

Trade name: PTH intact ELISA
Product number: DE3645

SECTION 1: IDENTIFICATION OF THE SUBSTANCE/MIXTURE AND OF THE COMPANY/UNDERTAKING**1.1 Product identifier**

Trade name: PTH intact ELISA
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1.2 Relevant identified uses of the substance or mixture and uses advised against

Recommended Use: For research or in vitro diagnostic use only
Uses Advised Against: Not for use on or in humans

1.3 Details of the supplier of the safety data sheet

Demeditec Diagnostics GmbH Phone: +49-(0)431 / 71922 0
Lise-Meitner-Str. 2 Fax: +49-(0)431 / 71922 55
24145 Kiel E-Mail: info@demeditec.de
Germany www.demeditec.de

1.4 Emergency telephone number

+49-(0)431 / 71922-0 (during opening time: 8:00 h – 16:30 h)

SECTION 2: HAZARDS IDENTIFICATION**2.1 Classification of the substance or mixture****Regulation (EC) No 1272/2008**

This mixture is classified as not hazardous according to regulation (EC) 1272/2008 [GHS]

2.2 Label elements**Product Identifier**

Contains Sulfuric acid

This mixture is classified as not hazardous according to regulation (EC) 1272/2008 [GHS]

Signal Word

None

EUH210 - Safety data sheet available on request

2.3 Other hazards

Calibrators are formulated with a buffer base, animal or human serum. The kit components that are made with human serum are tested by a United States Food and Drug Administration (USFDA) licensed method and found to be non-reactive for HIV-1, HIV-2, Hepatitis B surface antigen, and HCV. Because no test method can offer absolute assurance that these agents are absent, reagents should be handled at the Biosafety Level 2, as recommended for any potentially infectious human blood product, in the United States Center for Disease Control (USCDC) and National Institute of Health (USNIH) manual "Biosafety in Microbiological Laboratories", 1988. All bovine serum products used are derived from animals of US origin, processed in USDA licensed facilities ELISA Wash Concentrate contains Ciprofloxacin HCl. Keep from personnel who have demonstrated a sensitivity to Quinoline based drug products. Females who are, or may be pregnant, should avoid contact with Ciprofloxacin

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SECTION 3: COMPOSITION/INFORMATION ON INGREDIENTS
3.1 Substances

not applicable

3.2 Mixtures

Chemical Name	EC No	CAS No	Weight-%	Classification according to Regulation (EC) No. 1272/2008 [CLP]	REACH Registration Number
Sulphuric acid	231-639-5	7664-93-9	3	Skin Corr. 1A (H314)	Not determined

Full text of H- and EUH-phrases: see section 16

 This product does not contain candidate substances of very high concern at a concentration $\geq 0.1\%$ (Regulation (EC) No. 1907/2006 (REACH), Article 59)

SECTION 4: FIRST AID MEASURES
4.1 Description of first aid measures

Eye Contact	Rinse immediately with plenty of water, also under the eyelids, for at least 15 minutes.
Skin Contact	Immediately call a poison center or doctor/physician. Wash with soap and water. Take off contaminated clothing. If skin irritation occurs: Get medical advice/attention.
Inhalation	Remove victim to fresh air and keep at rest in a position comfortable for breathing. If breathing is difficult, give oxygen. Call a physician if you feel unwell.
Ingestion	Flush mouth with copious amounts of water, provided that the person is conscious, and seek medical attention.
Self-Protection of the First Aider	No specific precautions necessary.

4.2 Most important symptoms and effects, both acute and delayed

Symptoms May cause irritation to the mucous membranes and upper respiratory tract. May include redness, drying and cracking of skin. Causes serious eye damage.

4.3 Indication of any immediate medical attention and special treatment needed

Notes to Physician Treat symptomatically.

SECTION 5: FIREFIGHTING MEASURES
5.1 Extinguishing media

Suitable Extinguishing Media Chemical or water fire extinguisher.

Unsuitable Extinguishing Media None known

5.2 Special hazards arising from the substance or mixture

None known.

5.3 Advice for firefighters

Wear self-contained breathing apparatus and protective suit. Use personal protective equipment as required.



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SECTION 6: ACCIDENTAL RELEASE MEASURES

6.1 Personal precautions, protective equipment and emergency procedures

Personal Precautions Wear protective clothing as described in Section 8 of this safety data sheet.
Take care not to contaminate body.

For Emergency Responders Use personal protection recommended in Section 8.

6.2 Environmental precautions

Contain the spill to the smallest area possible. Avoid release to the environment.
See Section 12 for additional Ecological Information.

6.3 Methods and material for containment and cleaning up

Methods for Containment Prevent further leakage or spillage if safe to do so.

Methods for Clean-Up Neutralize a Stop Solution spill with dilute base, then absorb the material with disposable towels. Soak a calibrator or control spill area with a 10% bleach solution and wipe up with disposable towels. Dispose of all contaminated trash in accordance with local regulations.

6.4 Reference to other sections

See Section 13: DISPOSAL CONSIDERATIONS.

