

Trade name: 17-OH-Progesterone; DHEA-S; Cortisol ELISA
Article number: DEH3322; DEH3366; DEH3388

1. IDENTIFICATION OF THE SUBSTANCE / MIXTURE AND OF THE COMPANY / UNDERTAKING

1.1 Product identifier

Trade name: 17-OH-Progesterone ELISA
DHEA-S ELISA
Cortisol ELISA
Article number: DEH3322
DEH3366
DEH3388

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

Enzyme immunoassay for the laboratory use.

Kit content (name and label reference):

Microtiterplate	[SORB MT]
Calibrator 0-X	[CAL 0-X]
Control 1 & 2	[CONTROL 1/2]
Enzyme Conjugate	[ENZ CONJ]
TMB-Substrate Solution	[SUB TMB]
Stop Solution	[STOP SOLN]
Wash Solution	[WASH SOLN 10x]

1.3 Details of the supplier of the safety data sheet

Manufacturer/Supplier:
Demeditec Diagnostics GmbH
Lise-Meitner Straße 2
D-24145 Kiel

Phone: +49 (0)431-71922-0
Fax: +49 (0)431-7192255
E-mail: info@demeditec.de
<http://www.demeditec.de>

1.4 Emergency telephone number

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

2. HAZARDS IDENTIFICATION

2.1 Classification of the substance or mixture

Classification according to Regulation (EC) No. 1272/2008 [CLP]

Skin sensitisation, Category 1, H317

Full text of H statements see section 16

Adverse physicochemical, human health and environmental effects

No additional information available

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2.2 Label elements

Enzyme Conjugate

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

Hazard pictograms (CLP):



GHS07

Signal word (CLP):

Warning

Hazardous ingredients:

reaction mass of: 5-chloro-2-methyl-4-isothiazolin-3-one (EC no. 247-500-7), and 2-methyl-2H-isothiazol-3-one (EC no. 220-239-6) (3:1)

2-methyl-2H-isothiazol-3-one [EC no. 220-239-6]

Hazard statements (CLP):

H317 - May cause an allergic skin reaction

Precautionary statement(s):

P261 - Avoid breathing mist, vapors, spray

P272 - Contaminated work clothing should not be allowed out of the workplace

P280 - Wear eye protection, protective gloves, protective clothing

P302+P352 - IF ON SKIN: Wash with plenty of soap and water

P333+P313 - If skin irritation or rash occurs: Get medical advice/attention

P362+P364 - Take off contaminated clothing and wash it before reuse

EUH-statements

EUH208 - Contains CMIT/MIT. May produce an allergic reaction.

2.3 Other hazards

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

None of the components is listed as PBT or vPvB relevant.

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3. COMPOSITION / INFORMATION ON INGREDIENTS

3.1 Substances

3.2 Mixtures

Stop Solution						
Ingredients	CAS No [EC No]	Containing Conc. (%)	Classification according to regulation (EC) No 1272/2008 (CLP) (related to the concentrated form)		Pictogram, Signal Word Code(s)	Specific Conc. Limits, M-factors
			Hazard Class and Category Code(s)	Hazard statement Code(s)		
Hydro-chloric Acid (HCl) Index-No. 017-002-01-X	7647-01-0 [231-595-7]	< 10.0 %	Met. Corr. 1 Skin Corr. 1B Eye Dam. 1 STOT SE 3	H290 H314 H318 H335	GHS05 GHS07 Dgr	Skin Corr. 1B; H314: C ≥ 25% Skin Irrit. 2; H315: 10% ≤ C < 25% Eye Dam. 1; H318: C ≥ 25% Eye Irrit. 2; H319: 10% ≤ C < 25% STOT SE 3; H335: C ≥ 10%

*Dilution is not classified as hazardous according to the European Regulation 1999/45/EC or 1272/2008/EC.

