SAFETY DATA SHEET

according to Regulation 1907/2006/EC (REACh), including VO (EU) 453/2010 and VO (EU) 2015/830.

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

PRODUCT IDENTIFIER

Product name: ALEX² Allergy Explorer

Reference number: 02-2001-01	Reference number: 02-5001-01
2 x 10 ALEX² Cartridges	5 x 10 ALEX² Cartridges
2 x 50 mL ALEX² Washing Solution	1 x 250 mL ALEX² 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 ALEX² Stop Solution	1 x 10 mL ALEX² Stop Solution

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.

DETAILS OF THE SUPPLIER OF THE SAFETY DATA SHEET

Company: MacroArray Diagnostics GmbH
Address: Lemböckgasse 59/Top 4
A-1230 Wien
Austria
Phone: +43 (0)1 865 2573
Email: office@macroarraydx.com

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

CLASSIFICATION OF THE SUBSTANCE OR MIXTURE

Classification according to regulation EC No 1272/2008

Stop Solution

Serious eye damage/eye irritation (Category 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: P305+P351+P338 - If in eyes: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing

OTHER HAZARDS

None

SECTION 3: COMPOSITION/INFORMATION ON INGREDIENTS

DESCRIPTION OF THE COMPONENTS

Component	Chemical substance	Classification/Statements according to Regulation (EC) No 1272/2008 for pure chemical substance	Conc.
ALEX² Cartridge	-	non-hazardous no declaration necessary	-
ALEX² 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%
	Human Albumin infusion solution,	non-hazardous no declaration necessary	1-5%
	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 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	-
ALEX² Stop Solution	Ethylenediaminetetraacetic acid (EDTA)-Solution	Serious eye damage/eye irritation (Category 2)	1-10%

SECTION 4: FIRST AID MEASURES

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.

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.

INDICATION OF ANY IMMEDIATE MEDICAL ATTENTION AND SPECIAL TREATMENT NEEDED

No data available

SECTION 5: FIREFIGHTING MEASURES

EXTINGUISHING MEDIA

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

SPECIAL HAZARDS ARISING FROM THE SUBSTANCE OR MIXTURE

Carbon oxides, nitrogen oxides (NOx)

ADVICE FOR FIREFIGHTERS

Wear self-contained breathing apparatus for firefighting if necessary.

ADDITIONAL INFORMATION

Product package burns like paper or plastic.

SECTION 6: ACCIDENTAL RELEASE MEASURES

PERSONAL PRECAUTIONS, PROTECTIVE EQUIPMENT AND EMERGENCY PROCEDURES

Use personal protective equipment. Wear respiratory protection. Avoid dust formation. Avoid breathing vapours, mist or gas. Ensure adequate ventilation. Evacuate personnel to safe areas. Avoid breathing dust. For personal protection see section 8.

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.

METHODS AND MATERIAL FOR CONTAINMENT AND CLEANING UP

Pick up and arrange disposal without creating dust. Sweep up and shovel. Do not flush with water. