

Section 1: Identification of the substance/mixture and of the company/undertaking**1.1. Product identifier****Product name:** PATHOZYME ULTRASENSITIVE TSH**Product code:** OD447**1.2. Relevant identified uses of the substance or mixture and uses advised against**

Use of substance / mixture: This product is intended for IN VITRO diagnostic use only. NOT FOR USE IN HUMANS. Only blood from donors proven to have no antibodies against HIV I, HIV II, HCV and HBsAg, with the FDA-licensed tests, is used in the manufacture of this product. Since, nevertheless, the risk of infection cannot be fully precluded, the product must be handled with the same care as a patient sample.

1.3. Details of the supplier of the safety data sheet**Company name:** Omega Diagnostics Limited

Hillfoots Business Village

Alva

Scotland

FK12 5DQ

www.omegadiagnostics.com**Tel:** 01259 763030**Fax:** 01259 761853**Email:** odl@omegadiagnostics.co.uk**1.4. Emergency telephone number****Emergency tel:** 01259 763030

(office hours only)

Section 2: Hazards identification

2.1. Classification of the substance or mixture

Classification under CLP: This product has no classification under CLP.

2.2. Label elements

Label elements:

Reference Standards
Wash Buffer 20X
Conjugate

Pictogram:
Signal Word:
Hazard statement:
Precautionary statements:



Warning
H317: May cause an allergic skin reaction
P102: Keep out of reach of children.
P234: Keep only in original container.

Stop Solution

Pictogram
Signal Word:
Hazard statement:
Precautionary statements:



Danger
H314: Causes severe skin burns and eye damage.
P102: Keep out of reach of children.
P234: Keep only in original container.
P260: Do not breathe dust/fumes/gas/mist/vapours/spray.
P280: Wear protective gloves/protective clothing/eye protection/face protection.
P301+330+331: IF SWALLOWED: rinse mouth. Do NOT induce vomiting.
P303+361+353: IF ON SKIN (or hair): Take off immediately all contaminated clothing. Rinse skin with water/shower.
P304+340: IF INHALED: Remove person to fresh air and keep comfortable for breathing. P305+351+338: IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.

2.3. Other hazards

PBT: This product is not identified as a PBT/vPvB substance.

Section 3: Composition/information on ingredients

3.1. Substances

Chemical identity: PATHOZYME ULTRASENSITIVE TSH

Contains: Contains no hazardous substances in reportable quantities under the CLP.

3.2. Mixture

Chemical name	CAS (Chemical Abstracts Service) Number	Amount (%) in the mixture	Classification according Regulation (EC) No 1272/2008 [CLP] (relating to the 100% form)	
			Hazard class/ Hazard categories	Hazard- statement
Stop Solution				
Hydrochloric acid....%	None 231-595-7	< 3.65%	Skin Corr. 1B Specific Target Organ Toxicity - Single Exposure (STOT SE) 3	H314 H335
TMB Reagent				
3,3',5,5'-Tetramethylbenzidine	54827-17-7 259-364-6	< 0.05%	Skin Irrit. 2 Eye Irrit 2 STOT SE 3	H315 H319 H335
Reference Standards Wash Buffer 20X Conjugate				
Proclin 300 - modified alkyl carboxylate				
Mixture of:				
5-chloro-2-methyl-2H-isothiazolin-3- one	26172-55-4 247-500-7	< 0.1%	Skin Corrosive. 1B Resp. Sensitation. 1 Skin Sensitation. 1 Aquatic Acute 1 Aquatic Chronic 1	H314 H317 H334 H410
2-methyl-2H isothiazolin-3-one	2682-20-4 220-239-6	< 0.05%	Acute Toxicity. 4 Skin Corrosive. 1B Skin Sensitation. 1 STOT SE 3 Aquatic Acute 1 Aquatic Chronic 1	H302 H314 H317 H331 H335 H400
Ratio 3:1				

For reference only and not applicable to the concentrations supplied.

Valid for the 100% chemical only

H302	Harmful if swallowed.
H314	Causes severe skin burns and eye damage.
H315	Causes skin irritation
H317	May cause an allergic skin reaction.
H319	Causes serious eye irritation
H331	Toxic if inhaled
H334	May cause allergy or asthma symptoms or breathing difficulties if inhaled.
H335	May cause respiratory irritation
H400	Very toxic to aquatic life.
H410	Very toxic to aquatic life with long lasting effects.

Proclin 300

The Classification of this mixture at the contained concentration of < 0.05% of 2-methyl-2H isothiazolin-3-one (0.0015% ≤ C ≤ 0.06%) is Skin Sensitization (Category 1), H317.

All the other ingredients listed above or included but not listed are not classified as hazardous substances in the contained concentrations according to Regulation (EC) No 1272/2008 (CLP).

Section 4: First aid measures

4.1. Description of first aid measures

Skin contact: Wash immediately with plenty of soap and water.

Eye contact: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do so. Continue rinsing. If eye irritation persists, seek medical advice/attention.

Ingestion: Do not induce vomiting. Wash mouth with water and give plenty of water to drink immediately. Obtain medical attention if necessary and show label on container.

Inhalation: Irritation is unlikely to occur but in the event of discomfort, provide plenty of fresh air and if necessary seek medical assistance.

4.2. Most important symptoms and effects, both acute and delayed

Skin contact: There may be mild irritation at the site of contact.

Eye contact: There may be irritation and redness.

Ingestion: There may be irritation of the throat.

Inhalation: No symptoms.

4.3. Indication of any immediate medical attention and special treatment needed

Immediate / special treatment: Not applicable.