Calibrator, Controls, Wash Solution						
Ingredients	CAS No [EC No]	Containing Conc. (%)	Classification according to regulation (EC) No 1272/2008 (CLP) (related to the concentrated form)		Pictogram, Signal Word Code(s)	Specific Conc. Limits, M-factors
			Hazard Class and Category Code(s)	Hazard statement Code(s)		
Proclin 300* Index-No. 613-167-00-5	96118-96-6 [203-821-4]	< 0.0015 %**	Acute Tox. 3 * Acute Tox. 3 * Acute Tox. 3 * Skin Corr. 1B Skin Sens. 1 Aquatic Acute 1 Aquatic Chronic 1	H331 H311 H301 H314 H317 H400 H410	GHS06 GHS05 GHS09 Dgr	Skin Corr. 1B; H314: C ≥ 0.6% Skin Irrit. 2; H315: 0.06% ≤ C < 0.6% Eye Irrit. 2; H319: 0.06% ≤ C < 0.6% Skin Sens. 1; H317: C ≥ 0.0015%

* Proclin 300 is a mixture of substances of the components, 5-chloro-2-methyl-2H-isothiazol-3-one (EG-no 247-500-7) and 2-methyl-2H-isothiazol-3-one (EG-no 220-239-6).

**Dilution is not classified as hazardous according to the European Regulation 1999/45/EC and 1272/2008/EC.

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Enzyme Conjugate						
Ingredients	CAS No [EC Index No]	Containing Conc. (%)	Classification according to regulation (EC) No 1272/2008 (CLP) (related to the concentrated form)		Pictogram, Signal Word Code(s)	Specific Conc. Limits, M-factors
			Hazard Class and Category Code(s)	Hazard statement Code(s)		
CMIT/MIT: Mixture, 5-chloro-2-methyl-4- isothiazolin-3-one [EC no. 247-500-7]; and 2-methyl-2H - isothiazol-3-one [EC no. 220-239-6] (3:1)	55965-84-9 [613-167-00-5]	< 0.01 %	Acute Tox. 3 (Oral) Acute Tox. 3 (Dermal) Acute Tox. 3 (Inhalation)	H301 H311 H331	GHS06 GHS05 GHS09	Skin Sens. 1, H317 (C >= 0.0015%) Eye Irrit. 2, H319 (0.06% =<C < 0.6%) Skin Irrit. 2, H315 (0.06% =<C < 0.6%) Skin Corr. 1B, H314 (C >= 0.6%)
2-methyl-2H- isothiazol-3-one [EC no. 220-239-6]	2682-20-4 [613-167-00-5]	< 0.02%	Acute Tox. 3 (Inhalation:dust,mist) Skin Corr. 1B Skin Sens. 1 Aquatic Acute 1 Aquatic Chronic 1	H314 H317 H400 H410	Dgr	

Note: See section 16 for the detailed text of the above stated H-, P- and S-phrases.

4. FIRST AID MEASURES

4.1 Description of first aid measures

General advice: Take off contaminated clothing and shoes. Consult physician in case of complaints.

If inhaled: Provide fresh air. In all cases of doubt, or when symptoms persist, seek medical advice.

In case of skin contact: Rinse skin with water/shower. In all cases of doubt, or when symptoms persist, seek medical advice.

In case of eye contact: Check for and remove any contact lenses. Immediately flush eyes with plenty of water for at least 15 minutes. In all cases of doubt, or when symptoms persist, seek medical advice.

If swallowed: If swallowed, rinse mouth with plenty of water. Do NOT induce vomiting. Call a doctor if you feel unwell.

4.2 Most important symptoms and effects, both acute and delayed

Stop Solution:

Irritation.

Enzyme Conjugate:

Symptoms/effects: May cause an allergic skin reaction.

Symptoms/effects after inhalation: May cause respiratory irritation.

Symptoms/effects after skin contact: May cause an allergic skin reaction.

Symptoms/effects after eye contact: Direct contact with eyes is likely to be irritating.

Symptoms/effects after ingestion: May cause gastrointestinal irritation.

4.3 Indication of any immediate medical attention and special treatment needed

No data available.

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5. FIREFIGHTING MEASURES

5.1 Extinguishing media

Suitable extinguishing media

Use dry chemical powder, water spray or alcohol resistant foam.

Unsuitable extinguishing media

water jet

5.2 Special hazards arising from the substance or mixture

Non-combustible.

Hazardous combustion products

In case of fire may be liberated: hydrogen chloride (HCl), may produce toxic fumes of carbon monoxide if burning.

5.3 Advice for firefighters

Use water spray or fog for cooling exposed containers. Exercise caution when fighting any chemical fire.

Do not dispose of fire-fighting water in the environment.

Do not enter fire area without proper protective equipment, including respiratory protection.

6. ACCIDENTAL RELEASE MEASURES

6.1 Personal precautions, protective equipment and emergency procedures

Wearing of suitable protective equipment (including personal protective equipment) to prevent any contamination of skin, eyes and personal clothing.

Avoid contact with skin, eyes and clothes. Do not breathe vapour/spray. Ventilate area.

6.2 Environmental precautions

Keep away from drains, surface and ground water.

6.3 Methods and material for containment and cleaning up

Covering of drains. Absorb with liquid-binding material (sand, diatomite, acid binders, universal binders).

Wash spill area thoroughly with plenty of soap and water.

Place in appropriate containers for disposal.

6.4 Reference to other sections

For personal protection see section 8.

Incompatible materials see section 10.

For disposal see section 13.

7. HANDLING AND STORAGE

7.1 Precautions for safe handling

Use all reagents in accordance with the relevant package insert provided with the product.

Do not smoke, eat, drink or apply cosmetics in areas where kit reagents are handled.

Wear disposable gloves when handling reagents.

Wash hands and other exposed areas with mild soap and water before eating, drinking or smoking and when leaving work.

Never pipet by mouth and avoid contact of reagents and specimens with skin and mucous membranes.

Handling should be done in accordance with the procedures defined by an appropriate national biohazard safety guideline or regulation.

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7.2 Conditions for safe storage, including any incompatibilities

Store tightly closed on a cool dry place. Reseal opened bottles carefully and store in an upright position.

Keep only in the original container.

Recommended storage temperature: as indicated in the package inserts

Storage classification: 12 (non flammable liquids)

segregate from:	class 1 (explosives)	class 4.1A (flammable solids)
	class 4.3 (dangerous when wet)	class 6.2 (infectious)
	class 7 (radioactive)	

Further information:

Store separated from foodstuffs.

Protect from unauthorized access.

7.3 Specific end use(s)

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

Use only in accordance to the manual.

8. EXPOSURE CONTROLS / PERSONAL PROTECTION

8.1. Control parameters

Stop Solution

National limit values

Occupational exposure limit values (Workplace Exposure Limits)

Country	Name of agent	CAS No	Identifier	TWA [ppm]	TWA [mg/m ³]	STEL [ppm]	STEL [mg/m ³]	Source
EU	hydrogen chloride	7647-01-0	IOELV	5	8	10	15	2000/39/EC
Germany	hydrogen chloride	7647-01-0	AGW	2	3	4	6	TRGS 900

Notation

STEL: Short-term exposure limit: a limit value above which exposure should not occur and which is related to a 15-minute period unless otherwise specified

TWA: Time-weighted average (long-term exposure limit): measured or calculated in relation to a reference period of 8 hours time-weighted average

Relevant DNELs/DMELs/PNECs and other threshold levels

• relevant DNELs of components of the mixture

Name of substance	CAS No	End-point	Threshold level	Protection goal, route of exposure	Used in	Exposure time
Hydrochloric acid	7647-01-0	DNEL	8 mg/m ³	human, inhalatory	worker	chronic - local effects
Hydrochloric acid	7647-01-0	DNEL	15 mg/m ³	human, inhalatory	worker	acute - local effects

If the products are used according to the instructions, no air pollution is to be expected.

Enzyme Conjugate

Mixture, 5-chloro-2-methyl-4-isothiazolin-3-one [EC no. 247-500-7] and 2-methyl-2H -isothiazol-3-one [EC no. 220-239-6] (3:1) (CAS-No. 55965-84-9)		
Germany	TRGS 900 Occupational exposure limit value (mg/m ³)	0.2 mg/m ³ inhalable fraction
Germany	TRGS 900 Limitation of exposure peaks (mg/m ³)	0.4 mg/m ³ inhalable fraction

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8.2. Exposure controls

General hygiene directives should be considered.

Keep away from foodstuffs and beverages. Wash hands before breaks and at the end of the working day.

Provide adequate ventilation of the work station.

Personal protective equipment

Skin Protection: Protective gloves of nitril rubber or nature latex, satisfying the norm EN 374
Eye / face protection: Safety glasses with side shields conforming to EN 166 (EU), NIOSH (US)
Body protection: Impenetrable protective clothing
Respiratory protection: Respiratory protection necessary at: Aerosol or mist formation. Type: E (against acidic gases like sulphur dioxide or hydrogen chloride, colour code: Yellow). Use NIOSH (or other equivalent national standard) -approved dust/particulate respirator. Where vapor, mist, or dust exceed PELs or other applicable OELs, use NIOSH-approved respiratory protective equipment. EN 250.

