

Safety Data Sheet

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

Designation / Commercial name : Utrophin kit - control lysate 63ADK107TDA
Version: UK, Page 2 of 14, Revision date: 09/07/2021



Hazard pictograms

Signal word:

Hazard and precautionary statements:

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:

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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
4-(2-hydroxyethyl)piperazin-1-ylethanesulphonic acid	7365-45-9		230-907-9		< 3%		
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 Chronic 2 - H411 Serious eye damage/eye irritation - Eye Dam. 1 - H318 Skin corrosion/irritation - Skin Irrit. 2 - H315	< 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: /

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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

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:

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8.1.1 Occupational exposure limits:

- France

Source :	Informations 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)
7365-45-9 / 230-907-9	230-907-9	7365-45-9				

- 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				

- 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			

- 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)
7365-45-9 / 230-907-9	230-907-9	7365-45-9				

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Source :	INERIS													
Substance	EC-No.	CAS-No	Others											
			PNEC soil			PNEC sewage treatment plant			PNEC air			PNEC secondary poisoning		
			(mg/L)	(mg/kg)	(ppm)	(mg/L)	(mg/kg)	(ppm)	(mg/L)	(mg/kg)	(ppm)	(mg/L)	(mg/kg)	(ppm)
7365-45-9 / 230-907-9	230-907-9	7365-45-9												

PNEC remark:

Control parameters remark:

8.2 Exposure controls

8.2.1 Appropriate engineering controls:

8.2.2 Personal protective equipment:

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

Skin protection: Gloves ;

Respiratory protection: Ensure adequate ventilation ;

Thermal hazards:

8.2.3 Environmental exposure controls:

Section 9 : Physical and chemical properties

9.1 Information on basic physical and chemical properties

Appearance

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

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

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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

Substances

- **Acute toxicity**

Animal data:

Acute oral toxicity:

Substance name	LD50 (mg/kg)	Species	Method	Symptoms / delayed effects	Remark
9002-93-1	1800-1800	Rat			

Acute dermal toxicity:

Acute inhalative toxicity:

Practical experience / human evidence:

Assessment / Classification:

General Remark:

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- **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 (carcinogenicity, mutagenicity and toxicity for reproduction)**

- Germ cell mutagenicity:

Animal data:

Assessment / Classification:

- Carcinogenicity

Practical experience / human evidence:

Animal data:

Other information:

Assessment / Classification:

- Reproductive toxicity

Practical experience / human evidence:

Animal data:

Other information:

Assessment / Classification:

Overall assessment on CMR properties:

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

- STOT SE 1 and 2

Animal data:

Other information:

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- 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

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

Source :	Informations relatives à la réglementation VME (France) : ED 984, 07.2012								
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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 relatives à la réglementation VME (France) : ED 984, 07.2012							
Substance	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 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 relatives à la réglementation VME (France) : ED 984, 07.2012							
Substance	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 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)	pH	Method	Remark
9002-93-1		9002-93-1						

Assessment / Classification:

12.3 Bioaccumulative potential

Bioconcentration factor (BCF):

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

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12.4 Mobility in soil

Substance	EC n°	CAS n°	Distribution	Transport type	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:

Limited quantities for ADR/RID:

Packing Instructions for ADR/RID:

Mixed packing provisions:

Portable tanks and bulk containers Instructions:

Portable tanks and bulk containers Special Provisions:

ADR Tank Code:

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:

Special Provisions for ADR/RID:

Excepted Quantities for ADR/RID:

Special packing provisions for ADR/RID:

ADR Tank special provisions:

Transport category (Tunnel restriction code):

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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: 9002-93-1

Restrictions on use:

SVHC :9002-93-1

- 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

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Section 16 : Other information

16.1 Indication of changes

Date of the previous version:
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
H302	Harmful if swallowed
H315	Causes skin irritation
H318	Causes serious eye damage.
H411	Toxic to aquatic life with long lasting effects