

Trade name: Estriol free in Saliva ELISA
Article number: DES6644

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

1.1 Product identifier

Trade name: Estriol free in Saliva

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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]
Enzyme Conjugate Dilution Buffer	[DIL BUF]
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/GHS]

TMB-Substrate Solution

Hazard classes and Hazard categories	Hazard Statements
May damage the unborn child.	H360D

For full text of Hazard statements see SECTION 16.

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2.2 Label elements

TMB-Substrate Solution



Hazard pictogram(s):

Signal word(s):

Danger

Hazard statement(s):

H360D May damage the unborn child

Precautionary statement(s):

P280 Wear protective gloves/protective clothing/eye protection/face protection

For full text of statements see SECTION 16.

2.3 Other hazards

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

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

3. COMPOSITION / INFORMATION ON INGREDIENTS

3.1 Substances

3.2 Mixtures

<i>Stop Solution</i>						
<i>Ingredients</i>	<i>CAS No [EC No]</i>	<i>Containing Conc. (%)</i>	<i>Classification according to regulation (EC) No 1272/2008 (CLP) (related to the concentrated form)</i>		<i>Pictogram, Signal Word Code(s)</i>	<i>Specific Conc. Limits, M-factors</i>
			<i>Hazard Class and Category Code(s)</i>	<i>Hazard statement Code(s)</i>		
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.



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Calibrator, Controls, Enzyme Conjugate, Wash Solution, Enzyme Conjugate Dilution Buffer

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-nr 247-500-7) and 2-methyl-2H-isothiazol-3-one (EG-nr 220-239-6).

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

TMB-Substrate 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)		
N-Methyl-2-pyrrolidone Index-No. 606-021-00-7	212-828-1 [872-50-4]	< 5.0 %	Repr. 1B STOT SE 3 Skin Irrit. 2 Eye Irrit. 2	H360D*** H335 H315 H319	GHS08 GHS07 Dgr	STOT SE 3; H335: C ≥ 10 %*

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. Call a doctor if you feel unwell.

4.2 Most important symptoms and effects, both acute and delayed

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

Wear breath protective mask and protective clothes if necessary during fire fighting.

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.

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).

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.

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.

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: class1 (explosives)

class 4.3 (dangerous when wet)

class 7 (radioactive)

class 4.1A (flammable solids)

class 6.2 (infectious)

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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

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	Enpoint	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

TMB-Substrat Solution

EINECS	name	limit value according to MAK (TRGS 900)	limit value according to BGW (TRGS 903)
212-828-1	N-Methyl-2-pyrrolidone	82 mg/m ³	150 mg/l urine at the end of a shift, parameter: 5-Hydroxy-N-Methyl-2-pyrrolidone

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

8.2. Exposure controls

Pregnant women should strictly avoid inhalation or skin contact with TMB-Substrat Solution.

General hygiene directives should be considered.

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

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Personal protective equipment

Respiratory protection: Not required.
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).
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) Odour	(d) pH
Standards and Controls	liquid, colorless	odorless	7.4 ± 0.05
Enzyme Conjugate	liquid, red	odorless	7.4 ± 0.05
Microtiterplate	solid, white	odorless	not applicable
TMB-Substrate Solution	liquid, colourless to slightly bluish	characteristic	3,6 - 3,8
Stop Solution	liquid, colorless	odorless	acidic
Wash Buffer Concentrate	liquid, colorless	odorless	not applicable

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
(l) Density	Stop Solutuon: 1,032g/cm ³ at 20 °C TMB-Substrat Solution: 1.003 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

9.2 Other informations

No other information available.

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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:** No dangerous decomposition products known.

11. TOXICOLOGICAL INFORMATION

11.1 Information on toxicological effects

TMB Solution:

(a) acute toxicity

Component	valuation	value	species
N-Methyl-2-pyrrolidone	LD 50 (oral)	3598 mg/kg	rat
	LC 50 (inhalativ)	>5.1 mg/l	rat

(b) skin corrosion/irritation

Component	valuation	value	species
N-Methyl-2-pyrrolidone	LD 50 (dermal)	8000 mg/kg	rabbit

(a) Acute toxicity	Stop Solution: no data available
(b) Skin corrosion/irritation	TMB Solution: May cause irritation of the skin.
(c) Serious eye damage / irritation	TMB Solution: irritant
(d) Respiratory or skin sensitisation	no data available
(e) Germ cell mutagenicity	no data available
(f) Carcinogenicity	no data available
(g) Reproductive toxicity	TMB Solution: May damage the unborn child: N-Methyl-2-pyrrolidone (Repr. 1B)
(h) STOT-single exposure	TMB Solution: May cause respiratory irritation.
(i) STOT-repeated exposure	no data available
(j) Aspiration hazard	no data available

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: **TMB-Substrat Solution:**

N-Methyl-2-pyrrolidone:

Spezies	Art	Wert
bluegill (Lepomis macrochirus)	LC 50 (mg/l/96h)	832
gold orfe (Leuciscus idus)	LC 50 (mg/l/96h)	> 500
green alga (Desmodesmus subspicatus)	IC 50 (mg/l/72h)	> 500
invertebrates (Daphnia magna)	EC 50 (mg/l/48h)	4897

12.2 Persistence and degradability: **TMB-Substrat Solution:** N-Methyl-2-pyrrolidone > 90%/20d easily biologically degradable

12.3 Bioaccumulative potential: **TMB-Substrat Solution:** Distribution: log P(o/w): ≤ 4 (for N-Methyl-2-pyrrolidone) There is no Bioaccumulation expected

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:

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

"H code" used in this Safety data sheet






Reg. 1272/2008	
H290	May be corrosive to metals
H301	Toxic if swallowed.
H311	Toxic in contact with skin.
H314	Causes severe skin burns and eye damage.
H315	Cause skin irritation.
H317	May cause an allergic skin reaction.
H318	Causes serious eye damage
H319	Cause serious eye irritation.
H331	Toxic if inhaled.
H335	May cause respiratory irritation.
H360D	May damage the unborn child.
H400	Very toxic to aquatic life.
H410	Very toxic to aquatic life with long lasting effects.

"P statements" and "S Phrases" used in this Safety data sheet

Reg. 1272/2008	
P234	Keep only in original container
P280	Wear protective gloves/protective clothing/eye protection/face protection
P390	Absorb spillage to prevent material damage

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“GHS Pictograms” used in this Safety data sheet

<i>Reg. 1272/2008</i>	Pictograms
GHS05	
GHS06	
GHS07	
GHS08	
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.