SECTION 7: HANDLING AND STORAGE

7.1 Precautions for safe handling

Advice on Safe Handling

Use personal protection recommended in Section 8. Avoid breathing vapours or mists. Use only in well-ventilated areas. Take care not to splash, spill, or splatter standards, stop solution, or controls. Wash face, hands and any exposed skin thoroughly after handling.

General Hygiene Considerations

Handle in accordance with good industrial hygiene and safety practice.

7.2 Conditions for safe storage, including any incompatibilities

Storage Conditions

Store kit reagents at 2 °C to 8 °C in refrigerators designated and labeled to contain human blood products.

7.3 Specific end use(s)

Specific Use(s)

For research or in vitro diagnostic use only.

Risk Management Methods (RMM)

The information required is contained in this Safety Data Sheet.

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SECTION 8: EXPOSURE CONTROLS/PERSONAL PROTECTION

8.1 Control parameters

Exposure Limits

Chemical Name	European Union	United Kingdom	France	Spain	Germany
ulfuric acid 7664-93-9	-	STEL: 0.15 mg/m ³ TWA: 0.05 mg/m ³	TWA: 0.05 mg/m ³ STEL: 3 mg/m ³	TWA: 0.05 mg/m ³	TWA: 0.1 mg/m ³ Ceiling / Peak: 0.1 mg/m ³ Skin
Chemical Name	Italy	Portugal	Netherlands	Finland	Denmark
ulfuric acid 7664-93-9	TWA: 0.05 mg/m ³	TWA: 0.05 mg/m ³	TWA: 0.05 mg/m ³	TWA: 0.05 mg/m ³ STEL: 0.1 mg/m ³	TWA: 0.05 mg/m ³
Chemical Name	Austria	Switzerland	Poland	Norway	Ireland
ulfuric acid 7664-93-9	STEL 0.2 mg/m ³ TWA: 0.1 mg/m ³	STEL: 0.1 mg/m ³ TWA: 0.1 mg/m ³	STEL: 3 mg/m ³ TWA: 1 mg/m ³	TWA: 0.1 mg/m ³ STEL: 0.3 mg/m ³	TWA: 0.05 ppm STEL: 0.15 ppm

8.2 Exposure controls

Engineering Controls

Apply technical measures to comply with the occupational exposure limits.

Personal Protective Equipment

Eye/Face Protection

Wear approved safety goggles where a splash hazard exists.

Hand Protection

Wear non-permeable rubber, neoprene, latex, or nitrile disposable gloves.
Change gloves when they become contaminated.

Skin and Body Protection

Wear laboratory coat.

Respiratory Protection

In case of fire, wear self-contained breathing apparatus.

SECTION 9: PHYSICAL AND CHEMICAL PROPERTIES

9.1 Information on basic physical and chemical properties

Physical State Liquid

Appearance Liquid except for Calibrators A to Calibrator F and Control 1/Control 2 which are lyophilized and Streptavidin coated microwell

Colour Yellow for Reagent 1 (PTH Biotinylated Ab Solution), Blue for Reagent 2 (Enzyme labeled Ab Solution) and clear for all other liquid reagents

Odour None detectable

Odour Threshold Not determined

Property

Values

Remarks • Method

pH 5.56 - 7.4 Stop Solution pH < 2

Melting point/freezing point Not applicable

Boiling point/boiling range Not applicable

Flash point Not applicable

Evaporation rate Not determined

Flammability (solid, gas) Not flammable

Flammability limits in air

Upper flammability limits Not applicable

Lower flammability limit Not applicable

Vapor pressure Not applicable

Vapor density Not determined

Relative Density 1 - 3 (Water = 1)

Water solubility Completely soluble

Solubility(ies) Not determined

Partition coefficient Not determined

Auto-ignition temperature Will not occur

Decomposition temperature Not determined

Kinematic viscosity Not determined

Dynamic viscosity Not determined

Explosive Properties Not an explosive

Oxidising Properties Not an oxidizer

9.2 Other information

No further relevant information available. Stability and reactivity



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SECTION 10: STABILITY AND REACTIVITY

- | | |
|--|---------------------------------------|
| 10.1 Reactivity | Not reactive under normal conditions. |
| 10.2 Chemical stability | Stable under normal conditions. |
| 10.3 Possibility of hazardous reactions | None under normal processing. |
| 10.4 Conditions to avoid | None known. |
| 10.5 Incompatible materials | None known. |
| 10.6 Hazardous decomposition products | None known. |

SECTION 11: TOXICOLOGICAL INFORMATION

11.1 Information on toxicological effects

Acute Toxicity

Product Information

Potential biohazard.

