



Safety Data Sheet

According to Regulation (EC) No 1907/2006

Version 12

Revision: 2024-04-25

REF	<u>article name</u>
FR E-2800	17-OH-Progesterone ELISA
FR E-2800R	17-OH-Progesterone ELISA

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

Trade name: 17-OH-Progesterone ELISA
Article number: FR E-2800/FR E-2800R

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	FR E-2831
Standard A-F	FR E-2801 - FR E-2806
Control 1 & 2	FR E-2851 & FR E-2852
Enzyme Conjugate	FR E-2840
Substrate Solution	AR E-0055
Stop Solution	AR E-0080
Wash Solution	AR E-0030

1.3 Details of the supplier of the safety data sheet

Manufacturer/Supplier:
LDN Labor Diagnostika Nord GmbH & Co. KG
Am Eichenhain 1
D-48531 Nordhorn

Phone: +49 5921 8197 200
Fax: +49 5921 8197 201
E-mail: support@ldn.de
www.ldn.de

1.4 Emergency telephone number

+49 5921 8197 200 (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

Refer to section 9 to 12.

2.2 Label elements

Enzyme Conjugate

Labeling 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 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

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)		
Hydrochloric 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.

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) Acute Tox. 3 (Inhalation:dust,mist) Skin Corr. 1B Skin Sens. 1 Aquatic Acute 1 Aquatic Chronic 1	H301 H311 H331 H314 H317 H400 H410	GHS06 GHS05 GHS09 Dgr	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%				

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

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.

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: Hydrochloric acid (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 vapor/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).

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.

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	Hydrochloric acid	7647-01-0	IOELV	5	8	10	15	2000/39/EC
Germany	Hydrochloric acid	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

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, color 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) Physical state, (b) color	(c) Odor	(k) pH
Calibrators and Controls	liquid, colorless	odorless	7.4 ± 0.05
Enzyme Conjugate	liquid, red	odorless	7.4 ± 0.05
Microtiterplate	solid, clear	odorless	not applicable
Substrate Solution	liquid, colorless 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

(d) Melting point/freezing point	no data available
(e) Initial boiling point and boiling range	no data available
(f) Flammability	no data available
(g) Lower and upper explosion limit	no data available
(h) Flash point	no data available
(i) Auto-ignition temperature	no data available
(j) Decomposition temperature	no data available
(l) Kinematic viscosity	no data available
(m) Solubility	fully miscible
(n) Partition coefficient n-octanol/water (log value)	no data available
(o) Vapor pressure	no data available
(p) Density and/or relative density	Stop Solution: 1,032g/cm ³ at 20 °C Substrate Solution: 1.011 g/ml
(q) Relative vapor density	no data available
(r) Particle characteristics	no data available

9.2 Other information

Information with regard to physical hazard classes

(a) Explosives	not applicable
(b) Flammable gases	not applicable
(c) Aerosols	not applicable
(d) Oxidizing gases	not applicable
(e) Gases under pressure	not applicable
(f) Flammable liquids	no data available
(g) Flammable solids	no data available
(h) Self-reactive substances and mixtures	no data available
(i) Pyrophoric liquids	not applicable

(j) Pyrophoric solids	not applicable
(k) Self-heating substances and mixtures	not applicable
(l) Substances and mixtures, which emit flammable gases in contact with water	not applicable
(m) Oxidizing liquids	Enzyme Conjugate: Thermal decomposition generates: Carbon oxides (CO, CO ₂). Nitrogen oxides. Other toxic fumes.
(n) Oxidizing solids	not applicable
(o) Organic peroxides	not applicable
(p) Corrosive to metals	Stop Solution: Hydrochloric acid
(q) Desensitized explosives	no data 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

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.

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 hazard classes as defined in Regulation (EC) No 1272/2008

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

(j) Aspiration hazard

Stop Solution: not to be classified as dangerous for aspiration.

11.2 Information on other hazards

Additional information

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

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 Endocrine disrupting properties: no data available.

12.7 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 or ID 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 Maritime transport in bulk according to IMO instruments: no data available

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

15.2 Chemical safety assessment

No data available.

16. OTHER INFORMATION

Full text of 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

P statements 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

Reg. 1272/2008	Pictograms
GHS05	
GHS06	
GHS07	
GHS09	

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.