

Safety Data Sheet

according to regulation No 1907/2006
10. May 2019

Version 07

23. Dec 2022

Replaces:
Version 06 from 01 Apr 2021
and all preceding versions.

1 Product Identification

1.1 Product identifiers

Product Name:	e 1 Cartridge 150, 150 oQC, 300, 300 oQC, 600, 600oQC
Catalog Number:	M000338, M000339, M000137, M000138, M000139, M000140

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

The intended use of the product is the function in combination with the EXIAS e|1-ISE-Analyzer. Any other use is omitted.

1.3 Details of the supplier of the safety data sheet

EXIAS Medical GmbH
Kratkystraße 2, 8020 Graz, Austria
+43 316 922953
office@exias-medical.com
Responsible person:
Wolfgang Hofmann

1.4 Emergency telephone number

+43 1 4064343

2 Hazards Identification

2.1 Classification of the substance or mixture

This product does not meet the criteria for classification in any hazard class according to Regulation (EC) No 1272/2008 on classification, labelling and packaging of substances and mixtures.

2.2 Label elements

n/a

2.3 Other hazards

n/a

3 Composition / Information on ingredients

3.1 Substances

n/a

3.2 Mixtures

Chemical substances are part of the calibration and control liquids contained in pouches inside the cartridge. It is a mixture with the following composition:

Chemical Name	CAS-Nr.	EC-Nr.	Classification*	% Concentration W/V
Deionized water	7732-18-5	231-18-5		≥90 - < 99%
2-(4-(2-hydroxyethyl)-1-piperazinyl)-methanesulfonic (=HEPES)	7365-45-9	230-907-9		≥1 - < 5%
Sodium chloride	7647-14-5	231-598-3		≥0,2 - < 1%
Sodium acetate	127-09-3	204-823-8		≥0,1 - < 1%
Potassium chloride	7447-40-7	231-211-8		≤ 0,1%
Calcium chloride	22691-02-7	607-129-7	H319	≤ 0,1%

(*) according to Regulation (EC) No 1278/2008 (CLP)

All substances listed above fulfill the requirements of regulation (EC) No 1907/2006 and of the Globally Harmonized System of Classification and Labeling of Chemicals (GHS).

4 First aid measures

4.1 Description of first aid measures:

General notes: The mixture is not considered harmful, so no immediate medical treatment is required. However, the following list describes exposure means and the indicated first aid measures:

Inhalation:	If breathing becomes difficult, remove victim to fresh air, consult medical aid
Skin contact:	Remove contaminated clothes, rinse skin with water
Ingestions	Seek medical attention. Do not induce vomiting without medical advice
Eye contact:	Rinse with plenty of water
Self-protection of the first aider	Avoid contact to liquids

4.2 Most important symptoms and effects, both acute and delayed

Ingestions of this product may cause nausea and vomiting. Inhalation of mists or sprays may irritate respiratory passages. Symptoms are generally alleviated upon breathing fresh air

4.3 Indication of any immediate medical attention and special treatment needed

No special treatment or attention is advertised.

5 Fire Fighting Measures

5.1 Extinguishing media

No limitations for extinguishing media that are appropriate for the site conditions.

5.2 Special hazards arising from the substance or mixture

n/a

5.3 Advice for firefighters

n/a

6 Accidental Release Measures

6.1 Personal precautions, protective equipment and emergency procedures

Wear suitable protective equipment (including personal protective equipment referred to under Section 8 of the safety data sheet) to prevent any contamination of skin, eyes and personal clothing. Keep adequate aeration.

6.2 Environmental precautions

Prevent from entering sanitary drains in large quantities.

6.3 Methods and material for containment and cleaning up

Never return spills to original containers for re-use. Use an absorbent material to contain spilled solution. Please all contaminated disposables into a suitable container for disposal.

6.4 Reference to other sections

See section 8 and 13

7 Handling and Storage

7.1 Precautions for safe handling:

See user's manual for appropriate use of the cartridge. Do not disassemble the cartridge.

Do not to eat, drink and smoke in work areas. Wash hands after use. Remove contaminated clothing and protective equipment before entering eating areas.

7.2 Conditions for safe storage, including any incompatibilities:

This product consists of aqueous solutions. Note the reactivity with of metals (sodium / potassium) with water. Store materials in the original packages.

7.3 Specific end use(s)

Operation of EXIAS analytical systems in clinical and laboratory environment.

The e|1 cartridge is provided for function of the EXIAS e|1 analyzer. It is inserted into the analyzer prior to use of the instrument.

8 Exposure Controls / Personal Protection

8.1 Control parameters

Substances with occupational exposure limit values are not contained in adequate amounts

8.2 Appropriate engineering controls

Respiratory protection:	Not required
Hand protection:	Wear appropriate protective gloves to prevent skin contact
Skin and body protection:	Wear appropriate body protection to prevent skin contact
Eye protection:	Wear protective eye protection to prevent eye contact
Hygiene measures:	Avoid contact with eyes, skin and clothing

