

SECTION 1: Identification of the substance/mixture and of the company/undertaking

1.1. Product identifier

Product form : Mixture
 Product name : Leptin Sensitive ELISA E077
 UFI : -

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

1.2.1. Relevant identified uses

Use of the substance/mixture : In vitro diagnostic medical device
 Buffering Agents; Scientific research and development

1.2.2. Uses advised against

No additional information available

1.3. Details of the supplier of the safety data sheet

Mediagnost Gesellschaft für Forschung und Herstellung von Diagnostika GmbH
 Aspenhaustraße 25
 72770 Reutlingen - Germany
 T +49 (0)7121 51484 0 - F +49 (0)7121 51484 10
contact@mediagnost.de - www.mediagnost.de

1.4. Emergency telephone number

Emergency number : Mediagnost Gesellschaft für Forschung und Herstellung von Diagnostika GmbH
 +49 (0) 7121 51484 0

SECTION 2: Hazards identification

2.1. Classification of the substance or mixture

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

Skin sensitisation, Category 1A H317

Hazardous to the aquatic environment – Chronic Hazard, Category 3 H412

Full text of H-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.

2.2. Label elements

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

Hazard pictograms (CLP) :



GHS07

Signal word (CLP) : Warning
 Hazardous ingredients : 2-methyl-2H-isothiazol-3-one, reaction mass of 5-chloro-2-methyl-2H-isothiazol-3-one and 2-methyl-2H-isothiazol-3-one (3:1)
 Hazard statements (CLP) : H317 - May cause an allergic skin reaction.
 H412 - Harmful to aquatic life with long lasting effects.
 Precautionary statements (CLP) : P261 - Avoid breathing mist/vapours/spray.
 P273 - Avoid release to the environment.
 P280 - Wear protective gloves/protective clothing/eye protection.
 P333 + P313 - If skin irritation or rash occurs: Get medical advice/attention.
 P362 + P364 - Take off contaminated clothing and wash it before reuse.
 P501 - Dispose of contents/container in accordance with national regulations.

2.3. Other hazards

The mixture contains substance(s) included in the list established in accordance with Article 59(1) of REACH for having endocrine disrupting properties, or is 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.

SECTION 3: Composition/information on ingredients

3.1. Substances

Not applicable

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3.2. Mixtures

Name	Product identifier	%	Classification according to Regulation (EC) No. 1272/2008 [CLP]
Sucrose	(CAS No) 57-50-1 (EC No) 200-334-9	5 - < 7	Not classified
Sulphuric acid ... %	(CAS No) 7664-93-9 (EC No) 231-639-5 (EC index No) 016-020-00-8 (REACH No) 01-2119458838-20-xxxx	1 - ≤ 2	Met. Corr. 1, H290 Skin Corr. 1A, H314 Eye Dam. 1, H318
4-(1,1,3,3-tetramethylbutyl)phenol, ethoxylated (substance listed as REACH Candidate) (substance listed in REACH Annex XIV: Endocrine disrupting properties, Article 57(f) — environment)	(CAS No) 9036-19-5	0.1 - < 1	Acute Tox. 4 (Oral), H302 Skin Irrit. 2, H315 Eye Dam. 1, H318 Aquatic Acute 1, H400 (M=10) Aquatic Chronic 1, H410
2-methyl-2H-isothiazol-3-one	(CAS No) 2682-20-4 (EC No) 220-239-6 (EC index No) 613-326-00-9 (REACH No) 01-2120764690-50-xxxx	0.0015 - < 0.1	Acute Tox. 2 (Inhalation), H330 Acute Tox. 3 (Dermal), H311 Acute Tox. 3 (Oral), H301 Skin Corr. 1B, H314 Eye Dam. 1, H318 Skin Sens. 1A, H317 Aquatic Acute 1, H400 (M=10) Aquatic Chronic 1, H410
Reaction mass of 5-chloro-2-methyl-2H-isothiazol-3-one and 2-methyl-2H-isothiazol-3-one (3:1)	(CAS No) 55965-84-9 (EC index No) 613-167-00-5	0.0015 - < 0.06	Acute Tox. 2 (Inhalation), H330 Acute Tox. 2 (Dermal), H310 Acute Tox. 3 (Oral), H301 Skin Corr. 1C, H314 Eye Dam. 1, H318 Skin Sens. 1A, H317 Aquatic Acute 1, H400 (M=100) Aquatic Chronic 1, H410 (M=100)
Name	Product identifier	Specific concentration limits according to Regulation (EC) No. 1272/2008 [CLP]	
Sulphuric acid ... %	(CAS No) 7664-93-9 (EC No) 231-639-5 (EC index No) 016-020-00-8 (REACH No) 01-2119458838-20-xxxx	(5 ≤ C < 15) Skin Irrit. 2, H315 (5 ≤ C < 15) Eye Irrit. 2, H319 (C ≥ 15) Skin Corr. 1A, H314	
2-methyl-2H-isothiazol-3-one	(CAS No) 2682-20-4 (EC No) 220-239-6 (EC index No) 613-326-00-9 (REACH No) 01-2120764690-50-xxxx	(C ≥ 0.0015) Skin Sens. 1A, H317	
Reaction mass of 5-chloro-2-methyl-2H-isothiazol-3-one and 2-methyl-2H-isothiazol-3-one (3:1)	(CAS No) 55965-84-9 (EC index no) 613-167-00-5	(C ≥ 0.0015) Skin Sens. 1A, H317 (0.06 ≤ C < 0.6) Skin Irrit. 2, H315 (0.06 ≤ C < 0.6) Eye Irrit. 2, H319 (C ≥ 0.6) Skin Corr. 1C, H314 (C ≥ 0.6) Eye Dam. 1, H318	

Full text of H-phrases: see section 16

SECTION 4: First aid measures

4.1. Description of first aid measures

First-aid measures general	: Get medical advice/attention if you feel unwell. If possible show him this sheet. Failing this, show him the packaging or label. Never give anything by mouth to an unconscious person. Place the affected person in the recovery position.
First-aid measures after inhalation	: If breathing is difficult, remove victim to fresh air and keep at rest in a position comfortable for breathing.
First-aid measures after skin contact	: Remove affected clothing and wash all exposed skin area with mild soap and water, followed by warm water rinse. If skin irritation or rash occurs: Get medical advice/attention.
First-aid measures after eye contact	: IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.
First-aid measures after ingestion	: Rinse mouth. Drink water as a precaution. Do NOT induce vomiting.

4.2. Most important symptoms and effects, both acute and delayed

Symptoms/injuries after skin contact : May produce an allergic reaction.

4.3. Indication of any immediate medical attention and special treatment needed

No additional information available

SECTION 5: Firefighting measures

5.1. Extinguishing media

Suitable extinguishing media	: Use extinguishing agents that suit the environment. Extinguishing powder. Carbon dioxide. Foam. Water spray. Sand.
Unsuitable extinguishing media	: Do not use a heavy water stream.

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5.2. Special hazards arising from the substance or mixture

Fire hazard : None known.

5.3. Advice for firefighters

Firefighting instructions : Use water spray or fog for cooling exposed containers. Prevent fire-fighting water from entering environment.

Protection during firefighting : Do not enter fire area without proper protective equipment, including respiratory protection.

SECTION 6: Accidental release measures

6.1. Personal precautions, protective equipment and emergency procedures

General measures : Avoid contact with eyes and skin. Provide adequate ventilation.

6.1.1. For non-emergency personnel

Emergency procedures : Evacuate unnecessary personnel.

6.1.2. For emergency responders

Protective equipment : Equip cleanup crew with proper protection.

6.2. Environmental precautions

Prevent entry to sewers and public waters. Contain the spilled material by bunding (product is hazardous for the environment). Notify authorities if product enters sewers or public waters.

6.3. Methods and material for containment and cleaning up

Methods for cleaning up : Soak up spills with inert solids, such as clay or diatomaceous earth as soon as possible. Keep in suitable, closed containers for disposal. This material and its container must be disposed of in a safe way, and as per local legislation.

6.4. Reference to other sections

Concerning personal protective equipment to use, see section 8. Concerning disposal elimination after cleaning, see section 13.

SECTION 7: Handling and storage

7.1. Precautions for safe handling

Precautions for safe handling : Ensure good ventilation of the work station. Use personal protective equipment as required. Avoid contact with eyes and skin. Do not breathe vapours/spray.

Hygiene measures : Handle in accordance with good industrial hygiene and safety procedures. Do not eat, drink or smoke when using this product. Wash hands and other exposed areas with mild soap and water before eating, drinking or smoking and when leaving work. Contaminated work clothing should not be allowed out of the workplace. Wash contaminated clothing before reuse.

7.2. Conditions for safe storage, including any incompatibilities

Storage conditions : Store in original container. Keep container tightly closed. Store in a cool, well-ventilated place. Protect from direct sunlight.

Prohibitions on mixed storage : Keep away from food, drink and animal feedingstuffs.

7.3. Specific end use(s)

No additional information available

SECTION 8: Exposure controls/personal protection

8.1. Control parameters

Sucrose (57-50-1)		
Ireland	Local name	Sucrose
Ireland	OEL (8 hours ref) (mg/m ³)	10 mg/m ³
Ireland	OEL (15 min ref) (mg/m ³)	20 mg/m ³
United Kingdom	Local name	Sucrose
United Kingdom	WEL TWA (mg/m ³)	10 mg/m ³
United Kingdom	WEL STEL (mg/m ³)	20 mg/m ³
Sulphuric acid ... % (7664-93-9)		
EU	Local name	Sulphuric acid (mist)
EU	IOELV TWA (mg/m ³)	0.05 mg/m ³
Ireland	Local name	Sulphuric acid
Ireland	OEL (8 hours ref) (mg/m ³)	0.05 mg/m ³
Ireland	Notes (IE)	IOELV
Malta	Local name	Sulphuric acid mist
Malta	Limit value - eight hours (mg/m ³)	0.05 mg/m ³
Malta	Notes (MT)	11, 12
United Kingdom	Local name	Sulphuric acid (mist)
United Kingdom	WEL TWA (mg/m ³)	0.05 mg/m ³

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Sulphuric acid ... % (7664-93-9)		
United Kingdom	Remark (UK)	The mist is defined as the thoracic fraction
2-methyl-2H-isothiazol-3-one (2682-20-4)		
DNEL/DMEL (Workers)		
Long-term - local effects, inhalation		0.021 mg/m ³
Acute - local effects, inhalation		0.043 mg/m ³
DNEL/DMEL (General Population)		
Long-term - systemic effects, oral		0.027 mg/kg bodyweight/day
Acute - systemic effects, oral		0.053 mg/kg bodyweight/day
Long-term - local effects, inhalation		0.021 mg/m ³
Acute - local effects, inhalation		0.043 mg/m ³
PNEC (Water)		
PNEC aqua (freshwater)		3.39 µg/l
PNEC aqua (marine water)		3.39 µg/l
PNEC aqua (intermittent, freshwater)		3.39 µg/l
PNEC aqua (intermittent, marine water)		3.39 µg/l
PNEC (Soil)		
PNEC soil		0.047 mg/kg dwt
PNEC (STP)		
PNEC sewage treatment plant		0.23 mg/l

8.2. Exposure controls

Appropriate engineering controls	: Ensure good ventilation of the work station.
Hand protection	: Wear protective gloves (EN 374). Nitrile rubber, 0.35 mm. The exact break through time has to be found out by the manufacturer of the protective gloves and has to be observed.
Eye protection	: Wear closed safety glasses (EN 166).
Skin and body protection	: Wear suitable protective clothing.
Respiratory protection	: In case of inadequate ventilation wear respiratory protection. Filter type P.
Environmental exposure controls	: Avoid release to the environment.

SECTION 9: Physical and chemical properties

9.1. Information on basic physical and chemical properties

Physical state	: Liquid
Colour	: No data available
Odour	: No data available
Melting point/freezing point	: No data available
Boiling point or initial boiling point and boiling range	: No data available
Flammability	: Non flammable
Lower and upper explosion limit	: No data available
Flash point	: No data available
Auto-ignition temperature	: No data available
Decomposition temperature	: No data available
pH	: No data available
Kinematic viscosity	: No data available
Solubility	: No data available
Partition coefficient n-octanol/water (log value)	: Not applicable
Vapour pressure	: No data available
Density and/or relative density	: No data available
Relative vapour density	: No data available
Particle characteristics	: Not applicable

9.2. Other information

9.2.1. Information with regard to physical hazard classes

Explosive properties	: No explosive properties
Oxidising properties	: No oxidising properties

9.2.2. Other safety characteristics

No additional information available

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SECTION 10: Stability and reactivity

10.1. Reactivity

No dangerous reactions known under normal conditions of use.

10.2. Chemical stability

Stable under use and storage conditions as recommended in section 7.

10.3. Possibility of hazardous reactions

None under normal use.

10.4. Conditions to avoid

No conditions to avoid known.

10.5. Incompatible materials

None known.

10.6. Hazardous decomposition products

No hazardous decomposition products known.

SECTION 11: Toxicological information

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

Acute toxicity : Not classified
Based on available data, the classification criteria are not met

Sulphuric acid ... % (7664-93-9)	
LD50 oral rat	2140 mg/kg
2-methyl-2H-isothiazol-3-one (2682-20-4)	
LD50 oral rat	120 mg/kg
LD50 dermal rat	242 mg/kg
LC50 inhalation rat	0.1 mg/l/4h

Skin corrosion/irritation : Not classified
Based on available data, the classification criteria are not met

Serious eye damage/irritation : Not classified
Based on available data, the classification criteria are not met

Respiratory or skin sensitisation : May cause an allergic skin reaction.

Germ cell mutagenicity : Not classified
Based on available data, the classification criteria are not met

Carcinogenicity : Not classified
Based on available data, the classification criteria are not met

Reproductive toxicity : Not classified
Based on available data, the classification criteria are not met

Specific target organ toxicity (single exposure) : Not classified
Based on available data, the classification criteria are not met

Specific target organ toxicity (repeated exposure) : Not classified
Based on available data, the classification criteria are not met

Aspiration hazard : Not classified
Based on available data, the classification criteria are not met

11.2. Information on other hazards

Potential adverse human health effects and symptoms : Based on available data, the classification criteria are not met

SECTION 12: Ecological information

12.1. Toxicity

Acute aquatic toxicity : Not classified

Chronic aquatic toxicity : Harmful to aquatic life with long lasting effects.

Sulphuric acid ... % (7664-93-9)	
LC50 fish	> 16 - < 28 mg/l 96 h, <i>Lepomis macrochirus</i>
EC50 daphnia	> 100 mg/l 48 h, <i>Daphnia magna</i>
EC50 algae	> 100 mg/l 72 h, <i>Desmodesmus subspicatus</i>
2-methyl-2H-isothiazol-3-one (2682-20-4)	
LC50 fish	4.77 mg/l 96 h, <i>Oncorhynchus mykiss</i>

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2-methyl-2H-isothiazol-3-one (2682-20-4)	
EC50 daphnia	0.934 mg/l 48 h, Daphnia magna
EC50 algae	0.22 mg/l 120 h, Raphidocelis subcapitata
EC50 micro-organisms	41 mg/l 3 h, activated sludge
NOEC fish	4.93 mg/l 98 d, Oncorhynchus mykiss
NOEC daphnia	0.044 mg/l 21 d, Daphnia magna
NOEC algae	0.05 mg/l 120 h, Raphidocelis subcapitata

12.2. Persistence and degradability

2-methyl-2H-isothiazol-3-one (2682-20-4)	
Persistence and degradability	Not readily biodegradable.
Biodegradation	50 % 29 d (OECD 301 B)

12.3. Bioaccumulative potential

2-methyl-2H-isothiazol-3-one (2682-20-4)	
Log Pow	-0.486 (20 °C)

12.4. Mobility in soil

No additional information available

12.5. Results of PBT and vPvB assessment

Not fulfilling Persistent, Bioaccumulative and Toxic (PBT), very Persistent and very Bioaccumulative (vPvB) criteria.

12.6. Endocrine disrupting properties

Components with adverse effects on the environment caused by endocrine disrupting properties: 4-(1,1,3,3-tetramethylbutyl)phenol, ethoxylated (9036-19-5).

12.7. Other adverse effects

No additional information available

SECTION 13: Disposal considerations

13.1. Waste treatment methods

Waste treatment methods	: This material and its container must be disposed of in a safe way. Do not empty into drains. Avoid release to the environment.
Waste disposal recommendations	: Dispose in a safe manner in accordance with local/national regulations.
Waste code number	: The valid EWC waste code numbers are source related. The manufacturer is therefore unable to specify EWC waste codes for the articles or products used in the various sectors. The EWC codes listed are intended as a recommendation for users.

SECTION 14: Transport information

In accordance with ADR / IMDG / IATA

14.1. UN number or ID number

Not regulated for transport

14.2. UN proper shipping name

Proper Shipping Name (ADR)	: Not applicable
Proper Shipping Name (IMDG)	: Not applicable
Proper Shipping Name (IATA)	: Not applicable

14.3. Transport hazard class(es)

ADR

Transport hazard class(es) (ADR) : Not applicable

IMDG

Transport hazard class(es) (IMDG) : Not applicable

IATA

Transport hazard class(es) (IATA) : Not applicable

14.4. Packing group

Packing group (ADR)	: Not applicable
Packing group (IMDG)	: Not applicable
Packing group (IATA)	: Not applicable

14.5. Environmental hazards

Dangerous for the environment	: No
Marine pollutant	: No
Other information	: No supplementary information available

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14.6. Special precautions for user

14.6.1. Overland transport

Not applicable

14.6.2. Transport by sea

Not applicable

14.6.3. Air transport

Not applicable

14.7. Maritime transport in bulk according to IMO instruments

Not applicable

SECTION 15: Regulatory information

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

15.1.1. EU-Regulations

Contains substances on the REACH candidate list: 4-(1,1,3,3-tetramethylbutyl)phenol, ethoxylated (9036-19-5) (Endocrine disrupting properties, REACH Article 57(f) — environment).

Contains REACH Annex XIV substances: 4-(1,1,3,3-tetramethylbutyl)phenol, ethoxylated (9036-19-5) (Endocrine disrupting properties, REACH Article 57(f) — environment).

Not subject to REACH authorisation (REACH authorisation exemption: used in scientific research and development, REACH Article 56 (3)).

15.1.2. National regulations

No additional information available

15.2. Chemical safety assessment

No chemical safety assessment has been carried out for the substance or the mixture by the supplier.

SECTION 16: Other information

Data sources : REGULATION (EC) No 1272/2008 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 16 December 2008 on classification, labelling and packaging of substances and mixtures, amending and repealing Directives 67/548/EEC and 1999/45/EC, and amending Regulation (EC) No 1907/2006.

Changes compared to the previous version : -

Abbreviations and acronyms:

ADR	European Agreement concerning the International Carriage of Dangerous Goods by Road
CLP	Regulation (EC) No 1272/2008 on classification, labelling and packaging of substances and mixtures
DMEL	Derived Minimal Effect Level
DNEL	Derived No-Effect Level
EC50	The effective concentration of substance that causes 50% of the maximum response (Median Effective Concentration)
IATA	International Air Transport Association
IMDG	"International Maritime Dangerous Goods Code" for the transport of dangerous goods by sea
LC50	Lethal Concentration to 50 % of a test population (Median Lethal Concentration)
LD50	Lethal Dose to 50% of a test population (Median Lethal Dose)
LOAEL	Lowest Observed Adverse Effect Level
NOAEC/L	No Observed Adverse Effect Concentration/Level
NOEC/L	No Observed Effect Concentration/Level
OECD	Organisation for Economic Cooperation and Development
PBT	Persistent, Bioaccumulative and Toxic substance
PNEC	Predicted No-Effect Concentration
REACH	Regulation (EC) No 1907/2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals
SDS	Safety Data Sheet
STP	Sewage Treatment Plant
UFI	Unique Formula Identifier
vPvB	Very Persistent and Very Bioaccumulative

Full text of H- and EUH-phrases:

Acute Tox. 2 (Dermal)	Acute toxicity (dermal), Category 2
Acute Tox. 3 (Dermal)	Acute toxicity (dermal), Category 3
Acute Tox. 2 (Inhalation)	Acute toxicity (inhal.), Category 2
Acute Tox. 3 (Oral)	Acute toxicity (oral), Category 3

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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/ irritation, Category 1
Eye Irrit. 2	Serious eye damage/eye irritation, Category 2
Met. Corr. 1	Corrosive to metals, Category 1
Skin Corr. 1A	Skin corrosion/irritation, Category 1A
Skin Corr. 1B	Skin corrosion/irritation, Category 1B
Skin Corr. 1C	Skin corrosion/irritation, Category 1C
Skin Irrit. 2	Skin corrosion/irritation, Category 2
Skin Sens. 1A	Sensitisation — Skin, category 1A
H290	May be corrosive to metals
H301	Toxic if swallowed
H302	Harmful if swallowed
H310	Fatal in contact with skin
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
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

Safety Data Sheet (SDS), EU

This information is based on our current knowledge and is intended to describe the product for the purposes of health, safety and environmental requirements only. It should not therefore be construed as guaranteeing any specific property of the product.