

Trade name: HTRF CD16a(FcgRIIIa,F158) - 5 x 6FR3APAG / 6FR3APAE

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 Tag-lite Buffer (5X) - 1.5 mL		5	7	Colorless	Liquid
CD16A (F158 prelabelled cells)		5	-	Colorless	Liquid
HTRF IgG d2 conjugate CD16A F158 - 100 pts		5	7	Blue	Liquid





Designation / Commercial name: HTRF Tag-lite Buffer (5X) - 1.5 mL

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 Tag-lite Buffer (5X) - 1.5 mL

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

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

Relevant identified uses: Use of the substance or mixture for Laboratory Research use only; Uses advised against: Do not use for diagnostics, therapeutics or other clinical uses.;

1.3 Details of the supplier of the safety data sheet:

Supplier:

Name: CISBIO BIOASSAYS, company of Revvity Group - CBBIOA - Address: Parc Marcel Boiteux - BP 84175 - 30200 Codolet, France

Phone: +33 4 66 79 67 05 - Fax: +33 4 66 79 67 50 E-Mail (competent person): codolet.sds@revvity.com

1.4 EMERGENCY TELEPHONE NUMBER:

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

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

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

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

https://www.cisbio.com https://www.revvity.com

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

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

SECTION 2: HAZARDS IDENTIFICATION

2.1 Classification of the substance or mixture:

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

2.2 Label elements

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

Product identifier:

Designation / Commercial name : HTRF Tag-lite Buffer (5X) - 1.5 mL

Substances contained in this product:



Designation / Commercial name : HTRF Tag-lite Buffer (5X) - 1.5 mL

Version: UK, Page 2 of 13, 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 Tag-lite Buffer (5X) - 1.5 mL

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

SECTION 3: COMPOSITION/INFORMATION ON INGREDIENTS

3.2 Mixtures

Hazardous ingredients:

Substance name	CAS n°	Index n°	EC n°	Classification according Regulation (EC) No. 1272 [CLP]	Concentration (%)	SCL	M-factor
sodium chloride	7647-14-5		231-598-3		< 10%		
4-(2- hydroxyethyl)piperazin- 1-ylethanesulphonic acid	7365-45-9		230-907-9		< 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.;



Designation / Commercial name: HTRF Tag-lite Buffer (5X) - 1.5 mL

Version: UK, Page 4 of 13, 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

Protective measures:

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

Fire preventions:

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

Advice on general occupational hygiene

Handle in accordance with good industrial hygiene and safety practice;

7.2 Conditions for safe storage, including any incompatibilities

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

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

Hints on storage assembly:

Materials to avoid:

Further information on storage conditions:

7.3 Specific end uses:

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

SECTION 8: EXPOSURE CONTROLS/PERSONAL PROTECTION

8.1 Control parameters

Preliminary remark:

8.1.1 Occupational exposure limits:

France

Source : Informations relatives à la réglementation VME (France) : ED 984, 07.2012



Designation / Commercial name : HTRF Tag-lite Buffer (5X) - 1.5 mL

Version: UK, Page 5 of 13, Revision date: 07/09/2023

						v
Substance	EC-No.	CAS-No	VLE (mg/m3)	VLE (ppm)	VME (mg/m3)	VME (ppm)
7365-45-9 / 230- 907-9	230-907-9	7365-45-9				
7647-14-5 / 231- 598-3	231-598-3	7647-14-5				

Spain

		mites de Exposicion Profesional para Agentes Quimicos en Espana stituto Nacional de Seguridad e Higiene en el Trabajo ine 2015								
Substance	EC-No.	EC-No. CAS-No VLA-EC (mg/m3) VLA-EC (ppm) VLA-ED (mg/m3) VLA-ED (ppm)								
7365-45-9 / 230- 907-9	230-907-9	7365-45-9								
7647-14-5 / 231- 598-3	231-598-3	1-598-3 7647-14-5								

Germany

Source :	TRGS 900, June 2015, BAuA							
Substance	EC-No.	CAS-No	AGW (mg/m3)	AGW (ppm)				
7365-45-9 / 230-907-9	230-907-9	7365-45-9						
7647-14-5 / 231-598-3	231-598-3	7647-14-5						

