC-No.	CAS-No	VLE (mg/m3)	VLE (ppm)	VME (mg/m3)	VME (ppm)							
7778-77-0 / 231- 913-4	231-913-4	7778-77-0											
7789-23-3 / 232- 151-5	232-151-5	7789-23-3			2,5								

• Spain

Source :		mites de Exposicion Profesional para Agentes Quimicos en Espana Istituto Nacional de Seguridad e Higiene en el Trabajo Ine 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										
7789-23-3 / 232- 151-5	232-151-5	7789-23-3										

• Germany

Source :	TRGS 900, June 2015, BA			
Substance	EC-No.	CAS-No	AGW (mg/m3)	AGW (ppm)
7778-77-0 / 231-913-4	231-913-4	7778-77-0		
7789-23-3 / 232-151-5	232-151-5	7789-23-3		

- Italia
- Greece

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

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• UK

• OSHA (USA)

Source :	Occupational Safety and Health Administration (OSHA) Permissible Exposure Limits (PELS) from 29 CFR 1910.1000										
Substance	EC-No.			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		7778-77-0									
7789-23-3 / 232-151- 5	232-151-5	7789-23-3									

8.1.2 <u>Biological limit values (Germany):</u>

Source :	List of recommended heal	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										
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)							
7778-77-0 / 231-913-4	231-913-4	7778-77-0									
7789-23-3 / 232-151-5	232-151-5	7789-23-3									

8.1.4 <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)	systemic etterts	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							
7789-23-3 / 232-151-5	232-151-5	7789-23-3				3-3	3-3							

• DNEL consumer



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Source :	GESTIS – s	ubstance da	tabase						
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)	systemic effects
7778-77-0 / 231-913-4	231-913-4	7778-77-0							
7789-23-3 / 232-151-5	232-151-5	7789-23-3							

DNEL remark:

• PNEC

Source :	INERIS																
				PNEC AQUATIC									PNEC Sediment				
Substance E	EC-No.	CAS-No	freshwater		m	arine wat	er	intermittent release		fı	reshwate	er	marine water		ter		
Substance	tance EC-No. C		(mg/L)	(mg/kg)	(ppm)	(mg/L)	(mg/kg)	(ppm)	(mg/L)	(mg/kg)	(ppm)	(mg/L)	(mg/kg)	(ppm)	(mg/L)) (mg/kg) (ppn	(ppm)
7778-77-0 / 231-913- 4	231-913-4	7778-77-0															
7789-23-3 / 232-151- 5	232-151-5	7789-23-3															

Source :	INERIS													
Substance	EC-No.		Others											
		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)
7778-77-0 / 231-913-4	231-913-4	7778-77-0												
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 <u>Personal protective equipment:</u>

Eye / Face protection: Safety glasses with side-shields ; Skin protection:Gloves ; Respiratory protection:Ensure adequate ventilation ; Thermal hazards:

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

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

SECTION 9 : PHYSICAL AND CHEMICAL PROPERTIES

9.1 Information on basic physical and chemical properties

<u>Appearance</u>

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/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)	Vapour density (g/cm 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 Ponticient (log Ponticient) n-octanol/water at pH :	Partition coefficient (log Pow) n-octanol/water at pH :						
Auto-ignition temperature (°C)							
Decomposition temperature (°C) Decomposition energy : kJ							
Viscosity	/iscosity, dynamic (poiseuille)						
	Viscosity, cinematic (cm ³ /s)						
Oxidising properties							
Explosive properties							

9.2 Other information:

No other relevant data available

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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. ;

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			
9002-93-1	1800-1800	Rat			

Acute dermal toxicity:

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

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:

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

Designation / Commercial name : HTRF Lysis & Detect. Buf. 2 - 105 mL Version: UK, Page 10 of 15, Revision date: 07/09/2023

• Skin corrosion/irritation

Animal data:

Substance name	Species	Method	Exposure time	Result/evaluation	Score	Remark
9002-93-1						

In-vitro skin test method: In-vitro skin test result: Assessment / Classification:

• Eye damage/irritation

Animal data:

Substance name	Species	Method	Exposure time	Result/evaluation	Score	Remark
9002-93-1	Rabbit			Eye irritation		