9 Physical and chemical properties

9.1 Information on basic physical and chemical properties

Physical state	Liquid
Appearance:	Clear
Colour:	Transparent
Odor:	Odorless
pH:	6,5-7,8
Freezing point:	0 °C
Boiling point:	100 °C
Flash point:	n. a
Flammability:	n/a
Explosion properties:	n/a
Oxidising properties:	n/a
Auto-ignition:	n/a
Decomposition:	n/a
Vapor pressure: (20°C)	23 hPa
Vapor density: (absolute 20°C)	0,74 kg/m ³
Relative density:	1 g/mL
Solubility:	n/a
Water solubility:	Mixable with water
Partition coefficient: n-octanol/water:	n/a
Kinematic viscosity:	0,8 mm ² /s

9.2 Other information

n/a

10 Stability and Reactivity

10.1 Reactivity

n/a, the mixture is a water-based salt solution

10.2 Chemical stability

n/a, the mixture is a water-based salt solution

10.3 Possibility of hazardous reactions

As water-based solution the material may react with alkaline metals such as Sodium/Potassium

10.4 Conditions to avoid

Excessive heat, pressure, flame

10.5 Incompatible materials

Alkaline metals such as Sodium/Potassium

10.6 Hazardous decomposition products

Thermal decomposition may emit flue gases

11 Toxicological Information

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

acute toxicity	No data available
skin corrosion/irritation	No data available
serious eye damage/irritation	No data available
respiratory or skin sensitization	No data available
germ cell mutagenicity;	No data available
carcinogenicity	No data available
reproductive toxicity	No data available
STOT-single exposure;	No data available
STOT-repeated exposure;	No data available
aspiration hazard.	No data available

11.2 Information on other hazards:

Endocrine disrupting properties: (assessment)

The mixture does not contain components considered to have endocrine disrupting properties according to REACH Article 57(f) or Commission Delegated regulation (EU) 2017/2100 or Commission Regulation (EU) 2018 605 at levels of 0,1% or higher

12 Ecological information

12.1 Toxicity

No data available

12.2 Persistence and degradability

No data available

12.3 Bioaccumulative potential

No data available

12.4 Mobility in soil

No data available

12.5 Results of PBT and vPvB assessment

The mixture contains no components considered to be either persistent, bio-accumulative and toxic (PBT), or very persistent and very bio-accumulative (vPvB) at levels of 0,1% or higher

12.6 Endocrine disrupting properties

The mixture does not contain components considered to have endocrine disrupting properties according to REACH Article 57(f) or Commission Delegated regulation (EU) 2017/2100 or Commission Regulation (EU) 2018 605 at levels of 0,1% or higher

12.7 Other adverse effects

No data available

13 Disposal considerations

13.1 Waste treatment methods

Dispose the product according to local and federal regulations. Within the EU, attention must be paid to Directive 2008/98/EC.

13.2 Information regarding the disposal of the product

The product is not subject for waste separation. The liquids must be disposed together with the cartridge. Do not disassemble cartridges. However, after operation of the product in a clinical environment, cartridges are biologically contaminated, and disposal must be carried out accordingly.

14.7 Maritime transport in bulk according to IMO instruments:

n/a, no bulk shipment foreseen

15 Regulatory Information

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

This safety data sheet complies with the commission regulation No 1907/2006/EG in the current version of the European Parliament and of the Council concerning the Registration, Evaluation, Authorization and Restriction of Chemicals (REACH)

15.1.1 Further regulation regarded in this SDS:

Regulation (EC) No 1005/2009 of the European Parliament and of the Council of 16 September 2009
No ozone layer depleting substances contained

REACH Article 57(f) or Commission Delegated regulation (EU) 2017/2100 or Commission Regulation (EU) 2018 605

No substances with endocrine disrupting properties at levels of 0,1% or higher contained

Regulation (EC) No 850/2004 of the European Parliament and of the Council of 29 April 2004 and amending Directive 79/117/EEC, replaced by Regulation (EC) 2019/1021

No persistent organic pollutants contained

Regulation (EU) No 649/2012 of the European Parliament and of the Council of 4 July 2012

No hazardous chemicals contained

Council Directive 96/82/EC of 9 December 1996

No dangerous substances contained

15.2 Chemical safety assessment

For this product a chemical safety assessment was not carried out

16 Other Information

16.1 Abbreviations

ADR	Agreement concerning the International Carriage of Dangerous Goods by Road
CAS	Chemical Abstracts Service
EU	European Union
GHS	Globally Harmonized System of Classification, Labelling and Packaging of Chemicals
IATA	International Air Transport Association
IMDG	International Maritime Dangerous Goods Code
PBT	Persistent, Bio-accumulative and Toxic
REACH	Registration, Evaluation, Authorization and Restriction of Chemicals
RID	Regulations concerning the International Carriage of Dangerous Goods by Rail
STOT	Specific Target Organ Toxicity
vPvB	very Persistent and very Bio-accumulative

16.2 Revision of the current SDS

Version 07 of the SDS was revised on 23. Dec 2022.

Changes relate:

- to the commission regulation (EU) 2020/878 of 18 June 2020 amending Annex II to Regulation (EC) No 1907/2006.
- Adjusted template and restructuring

16.3 Disclaimer

The above information describes exclusively the safety requirements of the e|1 cartridge produced by EXIAS Medical GmbH and is based on our present-day knowledge. The information is intended to give you advice about the safe handling of the product named in this safety data sheet, for storage, processing, transport and disposal. The information cannot be transferred to other products. In the case of mixing the product with other products or in the case of processing, the information on this safety data sheet is not necessarily valid for the new made-up material.