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Trade name: Cortisol in urine ELISA

Product number: DE2989

SECTION 1: IDENTIFICATION OF THE SUBSTANCE/MIXTURE AND OF THE COMPANY/UNDERTAKING

1.1 Product identifier

Trade name: Cortisol in urine ELISA

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Kit Components: Standards

Control Low Control High Enzyme Conjugate Microtiterwells Substrate Solution Stop Solution

Wash Solution 10X Conc.

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

Components of an in vitro Medical-Diagnostic Device according to Directive (EC) 98/79/EC.

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 https://www.demeditec.com/

Emergency telephone number

+49 (0)431 / 71922-0

(Only available during the following office hours)

SECTION 2: HAZARDS IDENTIFICATION

2.1 Classification of the substance or mixture

Due to the low concentration of hazardous ingredients none of the listed components of this product may be classified as dangerous according to Regulation (EC) 1272/2008.

2.2 Label elements

This product is not under lebelling according to Regulation (EC) n. 1272/2008.

Hazard pictogram(s):

Signal word(s):

None

Hazard statement(s):

None

Precautionary statement(s):

None

2.3 Other hazards

No one.

Note: this product is intended for laboratory use by professional uses only. Use appropriate personal protective equipment while working with the reagents provided.



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SECTION 3: COMPOSITION/INFORMATION ON INGREDIENTS

3.1 Substances

| Stop Solution | | | | |
|----------------|-----------|-----------|-------------|----------------|
| Ingrediente | EC No | CAS No | Conc. (w/v) | Reg. 1272/2008 |
| Sulphuric Acid | 231-639-5 | 7664-93-9 | < 5 % | H314 |

3.2 Mixtures

Proclin 300 is a mixture of two substances (5-chloro-2-methyl-2Hisothiazol-3-one (EC 247-500-7) and 2-methyl-2Hisothiazol-3-one (EC 220-239-6)) mixed with the proportion 3:1.

| Calibrators - Controls - Conjugate - TMB Substrate - Conc. Wash Solution | | | | |
|--|-------|------------|------------|----------------|
| Ingrediente | EC No | CAS No | Conc. (%) | Reg. 1272/2008 |
| | | | | H302 - H314 |
| oclin 300 | _ | 55965-84-9 | < 0.0015 % | H317 - H332 |
| | | | | H400 - H411 |

Full text of H-phrases: see section 16

SECTION 4: FIRST AID MEASURES

4.1 Description of first aid measures

General advice: no special measures required. Consult a physician in case of complaints.

If inhaled: supply fresh air.

In case of skin contact: wash with plenty amounts of water.

In case of eye contact: rinse opened eye for few minutes with water.

If swallowed: contact the nearest first aid.

4.2 Most important symptoms and effects, both acute and delayed

To the best of our knowledge, the chemical, physical a toxicological properties have not been thoroughly investigated.

4.3 Indication of any immediate medical attention and special treatment needed

No data available.

SECTION 5: FIREFIGHTING MEASURES

5.1 Extinguishing media

No restriction.

5.2 Special hazards arising from the substance or mixture

To the best of our knowledge, special hazards are not known.

5.3 Advice for firefighters

Wear self contained breathing apparatus for fire fighting if necessary.

SECTION 6: ACCIDENTAL RELEASE MEASURES

6.1 Personal precautions, protective equipment and emergency procedures

Use appropriate personal protective equipment.



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6.2 Environmental precautions

Do not let product enter drains. Discharge into the environment must be avoided.

6.3 Methods and material for containment and cleaning up

Absorb with inert absorbent material and dispose of a waste (see section 13).

6.4 Reference to other sections

For disposal see section 13.

SECTION 7: HANDLING AND STORAGE

7.1 Precautions for safe handling

Use all reagents according to the Instruction For Use provided with the product.

7.2 Conditions for safe storage, including any incompatibilities

Store all reagents according to the Instruction For Use provided with the product.

7.3 Specific end use(s)

This product is intended for laboratory use, by professional users only.

SECTION 8: EXPOSURE CONTROLS/PERSONAL PROTECTION

8.1 Control parameters

Component with exposure limits: it doesn't contain substances with exposure limit value.

8.2 Exposure controls

Handle in accordance with good industrial hygiene and safety practice.

Wash hands before breaks at the end of workday.

