

Safety Data Sheet according to Regulation (EC) No 1907/2006

Date of issue: 22.01.2025

Revision date: 22.01.2025

Version/Replaced version: 09/08

Usable for:

REF	Name
MS E-5100	Cortisol Urine ELISA
MS E-5100R	Cortisol Urine ELISA

Single components where a safety data sheet is in attachment:

REF	Name		Annex
MS E-5101	Standard A	STANDARD A	
MS E-5102	Standard B	STANDARD B	
MS E-5103	Standard C	STANDARD C	
MS E-5104	Standard D	STANDARD D	I
MS E-5105	Standard E	STANDARD E	I
MS E-5151	Control 1	CONTROL 1	
MS E-5152	Control 2	CONTROL 2	
MS E-0030	Wash Solution	WASH-CONC 10x	
MS E-5140	Conjugate	CONJUGATE	II

Single components not listed, contain no hazardous substances in concentrations to be declared. A safety data sheet is not required.



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Annex I

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

1.1 Product identifier

Cortisol Urine ELISA Trade name: Product number: MS E-5100

Kit Components: Standards Controls TMB Substrate Conc. Wash Solution

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

Components of an in-vitro diagnostic device

Details of the supplier of the safety data sheet 1.3

Phone.: +49 5921 8197 200 LDN Labor Diagnostika Nord GmbH & Co.KG Am Eichenhain 1 Fax: +49 5921 8197 201 D-48531 Nordhorn E-Mail: support@ldn.de Germany

1.4 **Emergency telephone number**

+49 5921 8197 200

(Only available during the following office hours: 8:00 h – 16:00 h (CET))

SECTION 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- and EUH-statements: see section 16

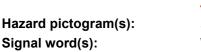
Adverse physicochemical, human health and environmental effects

May cause an allergic skin reaction.

2.2 Label elements

Signal word

Hazard-determining ingredient of labelling: A MIXTURE OF: 5-CHLORO-2-METHYL-2H-ISOTHIAZOL-3-ONE [EC NO 247-500-7] AND 2-METHYL-2H-ISOTHIAZOL-3-ONE [EC NO 220-239-6]



Signal word(s):	Warning	
Hazard statement(s):	H317 - May cause an allergic skin reaction.	
Precautionary statement(s):	s): P261 - Avoid breathing dust/fume/gas/mist/vapours/ spray.	
	P280 - Wear protective gloves.	
	P321 - Specific treatment (see supplemental first aid instruction on this label).	
	P333 + P313 If skin irritation or rach accurs: Cot modical advice/attention	

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

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

2.3 Other hazards

Contains no PBT/vPvB substances ≥ 0.1% assessed in accordance with REACH Annex XIII

The mixture does not contain substance(s) included in the list established in accordance with Article 59(1) of REACH for having endocrine disrupting properties, or is not identified as having endocrine disrupting properties in accordance with the criteria set out in Commission Delegated Regulation

(EU) 2017/2100 or Commission Regulation (EU) 2018/605 at a concentration equal to or greater than 0,1 %



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SECTION 3: COMPOSITION/INFORMATION ON INGREDIENTS

3.1 <u>Substances</u>

Not applicable.

3.2 <u>Mixtures</u>

Substance name	CAS No. Concentration in (EC No.) the mixture [Index No.]		Classification according to Regulation (EC) No 1272/2008 [CLP] (related to the concentrated form)		
	"REACH No."		Hazard class / Hazard categories	Hazard- statement	Specific Conc. Limits, M-factors and ATE
A MIXTURE OF: 5- CHLORO-2-METHYL-2H- ISOTHIAZOL-3-ONE [EC NO 247-500-7] AND 2METHYL-2H-ISOTHIAZOL- 3-ONE [EC NO 220-239-6]	CAS-No.: 55965-84-9 EC Index-No.: 613-167-00-5	< 1 %	Acute Tox. 3 (Oral) Acute Tox. 3 (Dermal) Acute Tox. 3 (Inhalation) Acute Tox. 2 (Inhalation:dust,mist) Skin Corr. 1A Eye Dam. 1 Skin Sens. 1 Aquatic Acute 1 Aquatic Chronic 1	H301 H311 H331 H330 H314 H318 H317 H400 H410	$(0,0015 \le C < 100)$ Skin Sens. 1, H317 $(0,06 \le C \le 0,6)$ Skin Irrit. 2, H315 $(0,06 \le C \le 0,6)$ Eye Irrit. 2, H319 $(0,6 \le C < 100)$ Skin Corr. 1B, H314

Full text of H-phrases: see section 16.

SECTION 4: FIRST AID MEASURES

4.1 <u>Description of first aid measures</u>

First-aid measures after inhalation	Remove person to fresh air and keep comfortable for breathing.
First-aid measures after skin contact	Wash skin with plenty of water. Take off contaminated clothing. If skin irritation or rash occurs: Get medical advice/attention.
First-aid measures after eye contact	Rinse eyes with water as a precaution.
First-aid measures after ingestion	Call a poison center or a doctor if you feel unwell.

4.2 Most important symptoms and effects, both acute and delayed

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

4.3 Indication of any immediate medical attention and special treatment needed

Treat symptomatically.

SECTION 5: FIREFIGHTING MEASURES

5.1 <u>Extinguishing media</u>

Suitable extinguishing media: Water spray. Dry powder. Foam. Carbon dioxide

5.2 Special hazards arising from the substance or mixture

Hazardous decomposition products in case of fire: Toxic fumes may be released

5.3 Advice for firefighters

Protection during firefighting: Do not attempt to take action without suitable protective equipment. Self-contained breathing apparatus. Complete protective clothing.

SECTION 6: ACCIDENTAL RELEASE MEASURES

6.1 Personal precautions, protective equipment and emergency procedures



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6.1.1. For non-emergency personnel

Emergency procedures: Ventilate spillage area. Avoid contact with skin and eyes. Avoid breathing dust/fume/gas/mist/vapours/spray.

6.1.2. For emergency responders

Protective equipment: Do not attempt to take action without suitable protective equipment. For further information refer to section 8: "Exposure controls/personal protection".