- Italia
- Greece
- UK
- OSHA (USA)

9	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 / Commercial name : $\,$ HTRF Tag-lite Buffer (5X) - 1.5 mL

Version: UK, Page 6 of 13, Revision date: 07/09/2023

7365-45-9 / 230-907- 9	230-907-9	7365-45-9		V
7647-14-5 / 231-598- 3	231-598-3	7647-14-5		

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

Source :	List of recommended health-based biological limit values (BLVs) and biological guidance values (BGVs), June 2014							
Substance	EC-No.	CAS-No	BLV (mg/m3)	BLV (ppm)				
7365-45-9 / 230-907-9	230-907-9	7365-45-9						
7647-14-5 / 231-598-3	231-598-3	7647-14-5						

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)			
7365-45-9 / 230-907-9	230-907-9	7365-45-9					
7647-14-5 / 231-598-3	231-598-3	7647-14-5					

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 ettects	Acute – inhalation, local effects (mg/m3)	cyctemic ettects	Long-term – inhalation, local effects (mg/m3)	systemic ettects		
7365-45-9 / 230-907-9	230-907-9	7365-45-9					23.5-23.5				
7647-14-5 / 231-598-3	231-598-3	7647-14-5					2068.62- 2068.62				

DNEL consumer

Source :	GESTIS – si	STIS – substance database								
Substance	EC-No.	CAS-No	Acute – dermal, local effects (mg/kg/day)	dermal, local	systemic effects	Acute – inhalation, local effects (mg/m3)	systemic ettects	Long-term – inhalation, local effects (mg/m3)	systemic ettects	
7365-45-9 / 230-907-9	230-907-9	7365-45-9								
7647-14-5 / 231-598-3	231-598-3	7647-14-5								



Designation / Commercial name : HTRF Tag-lite Buffer (5X) - 1.5 mL

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

DNEL remark:

PNEC

Source :	INERIS																
				PNEC AQUATIC								P	NEC Se	edimen	t		
Substance	EC-No.	CAS-No	freshwater		m	arine wat	ter	interr	nittent re	lease	fı	reshwate	er	ma	arine wat	ter	
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)	
7365-45-9 / 230-907- 9	230-907-9	7365-45-9															
7647-14-5 / 231-598- 3	231-598-3	7647-14-5															

Source :	INERIS	NERIS												
			Others											
Substance EC-No.		CAS-No	PNEC soil		PNEC s	NEC 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)
7365-45-9 / 230-907-9	230-907-9	7365-45-9												
7647-14-5 / 231-598-3	231-598-3	7647-14-5												

PNEC remark:

Control parameters remark:

8.2 Exposure controls

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

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>

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



Designation / Commercial name : HTRF Tag-lite Buffer (5X) - 1.5 mL

Version: UK, Page 8 of 13, Revision date: 07/09/2023

		Value	Concentration (mol/L)	Method	Temperature (°C)	Pressure (kPa)	Remark
pH		7,4					
Melting point (°C)							
Freezing point (°C)							
Initial boiling point/boil	ng range (°C)						
Flash point (°C)							
Evaporation rate (kg/m ²	?/h)						
Flammability (type :) (%	5)						
Upper/lower flammability or explosiv limits	Upper explosive limit (%)						
IIIIIICS	Lower explosive limit (%)						
Vapour pressure (kPa)							
Vapour density (g/cm³)							
	Density (g/cm³)						
Densities	Relative density (g/cm³)						
	Bulk density (g/cm³)						
Solubility (Type:) (g/L	Critical density (g/cm³)						
Partition coefficient (log n-octanol/water at pH :							
Auto-ignition temperati	ıre (°C)						
Decomposition tempera Decomposition energy :							
Viscosity	Viscosity, dynamic (poiseuille)						
	Viscosity, cinematic (cm ³ /s)						
Oxidising properties							
Explosive properties							

