

SAFETY DATA SHEET (SDS) IN ACCORDANCE WITH REGULATION (EC) NO. 1907/2006, AS AMENDED BY COMMISSION REGULATION (EU) 2020/878					
ELAEXIA® FC KIT Product Category: Multi-Component Kit (Research Use Only)					
First Release Date:	16.07.2026	Last Release Date:	16.07.2026	Version: 01 Effective date: 16.07.2026	

Safety Data Sheet (SDS) - Product Information Sheet:

ELAEXIA® FC Kit

Order-Number	:	ELAEXIA® FC
Document-ID	:	SDS-ELX-200-01
Country / Language	:	Germany / English

The information provided in this Safety Data Sheet is based on the safety information available for the individual components and on their concentrations in the final mixture. Safety Data Sheets are available for the following materials:

Product Identifier	Mol. Formula	Product number	Version SDS
ELAEXIA® FC	: $C_{214}H_{291}N_{59}O_{62}S_6$	ELX-100	01
Buffer components:			
Natriumbicarbonat, Sigma (0.1 M)	: $CHNaO_3$	S6297	6.5
DMSO, Carl Roth (<1%)	: C_2H_6OS	5179	07

SECTION 1: IDENTIFICATION OF SUBSTANCE/MIXTURE & COMPANY

1.1 Product Identifier:

Product Name	:	ELAEXIA® FC
Product Code	:	TH-ELX-200
Brand	:	therawis diagnostics
REACH Nr.	:	No registration number is provided for this substance or these substances in this mixture because the annual import volume is less than one metric ton per year or the transition period for registration under Article 23 of REACH has not yet expired.
CAS-Nr.	:	Mixture. Not applicable.

1.2 Intended Use:

Use of the Substance / Mixture	:	Research use only (RUO). Not for diagnostic or therapeutic use in humans or animals. Detection of ELAEXIA® FC-labelled exosomes from plasma or cell-culture supernatant with flow cytometry.
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1.3 Details about the supplier providing the safety data sheet:

Company	:	therawis diagnostics GmbH, Grillparzerstr. 14, D-81675 Munich
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0.1% or more, as defined in REACH Article 57(f), Commission Delegated Regulation (EU) 2017/2100, or Commission Delegated Regulation (EU) 2018/605.

Toxicological information: Not available, but the substance/mixture is not expected to contain any components that exhibit endocrine-disrupting properties in concentrations of 0.1% or more, as defined in REACH Article 57(f), Commission Delegated Regulation (EU) 2017/2100, or Commission Delegated Regulation (EU) 2018/605.

SECTION 3: COMPOSITION / INFORMATION ON INGREDIENTS

3.1 Ingredients:

Component	CAS-Nr.	Classification EG Regulation 1272/2008	Concentration v/v (%)
Substances with an occupational exposure limit in mixture: none			
ELAEXIA®-T MS	Not available	Unclassified	<1%
Dimethyl Sulfoxide (DMSO)	67-68-5	This substance does not meet the criteria for classification.	<1%
Sodium Bicarbonate Buffer (0.1M; 8.4 g Bicarbonate/L)	144-55-8	This substance does not meet the criteria for classification.	98%

SECTION 4: FIRST AID MEASURES

4.1 Description of first aid measures

General advice	:	Consult a doctor or contact a poison center if you feel unwell, experience any symptoms or are unsure following exposure.
Inhalation	:	Move to fresh air. Seek medical attention if symptoms persist.
Skin Contact	:	Take off contaminated clothing. As a precaution, wash exposed area with soap and water.
Eye Contact	:	As a precaution, rinse eyes with water for 5 minutes.
Swallowing	:	As a precaution, rinse mouth with water. Seek medical attention or contact a poison center if you feel unwell following exposure.

4.2 Most important symptoms and effects, both acute and delayed

Known symptoms and effects can be found in section 2.2 and/or in Section 11.

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4.3 Indication of any immediate medical attention and treatment needed

Treatment : No data available.

SECTION 5: FIRE-FIGHTING-MEASURES

5.1 Extinguishing media – suitable media

Suitable fire extinguishing agents : Adapt firefighting measures to the surrounding area. Carbon dioxide, Dry chemical or foam recommended.