Environmental exposure controls:

Keep away from drains. Avoid contamination of water or soil.

9. PHYSICAL AND CHEMICAL PROPERTIES

9.1 Information on basic physical and chemical properties

Component	(a) Appearance	(b) Odor	(d) pH
Standards and Controls	liquid, colorless	odorless	7.4 ± 0.05
Enzyme Conjugate	liquid, red	odorless	7.4 ± 0.05
Microtiterplate	solid, clear	odorless	not applicable
TMB-Substrate Solution	liquid, colourless to pale yellow	characteristic	3,5 – 4,0
Stop Solution	liquid, colorless	odorless	acidic
Wash Buffer Concentrate	liquid, colorless	odorless	not applicable

For all components

(c) Odor 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
(l) Density	Stop Solution: 1,032g/cm ³ at 20 °C TMB-Substrate Solution: 1.011 g/ml
(m) Relative density	no data available
(n) Solubility(ies)	Fully miscible
(o) Partition coefficient: n-octanol/water	no data available
(p) Auto-ignition temperature	product is not selfigniting
(q) Decomposition temperature	no data available
(r) Viscosity	no data available
(s) Explosive properties	product does not present an explosion hazard
(t) Oxidising properties	no data available

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9.2 Other informations

No other information available.

10. STABILITY AND REACTIVITY

10.1 Reactivity: Stop Solution: Substance or mixture corrosive to metals.

10.2 Chemical stability: The materials are stable under normal ambient and anticipated storage and handling conditions of temperature and pressure.

10.3 Possibility of hazardous reactions: Stop Solution: Release of an acute toxic gas: Metals

10.4 Conditions to avoid

TMB-Substrate Solution: Protect from direct UV light, avoid elevated temperatures. Light, heat, moisture (will not cause a dangerous reaction, but destroys the quality of the products)

10.5 Incompatible materials:

Stop Solution: different metals.

TMB-Substrate Solution: heavy metal salts, complex forming agents and catalases (will not cause a dangerous reaction, but destroys the quality of the products)

10.6 Hazardous decomposition products:

Stop Solution: Dangerous products of combustion (see chapter 5).

Enzyme Conjugate: Thermal decomposition generates: Carbon oxides (CO, CO₂). Nitrogen oxides. Other toxic fumes.

11. TOXICOLOGICAL INFORMATION

11.1 Information on toxicological effects

(a) Acute toxicity	<u>Stop Solution:</u> not to be classified as acutely toxic.
(b) Skin corrosion/irritation	<u>Stop Solution:</u> not to be classified as skin corrosive/irritant.
(c) Serious eye damage / irritation	<u>Stop Solution:</u> not to be classified as seriously damaging or irritating to the eyes.
(d) Respiratory or skin sensitisation	<u>Stop Solution:</u> not to be classified as inhalation or skin allergen. <u>Enzyme Conjugate:</u> May cause an allergic skin reaction.
(e) Germ cell mutagenicity	<u>Stop Solution:</u> not classified as germ cell mutagenic
(f) Carcinogenicity	<u>Stop Solution:</u> not classified as carcinogenic or toxic for reproduction
(g) Reproductive toxicity	no data available
(h) STOT-single exposure	<u>TMB Solution:</u> based on availability data, the classification criteria are not met
(i) STOT-repeated exposure	<u>TMB Solution:</u> based on availability data, the classification criteria are not met
(j) Aspiration hazard	<u>Stop Solution:</u> not to be classified as dangerous for aspiration.

Additional Informations

Hazardous properties cannot be excluded but are unlikely when the products are handled appropriately.

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12. ECOLOGICAL INFORMATION

12.1 Toxicity: According to 1272/2008/EU: It is not classified as water hazardous.

Enzyme Conjugate:

Mixture, 5-chloro-2-methyl-4-isothiazolin-3-one [EC no. 247-500-7]; and 2-methyl-2H -isothiazol-3-one [EC no. 220-239-6] (3:1) (CAS-No. 55965-84-9)	
LC50 fish 1	0.19 mg/l Salmo Gairdneri
EC50 Daphnia 1	0.028 mg/l Crassostrea virg
EC50 72h algae (1)	0.018 mg/l Selenastrum cap

12.2 Persistence and degradability:

Mixture, 5-chloro-2-methyl-4-isothiazolin-3-one [EC no. 247-500-7]; and 2-methyl-2H -isothiazol-3-one [EC no. 220-239-6] (3:1) (CAS-No. 55965-84-9): Not rapidly degradable

12.3 Bioaccumulative potential:

Mixture, 5-chloro-2-methyl-4-isothiazolin-3-one [EC no. 247-500-7]; and 2-methyl-2H -isothiazol-3-one [EC no. 220-239-6] (3:1) (CAS-No. 55965-84-9)

Log Kow > 5 Significant bioaccumulation

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.