Personal protective equipment

Eye/face protection: goggles with UNI EN 166 (and subsequent updates), or other international standard certification

Skin protection: lab coats, gloves with UNI EN 374 (and subsequent updates), or other international standard

certification

Body protection: lab coats
Respiratory protection: not required

SECTION 9: PHYSICAL AND CHEMICAL PROPERTIES

9.1 Information on basic physical and chemical properties

| Component | a) Appearance | b) Odour | d) pH |
|---------------------|---------------------|-----------|----------------|
| Standards | liquid, faint brown | odourless | 7.5 |
| Enzyme Conjugate | liquid, red | odourless | 7.5 |
| Microtiterwells | solid, white | odourless | not applicable |
| Substrate Solution | liquid, colourless | odourless | 3.2 - 3.8 |
| Stop Solution | liquid, colourless | odourless | < 1 |
| Controls | liquid, faint brown | odourless | 7.5 |
| Wash Solution Conc. | liquid, colourless | odourless | 7.4 |



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| For all components | | |
|---|-------------------|--|
| c) odour threshold | no data available | |
| e) melting point / freezing point | no data available | |
| f) initial boiling point and boiling range | no data available | |
| g) flash point | no data available | |
| h) evaporation rate | no data available | |
| i) flammability (solid, gas) | no data available | |
| j) upper/lower flammability or explosive limits | no data available | |
| k) vapour pressure | no data available | |
| I) vapour density | no data available | |
| m) relative density | no data available | |
| n) solubility(ies) | no data available | |
| o) partition coefficient: n-octanol / water; | no data available | |
| p) auto-ignition temperature | no data available | |
| q) decomposition temperature | no data available | |
| r) viscosity | no data available | |
| s) explosive properties | no data available | |
| t) oxidising properties | no data available | |

9.2 Other information

No other information available.

SECTION 10: STABILITY AND REACTIVITY

10.1 Reactivity

No data available.

10.2 Chemical stability

No data available.

10.3 Possibility of hazardous reactions

No data available.

10.4 Conditions to avoid

For the <u>functional</u> stability and reactivity of "Substrate Solution" avoid its exposure to directed sunlight, metals or oxidants and do not freeze the solution.

10.5 Incompatible materials

No data available.

10.6 Hazardous decomposition products

No data available.



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SECTION 11: TOXICOLOGICAL INFORMATION

11.1 Information on toxicological effects

| a) acute toxicity | no data available |
|--------------------------------------|-------------------|
| b) skin corrosion/irritation | no data available |
| c) serious eye damage / irritation | no data available |
| d) respiratory or skin sensitisation | no data available |
| e) germ cell mutagenicity | no data available |
| f) carcinogenicity | no data available |
| g) reproductive toxicity | no data available |
| h) STOT-single exposure | no data available |
| i) STOT-repeated exposure | no data available |
| j) aspiration hazard | no data available |
| | |

| Potential health effects | |
|--------------------------|-------------------|
| Inhalation | no data available |
| Ingestion | no data available |
| Skin | no data available |
| Eyes | no data available |

Signs and Symptoms of Exposure

To the best of our knowledge, the chemical, physical and toxicological properties have not been thoroughly investigated.

Additional Information

No one.

SECTION 12: ECOLOGICAL INFORMATION

12.1 Toxicity

No data available.

12.2 Persistence and degradability

No data available.

12.3 Bioaccumulative potential

No data available.

12.4 Mobility in soil

No data available.

12.5 Results of PBT and vPvB assessment

No data available.

12.6 Other adverse effects

No data available.



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SECTION 13: DISPOSAL CONSIDERATIONS

13.1 Waste treatment methods

Reagents must be disposed of in accordance with local regulations. Do not disposed of in waste water. If appropriate, contact a licensed disposal company.

SECTION 14: TRANSPORT INFORMATION

The product is not under transport regulations.

14.1 UN No. No data available.

14.2 UN Proper shipping name No data available.

14.3 Transport hazard class(es) No data available.

14.4 Packing group No data available.

14.5 Environmental hazards No data available.

14.6 Special precautions for userNo data available.

14.7 Transport in bulk according to Annex II of MARPOL73/78 and the IBC Code No data available.

SECTION 15: REGULATORY INFORMATION

This Safety Data Sheet is according to Regulation (CE) n. 1907/2006 (REACH); this product is classified and labelled according the Regulation (EC) n. 1272/2008 (CLP).

15.1 Safety, health and environmental regulations/legislation specific for the substance or mixture No data available.

15.2 Chemical safety assessment

No data available.

SECTION 16: OTHER INFORMATION

"H code" used in this Safety data sheet

| Reg. 1272/2008 | |
|----------------|--|
| H302 | Harmful if swallowed. |
| H314 | Causes severe skin burns and eye damage. |
| H317 | May cause an allergic skin reaction. |
| H332 | Harmful if inhaled. |
| H400 | Very toxic to aquatic life. |
| H411 | Toxic to aquatic life with long lasting effects. |

Changing against the last version:

Updating to Regulation (CE) n. 1907/2006, Regulation (EC) n. 453/2010, and according to Regulation (EC) n. 1272/2008 (CLP). Introduction of component "*Wash Solution Conc.*" and elimination of component "*Incubation buffer*"

Note: The information in this document is believed to be accurate and represents the best information currently available to us. However, this shall not constitute a guarantee for any specific product features and shall not establish a legally valid contractual relationship.