SAFETY DATA SHEET

according to Regulation 1907/2006/EC (REACH)

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

1.1. PRODUCT IDENTIFIER

Product name: **ALEX² Allergy Xplorer**

Reference number: 02-2001-01	Reference number: 02-5001-01
2 x 10 ALEX² Cartridges	5 x 10 ALEX² Cartridges
1 x 50 mL Washing Solution	1 x 250 mL Washing Solution 4 x conc.
1 x 9 mL ALEX² Sample Diluent	1 x 30 mL ALEX² Sample Diluent
1 x 11 mL ALEX² Detection Antibody	1 x 30 mL ALEX² Detection Antibody
1 x 11 mL ALEX² Substrate Solution	1 x 30 mL ALEX² Substrate Solution
1 x 2.4 mL Stop Solution	1 x 10 mL Stop Solution

1.2. RELEVANT IDENTIFIED USES OF THE SUBSTANCE OR MIXTURE AND USES ADVISED AGAINST

Identified uses: The test system is for laboratory use only, not for drug, household or other purposes. The product is intended for professional users only.

1.3. DETAILS OF THE SUPPLIER OF THE SAFETY DATA SHEET

Company: MacroArray Diagnostics GmbH
Address: Lemböckgasse 59, Top 4
1230 Vienna
Austria
Phone: +43 (0)1 865 2573
Email: office@madx.com

1.4. EMERGENCY TELEPHONE NUMBER

Poison information center: +43 1 406 43 43

Outside Austria (AT): Call your regional Poisons Information Service or call local Life Saving Service

SECTION 2: HAZARDS IDENTIFICATION

2.1. CLASSIFICATION OF THE SUBSTANCE OR MIXTURE

Classification according to regulation EC No 1272/2008
Stop Solution: Eye irritation (Category 2), H319

2.2. LABEL ELEMENTS

Stop Solution: Ethylenediaminetetraacetic acid, 1-10%, CAS 60-00-4

GHS07

Signal Word: Warning

Hazard statements: H319 - Causes serious eye irritation

Precautionary statements: P264 – Wash skin intensively after use.
P280 – wear eye protection/face protection.
P305+P351+P338 - If in eyes: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.
P337 + P313 – in case of persisting eye irritation – contact medical advice.

2.3. OTHER HAZARDS

This mixture contains no components considered to be either persistent, bioaccumulative and toxic (PBT), or very persistent and very bioaccumulative (vPvB) at levels of 0.1% or higher

SECTION 3: COMPOSITION/INFORMATION ON INGREDIENTS

3.1. SUBSTANCES

Not applicable

3.2. MIXTURES

Component	Chemical substance	Classification/Statements according to Regulation (EC) No 1272/2008 for pure chemical substance	Conc.
ALEX² cartridge	-	non-hazardous no declaration necessary	-
Washing Solution	TRIS buffered saline	non-hazardous no declaration necessary	-
	Tween 20 CAS 9005-64-5	non-hazardous no declaration necessary	< 1%
	Sodium Azide CAS 26628-22-8	Acute toxicity, Oral (Category 2) Acute toxicity, Dermal (Category 1) Acute aquatic toxicity (Category 1) Chronic aquatic toxicity (Category 1)	< 0.1%
ALEX² Sample Diluent	TRIS buffered saline	non-hazardous no declaration necessary	-
	Tween 20 CAS 9005-64-5	non-hazardous no declaration necessary	< 1%
	Sodium Azide CAS 26628-22-8	Acute toxicity, Oral (Category 2) Acute toxicity, Dermal (Category 1) Acute aquatic toxicity (Category 1) Chronic aquatic toxicity (Category 1)	< 0.1%
	CCD Blocker	non-hazardous no declaration necessary	-
ALEX² Detection Antibody	hu Anti-IgE detection antibody dissolved in a stabilizer	non-hazardous no declaration necessary	-
	BSA	non-hazardous no declaration necessary	1-5%
ALEX² Substrate Solution	NBT/BCIP (NBT: 4-Nitro blue tetrazolium chloride, solution, BCIP: 5-bromo-4-chloro-3-indolyl-phosphate, 4-toluidine salt)	non-hazardous no declaration necessary	-
	0.1M Tris-HCl buffer solution	non-hazardous no declaration necessary	-
Stop Solution	Ethylenediaminetetraacetic acid (EDTA)-Solution CAS-Nr.: 60-00-4	Serious eye damage/eye irritation (Category 2)	1-10%