- | | |
|-------------------------------|---|
| Inhalation | Avoid breathing vapors or mists. |
| Eye Contact | Avoid contact with eyes. |
| Skin Contact | Avoid contact with skin. |
| Ingestion | Do not ingest. |
| Unknown Acute Toxicity | 0.18% of the mixture consists of ingredient(s) of unknown toxicity. |

The following values are calculated based on chapter 3.1 of the GHS document

- | | |
|--------------------|-----------------|
| Oral LD50 | 71 333.00 mg/kg |
| Inhalation) | |
| Mist | 8.50 mg/L |
| Vapor | 17 000.00 mg/L |

Component Information

Chemical Name	Oral LD50	Dermal LD50	Inhalation LC50
Sulfuric acid	= 2140 mg/kg (Rat)		= 510 mg/m3 (Rat) 2 h

- | | |
|--|--|
| Skin corrosion/irritation | Causes skin irritation. |
| Serious eye damage/eye irritation | Causes serious eye damage |
| Sensitisation | Not classified. |
| Germ cell mutagenicity | Not classified. |
| Carcinogenicity | Not classified. |
| Reproductive toxicity | Not classified. |
| STOT - single exposure | Not classified. |
| STOT - repeated exposure | Not classified. |
| Aspiration hazard | Not classified. |
| Symptoms | Please see section 4 of this SDS for symptoms. |

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SECTION 12: ECOLOGICAL INFORMATION
12.1 Toxicity

Harmful to aquatic life with long lasting effects.

Chemical Name	Algae/aquatic plants	Fish	Crustacea
Sulfuric acid		500: 96 h Brachydanio rerio mg/L LC50 static	29: 24 h Daphnia magna mg/L EC50

12.2 Persistence and degradability

Not determined.

12.3 Bioaccumulative potential

Not determined.

12.4 Mobility in soil

Not determined.

12.5 Results of PBT and vPvB assessment

Not determined.

12.6 Other adverse effects

Not determined.

SECTION 13: DISPOSAL CONSIDERATIONS
13.1 Waste treatment methods

Waste from Residues / Unused Products Disposal should be in accordance with applicable regional, national and local laws and regulations.
 Contaminated Packaging Improper disposal or reuse of this container may be dangerous and illegal.

SECTION 14: TRANSPORT INFORMATION
14.1 UN No.

ADR, ADN, IMDG, ICAO, IATA Void

14.2 UN Proper shipping name

ADR, ADN, IMDG, ICAO, IATA Void

14.3 Transport hazard class(es)

ADR, ADN, IMDG, ICAO, IATA Void

14.4 Packing group

ADR, ADN, IMDG, ICAO, IATA Void

14.5 Environmental hazards

Not applicable.

14.6 Special precautions for user

Not applicable.

14.7 Transport in bulk according to Annex II of MARPOL73/78 and the IBC Code

Not applicable.

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SECTION 15: REGULATORY INFORMATION

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

European Union

Take note of Directive 98/24/EC on the protection of the health and safety of workers from the risks related to chemical agents at work.

Authorisations and/or restrictions on use:

This product does not contain substances subject to authorisation (Regulation (EC) No. 1907/2006 (REACH), Annex XIV)
 This product does not contain substances subject to restriction (Regulation (EC) No. 1907/2006 (REACH), Annex XVII)

Persistent Organic Pollutants

Not applicable

Ozone-depleting substances (ODS) regulation (EC) 1005/2009

Not applicable

International Inventories

Component	TSCA	DSL/NDSL	EINECS/ ELINCS	PICCS	ENCS	IECSC	AICS	KECL
Sulfuric acid 7664-93-9 (3)	X	X	X	X	Present	X	X	Present

Legend

TSCA - United States Toxic Substances Control Act Section 8(b) Inventory

EINECS/ELINCS - European Inventory of Existing Chemical Substances/European List of Notified Chemical Substances

DSL/NDSL - Canadian Domestic Substances List/Non-Domestic Substances List

PICCS - Philippines Inventory of Chemicals and Chemical Substances

ENCS - Japan Existing and New Chemical Substances

IECSC - China Inventory of Existing Chemical Substances

AICS - Australian Inventory of Chemical Substances

KECL - Korean Existing and Evaluated Chemical Substances

15.2 Chemical safety assessment

No Chemical Safety Assessment has been carried out for this substance/mixture by the supplier.



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SECTION 16: OTHER INFORMATION

Full text of H-Statements referred to under section 3
H314 - Causes severe skin burns and eye damage

Legend

SVHC: Substances of Very High Concern for Authorisation:

Legend

Section 8: EXPOSURE CONTROLS/PERSONAL PROTECTION

TWA	TWA (time-weighted average)	STEL	STEL (Short Term Exposure Limit)
Ceiling	Maximum limit value	*	Skin designation

Classification Procedure

Calculation method

Revision Date: 29-Mar-2018

Revision Note: Regulatory update.

This safety data sheet complies with the requirements of Regulation (EC) No. 1907/2006, as amended by Commission Regulation (EU) No. 2015/830

Disclaimer

The information provided in this Safety Data Sheet is correct to the best of our knowledge, information and belief at the date of its publication. The information given is designed only as a guidance for safe handling, use, processing, storage, transportation, disposal and release and is not to be considered a warranty or quality specification. The information relates only to the specific material designated and may not be valid for such material used in combination with any other materials or in any process, unless specified in the text.