6.2 Environmental precautions

Avoid release to the environment

6.3 Methods and material for containment and cleaning up

Methods for cleaning up:Take up liquid spill into absorbent material.Other information:Dispose of materials or solid residues at an authorized site.

6.4 Reference to other sections

For further information refer to section 13.

SECTION 7: HANDLING AND STORAGE

7.1 Precautions for safe handling

Precautions for safe handling:Ensure good ventilation of the work station. Avoid contact with skin and eyes. Avoid
breathing dust/fume/gas/mist/vapours/spray. Wear personal protective equipment.Hygiene measures:Contaminated work clothing should not be allowed out of the workplace. Wash
contaminated clothing before reuse. Do not eat, drink or smoke when using this
product.
Always wash hands after handling the product.

7.2 Conditions for safe storage, including any incompatibilities

Storage conditions: Store in a well-ventilated place. Keep cool

7.3 Specific end use(s)

No additional information available.

SECTION 8: EXPOSURE CONTROLS/PERSONAL PROTECTION

8.1 <u>Control parameters</u>

8.1.1 National occupational exposure and biological limit values

A MIXTURE OF: 5-CHLORO-2-METHYL-2H-ISOTHIAZOL-3-ONE [EC NO 247-500-7] AND 2-METHYL-2H-ISOTHIAZOL-3- ONE [EC NO 220-239-6] (55965-84-9)			
Austria - Occupational Exposure Limits			
Local name	5-Chlor-2-methyl-2,3-dihydroisothiazol-3-on und 2-Methyl-2,3-di-hydroisothiazol-3-on (Gemisch im Verhältnis 3:1)		
MAK (OEL TWA)	0,05 mg/m³		
Remark	Sh		
Regulatory reference	BGBI. II Nr. 156/2021		
Switzerland - Occupational Exposure Limits			
Local name	2,3-Dihydro-isothiazol-3-one de 5-chloro-2-méthyle et 2,3-dihydro-isothiazol-3-one de 2méthyle [2,3-Dihydro-isothiazol-3-one de 5-chloro-2-méthyle, 2,3-Dihydro-isothiazol-3-one de 2-méthyle] / 5-Chlor-2-methyl-2,3-dihydro-isothiazol-3-on und 2-Methyl-2,3dihydroisothiazol-3-on [2-Methyl-2,3-dihydroisothiazol-3-on, 5-Chlor-2-methyl-2,3dihydroisothiazol-3-on]		



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MAK (OEL TWA) [1]	0,2 mg/m³ (i) / (e)
KZGW (OEL STEL)	0,4 mg/m³ (i) / (e)
Critical toxicity	VRS, Peau, Yeux / OAW, Haut, Auge
Notation	S, SS _C / S, SS _C
Regulatory reference	www.suva.ch, 01.01.2023

8.1.2 Recommended monitoring procedures

No additional information available

8.1.3 Air contaminants formed

No additional information available

8.1.4 DNEL and PNEC

No additional information available

8.1.5 Control banding

No additional information available

8.2 Exposure controls

8.2.1 Appropriate engineering controls

Appropriate engineering controls: Ensure good ventilation of the work station.

8.2.2 Personal protection equipment

Personal protective equipment symbol(s):



8.2.2.1 Eye and face protection

Eye protection: Safety glasses

8.2.2.2 Skin protection

Skin and body protection: Wear suitable protective clothing Hand protection: Protective gloves

8.2.2.3 Respiratory protection

Respiratory protection: In case of insufficient ventilation, wear suitable respiratory equipment

8.2.2.4 Thermal hazards

No additional information available

8.2.3 Environmental exposure controls

Environmental exposure controls: Avoid release to the environment.

SECTION 9: PHYSICAL AND CHEMICAL PROPERTIES

9.1 Information on basic physical and chemical properties



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Physical state:	Liquid
Colour:	Colourless.
Appearance:	Liquid.
Odour:	odourless.
Odour threshold:	Not available
Melting point:	Not applicable
Freezing point:	Not available
Boiling point:	Not available
Flammability:	Non flammable.
Lower explosion limit:	Not available
Upper explosion limit:	Not available
Flash point:	Not available
Auto-ignition temperature:	Not available
Decomposition temperature:	Not available
pH:	Not available
Viscosity, kinematic:	Not available
Solubility:	Not available
Partition coefficient n-octanol/water (Log Kow):	Not available
Vapour pressure:	Not available
Vapour pressure at 50°C:	Not available
Density:	Not available
Relative density:	Not available
Relative vapour density at 20°C:	Not available
Particle characteristics:	Not applicable

9.2 Other information

9.2.1 Information with regard to physical hazard classes

No additional information available

9.2.2 Other safety characteristics

No additional information available

SECTION 10: STABILITY AND REACTIVITY

10.1 Reactivity

The product is non-reactive under normal conditions of use, storage and transport.

10.2 Chemical stability

Stable under normal conditions.

10.3 **Possibility of hazardous reactions**

No dangerous reactions known under normal conditions of use.

10.4 Conditions to avoid

None under recommended storage and handling conditions (see section 7).

10.5 Incompatible materials

No additional information available

10.6 <u>Hazardous decomposition products</u>

Under normal conditions of storage and use, hazardous decomposition products should not be produced.



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SECTION 11: TOXICOLOGICAL INFORMATION

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

Acute toxicity (oral):	Not classified
Acute toxicity (dermal):	Not classified
Acute toxicity (inhalation):	Not classified
Skin corrosion/irritation:	Not classified
Serious eye damage/irritation:	Not classified
Respiratory or skin sensitisation:	May cause an allergic skin reaction.
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

11.2 Information on other hazards

No additional information available.

SECTION 12: ECOLOGICAL INFORMATION

12.1 Toxicity

Ecology - general:

Hazardous to the aquatic environment, short–term (acute): Hazardous to the aquatic environment, long–term (chronic): Not rapidly degradable

12.2 Persistence and degradability

No additional information available

12.3 Bioaccumulative potential

No additional information available

12.4 Mobility in soil

No additional information available

12.5 Results of PBT and vPvB assessment

No additional information available

12.6 Endocrine disrupting properties

No additional information available

12.7 Other adverse effects

No additional information available

SECTION 13: DISPOSAL CONSIDERATIONS

13.1 Waste treatment methods

Waste treatment methods: Dispose of contents/container in accordance with licensed collector's sorting instructions.