SECTION 4: FIRST AID MEASURES

4.1. DESCRIPTION OF FIRST AID MEASURES

General advice: Consult a physician. Show this safety data sheet to the doctor in attendance. Move out of dangerous area.

If inhaled: If breathed in, move person into fresh air. If not breathing, give artificial respiration. Consult a physician.

In case of skin contact: Wash off with soap and plenty of water. Take victim immediately to hospital. Consult a physician.

In case of eye contact: Rinse thoroughly with plenty of water for at least 15 minutes and consult a physician.

If swallowed: Never give anything by mouth to an unconscious person. Rinse mouth with water. Consult a physician.

4.2. MOST IMPORTANT SYMPTOMS AND EFFECTS, BOTH ACUTE AND DELAYED

The most important known symptoms and effects are described in the labelling (see section 2.2) and/or in section 11.

4.3. INDICATION OF ANY IMMEDIATE MEDICAL ATTENTION AND SPECIAL TREATMENT NEEDED

No data available

SECTION 5: FIREFIGHTING MEASURES

5.1. EXTINGUISHING MEDIA

Use water spray, alcohol-resistant foam, dry chemical or carbon dioxide, dry powder

5.2. SPECIAL HAZARDS ARISING FROM THE SUBSTANCE OR MIXTURE

Carbon oxides, nitrogen oxides (NOx)

5.3. ADVICE FOR FIREFIGHTERS

Wear self-contained breathing apparatus for firefighting if necessary.

5.4. ADDITIONAL INFORMATION

Product package burns like paper or plastic.

SECTION 6: ACCIDENTAL RELEASE MEASURES

6.1. PERSONAL PRECAUTIONS, PROTECTIVE EQUIPMENT AND EMERGENCY PROCEDURES

Advice for non-emergency personnel: Do not breathe vapors, aerosols. Avoid substance contact. Ensure adequate ventilation. Evacuate the danger area, observe emergency procedures, consult an expert. For personal protection see section 8.

6.2. ENVIRONMENTAL PRECAUTIONS

Prevent further leakage or spillage if safe to do so. Do not let product enter drains. Discharge into the environment must be avoided.

6.3. METHODS AND MATERIAL FOR CONTAINMENT AND CLEANING UP

Cover drains. Collect, bind, and pump off spills. Observe possible material restrictions (see sections 7 and 10). Take up with liquid-absorbent material. Dispose of properly. Clean up affected area.

6.4. REFERENCE TO OTHER SECTIONS

For disposal see section 13.

SECTION 7: HANDLING AND STORAGE

7.1. PRECAUTIONS FOR SAFE HANDLING

Avoid contact with skin and eyes. Avoid formation of aerosols. For precautions see section 2.2.

7.2. CONDITIONS FOR SAFE STORAGE, INCLUDING ANY INCOMPATIBILITIES

Keep container tightly closed in a dry place. See product label for recommended storage temperature.

7.3. SPECIFIC END USE(S)

Apart from the uses mentioned in section 1.2 no other specific uses are stipulated.

SECTION 8: EXPOSURE CONTROLS/PERSONAL PROTECTION

8.1. CONTROL PARAMETERS

Does not contain substances with occupational exposure limits exceeding a concentration of 0.1% in the product.

8.2. EXPOSURE CONTROLS

Appropriate engineering controls: Handle in accordance with good industrial hygiene and safety practice. Avoid contact with skin, eyes and clothing. Wash hands before breaks and immediately after handling the product.