9.2 Other information:

No other relevant data available

SECTION 10: STABILITY AND REACTIVITY

- 10.1 Reactivity This material is considered to be non-reactive under normal use conditions.;
- 10.2 Chemical stability
- 10.3 Possibility of hazardous reactions
- 10.4 Conditions to avoid:
- 10.5 Incompatible materials:

10.6 Hazardous decomposition products:

Does not decompose when used for intended uses.;

SECTION 11: TOXICOLOGICAL INFORMATION

Toxicokinetics, metabolism and distribution

11.1 Information on toxicological effects



Designation / Commercial name : HTRF Tag-lite Buffer (5X) - 1.5 mL

Version: UK, Page 9 of 13, Revision date: 07/09/2023

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:

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

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

Animal data:

Assessment / Classification:

Carcinogenicity

Practical experience / human evidence:

Animal data:

Other information:

Assessment / Classification:

Reproductive toxicity

Practical experience / human evidence:



Designation / Commercial name: HTRF Tag-lite Buffer (5X) - 1.5 mL

Version: UK, Page 10 of 13, Revision date: 07/09/2023

Animal data:

Other information:

Assessment / Classification:

Overall assessment on CMR properties:

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

Animal data:

Other information:

STOT SE 3

Practical experience / human evidence:

Other information:

Assessment / Classification:

• Specific target organ toxicity (repeated exposure)

Practical experience / human evidence:

Animal data:

Assessment / Classification:

Other information

Aspiration hazard

Practical experience / human evidence:

Experimental data: viscosity data: see SECTION 9.

Assessment / Classification:

Remark:

11.1.1 Mixtures

No toxicological information is available for the mixture itself

SECTION 12: ECOLOGICAL INFORMATION

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

12.1 Aquatic toxicity:

Acute (short-term) fish toxicity

Chronic (long-term) fish toxicity



Designation / Commercial name : HTRF Tag-lite Buffer (5X) - 1.5 mL

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

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:

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

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



Designation / Commercial name: HTRF Tag-lite Buffer (5X) - 1.5 mL

Version: UK, Page 12 of 13, Revision date: 07/09/2023

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: Excepted Quantities for ADR/RID: Packing Instructions for ADR/RID: Special packing provisions for ADR/RID:

Mixed packing provisions:

Portable tanks and bulk containers Instructions: Portable tanks and bulk containers Special Provisions:

ADR Tank Code: ADR Tank special provisions:

Vehicle for tank carriage:

Special provisions for carriage Packages: Special provisions for carriage Bulk:

Special provisions for carriage for loading, unloading and handling:

Special Provisions for carriage Operation:

Hazard identification No: Transport category (Tunnel restriction code):

Sea transport (IMDG)

Marine Pollutant: Subsidiary risk(s) for IMDG: Packing provisions for IMDG: Limited quantities for IMDG:

Packing instructions for IMDG: IBC Instructions:

IBC Provisions: IMO tank instructions:

UN tank instructions: Tanks and bulk Provisions:

EmS: Stowage and segregation for IMDG:

Properties and observations:

Inland waterway transport (ADN)

Classification Code ADN: Special Provisions ADN:
Limited quantities ADN: Excepted quantities ADN:
Carriage permitted: Equipment required:

Provisions concerning loading and unloading: Provisions concerning carriage:

Number of blue cones/lights: Remark:

Air transport (ICAO-TI / IATA-DGR)

Subsidiary risk for IATA: Excepted quantity for IATA:

Passenger and Cargo Aircraft Limited Quantities Packing Instructions: Passenger and Cargo Aircraft Limited Quantities Maximal Net Quantity:

Passenger and Cargo Aircraft Packaging Instructions: Passenger and Cargo Aircraft Maximal Net Quantity:

Cargo Aircraft only Packaging Instructions: Cargo Aircraft only Maximal Net Quantity:

ERG code: Special Provisions for IATA:

SECTION 15: REGULATORY INFORMATION

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

EU regulations

Authorisations and/or restrictions on use:

Authorisations:

Restrictions on use:

SVHC:



Designation / Commercial name : HTRF Tag-lite Buffer (5X) - 1.5 mL

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

- 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: CD16A (F158 prelabelled cells)