13. DISPOSAL CONSIDERATIONS

13.1. Waste treatment methods

Product:

This product and its container must be disposed of as hazardous waste. Waste should be disposed of in accordance with federal, state and local environmental control regulations. Must not be composed together with household garbage.

Uncleaned packaging:

Waste should be disposed of in accordance with federal, state and local environmental control regulations. Must not be composed together with household garbage.

General notes:

Do not empty into drains.

14. TRANSPORT INFORMATION

No hazardous material as defined by the transport regulations (ADR/RID, IMDG Code, ICAO TI/IATA DGR).

- 14.1 UN number: 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 user: no data available
- 14.7 Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code: no data available

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15. REGULATORY INFORMATION

15.1 Safety, health and environmental regulations/legislation specific for the substance or mixture This Safety Data Sheet is according to:

- 1907/2006/EC Registration, evaluation and authorization of chemicals regulation (REACH)
1272/2008/EC Classification, labelling and packaging regulation (CLP, globally harmonized system GHS) replaces 67/548/EEC and 1999/45/EC, amending 1907/2006/EC
453/2010/EC Compilation of safety data sheets regulation (SDS), amending 1907/2006/EC
2016/1179/EC Commission Regulation (EU) 2016/1179 of 19 July 2016 amending, for the purposes of its adaptation to technical and scientific progress, Regulation (EC) No 1272/2008 of the European Parliament and of the Council on classification, labelling and packaging of substances and mixtures
487/2013/EC COMMISSION REGULATION (EU) No 487/2013 of 8 May 2013 amending, for the purposes of its adaptation to technical and scientific progress, Regulation (EC) No 1272/2008 of the European Parliament and of the Council on classification, labelling and packaging of substances and mixtures

15.2 Chemical safety assessment

No data available.

16. OTHER INFORMATION

Full text of R-, H- and EUH-statements:

Acute Tox. 3 (Dermal)	Acute toxicity (dermal), Category 3
Acute Tox. 3 (Inhalation)	Acute toxicity (inhal.), Category 3
Acute Tox. 3 (Inhalation:dust,mist)	Acute toxicity (inhalation:dust,mist) Category 3
Acute Tox. 3 (Oral)	Acute toxicity (oral), Category 3
Aquatic Acute 1	Hazardous to the aquatic environment — Acute Hazard, Category 1
Aquatic Chronic 1	Hazardous to the aquatic environment — Chronic Hazard, Category 1
Eye Irrit. 2	Serious eye damage/eye irritation, Category 2
Skin Corr. 1B	Skin corrosion/irritation, Category 1B
Skin Sens. 1	Skin sensitisation, Category 1
H301	Toxic if swallowed
H311	Toxic in contact with skin
H314	Causes severe skin burns and eye damage
H317	May cause an allergic skin reaction
H319	Causes serious eye irritation
H331	Toxic if inhaled
H400	Very toxic to aquatic life
H410	Very toxic to aquatic life with long lasting effects
EUH208	Contains. May produce an allergic reaction
EUH210	Safety data sheet available on request

Classification according to Regulation (EC) 1272/2008 Classification procedure





Skin Sens. 1 Calculation method

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“P statements” and “S Phrases” used in this Safety data sheet

<u>Reg. 1272/2008</u>	
P261	Avoid breathing mist, vapors, spray
P272	Contaminated work clothing should not be allowed out of the workplace
P280	Wear eye protection, protective gloves, protective clothing
P302+P352	IF ON SKIN: Wash with plenty of soap and water
P333 + P313	If skin irritation or rash occurs: Get medical advice/attention
P362+P364	Take off contaminated clothing and wash it before reuse

“GHS Pictograms” used in this Safety data sheet

<u>Reg. 1272/2008</u>	<u>Pictograms</u>
GHS05	
GHS06	
GHS07	
GHS09	

Department issuing MSDS: Product Management

This information is based on our present knowledge. However, this shall not constitute a guarantee for any specific product features and shall not establish a legally valid contractual relationship.