Personal protective equipment

- **Eye/face protection**: Face shield and safety glasses Use equipment for eye protection tested and approved under appropriate government standards such as NIOSH (US) or EN 166(EU).
- **Skin protection**: Handle with gloves. Gloves must be inspected prior to use. Use proper glove removal technique (without touching glove's outer surface) to avoid skin contact with this product. Dispose of contaminated gloves after use in accordance with applicable laws and good laboratory practices. Wash and dry hands.

  The selected protective gloves have to satisfy the specifications of EU Directive 89/686/EEC and the standard EN 374 derived from it.

  Full contact
  Material: Nitrile rubber
  Minimum layer thickness: 0.11 mm
  Break through time: > 480 min
  Material tested: Dermatril® (KCL 740 / Aldrich Z677272, Size M)

  Splash contact
  Material: Nitrile rubber
  Minimum layer thickness: 0.11 mm

Break through time: > 480 min
Material tested: Dermatril® (KCL 740 / Aldrich Z677272, Size M)

- **Body Protection**: Complete suit protecting against chemicals, the type of protective equipment must be selected according to the concentration and amount of the dangerous substance at the specific workplace.
- **Respiratory protection**: Where risk assessment shows air-purifying respirators are appropriate use a full-face particle respirator type N100 (US) or type P3 (EN 143) respirator cartridges as a backup to engineering controls. If the respirator is the sole means of protection, use a full-face supplied air respirator. Use respirators and components tested and approved under appropriate government standards such as NIOSH (US) or CEN (EU).
- **Control of environmental exposure**: Prevent further leakage or spillage if safe to do so. Do not let product enter drains. Discharge into the environment must be avoided.

SECTION 9: PHYSICAL AND CHEMICAL PROPERTIES

9.1. INFORMATION ON BASIC PHYSICAL AND CHEMICAL PROPERTIES

Properties	**Sodium azide** *(ALEX² Sample Diluent and Washing Solution)*	**EDTA** *(Stop Solution)*
Physical state	liquid	liquid
Color	clear, colorless	Clear colorless
Odour	odourless	Odourless
Odour Threshold	No data available	No data available
Melting point/freezing point	No data available	No data available
Initial boiling point and boiling range	No data available	No data available
Flammability	No data available	No data available
Lower/upper explosive limits	No data available	No data available
Flash point	No data available	No data available
Auto-ignition temperature	No data available	No data available
Decomposition temperature	No data available	No data available
pH	No data available	No data available
Viscosity	No data available	No data available
Solubility	No data available	No data available
Partition coefficient: n-octanol/water	No data available	No data available
Vapour pressure	No data available	No data available
Density	No data available	No data available
Vapour density	No data available	No data available
Particle characteristics	Not applicable	Not applicable
Explosive properties	No data available	No data available
Oxidizing properties	No data available	No data available

9.2. OTHER INFORMATION

No data available

SECTION 10: STABILITY AND REACTIVITY

10.1. REACTIVITY

No data available.

10.2. CHEMICAL STABILITY

Stable under recommended storage conditions.

10.3. POSSIBILITY OF HAZARDOUS REACTIONS

No data available.

10.4. CONDITIONS TO AVOID

Sodium azide (ALEX² Sample Diluent and Washing Solution): An explosion occurred when a mixture of sodium azide, methylene chloride, dimethyl sulfoxide, and sulfuric acid were being concentrated on a rotary evaporator.

10.5. INCOMPATIBLE MATERIALS

Sodium azide (ALEX² Sample Diluent and Washing Solution): Halogenated hydrocarbon, Metals, Acids, Acid chlorides, Hydrazine, Dimethyl sulfate, Inorganic acid chlorides. Strong oxidizing agents.