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 : CD16A (F158 prelabelled cells)

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 : CD16A (F158 prelabelled cells)

Substances contained in this product:



Designation / Commercial name: CD16A (F158 prelabelled cells)

Version: UK, Page 2 of 13, 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: CD16A (F158 prelabelled cells)

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

SECTION 3: COMPOSITION/INFORMATION ON INGREDIENTS

3.2 Mixtures

Hazardous ingredients:

Substance name	CAS n°	Index n°	EC n°	Classification according Regulation (EC) No. 1272 [CLP]	Concentration (%)	SCL	M-factor
dimethyl sulfoxide	67-68-5		200-664-3		≤ 100%		

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.;



Designation / Commercial name: CD16A (F158 prelabelled cells)

Version: UK, Page 4 of 13, 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

Protective measures:

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

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

Advice on general occupational hygiene

Handle in accordance with good industrial hygiene and safety practice;

7.2 Conditions for safe storage, including any incompatibilities

Technical measures and storage conditions:

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

Hints on storage assembly:

Materials to avoid:

Further information on storage conditions:

7.3 Specific end uses:

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

SECTION 8: EXPOSURE CONTROLS/PERSONAL PROTECTION

8.1 Control parameters

Preliminary remark:

8.1.1 Occupational exposure limits:

France

Source :	Informations rela	formations 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)				
67-68-5 / 200-664- 3	200-664-3	67-68-5								



Designation / Commercial name : CD16A (F158 prelabelled cells)

Version: UK, Page 5 of 13, Revision date: 07/09/2023

Source :	•	imites de Exposicion Profesional para Agentes Quimicos en Espana nstituto Nacional de Seguridad e Higiene en el Trabajo une 2015								
Substance	EC-No.	CAS-No	VLA-EC (mg/m3)	VLA-EC (ppm)	VLA-ED (mg/m3)	VLA-ED (ppm)				
67-68-5 / 200-664- 3	200-664-3	67-68-5								

Germany

Source :	TRGS 900, June 2015, BAuA							
Substance	EC-No.	CAS-No	AGW (mg/m3)	AGW (ppm)				
67-68-5 / 200-664-3	200-664-3	67-68-5	320	100				

- Italia
- Greece
- UK
- OSHA (USA)

Source :	Occupational Safety and Health Administration (OSHA) Permissible Exposure Limits (PELS) from 29 CFR 1910.1000							
Substance	EC-No.	CAS-No	OSHA Permissible Exposure Limit (PEL) 8-hour TWA (ppm)	OSHA Permissible Exposure Limit (PEL) 8- hour TWA (mg/m3)	OSHA Permissible Exposure Limit (PEL) STEL (ppm)	OSHA Permissible Exposure Limit (PEL) STEL (mg/m3)		
67-68-5 / 200-664-3	200-664-3	67-68-5						

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

Source : List of recommended health-based biological limit values (BLVs) and biological guidance values (BGVs), Ju						
Substance	EC-No.	CAS-No	BLV (mg/m3)	BLV (ppm)		
67-68-5 / 200-664-3	200-664-3	67-68-5				

8.1.3 Exposure limits at intended use (Germany):



Designation / Commercial name : CD16A (F158 prelabelled cells)

Version: UK, Page 6 of 13, Revision date: 07/09/2023

Source :	TRGS 903, November 2015, BAuA								
Substance	EC-No.	CAS-No	BGW (mg/m3)	BGW (ppm)					
67-68-5 / 200-664-3	200-664-3	67-68-5							

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

• DNEL worker

Source :	GESTIS – su	GESTIS – substance database											
Substance	EC-No.	CAS-No	Acute – dermal, local effects (mg/kg/day)	Long-term – dermal, local effects (mg/kg/day)	Isystemic effects	Acute – inhalation, local effects (mg/m3)	systemic effects	Long-term – inhalation, local effects (mg/m3)	systemic effects				
67-68-5 / 200-664-3	200-664-3	67-68-5				265-265	484-484						