5.2 Special hazards arising from the substance or mixture

Specific Hazards in Firefighting : Non-flammable. No data available. .
Hazardous combustion products : Inhaling decomposition products can be harmful to your health. Carbon monoxide, carbon dioxide, and unburned hydrocarbons (smoke).

5.3 Advice for fire fighters

Special Protective Equipment for Firefighting : In the event of a fire, wear self-contained breathing apparatus if necessary. Remove all ignition sources if it can be done safely.
Additional Information : Do not inhale explosion aerosols or fire fumes.

SECTION 6: ACCIDENTAL RELEASE MEASURES

6.1 Personal Precautions, Protective Equipment, and Emergency Procedures

Personal Precautions : Wear laboratory coat, safety glasses, gloves and dust masks if applicable.

6.2 Environmental Precautions

Environmental Precautions : Prevent uncontrolled release of the product into the environment. Prevent entry into the sewer system, groundwater, or surface water.

6.3 Methods and Materials for Containment and Cleanup

For Containment and Cleanup : Absorb with inert material. Collect into suitable waste containers. Clean area with water. Wear appropriate personal protective equipment (PPE) gear as outlined in section 8. Avoid raising dust and/or aerosols. Ensure adequate ventilation until all material has been removed. Cover the Sewer System.

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6.4 Reference to other sections

For personal protective equipment, see Section 8.

SECTION 7: HANDLING AND STORAGE

7.1 Safety Precautions for Safe Handling

Safety Guidelines	:	For personal protective equipment, see Section 8. Do not eat, drink, or smoke in the work area. Ensure appropriate ventilation.
Fire and Explosion Safety Guidelines	:	Prevent leakage or spillage. Standard preventive fire safety measures. Keep away from heat and fire.
Hygiene Measures	:	Keep away from food and beverages. Do not eat, drink, or smoke while working.

7.2 Conditions for Safe Storage, Considering Incompatibilities

Storage class (TRGS 510)	:	Not available. Use according to good laboratory practices. Avoid: ingestion, inhalation of aerosols and contact with eyes and skin.
Storage conditions	:	Store protected from light at 2 to 8°C or according to product specification. Protect from light. Keep container tightly closed.

7.3 Specific end use

Specific end use(s)	:	This product is intended for in vitro laboratory research use (RUO) only.
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SECTION 8: EXPOSURE CONTROLS/PERSONAL PROTECTION

8.1 Control parameters: Ingredients with workplace control parameters: No data available.

8.2 Safety precautions for safe handling (personal protection equipment)

Eye/Face/Hand Protection	:	Eye Protection: Avoid contact with eyes. DMSO can promote the absorption of dissolved substances through the eyes. Wear safety glasses. Hand Protection: Wear nitrile or butyl rubber gloves Change gloves after contamination.
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Notes	:	Choosing the right glove depends not only on the material but also on other quality characteristics, and these vary from manufacturer to manufacturer. Be sure to follow the manufacturer's specifications regarding permeability and breakthrough time, as well as the specific conditions at your workplace (mechanical stress, duration of contact).
Respiration Protection	:	Do not inhale vapor or aerosols. Respiratory protection is not required under normal laboratory conditions. Ensure adequate ventilation. If work outside normal laboratory conditions, use type P2 (EN 143(EU)) or type N95 (NIOSH(USA)) dust masks to avoid breathing in aerosols.
Skin and Body Protection	:	Avoid contact with skin. DMSO can promote the absorption of dissolved substances through the skin. Select personal protective equipment based on the amount and concentration of the hazardous substance in the workplace. Preventive skin protection with creams is recommended. Use close shoes for protection against chemicals.

8.3 Environment exposure controls: No data available.

SECTION 9: PHYSICAL AND CHEMICAL PROPERTIES

9.1 Information on the basic physical and chemical properties

Appearance	:	Clear yellow-green solution.
Colour	:	Colourless liquid.
Odor	:	No data available.
Melting Point/Melting Range	:	No data available.
Boiling point/boiling range	:	No data available.
Upper explosion limit / Upper flammability limit	:	No data available.
Lower explosion limit / Lower flammability limit	:	No data available.
Flash point	:	No data available.
Ignition temperature	:	No data available.
Decomposition temperature	:	No data available.
pH value	:	Approx. 8–9
Viscosity		
Dynamic viscosity	:	No data available.
Kinematic viscosity	:	No data available.