EDTA (Stop Solution): Copper, Copper alloys, Nickel

10.6. HAZARDOUS DECOMPOSITION PRODUCTS

Hazardous decomposition products formed under fire conditions. - Sodium oxides for **Sodium azide** (ALEX² Sample Diluent and Washing Solution)
Other decomposition products - No data available
In the event of fire: see section 5

SECTION 11: TOXICOLOGICAL INFORMATION

11.1. INFORMATION ON HAZARD CLASSES AS DEFINED IN REGULATION (EC) NO 1272/2008

Mixtures:

Toxicological effects	**Sodium azide** *(ALEX² Sample Diluent and Washing Solution)*	**EDTA** *(Stop Solution)*
Acute toxicity	Oral: No data available Inhalation: No data available Dermal: No data available	Oral: No data available Dermal: No data available
Skin corrosion/irritation	No data available	No data available
Serious eye damage/eye irritation	No data available	Mixture causes serious eye irritation
Respiratory or skin sensitisation	No data available	No data available
Germ cell mutagenicity	No data available	No data available
Carcinogenicity	No data available	No data available
Reproductive toxicity	No data available	No data available
Specific target organ toxicity - single exposure	No data available	No data available
Specific target organ toxicity - repeated exposure	No data available	No data available
Aspiration hazard	No data available	No data available

11.2. INFORMATION ON OTHER HAZARDS

Endocrine disrupting properties

Assessment: The substance/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.
To the best of our knowledge, the chemical, physical, and toxicological properties have not been thoroughly investigated. Nausea, Headache, Vomiting, Laboratory experiments in animals have shown sodium azide to produce a profound hypotensive effect, demyelination of myelinated nerve fibers in the central nervous system, testicular damage, blindness, attacks of rigidity, and hepatic and cerebral effects.

Components:

Sodium Azide (RTECS: VY8050000): Repeated dose toxicity: Rat - male and female - Oral - LOAEL: 5 mg/kg,

Ethylenediaminetetraacetic acid (EDTA; RTECS: AH4025000)

Toxicological effects	**Sodium azide** *(ALEX² Sample Diluent and Washing Solution)*	**EDTA** *(Stop Solution)*
Acute toxicity	LD50 Oral - Rat - 27 mg/kg Inhalation: No data available Dermal: No data available	LD50 Oral - rat - male and female – 4 500 mg/kg
Skin corrosion/irritation	Skin - reconstructed human epidermis (RhE) Result: No skin irritation - 15 min	Skin - rabbit Result: No skin irritation
Serious eye damage/eye irritation	Eyes - Bovine cornea Result: No eye irritation - 4 h (OECD Test Guideline 437)	Eyes - rabbit Result: Eye irritation
Respiratory or skin sensitisation	in vivo assay - Mouse Result: Does not cause skin sensitisation. (OECD Test Guideline 429)	Maximisation Test - rabbit Result: Does not cause skin sensitisation.
Germ cell mutagenicity	No data available	No data available
Carcinogenicity	Carcinogenicity - Rat - male and female - Oral No significant adverse effects were reported IARC: No component of this product present at levels greater than or equal to 0.1% is identified as probable, possible or confirmed human carcinogen by IARC.	IARC: No component of this product present at levels greater than or equal to 0.1% is identified as probable, possible or confirmed human carcinogen by IARC.
Reproductive toxicity	No data available	No data available
Specific target organ toxicity - single exposure	No data available	No data available
Specific target organ toxicity - repeated exposure	Oral - May cause damage to organs through prolonged or repeated exposure. – Brain	No data available
Aspiration hazard	No data available	No data available

SECTION 12: ECOLOGICAL INFORMATION

12.1. TOXICITY

Mixture:
No data available

Components:
Sodium Azide (RTECS: VY8050000)
Ethylenediaminetetraacetic acid (EDTA; RTECS: AH4025000)

Toxicity	**Sodium azide** *(ALEX² Sample Diluent and Washing Solution)*	**EDTA** *(Stop Solution)*
Toxicity to fish	mortality LC50 - Pimephales promelas (fathead minnow) - 5.46 mg/l - 96 h (OECD Test Guideline 203)	static test LC50 - Lepomis macrochirus (Bluegill sunfish) - 41 mg/l - 96 h