DNEL consumer

Source :	GESTIS – sı	ESTIS – substance database											
Substance	EC-No.	CAS-No	Acute – dermal, local effects (mg/kg/day)	dermal, local	systemic effects	Acute – inhalation, local effects (mg/m3)	systemic effects	Long-term – inhalation, local effects (mg/m3)	systemic effects				
67-68-5 / 200-664-3	200-664-3	67-68-5											

DNEL remark:

PNEC

Source :	INERIS																
				PNEC AQUATIC							PNEC Sediment						
Substance	EC-No.	CAS-No	1	reshwate	r	ma	arine wat	er	interr	mittent re	lease	fı	reshwate	er	ma	rine wat	er
Substance	EC-NO.	CAS-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)
67-68-5 / 200-664-3	200-664-3	67-68-5															

Source :	INERIS													
				Others										
Substance	EC-No.	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)
67-68-5 / 200-664-3	200-664-3	67-68-5												



Designation / Commercial name: CD16A (F158 prelabelled cells)

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

Control parameters remark:

8.2 Exposure controls

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

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

Appearance

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

		Value	Concentration	Method	Temperature (°C)	Pressure (kPa)	Remark
		value	(mol/L)	ivietilou	remperature (C)	riessure (kra)	Remark
pH			(, -)				
Melting point (°C)							
Freezing point (°C)							
Initial boiling point/boilir	itial boiling point/boiling range (°C)						
Flash point (°C)	lash point (°C)						
Evaporation rate (kg/m²/	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/cm³)							
	Density (g/cm³)						
Densities	Relative density (g/cm³)						
	Bulk density (g/cm³)						
	Critical density (g/cm³)						
Solubility (Type:) (g/L)							
Partition coefficient (log n-octanol/water at pH:	Pow)						
Auto-ignition temperatur	e (°C)						
Decomposition temperature (°C) Decomposition energy : kJ							
Viscosity	Viscosity, dynamic (poiseuille)						
	Viscosity, cinematic (cm ³ /s)						
Oxidising properties							
Explosive properties	<u> </u>						

9.2 Other information:

No other relevant data available



Designation / Commercial name: CD16A (F158 prelabelled cells)

Version: UK, Page 8 of 13, 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.;

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:

In-vitro skin test method: In-vitro skin test result:

Assessment / Classification:

Eye damage/irritation

Animal data:

In vitro eye test method:



Designation / Commercial name : CD16A (F158 prelabelled cells)

Version: UK, Page 9 of 13, Revision date: 07/09/2023

In vitro eye test result: Assessment / Classification:

- CMR effects (carcinogenity, mutagenicity and toxicity for reproduction)
 - o 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)
 - o 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



Designation / Commercial name: CD16A (F158 prelabelled cells)

Version: UK, Page 10 of 13, Revision date: 07/09/2023

Practical experience / human evidence:

Experimental data: viscosity data: see SECTION 9.

Assessment / Classification:

Remark:

11.1.1 Mixtures

No toxicological information is available for the mixture itself

SECTION 12: ECOLOGICAL INFORMATION

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

12.1 Aquatic toxicity:

Acute (short-term) fish toxicity

Chronic (long-term) fish toxicity

Acute (short-term) toxicity to crustacea

Chronic (long-term) toxicity to crustacea

Acute (short-term) toxicity to algae and cyanobacteria

Toxicity to microorganisms and other aquatic plants / organisms

Assessment / Classification:

12.2 Persistence and degradability

Biodegradation:

Abiotic Degradation:

Assessment / Classification:

12.3 Bioaccumulative potential

Bioconcentration factor (BCF):

12.4 Mobility in soil

12.5 Results of PBT and vPvB assessment



Designation / Commercial name: CD16A (F158 prelabelled cells)

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

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: Excepted Quantities for ADR/RID: Packing Instructions for ADR/RID: Special packing provisions for ADR/RID:

Mixed packing provisions:

Portable tanks and bulk containers Instructions: Portable tanks and bulk containers Special Provisions:

ADR Tank Code: ADR Tank special provisions:

Vehicle for tank carriage:

Special provisions for carriage Packages: Special provisions for carriage Bulk:

Special provisions for carriage for loading, unloading and handling:

Special Provisions for carriage Operation:

Hazard identification No: Transport category (Tunnel restriction code):

Sea transport (IMDG)

Marine Pollutant: Subsidiary risk(s) for IMDG: Packing provisions for IMDG: Limited quantities for IMDG:

Packing instructions for IMDG: IBC Instructions:

IBC Provisions: IMO tank instructions:

UN tank instructions: Tanks and bulk Provisions:

EmS: Stowage and segregation for IMDG:

Properties and observations:

Inland waterway transport (ADN)

Classification Code ADN: Special Provisions ADN:
Limited quantities ADN: Excepted quantities ADN:
Carriage permitted: Equipment required:

Provisions concerning loading and unloading: Provisions concerning carriage:

Number of blue cones/lights: Remark:



Designation / Commercial name: CD16A (F158 prelabelled cells)

Version: UK, Page 12 of 13, Revision date: 07/09/2023

Air transport (ICAO-TI / IATA-DGR)

Subsidiary risk for IATA: Excepted quantity for IATA:

Passenger and Cargo Aircraft Limited Quantities Packing Instructions:

Passenger and Cargo Aircraft Limited Quantities Maximal Net Quantity:

Passenger and Cargo Aircraft Packaging Instructions: Passenger and Cargo Aircraft Maximal Net Quantity:

Cargo Aircraft only Packaging Instructions : Cargo Aircraft only Maximal Net Quantity :

ERG code: Special Provisions for IATA:

SECTION 15: REGULATORY INFORMATION

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

EU regulations

• Authorisations and/or restrictions on use:

Authorisations:

Restrictions on use:

SVHC:

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

Not relevant

National regulations

15.2 Chemical Safety Assessment:

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

SECTION 16: OTHER INFORMATION

16.1 Indication of changes

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

16.2 Other informations

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

See SECTION 2.1 (classification).

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





Designation / Commercial name : CD16A (F158 prelabelled cells)

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





Designation / Commercial name: HTRF IgG d2 conjugate CD16A F158 - 100 pts

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 IgG d2 conjugate CD16A F158 - 100 pts

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 IgG d2 conjugate CD16A F158 - 100 pts

Substances contained in this product:



Designation / Commercial name : HTRF IgG d2 conjugate CD16A F158 - 100 pts

Version: UK, Page 2 of 13, 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 IgG d2 conjugate CD16A F158 - 100 pts

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

SECTION 3: COMPOSITION/INFORMATION ON INGREDIENTS

3.2 Mixtures

Hazardous ingredients:

Substance name	CAS n°	Index n°	EC n°	Classification according Regulation (EC) No. 1272 [CLP]	Concentration (%)	SCL	M-factor
sodium chloride	7647-14-5		231-598-3		< 10%		
4-(2- hydroxyethyl)piperazin- 1-ylethanesulphonic acid	7365-45-9		230-907-9		< 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.;



Designation / Commercial name: HTRF IgG d2 conjugate CD16A F158 - 100 pts

Version: UK, Page 4 of 13, 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

Protective measures:

 $\label{prop:advice} \mbox{Advice on safe handling:} \mbox{Avoid contact with skin, eyes and clothes.} \; ;$

Fire preventions:

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

Advice on general occupational hygiene

Handle in accordance with good industrial hygiene and safety practice;

7.2 Conditions for safe storage, including any incompatibilities

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

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

Hints on storage assembly:

Materials to avoid:

Further information on storage conditions:

7.3 Specific end uses:

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

SECTION 8: EXPOSURE CONTROLS/PERSONAL PROTECTION

8.1 Control parameters

Preliminary remark:

8.1.1 Occupational exposure limits:

France

Source : Informations relatives à la réglementation VME (France) : ED 984, 07.2012



Designation / Commercial name : HTRF IgG d2 conjugate CD16A F158 - 100 pts

Version: UK, Page 5 of 13, Revision date: 07/09/2023

						v
Substance	EC-No.	CAS-No	VLE (mg/m3)	VLE (ppm)	VME (mg/m3)	VME (ppm)
7365-45-9 / 230- 907-9	230-907-9	7365-45-9				
7647-14-5 / 231- 598-3	231-598-3	7647-14-5				

Spain

Source :	Limites de Exposicion Profesional para Agentes Quimicos en Espana Instituto Nacional de Seguridad e Higiene en el Trabajo June 2015										
Substance	EC-No.	CAS-No	VLA-EC (mg/m3)	VLA-EC (ppm)	VLA-ED (mg/m3)	VLA-ED (ppm)					
7365-45-9 / 230- 907-9	230-907-9	7365-45-9									
7647-14-5 / 231- 598-3	231-598-3	7647-14-5									

Germany

Source :	TRGS 900, June 2015, BA	GS 900, June 2015, BAuA								
Substance	EC-No.	CAS-No	AGW (mg/m3)	AGW (ppm)						
7365-45-9 / 230-907-9	230-907-9	7365-45-9								
7647-14-5 / 231-598-3	231-598-3	7647-14-5								

- 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)					



Designation / Commercial name : HTRF IgG d2 conjugate CD16A F158 - 100 pts

Version: UK, Page 6 of 13, Revision date: 07/09/2023

7365-45-9 / 230-907- 9	230-907-9	7365-45-9		V
7647-14-5 / 231-598- 3	231-598-3	7647-14-5		

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

Source :	List of recommended heal	lth-based biological limit val	ues (BLVs) and biological guidance va	lues (BGVs), June 2014
Substance	EC-No.	CAS-No	BLV (mg/m3)	BLV (ppm)
7365-45-9 / 230-907-9	230-907-9	7365-45-9		
7647-14-5 / 231-598-3	231-598-3	7647-14-5		

8.1.3 Exposure limits at intended use (Germany):

Source :	TRGS 903, November 201	GS 903, November 2015, BAuA							
Substance	EC-No.	CAS-No	BGW (mg/m3)	BGW (ppm)					
7365-45-9 / 230-907-9	230-907-9	7365-45-9							
7647-14-5 / 231-598-3	231-598-3	7647-14-5							

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 ettects	Acute – inhalation, local effects (mg/m3)	systemic ettects	Long-term – inhalation, local effects (mg/m3)	systemic ettects		
7365-45-9 / 230-907-9	230-907-9	7365-45-9					23.5-23.5				
7647-14-5 / 231-598-3	231-598-3	7647-14-5					2068.62- 2068.62				

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)	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 ettects
7365-45-9 / 230-907-9	230-907-9	7365-45-9							
7647-14-5 / 231-598-3	231-598-3	7647-14-5							



Designation / Commercial name : HTRF IgG d2 conjugate CD16A F158 - 100 pts

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

DNEL remark:

PNEC

Source :	INERIS																
						PNI	EC AQUA	TIC					PNEC Sediment				
Substance	EC-No.	CAS-No	freshwater		m	arine wat	er	interr	intermittent release		fı	reshwate	er	ma	arine wat	ter	
Substance	EC-NO.	CAS-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)
7365-45-9 / 230-907- 9	230-907-9	7365-45-9															
7647-14-5 / 231-598- 3	231-598-3	7647-14-5															

Source :	INERIS													
								Oth	ers					
Substance	EC-No.	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)
7365-45-9 / 230-907-9	230-907-9	7365-45-9												
7647-14-5 / 231-598-3	231-598-3	7647-14-5												

PNEC remark:

Control parameters remark:

8.2 Exposure controls

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

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

Appearance

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



Designation / Commercial name : HTRF IgG d2 conjugate CD16A F158 - 100 pts

Version: UK, Page 8 of 13, Revision date: 07/09/2023

		Value	Concentration (mol/L)	Method	Temperature (°C)	Pressure (kPa)	Remark
рН		7					
Melting point (°C)							
Freezing point (°C)							
Initial boiling point/boili	ng range (°C)						
Flash point (°C)							
Evaporation rate (kg/m ²	/h)						
Flammability (type :) (%)						
Upper/lower flammability or explosiv limits	Upper explosive limit e (%)						
	Lower explosive limit (%)						
Vapour pressure (kPa)							
Vapour density (g/cm³)							
	Density (g/cm³)						
Densities	Relative density (g/cm³)						
	Bulk density (g/cm³)						
C 1 1:1: (T) ((1)	Critical density (g/cm³)						
Solubility (Type:) (g/L)							
Partition coefficient (log n-octanol/water at pH :	Pow)						
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