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Solubility(ies)

Water solubility	: Completely miscible with water.
Solubility in other solvents	: No data available.
Partition coefficient	: No data available.
Vapor pressure	: No data available.
Relative density	: No data available.
Density	: Like water.
Relative vapor density	: No data available.

9.2 Additional Information

Explosive substances/mixtures	: No data available.
Available oxidizing properties	: No data available.
Flammable solids burning rate	: No data available.
Evaporation rate	: No data available.

SECTION 10: STABILITY AND REACTIVITY

10.1 Reactivity:

No dangerous reactions expected. This material is not reactive under normal environmental conditions.

10.2 Chemical stability:

Stable under recommended storage conditions.

10.3 Potential for Hazardous Reactions

Dangerous reactions	: Stable under specified storage conditions. In the event of a fire, hazardous decomposition products may be formed.
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10.4 Conditions to Avoid

Conditions to avoid	: Excessive heat No freezing Repeated freeze-thaw cycles Exposure to light
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10.5 Incompatible Materials

Incompatible Materials	: No data available.
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10.6 Hazardous decomposition products

No decomposition occurs when stored and used as intended. No hazardous decomposition products are known.

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SECTION 11: TOXICOLOGICAL INFORMATION

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

Acute oral toxicity mixture	:	No toxicity data available for the mixture.
Acute inhalation toxicity mixture	:	No toxicity data available for the mixture.
Acute inhalation toxicity	:	No toxicity data available for the mixture.
Acute dermal toxicity	:	No toxicity data available for the mixture.
Skin corrosion/irritation	:	No toxicity data available for the mixture.
Serious eye damage/irritation	:	No toxicity data available for the mixture.
Germ Cell Mutagenicity	:	No toxicity data available for the mixture.
Carcinogenicity	:	No known carcinogenic components at relevant concentrations.
Reproductive Toxicity	:	No known reproductive toxicity components at relevant concentrations.
Specific Target Organ Toxicity Following Single Exposure	:	No toxicity data available for the mixture.
Specific Target Organ Toxicity Following Repeated Exposure	:	No toxicity data available for the mixture.
Aspiration Toxicity	:	No toxicity data available for the mixture.

11.2 Information on Other Hazards: No data available.

Product Endocrine-disrupting properties	:	The substance/mixture is not expected to contain any components that exhibit endocrine-disrupting properties in concentrations of 0.1% or more, as defined in REACH Article 57(f), Commission Delegated Regulation (EU) 2017/2100, or Commission Delegated Regulation (EU) 2018/605. However, if handled properly, the risk is unlikely. The standard safety precautions for handling chemicals must be followed.
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SECTION 12: ECOLOGICAL INFORMATION

12.1 Acute (short term) toxicity	:	No data available.
12.2 Chronic (long term) toxicity	:	No data available.
12.3 Persistence and Degradability	:	No data available.
12.4 Bioaccumulation potential	:	No data available.
12.5 Mobility in soil	:	None known or required.

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12.6	Results of PBT- and PvB-assessment	:	No data available.
12.7	Endocrine disrupting properties	:	No data available.
12.8	Other adverse effects	:	No data available.

SECTION 13: DISPOSAL CONSIDERATIONS

13.1 Waste treatment methods

13.1.1	Product disposal	:	Do not allow this product to enter the sewer system. Dispose as toxic waste. Ensure compliance with all relevant local, state and national laws and regulations. Small quantities may be disposed of as aqueous laboratory chemical waste. Collect and dispose of contaminated wash water. Follow institutional biosafety procedures.
13.1.2	Packaging disposal	:	Contaminated packaging should be treated in the same manner as the substance itself. Packaging that has been completely emptied may be sent for recycling.
13.1.3	Sewerage disposal	:	The assignment of waste code numbers and waste descriptions must be carried out in accordance with the EAKV on an industry- and process-specific basis. Waste Catalog Regulation (The AVV replaces the EAK Regulation/European Waste Catalog Regulation).
13.1.4	Other disposal recommendations	:	Waste must be sorted so that it can be processed separately by municipal or national waste disposal facilities. Please observe the relevant national or regional regulations.