Section 5: Fire-fighting measures

5.1. Extinguishing media

Extinguishing media: Suitable extinguishing media for the surrounding fire should be used. Use water spray to cool containers.

5.2. Special hazards arising from the substance or mixture

Exposure hazards: No known specific hazards

5.3. Advice for fire-fighters

Advice for fire-fighters: Do not enter fire without proper protective equipment, including respiratory protection.

Section 6: Accidental release measures**6.1. Personal precautions, protective equipment and emergency procedures**

Personal precautions: Refer to section 8 of SDS for personal protection details.

Turn leaking containers leak-side up to prevent the escape of liquid.

6.2. Environmental precautions

Environmental precautions: Do not discharge into drains or rivers.

6.3. Methods and material for containment and cleaning up

Clean-up procedures: For small spills, clean up with paper/cloth, or mop up, and dispose of safely.

Clean area of spillage down with plenty of water.

6.4. Reference to other sections

Reference to other sections: Refer to section 8 of SDS.

Section 7: Handling and storage**7.1. Precautions for safe handling**

Handling requirements: No special requirements.

7.2. Conditions for safe storage, including any incompatibilities

Storage conditions: Store between 2 deg C (35 F) and 8 deg C (46 F). Keep container tightly closed.

Suitable packaging: Must only be kept in original packaging.

7.3. Specific end use(s)

Specific end use(s): No data available.

Section 8: Exposure controls/personal protection**8.1. Control parameters**

Workplace exposure limits: No data available.

DNEL/PNEC Values

DNEL / PNEC No data available.

8.2. Exposure controls

Engineering measures: Ensure all engineering measures mentioned in section 7 of SDS are in place.

Respiratory protection: Respiratory protection not required.

Hand protection: Protective gloves.

Eye protection: No specific measures are required when using good safe practice.

Skin protection: Protective clothing not required in normal use.

Section 9: Physical and chemical properties

9.1. Information on basic physical and chemical properties

Component	Plate	Reference Standards* Wash Buffer 20X Conjugate	TMB Reagent	Stop Solution
State	Solid	Lyophilised* Liquid	Liquid	Liquid
Colour	Clear	Diverse (has no influence to the properties of the mixture)		
Odour	Odourless			
Solubility in water:	Insoluble	Soluble		
Viscosity	Non-viscous			
pH	Not applicable	7.0 – 7.4	3.35 – 3.75	< 1.0
Boiling point/range°C	>35			
Flash point°C	>93			
Vapour pressure	Not applicable	No data available	No data available	No data available
Melting point/range°C	No data available			
Autoflammability°C	No data available			
Relative density	Not applicable	1.0	1.0	1.0

9.2 Other information

Other information: No data available.

Section 10: Stability and reactivity

10.1. Reactivity

Reactivity: Stable under recommended transport or storage conditions.

10.2. Chemical stability

Chemical stability: Stable under normal conditions.

10.3. Possibility of hazardous reactions

Hazardous reactions: Hazardous reactions will not occur under normal transport or storage conditions.

10.4. Conditions to avoid

Conditions to avoid: Save under storage conditions outlined in Section 7 of this SDS.

10.5. Incompatible materials

Materials to avoid: None known.

10.6. Hazardous decomposition products

Decomposition products: No known specific hazards

Section 11: Toxicological information

11.1. Information on toxicological effects

Toxicity values: No data available.

Symptoms / routes of exposure

Skin contact: There may be mild irritation at the site of contact.

Eye contact: There may be irritation and redness.

Ingestion: There may be irritation of the throat.

Inhalation: No symptoms.

Section 12: Ecological information

12.1. Toxicity

Ecotoxicity values: No data available.

12.2. Persistence and degradability

Persistence and degradability: Biodegradable.

12.3. Bioaccumulative potential

Bioaccumulative potential: No bioaccumulation potential.

12.4. Mobility in soil

Mobility: Reagents - readily absorbed into soil.

Plate -Not Readily absorbed into soil.

12.5. Results of PBT and vPvB assessment

PBT identification: This product is not identified as a PBT/vPvB substance.

12.6. Other adverse effects

Other adverse effects: Negligible ecotoxicity.

Section 13: Disposal considerations

13.1. Waste treatment methods

Disposal operations: Dispose of in accordance with current legislation and local authority regulations.

If outside the U.K, comply with local waste disposal regulations.

NB: The user's attention is drawn to the possible existence of regional or national regulations regarding disposal.

Section 14: Transport information**14.1. UN number**

UN number: Not applicable.

14.2. UN proper shipping name

Shipping name: This product is not covered by international regulation on the transport of dangerous goods (IMDG, IATA, ADR/RID).

14.3. Transport hazard class(es)

Hazard Class: Product is not classified as hazardous

14.4. Packing group

Group: Product is not classified as dangerous goods

14.5. Environmental hazards

Environmentally hazardous: No

Marine pollutant: No

14.6. Special precautions for user

Special precautions: No special precautions.

Section 15: Regulatory information**15.1. Safety, health and environmental regulations/legislation specific for the substance or mixture**

Specific regulations: Not applicable.

15.2. Chemical Safety Assessment

CSA: Not applicable - product not subject to registration under REACH

Section 16: Other information**Other information**

Other information: This safety data sheet is prepared in accordance with Commission Regulation (EU) No 453/2010.

Legal disclaimer: The above information is believed to be correct but does not purport to be all inclusive and shall be used only as a guide. This company shall not be held liable for any damage resulting from handling or from contact with the above product.