The product is not considered harmful to aquatic organisms nor to cause long-term adverse effects in the environment. Not classified Not classified



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SECTION 14: TRANSPORT INFORMATION

		ΙΑΤΑ	IMDG	RID	ADR	ADN
1.1	<u>UN number or ID number</u>	Not applicable	Not applicable	Not applicable	Not applicable	Not applicable
1.2	UN Proper shipping name	Not applicable	Not applicable	Not applicable	Not applicable	Not applicable
1.3	Transport hazard class(es)	Not applicable	Not applicable	Not applicable	Not applicable	Not applicable
1.4	Packing group	Not applicable	Not applicable	Not applicable	Not applicable	Not applicable
1.5	Environmental hazards	Not applicable	Not applicable	Not applicable	Not applicable	Not applicable
1.6	<u>Special precautions for</u> <u>user</u> Special Provisions	Not applicable	Not applicable	Not applicable	Not applicable	Not applicable
1.7	<u>Maritime transport in bulk</u> according to IMO instruments	Not applicable	Not applicable	Not applicable	Not applicable	Not applicable

SECTION 15: REGULATORY INFORMATION

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

15.1.1 15.1.1. EU-Regulations

REACH Annex XVII (Restriction List)

Contains no substance(s) listed on REACH Annex XVII (Restriction Conditions)

REACH Annex XIV (Authorisation List)

Contains no substance(s) listed on REACH Annex XIV (Authorisation List)

REACH Candidate List (SVHC)

Contains no substance(s) listed on the REACH Candidate List

PIC Regulation (Prior Informed Consent)

Contains no substance(s) listed on the PIC list (Regulation EU 649/2012 concerning the export and import of hazardous chemicals)

POP Regulation (Persistent Organic Pollutants)

Contains no substance(s) listed on the POP list (Regulation EU 2019/1021 on persistent organic pollutants)

Ozone Regulation (1005/2009)

Contains no substance(s) listed on the Ozone Depletion list (Regulation EU 1005/2009 on substances that deplete the ozone layer)

Explosives Precursors Regulation (2019/1148)

Contains no substance(s) listed on the Explosives Precursors list (Regulation EU 2019/1148 on the marketing and use of explosives precursors)

Drug Precursors Regulation (273/2004)

Contains no substance(s) listed on the Drug Precursors list (Regulation EC 273/2004 on the manufacture and the placing on market of certain substances used in the illicit manufacture of narcotic drugs and psychotropic substances) 15.1.2. National regulations



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<u>Germany</u>

Employment restrictions: Observe restrictions according Act on the Protection of Working Mothers (MuSchG). Observe restrictions according Act on the Protection of Young People in Employment (JArbSchG).

Water hazard class (WGK): WGK 1, Slightly hazardous to water (Classification according to AwSV, Annex 1).

Hazardous Incident Ordinance (12. BImSchV): Is not subject of the Hazardous Incident Ordinance (12. BImSchV)

Netherlands

SZW-lijst van kankerverwekkende stoffen: None of the components are listed

SZW-lijst van mutagene stoffen: None of the components are listed

SZW-lijst van reprotoxische stoffen – Borstvoeding: None of the components are listed

SZW-lijst van reprotoxische stoffen – Vruchtbaarheid: None of the components are listed

SZW-lijst van reprotoxische stoffen – Ontwikkeling: None of the components are listed

<u>Denmark</u>

Danish National Regulations: Young people below the age of 18 years are not allowed to use the product. Pregnant/breastfeeding women working with the product must not be in direct contact with the product

Switzerland:

Storage class (LK): LK 10/12 - Liquids

15.2 Chemical safety assessment

No chemical safety assessment has been carried out.

SECTION 16: OTHER INFORMATION

Abbreviations and acronyms:

<u>Abbreviatio</u>	ons and acronyms:
ADN	European Agreement concerning the International Carriage of Dangerous Goods by Inland Waterways
ADR	European Agreement concerning the International Carriage of Dangerous Goods by Road
ATE	Acute Toxicity Estimate
BCF	Bioconcentration factor
BLV	Biological limit value
BOD	Biochemical oxygen demand (BOD)
COD	Chemical oxygen demand (COD)
DMEL	Derived Minimal Effect level
DNEL	Derived-No Effect Level
EC-No.	European Community number
EC50	Median effective concentration
EN	European Standard
IARC	International Agency for Research on Cancer
IATA	International Air Transport Association
IMDG	International Maritime Dangerous Goods
LC50	Median lethal concentration
LD50	Median lethal dose
LOAEL	Lowest Observed Adverse Effect Level
NOAEC	No-Observed Adverse Effect Concentration
NOAEL	No-Observed Adverse Effect Level
NOEC	No-Observed Effect Concentration
OECD	Organisation for Economic Co-operation and Development
OEL	Occupational Exposure Limit
PBT	Persistent Bioaccumulative Toxic
PNEC	Predicted No-Effect Concentration
RID	Regulations concerning the International Carriage of Dangerous Goods by Rail
SDS	Safety Data Sheet
STP	Sewage treatment plant
ThOD	Theoretical oxygen demand (ThOD)



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TLM VOC CAS-No. N.O.S. vPvB	Median Tolerance Limit Volatile Organic Compounds Chemical Abstract Service number Not Otherwise Specified Very Persistent and Very Bioaccumulative
vPvB	
ED	Endocrine disrupting properties

Full text of H- and EUH-statements:

Acute Tox. 3 (Dermal)Acute toxicity (dermal), Category 3Acute Tox. 3 (Inhalation)Acute toxicity (inhal.), Category 3Acute Tox. 3 (Oral)Acute toxicity (oral), Category 3Aquatic Acute 1Hazardous to the aquatic environment – Acute Hazard, Category 1Aquatic Chronic 1Hazardous to the aquatic environment – Chronic Hazard, Category 1Eye Dam. 1Serious eye damage/eye irritation, Category 1Eye Irrit. 2Serious eye damage/eye irritation, Category 2H301Toxic if swallowed.H314Causes severe skin burns and eye damage.H315Causes sevine sevin burns and eye damage.H318Causes serious eye damage.H319Causes serious eye irritation.H318Causes serious eye irritation.H319Causes serious eye irritation.H310Toxic if inhaled.H400Very toxic to aquatic life.H410Very toxic to aquatic life with long lasting effects.Skin Corr. 1ASkin corrosion/irritation, Category 1, Sub-Category 1ASkin corrosion/irritation, Category 1, Sub-Category 1ASkin corrosion/irritation, Category 1, Sub-Category 1A	Acute Tox. 2 (Inhalation:dust,mist)	Acute toxicity (inhalation:dust,mist) Category 2
Acute Tox. 3 (Oral)Acute toxicity (oral), Category 3Aquatic Acute 1Hazardous to the aquatic environment – Acute Hazard, Category 1Aquatic Chronic 1Hazardous to the aquatic environment – Chronic Hazard, Category 1Eye Dam. 1Serious eye damage/eye irritation, Category 1Eye Irrit. 2Serious eye damage/eye irritation, Category 2H301Toxic if swallowed.H311Toxic in contact with skin.H314Causes severe skin burns and eye damage.H315Causes sevin skin irritation.H318Causes serious eye damage.H319Causes serious eye damage.H331Toxic if inhaled.H400Very toxic to aquatic life.H410Very toxic to aquatic life with long lasting effects.Skin Corr. 1ASkin corrosion/irritation, Category 1, Sub-Category 1A	Acute Tox. 3 (Dermal)	Acute toxicity (dermal), Category 3
Aquatic Acute 1Hazardous to the aquatic environment – Acute Hazard, Category 1Aquatic Chronic 1Hazardous to the aquatic environment – Chronic Hazard, Category 1Eye Dam. 1Serious eye damage/eye irritation, Category 1Eye Irrit. 2Serious eye damage/eye irritation, Category 2H301Toxic if swallowed.H311Toxic in contact with skin.H314Causes severe skin burns and eye damage.H315Causes skin irritation.H317May cause an allergic skin reaction.H318Causes serious eye damage.H319Causes serious eye irritation.H331Toxic if inhaled.H400Very toxic to aquatic life.H410Very toxic to aquatic life with long lasting effects.Skin Corr. 1ASkin corrosion/irritation, Category 1, Sub-Category 1ASkin corrosion/irritation, Category 1, Sub-Category 1B	Acute Tox. 3 (Inhalation)	Acute toxicity (inhal.), Category 3
Aquatic Chronic 1Hazardous to the aquatic environment – Chronic Hazard, Category 1Eye Dam. 1Serious eye damage/eye irritation, Category 1Eye Irrit. 2Serious eye damage/eye irritation, Category 2H301Toxic if swallowed.H311Toxic in contact with skin.H314Causes severe skin burns and eye damage.H315Causes skin irritation.H317May cause an allergic skin reaction.H318Causes serious eye damage.H319Causes serious eye irritation.H330Fatal if inhaled.H331Toxic if inhaled.H400Very toxic to aquatic life.H410Very toxic to aquatic life with long lasting effects.Skin Corr. 1ASkin corrosion/irritation, Category 1, Sub-Category 1ASkin Corr. 1BSkin corrosion/irritation, Category 1, Sub-Category 1B	Acute Tox. 3 (Oral)	Acute toxicity (oral), Category 3
Eye Dam. 1Serious eye damage/eye irritation, Category 1Eye Irrit. 2Serious eye damage/eye irritation, Category 2H301Toxic if swallowed.H311Toxic in contact with skin.H314Causes severe skin burns and eye damage.H315Causes skin irritation.H317May cause an allergic skin reaction.H318Causes serious eye damage.H319Causes serious eye irritation.H330Fatal if inhaled.H331Toxic if inhaled.H400Very toxic to aquatic life.H410Very toxic to aquatic life with long lasting effects.Skin Corr. 1ASkin corrosion/irritation, Category 1, Sub-Category 1ASkin corr. 1BSkin corrosion/irritation, Category 1, Sub-Category 1B	Aquatic Acute 1	Hazardous to the aquatic environment – Acute Hazard, Category 1
Eye Irrit. 2Serious eye damage/eye irritation, Category 2H301Toxic if swallowed.H311Toxic in contact with skin.H314Causes severe skin burns and eye damage.H315Causes skin irritation.H317May cause an allergic skin reaction.H318Causes serious eye damage.H319Causes serious eye irritation.H331Toxic if inhaled.H331Toxic if inhaled.H331Skin corr. 1ASkin corr. 1BSkin corrosion/irritation, Category 1, Sub-Category 1B	Aquatic Chronic 1	Hazardous to the aquatic environment – Chronic Hazard, Category 1
H301Toxic if swallowed.H311Toxic in contact with skin.H314Causes severe skin burns and eye damage.H315Causes skin irritation.H317May cause an allergic skin reaction.H318Causes serious eye damage.H319Causes serious eye irritation.H330Fatal if inhaled.H331Toxic if inhaled.H400Very toxic to aquatic life.H410Very toxic to aquatic life with long lasting effects.Skin Corr. 1ASkin corrosion/irritation, Category 1, Sub-Category 1ASkin corrosion/irritation, Category 1, Sub-Category 1B	Eye Dam. 1	Serious eye damage/eye irritation, Category 1
H311Toxic in contact with skin.H314Causes severe skin burns and eye damage.H315Causes skin irritation.H317May cause an allergic skin reaction.H318Causes serious eye damage.H319Causes serious eye irritation.H330Fatal if inhaled.H331Toxic if inhaled.H400Very toxic to aquatic life.H410Very toxic to aquatic life with long lasting effects.Skin Corr. 1ASkin corrosion/irritation, Category 1, Sub-Category 1ASkin corrosion/irritation, Category 1, Sub-Category 1B	Eye Irrit. 2	Serious eye damage/eye irritation, Category 2
H314Causes severe skin burns and eye damage.H315Causes skin irritation.H317May cause an allergic skin reaction.H318Causes serious eye damage.H319Causes serious eye irritation.H330Fatal if inhaled.H331Toxic if inhaled.H400Very toxic to aquatic life.H410Very toxic to aquatic life with long lasting effects.Skin Corr. 1ASkin corrosion/irritation, Category 1, Sub-Category 1B	H301	Toxic if swallowed.
H315Causes skin irritation.H317May cause an allergic skin reaction.H318Causes serious eye damage.H319Causes serious eye irritation.H330Fatal if inhaled.H331Toxic if inhaled.H400Very toxic to aquatic life.H410Very toxic to aquatic life with long lasting effects.Skin Corr. 1ASkin corrosion/irritation, Category 1, Sub-Category 1ASkin Corr. 1BSkin corrosion/irritation, Category 1, Sub-Category 1B	H311	Toxic in contact with skin.
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H318Causes serious eye damage.H319Causes serious eye irritation.H330Fatal if inhaled.H331Toxic if inhaled.H400Very toxic to aquatic life.H410Very toxic to aquatic life with long lasting effects.Skin Corr. 1ASkin corrosion/irritation, Category 1, Sub-Category 1ASkin Corr. 1BSkin corrosion/irritation, Category 1, Sub-Category 1B	H315	Causes skin irritation.
H319Causes serious eye irritation.H330Fatal if inhaled.H331Toxic if inhaled.H400Very toxic to aquatic life.H410Very toxic to aquatic life with long lasting effects.Skin Corr. 1ASkin corrosion/irritation, Category 1, Sub-Category 1ASkin corr. 1BSkin corrosion/irritation, Category 1, Sub-Category 1B	H317	May cause an allergic skin reaction.
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H410Very toxic to aquatic life with long lasting effects.Skin Corr. 1ASkin corrosion/irritation, Category 1, Sub-Category 1ASkin Corr. 1BSkin corrosion/irritation, Category 1, Sub-Category 1B	H331	Toxic if inhaled.
Skin Corr. 1ASkin corrosion/irritation, Category 1, Sub-Category 1ASkin Corr. 1BSkin corrosion/irritation, Category 1, Sub-Category 1B	H400	Very toxic to aquatic life.
Skin Corr. 1B Skin corrosion/irritation, Category 1, Sub-Category 1B	H410	Very toxic to aquatic life with long lasting effects.
	Skin Corr. 1A	Skin corrosion/irritation, Category 1, Sub-Category 1A
	Skin Corr. 1B	Skin corrosion/irritation, Category 1, Sub-Category 1B
Skin irrit. 2 Skin corrosion/irritation, Category 2	Skin Irrit. 2	Skin corrosion/irritation, Category 2
Skin Sens. 1 Skin sensitisation, Category 1	Skin Sens. 1	Skin sensitisation, Category 1

Safety Data Sheet (SDS), EU

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Annex II

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

1.1 Product identifier

<u>Trade name:</u> Cortisol Urine ELISA <u>Product number:</u> MS E-5100

Kit Components: Conjugate

1.2 <u>Relevant identified uses of the substance or mixture and uses advised against</u>

Components of an in-vitro diagnostic device

1.3 Details of the supplier of the safety data sheet

LDN Labor Diagnostika Nord GmbH & Co.KG Am Eichenhain 1 D-48531 Nordhorn Germany Phone.: +49 5921 8197 200 Fax: +49 5921 8197 201 E-Mail: support@ldn.de

1.4 <u>Emergency telephone number</u>

+49 5921 8197 200

(Only available during the following office hours: 8:00 h - 16:00 h (CET))

SECTION 2: HAZARDS IDENTIFICATION

2.1 <u>Classification of the substance or mixture</u>

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

Skin sensitisation, Category 1	H317
Hazardous to the aquatic environment – Chronic Hazard, Category 3	H412
Full text of H- and EUH-statements: see section 16	

Adverse physicochemical, human health and environmental effects

May cause an allergic skin reaction. Harmful to aquatic life with long lasting effects.

 \wedge

2.2 Label elements

Hazard-determining ingredient of labelling: A MIXTURE OF: 5-CHLORO-2-METHYL-2H-ISOTHIAZOL-3-ONE [EC NO 247-500-7] AND 2-METHYL-2H-ISOTHIAZOL-3-ONE [EC NO 220-239-6]

Hazard pictogram(s): Signal word(s):	Warning
Hazard statement(s):	H317 - May cause an allergic skin reaction.
	H412 - Harmful to aquatic life with long lasting effects
Precautionary statement(s):	 P261 - Avoid breathing dust/fume/gas/mist/vapours/spray. P280 - Wear protective gloves/protective clothing/eye protection/face protection/hearing protection. P321 - Specific treatment (see supplemental first aid instruction on this label). P333+P313 - If skin irritation or rash occurs: Get medical advice/attention. P362+P364 - Take off contaminated clothing and wash it before reuse. Other hazards

2.3 Other hazards

Contains no PBT/vPvB substances ≥ 0.1% assessed in accordance with REACH Annex XIII



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The mixture does not contain substance(s) included in the list established in accordance with Article 59(1) of REACH for having endocrine disrupting properties, or is not identified as having endocrine disrupting properties in accordance with the criteria set out in Commission Delegated Regulation

(EU) 2017/2100 or Commission Regulation (EU) 2018/605 at a concentration equal to or greater than 0,1 %

SECTION 3: COMPOSITION/INFORMATION ON INGREDIENTS

3.1 <u>Substances</u>

Not applicable.

3.2 <u>Mixtures</u>

Substance name	CAS No. (EC No.) [Index No.] "REACH No."	Concentration in the mixture	Classification according to Regulation (EC) No 1272/2008 [CLP] (related to the concentrated form)		
			Hazard class / Hazard categories	Hazard- statement	Specific Conc. Limits, M-factors and ATE
CALCIUM CHLORIDE DIHYDRATE	CAS-No.: 10035-04-8 EC-No.: 600-075-5	N/A	Acute Tox. 4 (Oral) Eye Irrit. 2 Aquatic Chronic 1	H302 H319 H410	N/A
NO 247-500-7] AND EC Index-N			Acute Tox. 3 (Oral) Acute Tox. 3 (Dermal) Acute Tox. 3	H301 H311	(0,0015 ≤ C < 100) Skin Sens. 1, H317
	55965-84-9	-9 < 1 %	(Inhalation) Acute Tox. 2 (Inhalation:dust,mist)	H331 H330	(0,06 ≤ C ≤ 0,6) Skin Irrit. 2, H315
	EC Index-No.: 613-167-00-5		Skin Corr. 1A Eye Dam. 1 Skin Sens. 1	H314 H318 H317	(0,06 ≤ C ≤ 0,6) Eye Irrit. 2, H319
			Aquatic Acute 1 Aquatic Chronic 1	H400 H410	(0,6 ≤ C < 100) Skin Corr. 1B, H314

Full text of H-phrases: see section 16.

SECTION 4: FIRST AID MEASURES

4.1 Description of first aid measures

First-aid measures after inhalation:	Remove person to fresh air and keep comfortable for breathing.
First-aid measures after skin contact:	Wash skin with plenty of water. Take off contaminated clothing. If skin irritation or rash occurs: Get medical advice/attention.
First-aid measures after eye contact:	Rinse eyes with water as a precaution.
First-aid measures after ingestion:	Call a poison center or a doctor if you feel unwell.

4.2 Most important symptoms and effects, both acute and delayed

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

4.3 Indication of any immediate medical attention and special treatment needed

Treat symptomatically.

SECTION 5: FIREFIGHTING MEASURES

5.1 Extinguishing media

Suitable extinguishing media: Water spray. Dry powder. Foam. Carbon dioxide.

5.2 Special hazards arising from the substance or mixture

Hazardous decomposition products in case of fire : Toxic fumes may be released.

5.3 Advice for firefighters



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Protection during firefighting: Do not attempt to take action without suitable protective equipment. Self-contained breathing apparatus. Complete protective clothing

SECTION 6: ACCIDENTAL RELEASE MEASURES

6.1 <u>Personal precautions, protective equipment and emergency procedures</u>

6.1.1 For non-emergency personnel

Emergency procedures: Ventilate spillage area. Avoid contact with skin and eyes. Avoid breathing dust/fume/gas/mist/vapours/spray.

6.1.2 For emergency responders

Protective equipment: Do not attempt to take action without suitable protective equipment. For further information refer to section 8: "Exposure controls/personal protection".

6.2 <u>Environmental precautions</u>

Avoid release to the environment.

6.3 Methods and material for containment and cleaning up

Methods for cleaning up: Take up liquid spill into absorbent material. Other information: Dispose of materials or solid residues at an authorized site.

6.4 <u>Reference to other sections</u>

For further information refer to section 13.

SECTION 7: HANDLING AND STORAGE

7.1 Precautions for safe handling

Precautions for safe handling:Ensure good ventilation of the work station. Avoid contact with skin and eyes. Avoid
breathing dust/fume/gas/mist/vapours/spray. Wear personal protective equipment.Hygiene measures:Contaminated work clothing should not be allowed out of the workplace. Wash
contaminated clothing before reuse. Do not eat, drink or smoke when using this product.
Always wash hands after handling the product.

7.2 <u>Conditions for safe storage, including any incompatibilities</u>

Storage conditions: Store in a well-ventilated place. Keep cool.

7.3 Specific end use(s)

No additional information available



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SECTION 8: EXPOSURE CONTROLS/PERSONAL PROTECTION

8.1 **Control parameters**

8.1.1 National occupational exposure and biological limit values

A MIXTURE OF: 5-CHLORO-2-METHYL-2H-ISOTHIAZOL-3-ONE [EC NO 247-500-7] AND 2-METHYL-2H-ISOTHIAZOL-3-ONE [EC NO 220-239-6] (55965-84-9)

Austria - Occupational Exposure Limits

Austria - Occupational Exposure Limits		
Local name	5-Chlor-2-methyl-2,3-dihydroisothiazol-3-on und 2-Methyl-2,3-di-hydroisothiazol-3-on (Gemisch im Verhältnis 3:1)	
MAK (OEL TWA)	0,05 mg/m³	
Remark	Sh	
Regulatory reference	BGBI. II Nr. 156/2021	
Switzerland - Occupational Exposure L	imits	
Local name	2,3-Dihydro-isothiazol-3-one de 5-chloro-2-méthyle et 2,3-dihydro-isothiazol-3-one de 2méthyle [2,3-Dihydro-isothiazol-3-one de 5-chloro-2-méthyle, 2,3-Dihydro-isothiazol-3-one de 2-méthyle] / 5-Chlor-2-methyl-2,3-dihydro-isothiazol-3-on und 2-Methyl-2,3dihydroisothiazol-3-on [2-Methyl-2,3-dihydroisothiazol-3-on, 5-Chlor-2-methyl-2,3dihydroisothiazol-3-on]	
MAK (OEL TWA) [1]	0,2 mg/m³ (i) / (e)	
KZGW (OEL STEL)	0,4 mg/m³ (i) / (e)	
Critical toxicity	VRS, Peau, Yeux / OAW, Haut, Auge	
Notation	S, SS _c / S, SS _c	
Regulatory reference	www.suva.ch, 01.01.2023	

Exposure limit values for the other components

4-CHLORO-3-METHYLPHENOL (59-50-7)		
Estonia - Occupational Exposure Limits		
Local name	Klorokresool	
OEL TWA	3 mg/m ³	
OEL STEL	6 mg/m³	
Regulatory reference	Vabariigi Valitsuse 20. märtsi 2001. a määruse nr 105 (RT I, 21.12.2022, 3)	
Poland - Occupational Exposure Limits		
Local name	4-Chloro-3-metylofenol	
NDS (OEL TWA)	5 mg/m³ frakcja wdychalna	
Remark	Frakcja wdychalna – frakcja aerozolu wnikająca przez nos i usta, która po zdeponowaniu w drogach oddechowych stwarza zagrożenie dla zdrowia.	
Regulatory reference	Dz. U. 2018 poz. 1286 wraz z późn. zm.	



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Sweden - Occupational Exposure Limits		
Local name	Klorkresol	
4-CHLORO-3-METHYLPHENOL (59-50-7)		
NGV (OEL TWA)	3 mg/m ³	
KTV (OEL STEL)	6 mg/m³	
Remark	S (Ämnet är sensibiliserande. Sensibiliserande ämnen kan ge allergi eller annan överkänslighet. Överkänslighetsbesvären drabbar främst huden eller andningsorganen. Överkänslighet innebär att man reagerar vid kontakt med ämnen som normalt inte ger besvär. Allergi är en undergrupp av överkänslighet som orsakas av reaktioner i kroppens immunsystem. Särskilt låga gränsvärden har fastställts för ämnen med mer uttalat luftvägssensibiliserande egenskaper. Några ämnen med starkt sensibiliserande egenskaper får endast hanteras efter tillstånd från Arbetsmiljöverket, se föreskrifterna om kemiska arbetsmiljörisker. Dessa ämnen har inga gränsvärden men i vissa fall riktvärden); V (Vägledande korttidsgränsvärde ska användas som ett rekommenderat högsta värde som inte bör överskridas)	
Regulatory reference	Hygieniska gränsvärden (AFS 2018:1)	

8.1.2 Recommended monitoring procedures

No additional information available

8.1.3 Air contaminants formed

No additional information available

8.1.4 DNEL and PNEC

No additional information available

8.1.5 Control banding

No additional information available

8.2 Exposure controls

8.2.1 Appropriate engineering controls

Appropriate engineering controls:

Ensure good ventilation of the work station.

8.2.2 Personal protection equipment

Personal protective equipment symbol(s):



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8.2.2.1. Eye and face protection

Eye protection: Safety glasses

8.2.2.2. Skin protection

Skin and body protection: Wear suitable protective clothing

Hand protection: Protective gloves

8.2.2.3. Respiratory protection Respiratory protection: In case of insufficient ventilation, wear suitable respiratory equipment

8.2.2.4. Thermal hazards

No additional information available

8.2.3 Environmental exposure controls

Environmental exposure controls: Avoid release to the environment.

SECTION 9: PHYSICAL AND CHEMICAL PROPERTIES

9.1 Information on basic physical and chemical properties

	nour properties
Physical state:	Liquid
Colour:	red.
Appearance:	Liquid.
Odour:	characteristic.
Odour threshold:	Not available
Melting point:	Not applicable
Freezing point:	< 0 °C
Boiling point:	> 100 °C
Flammability:	Non flammable
Lower explosion limit:	Not available
Upper explosion limit:	Not available
Flash point:	Not available
Auto-ignition temperature:	Not available
Decomposition temperature:	Not available
pH:	7,4
Viscosity, kinematic:	Not available
Solubility:	Not available
Partition coefficient n-octanol/water (Log Kow):	Not available
Vapour pressure:	Not available
Vapour pressure at 50°C:	Not available
Density:	Not available
Relative density:	Not available



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Relative vapour density at 20°C: Particle characteristics: Not available Not applicable

9.2 Other information

9.2.1 Information with regard to physical hazard classes

No additional information available

9.2.2 Other safety characteristics

No additional information available

SECTION 10: STABILITY AND REACTIVITY

10.1 Reactivity

The product is non-reactive under normal conditions of use, storage and transport.

10.2 Chemical stability

Stable under normal conditions.

10.3 **Possibility of hazardous reactions**

No dangerous reactions known under normal conditions of use.

10.4 Conditions to avoid

None under recommended storage and handling conditions (see section 7).

10.5 Incompatible materials

No additional information available

10.6 <u>Hazardous decomposition products</u>

Under normal conditions of storage and use, hazardous decomposition products should not be produced

SECTION 11: TOXICOLOGICAL INFORMATION

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

Acute toxicity (oral): Not classified Acute toxicity (dermal): Not classified Acute toxicity (inhalation): Not classified

CALCIUM CHLORIDE DIHYDRATE (10035-04-8)	
LD50 oral	1000 mg/kg bodyweight Animal: rabbit, Animal sex: male, Guideline: OECD Guideline 401 (Acute Oral Toxicity)
LD50 dermal rabbit	> 5000 mg/kg bodyweight Animal: rabbit

Skin corrosion/irritation:	Not classified
Serious eye damage/irritation:	Not classified pH: 7,4
Respiratory or skin sensitisation:	May cause an allergic skin reaction.
Germ cell mutagenicity:	Not classified
Carcinogenicity:	Not classified
Reproductive toxicity:	Not classified
STOT-single exposure:	Not classified
STOT-repeated exposure:	Not classified



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Aspiration hazard:

Not classified

11.2 Information on other hazards

No additional information available

SECTION 12: ECOLOGICAL INFORMATION

12.1 Toxicity

Ecology – general:

Hazardous to the aquatic environment, short–term (acute): Hazardous to the aquatic environment, long–term (chronic): Not rapidly degradable Harmful to aquatic life with long lasting effects. Not classified

Harmful to aquatic life with long lasting effects.

CALCIUM CHLORIDE DIHYDRATE (10035-04-8)		
LC50 - Fish [1]	4630 mg/l Test organisms (species): Pimephales promelas	
LOEC (chronic)	240 mg/l Test organisms (species): Daphnia magna Duration: '21 d'	
NOEC (chronic)	481 mg/l Test organisms (species): Daphnia magna Duration: '21 d'	
NOEC chronic fish	230 mg/l Test organisms (species): Oncorhynchus mykiss (previous name: Salmo gairdneri) Duration: '25 d'	

12.2 Persistence and degradability

No additional information available

12.3 Bioaccumulative potential

No additional information available

12.4 Mobility in soil

No additional information available

12.5 <u>Results of PBT and vPvB assessment</u>

No additional information available

12.6 Endocrine disrupting properties

No additional information available

12.7 Other adverse effects

No additional information available

SECTION 13: DISPOSAL CONSIDERATIONS

Waste treatment methods: Dispose of contents/container in accordance with licensed collector's sorting instructions.



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SECTION 14: TRANSPORT INFORMATION

		ΙΑΤΑ	IMDG	RID	ADR	ADN
1.1	UN number or ID number	Not regulated				
1.2	UN Proper shipping name	Not regulated				
1.3	Transport hazard class(es)	Not regulated				
1.4	Packing group	Not regulated				
1.5	Environmental hazards	Not applicable	Not applicable	Not applicable	Not applicable	Not applicable
1.6	<u>Special precautions for</u> <u>user</u> Special Provisions	Not regulated				
1.7	<u>Maritime transport in bulk</u> according to IMO instruments	Not regulated				

SECTION 15: REGULATORY INFORMATION

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

15.1.1 EU-Regulations

REACH Annex XVII (Restriction List)

Contains no substance(s) listed on REACH Annex XVII (Restriction Conditions)

REACH Annex XIV (Authorisation List)

Contains no substance(s) listed on REACH Annex XIV (Authorisation List)

REACH Candidate List (SVHC)

Contains no substance(s) listed on the REACH Candidate List

PIC Regulation (Prior Informed Consent)

Contains no substance(s) listed on the PIC list (Regulation EU 649/2012 concerning the export and import of hazardous chemicals)

POP Regulation (Persistent Organic Pollutants)

Contains no substance(s) listed on the POP list (Regulation EU 2019/1021 on persistent organic pollutants)

Ozone Regulation (1005/2009)

Contains no substance(s) listed on the Ozone Depletion list (Regulation EU 1005/2009 on substances that deplete the ozone layer)

Explosives Precursors Regulation (2019/1148)

Contains no substance(s) listed on the Explosives Precursors list (Regulation EU 2019/1148 on the marketing and use of explosives precursors)

Drug Precursors Regulation (273/2004)

Contains no substance(s) listed on the Drug Precursors list (Regulation EC 273/2004 on the manufacture and the placing on market of certain substances used in the illicit manufacture of narcotic drugs and psychotropic substances)

15.1.2 National regulations

<u>Germany</u>

Employment restrictions: Observe restrictions according Act on the Protection of Working Mothers (MuSchG). Observe restrictions according Act on the Protection of Young People in Employment (JArbSchG).

Water hazard class (WGK): WGK 2, Significantly hazardous to water (Classification according to AwSV, Annex 1).



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Hazardous Incident Ordinance (12. BImSchV): Is not subject of the Hazardous Incident Ordinance (12. BImSchV)

Netherlands

SZW-lijst van kankerverwekkende stoffen: None of the components are listed
SZW-lijst van mutagene stoffen: None of the components are listed
SZW-lijst van reprotoxische stoffen – Borstvoeding: None of the components are listed
SZW-lijst van reprotoxische stoffen – Vruchtbaarheid: None of the components are listed
SZW-lijst van reprotoxische stoffen – Ontwikkeling: None of the components are listed

Denmark

Danish National Regulations: Young people below the age of 18 years are not allowed to use the product Pregnant/breastfeeding women working with the product must not be in direct contact with the product

Switzerland

Storage class (LK): LK 10/12 - Liquids

15.2 Chemical safety assessment

No chemical safety assessment has been carried out.

SECTION 16: OTHER INFORMATION

Abbreviations and acronyms:

Abbreviations and acronyms:					
ADN	European Agreement concerning the International Carriage of Dangerous Goods by Inland Waterways				
ADR	European Agreement concerning the International Carriage of Dangerous Goods by Road				
ATE	Acute Toxicity Estimate				
BCF	Bioconcentration factor				
BLV	Biological limit value				
BOD	Biochemical oxygen demand (BOD)				
COD	Chemical oxygen demand (COD)				
DMEL	Derived Minimal Effect level				
DNEL	Derived-No Effect Level				
EC-No.	European Community number				
EC50	Median effective concentration				
EN	European Standard				
IARC	International Agency for Research on Cancer				
IATA	International Air Transport Association				
IMDG	International Maritime Dangerous Goods				
LC50	Median lethal concentration				
LD50	Median lethal dose				
LOAEL	Lowest Observed Adverse Effect Level				
NOAEC	No-Observed Adverse Effect Concentration				
NOAEL	No-Observed Adverse Effect Level				
NOEC	No-Observed Effect Concentration				
OECD	Organisation for Economic Co-operation and Development				
OEL	Occupational Exposure Limit				
PBT	Persistent Bioaccumulative Toxic				
PNEC	Predicted No-Effect Concentration				
RID	Regulations concerning the International Carriage of Dangerous Goods by Rail				
SDS	Safety Data Sheet				
STP	Sewage treatment plant				
ThOD	Theoretical oxygen demand (ThOD)				
TLM	Median Tolerance Limit				
VOC	Volatile Organic Compounds				
CAS-No.	Chemical Abstract Service number				
N.O.S.	Not Otherwise Specified				
vPvB	Very Persistent and Very Bioaccumulative				



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ED

Endocrine disrupting properties

Full text of H- and EUH-statements:

	Acute Tox. 2 (Inhalation:dust,mist)	Acute toxicity (inhalation:dust,mist) Category 2			
Acute Tox. 3 (Dermal)		Acute toxicity (dermal), Category 3			
Acute Tox. 3 (Inhalation)		Acute toxicity (inhal.), Category 3			
Acute Tox. 3 (Oral)		Acute toxicity (oral), Category 3			
Acute Tox. 4 (Oral)		Acute toxicity (oral), Category 4			
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 Dam. 1	Serious eye damage/eye irritation, Category 1			
	Eye Irrit. 2	Serious eye damage/eye irritation, Category 2			
	H301	Toxic if swallowed.			
	H302	Harmful if swallowed.			
	H311	Toxic in contact with skin.			
	H314	Causes severe skin burns and eye damage.			
	H315	Causes skin irritation.			
	H317	May cause an allergic skin reaction.			
	H318	Causes serious eye damage.			
	H319	Causes serious eye irritation.			
	H330	Fatal if inhaled.			
	H331	Toxic if inhaled.			
	H335	May cause respiratory irritation.			
	H400	Very toxic to aquatic life.			
	H410	Very toxic to aquatic life with long lasting effects.			
	H412	Harmful to aquatic life with long lasting effects.			
	Skin Corr. 1A	Skin corrosion/irritation, Category 1, Sub-Category 1A			
	Skin Corr. 1B	Skin corrosion/irritation, Category 1, Sub-Category 1B			
	Skin Irrit. 2	Skin corrosion/irritation, Category 2			
	Skin Sens. 1	Skin sensitisation, Category 1			
	STOT SE 3	Specific target organ toxicity – Single exposure, Category 3, Respiratory tract irritation			

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