SECTION 14: TRANSPORT INFORMATION

14.1	UN-Number or ID-Number	:	Is not subject to transportation regulations
14.2	Proper UN shipping name	:	Unassigned
14.3	Transport Hazard Classes	:	None.
14.4	Packaging group	:	Unassigned.

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14.5 Environmental hazards : Not hazardous to the environment according to hazardous materials regulations.

14.6 Special precautions for users

No additional information is available.

14.7 Transportation of Bulk Cargo by Sea in Accordance with IMO Instruments

The kits are not transported as bulk cargo.

14.8 Information in accordance with the individual UN Regulations

The kits are not transported as bulk cargo.

Transportation of dangerous goods by road, rail, or inland waterways (ADR/RID/ADN) - Additional Information: Is not subject to the provisions of the ADR, RID and AND.

International Maritime Dangerous Goods (IMDG) Code - Additional Information: Is not subject to the provisions of the IMDG-

International Civil Aviation Organization (ICAO-IATA/DRG) - Additional Information: Is not subject to the provisions of the ICAO-IATA-

SECTION 15: REGULATORY INFORMATION

15.1 Safety, health, and environmental regulations/legislations specific to the substance or mixture

This material safety data sheet complies with the requirements of Regulation (EC) No. 1907/2006.

Authorisations and/or restrictions on use

Product is supplied for Research Use Only (RUO). Not intended for:

- human consumption
- therapeutic use
- diagnostic use

Subject to local laboratory chemical regulations.

15.2 Chemical Safety Assessment

For this product a chemical safety assessment was not carried out.

SECTION 16: OTHER INFORMATION

16.1 References to regulations and abbreviations

DE DFG MAK	:	Germany. MAK and BAT Annex IIa.
DE TRGS 900	:	Germany. TRGS 900 - Occupational Exposure Limits
DE DFG MAK / MAK	:	MAK value.
DE TRGS 900 / AGW	:	Occupational exposure limit.

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Abbreviations and Acronyms	
ADN	European Agreement concerning the International Carriage of Dangerous Goods by Inland Waterways
ADR	Agreement concerning the International Carriage of Dangerous Goods by Road
CAS	Chemical Abstracts Service (database of chemical compounds and their unique keys, the CAS Registry number).
CLP	Classification, Labelling and Packaging Regulation, Regulation (EC) No. 1272/2008
DIN	German Institute for Standardization Standard
DMSO	Dimethyl Sulfoxide
ECHA	European Chemicals Agency
EC Number	European Community Number
GHS	Globally Harmonized System
IATA	International Air Transport Association
IMDG Code	International Maritime Dangerous Goods Code
ISO	International Organization for Standardization
MAK	Maximale Arbeitsplatzkonzentration (Maximum workplace concentration)
OPPTS	Office of Prevention, Pesticides and Toxic Substances (OPPTS)
PBT	Persistent, Bioaccumulative and Toxic Substance
PPE	Personal Protective Equipment
REACH	Regulation (EC) No. 1907/2006 of the European Parliament and of the Council concerning Registration, Evaluation, Authorization and Restriction of Chemicals
RID	Regulations concerning the International Carriage of Dangerous Goods by Rail
RUO	Research Use Only. Not intended for use in humans or animals.
SDS	Safety Data Sheet
TRGS	Technical Rules for Hazardous Substances
UN	United Nations
vPvB	Very Persistent and Very Bioaccumulative

The information provided in this Safety Data Sheet is, to the best of our knowledge, accurate and reliable as of the date of revision. The information is intended to provide guidance for the safe handling, storage, processing, transportation, and disposal of the product covered by this Safety Data Sheet. The information does not apply to other products. If the product referred to in this Safety Data Sheet is mixed, blended, or processed with other materials, or subjected to any form of treatment, the information contained herein shall not apply to the resulting new material unless explicitly stated otherwise.

SECTION 17: REVISION HISTORY

SDS Version	Key Changes	Replaced with
1.0	Initial SDS	Not applicable