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



Designation / Commercial name : HTRF IgG d2 conjugate CD16A F158 - 100 pts

Version: UK, Page 9 of 13, Revision date: 07/09/2023

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:

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

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

Animal data:

Assessment / Classification:

Carcinogenicity

Practical experience / human evidence:

Animal data:

Other information:

Assessment / Classification:

o Reproductive toxicity

Practical experience / human evidence:



Designation / Commercial name : HTRF IgG d2 conjugate CD16A F158 - 100 pts

Version: UK, Page 10 of 13, Revision date: 07/09/2023

Animal data:

Other information:

Assessment / Classification:

Overall assessment on CMR properties:

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

Animal data:

Other information:

STOT SE 3

Practical experience / human evidence:

Other information:

Assessment / Classification:

• Specific target organ toxicity (repeated exposure)

Practical experience / human evidence:

Animal data:

Assessment / Classification:

Other information

Aspiration hazard

Practical experience / human evidence:

Experimental data: viscosity data: see SECTION 9.

Assessment / Classification:

Remark:

11.1.1 Mixtures

No toxicological information is available for the mixture itself

SECTION 12: ECOLOGICAL INFORMATION

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

12.1 Aquatic toxicity:

Acute (short-term) fish toxicity

Chronic (long-term) fish toxicity



Designation / Commercial name : HTRF IgG d2 conjugate CD16A F158 - 100 pts

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

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:

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	



Designation / Commercial name : HTRF IgG d2 conjugate CD16A F158 - 100 pts

Version: UK, Page 12 of 13, Revision date: 07/09/2023

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: Excepted Quantities for ADR/RID: Packing Instructions for ADR/RID: Special packing provisions for ADR/RID:

Mixed packing provisions:

Portable tanks and bulk containers Instructions: Portable tanks and bulk containers Special Provisions:

ADR Tank Code: ADR Tank special provisions:

Vehicle for tank carriage:

Special provisions for carriage Packages: Special provisions for carriage Bulk:

Special provisions for carriage for loading, unloading and handling:

Special Provisions for carriage Operation:

Hazard identification No: Transport category (Tunnel restriction code):

Sea transport (IMDG)

Marine Pollutant: Subsidiary risk(s) for IMDG: Packing provisions for IMDG: Limited quantities for IMDG:

Packing instructions for IMDG: IBC Instructions:
IBC Provisions: IMO tank instructions:
UN tank instructions: Tanks and bulk Provisions:
EmS: Stowage and segregation for IMDG:

Properties and observations:

Inland waterway transport (ADN)

Classification Code ADN: Special Provisions ADN:
Limited quantities ADN: Excepted quantities ADN:
Carriage permitted: Equipment required:

Provisions concerning loading and unloading: Provisions concerning carriage:

Number of blue cones/lights: Remark:

Air transport (ICAO-TI / IATA-DGR)

Subsidiary risk for IATA: Excepted quantity for IATA:

Passenger and Cargo Aircraft Limited Quantities Packing Instructions: Passenger and Cargo Aircraft Limited Quantities Maximal Net Quantity:

Passenger and Cargo Aircraft Packaging Instructions: Passenger and Cargo Aircraft Maximal Net Quantity:

Cargo Aircraft only Packaging Instructions : Cargo Aircraft only Maximal Net Quantity :

ERG code: Special Provisions for IATA:

SECTION 15: REGULATORY INFORMATION

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

EU regulations

• Authorisations and/or restrictions on use:

Authorisations:

Restrictions on use:

SVHC:



Designation / Commercial name : HTRF IgG d2 conjugate CD16A F158 - 100 pts

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

- 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):