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)
 - STOT SE 1 and 2

Animal data:



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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

Source :	Informatio	ormations relatives à la réglementation VME (France) : ED 984, 07.2012										
Substance	EC-No.	CAS-No	LC50 (mg/L)	EC50 (mg/L)	Test duration	Species	Result/ Evaluation	Method	Remark	General Remark		
9002-93-1		9002-93-1	8,9		96	Pimephales promelas (fathead minnow)						

Chronic (long-term) fish toxicity

Source :	Informations r	formations relatives à la réglementation VME (France) : ED 984, 07.2012								
Substance	EC-No.	EC-No. CAS-No NOEC (mg/L) Test duration Species Method Remark General Remark								
9002-93-1		9002-93-1								

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

Designation / Commercial name : HTRF Lysis & Detect. Buf. 2 - 105 mL Version: UK, Page 12 of 15, Revision date: 07/09/2023

Acute (short-term) toxicity to crustacea

Source :	Information	nformations relatives à la réglementation VME (France) : ED 984, 07.2012								
Substance	EC-No.	CAS-No	EC50 (mg/L)	Test duration	Species	Result/ Evaluation	Method	Remark	General Remark	
9002-93-1		9002-93-1	26	48						

Chronic (long-term) toxicity to crustacea

Source :	Informations r	nformations relatives à la réglementation VME (France) : ED 984, 07.2012								
Substance	EC-No.	EC-No. CAS-No NOEC (mg/L) Test duration Species Method Remark General Remark								
9002-93-1		9002-93-1								

Acute (short-term) toxicity to algae and cyanobacteria

Source :	Informations	Informations relatives à la réglementation VME (France) : ED 984, 07.2012								
Substance	EC-No.	CAS-No	EC50 (mg/L)	Test duration	Species	Result/ Evaluation	Method	Remark	General Remark	
9002-93-1		9002-93-1								

Toxicity to microorganisms and other aquatic plants / organisms

Source :	Informations rela	formations relatives à la réglementation VME (France) : ED 984, 07.2012								
Substance	EC-No.	EC-No. CAS-No EC50 (mg/L) Species Method Remark General Remark								
9002-93-1		9002-93-1								

Assessment / Classification:

12.2 Persistence and degradability

Biodegradation:

Source :	Informations r	formations relatives à la réglementation VME (France) : ED 984, 07.2012								
Substance	EC-No.	CAS-No	Inoculum	Biodegradation parameter	Degradation rate (%)	Method	Remark			
9002-93-1		9002-93-1		BOD (% of COD).	36-36		In accordance with the required stability the product is poorly biodegradable.			

Abiotic Degradation:

Source :								
Substance	EC-No.	CAS-No	Abiotic degradation test type	Half-life time (j)	Temperature (°C)	рН	Method	Remark
9002-93-1		9002-93-1						

Assessment / Classification:

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

Designation / Commercial name : HTRF Lysis & Detect. Buf. 2 - 105 mL Version: UK, Page 13 of 15, Revision date: 07/09/2023

12.3 Bioaccumulative potential

Bioconcentration factor (BCF):

Source :						
Substance	EC-No.	CAS-No	Species	Result	Method	Remark
9002-93-1		9002-93-1				

12.4 Mobility in soil

Source :											
Substance	EC n°	CAS n°	Distribution	Transport	Henry's law constant (Pa.m3/mol)	Log KOC	Half-life time in soil (j)	Half-life time in fresh water (j)	Half-life time in sea water (j)	Method	Remark
9002-93-1		9002- 93-1									

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 Provision	15:
ADR Tank Code:	ADR Tank special provisions:

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

Designation / Commercial name : HTRF Lysis & Detect. Buf. 2 - 105 mL Version: UK, Page 14 of 15, Revision date: 07/09/2023

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):

<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:	
IBC Provisions: UN tank instructions: EmS :	IMO tank instructions: Tanks and bulk Provisions:

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 :Passenger and Cargo Aircraft Maximal Net Quantity :Cargo Aircraft only 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 <u>EU regulations</u>

• Authorisations and/or restrictions on use:

Authorisations: 9002-93-1 Restrictions on use: 7789-23-3 / 232-151-5 SVHC :9002-93-1

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

Not relevant

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

Designation / Commercial name : HTRF Lysis & Detect. Buf. 2 - 105 mL Version: UK, Page 15 of 15, Revision date: 07/09/2023

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):

Code	Hazard statments
H301	Toxic if swallowed
H302	Harmful if swallowed
H311	Toxic in contact with skin
H315	Causes skin irritation
H318	Causes serious eye damage.
H331	Toxic if inhaled
H400	Very toxic to aquatic life
H410	Very toxic to aquatic life with long lasting effects



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

Designation / Commercial name : HTRF cGMP kit - 10K pts d2 reagent 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 cGMP kit - 10K pts d2 reagentCAS 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: 0:00 am to 5:30 pm 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 cGMP kit - 10K pts d2 reagent

Substances contained in this product:



Designation / Commercial name : HTRF cGMP kit - 10K pts d2 reagent 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) >= 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:

Designation / Commercial name : HTRF cGMP kit - 10K pts d2 reagent 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.

<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.;

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 cGMP kit - 10K pts d2 reagent 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

<u>Technical measures and storage conditions:</u> <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:

• France



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- Spain
- Germany
- Italia
- Greece
- UK
- OSHA (USA)
- 8.1.2 <u>Biological limit values (Germany):</u>
- 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 <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>

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	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/cm³)							
	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 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)		1				
Oxidising properties							
Explosive properties							

9.2 Other information:

No other relevant data available



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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 (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:

- 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

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

Designation / Commercial name : HTRF cGMP kit - 10K pts d2 reagent 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 <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:

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 cGMP kit - 10K pts d2 reagent 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. ;

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

SECTION 14 : TRANSPORT INFORMATION

ADR/RID/AND/IMDG/IATA

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

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	ons:
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, unloadi	ng 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:
	ge 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 cGMP kit - 10K pts d2 reagent 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 :Passenger and Cargo Aircraft Maximal Net Quantity :Cargo Aircraft only Packaging Instructions :Passenger and Cargo Aircraft Maximal Net Quantity :Cargo Aircraft only Maximal Net Quantity :Cargo Aircraft only Packaging Instructions :Special Provisions for IATA:

SECTION 15 : REGULATORY INFORMATION

15.1 Safety, health and environmental regulations/legislation specific for the substance or mixture <u>EU regulations</u>

• 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):



Designation / Commercial name : HTRF cGMP kit - 10K pts d2 reagent Version: UK, Page 12 of 12, Revision date: 07/09/2023



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

Designation / Commercial name : HTRF cGMP 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 cGMP kit - 10K pts Eu Cryptate 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 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 cGMP kit - 10K pts Eu Cryptate antibody

Substances contained in this product:



Designation / Commercial name : HTRF cGMP 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) >= 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 cGMP 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.

<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.;

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)

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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 ;

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

<u>Technical measures and storage conditions:</u> <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:

• France

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- Spain
- Germany
- Italia
- Greece
- UK
- OSHA (USA)
- 8.1.2 <u>Biological limit values (Germany):</u>
- 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 <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>

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	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)							
	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 Pow) n-octanol/water at pH :							
Auto-ignition temperature	(°C)						
Decomposition temperature (°C) Decomposition energy : kJ							
Viscosity	/iscosity, dynamic (poiseuille)						
	Viscosity, cinematic (cm ³ /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 (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:

- 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

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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:

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. ;

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

SECTION 14 : TRANSPORT INFORMATION

ADR/RID/AND/IMDG/IATA

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

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):
<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 : Stowa	ge 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 :Passenger and Cargo Aircraft Maximal Net Quantity :Cargo Aircraft only Packaging Instructions :Passenger and Cargo Aircraft Maximal Net Quantity :Cargo Aircraft only Maximal Net Quantity :Cargo Aircraft only Packaging Instructions :Special Provisions for IATA:

SECTION 15 : REGULATORY INFORMATION

15.1 Safety, health and environmental regulations/legislation specific for the substance or mixture <u>EU regulations</u>

• 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):



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