Toxicity to algae	static test EC50 - Pseudokirchneriella subcapitata - 0.35 mg/l - 96 h (OECD Test Guideline 201)	-
Toxicity to daphnia and other aquatic invertebrates	-	static test EC50 - Daphnia magna (Water flea) – 625 mg/l - 48 h

12.2. PERSISTENCE AND DEGRADABILITY

No data available

12.3. BIOACCUMULATIVE POTENTIAL

Mixture:
No data available

Components:
Sodium Azide (RTECS: VY8050000)
Bioaccumulation Lepomis macrochirus - 28 d - 80 µg/l, Bioconcentration factor (BCF): 1.8

12.4. MOBILITY IN SOIL

No data available

12.5. RESULTS OF PBT AND VPVB ASSESSMENT

This substance/mixture contains no components considered to be either persistent, bioaccumulative and toxic (PBT), or very persistent and very bioaccumulative (vPvB) at levels of 0.1% or higher.

12.6. ENDOCRINE DISRUPTING PROPERTIES

The substance/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

EDTA (Stop Solution): A contamination of the environment has to be avoided.

SECTION 13: DISPOSAL CONSIDERATIONS

13.1. WASTE TREATMENT METHODS

Product
Product residues must be disposed of in compliance with national and regional regulations. Leave chemicals in original containers. Do not mix with other waste.

Contaminated packaging
Dispose of as unused product.

SECTION 14: TRANSPORT INFORMATION

14.1. UN NUMBER OR ID NUMBER

ADR/RID: - IMDG: - IATA: -

14.2. UN PROPER SHIPPING NAME

ADR/RID: No dangerous good IMDG: No dangerous good IATA: No dangerous good

14.3. TRANSPORT HAZARD CLASS(ES)

ADR/RID: - IMDG: - IATA: -

14.4. PACKAGING GROUP

ADR/RID: - IMDG: - IATA: -

14.5. ENVIRONMENTAL HAZARDS

ADR/RID: no IMDG Marine pollutant: no IATA: no

14.6. SPECIAL PRECAUTIONS FOR USER

No data available

14.7. MARITIME TRANSPORT IN BULK ACCORDING TO IMO INSTRUMENTS

No data available

SECTION 15: REGULATORY INFORMATION

15.1. SAFETY, HEALTH AND ENVIRONMENTAL REGULATIONS/LEGISLATION SPECIFIC FOR THE SUBSTANCE OR MIXTURE

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

15.2. CHEMICAL SAFETY ASSESSMENT

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

SECTION 16: OTHER INFORMATION

16.1. LIST OF H AND P STATEMENTS

EDTA (Stop Solution):
H319 - Causes serious eye irritation
P264 – Wash skin intensively after use.
P280 – wear eye protection/face protection
P305+P351+P338 - If in eyes: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.
P337 + P313 – in case of persisting eye irritation – contact medical advice.

16.2. TRAINING ADVICE

Regular safety training.

16.3. RECOMMENDED RESTRICTIONS ON USE

Only for professional users.

16.4. FURTHER INFORMATION

This document is intended only as a guide to the appropriate precautionary handling of the material by a properly trained person using this product. Individuals receiving the information must exercise their independent judgment in determining its appropriateness for a particular purpose. MacroArray Diagnostics makes NO REPRESENTATIONS or WARRANTIES, either expressed or implied, including without limitation any warranties of merchantability, fitness for a particular purpose with respect to the information set forth herein or the product to which the information refers. Accordingly, MacroArray Diagnostics will not be responsible for damages resulting from use of or reliance upon this information.

16.5. CHANGE HISTORY

Version	Description	Replaces
01 - 06	Change History available on demand	-
07	Implementation of Regulation (EU) 2020/878	06
08	Section 14.7 added	07
09	P280 added to Section 2.2 and 16.1 “0.1M Tris-HCl buffer solution” – added in Chapter 3.2 The product names of Stop Solution and Washing Solution have been adjusted.	08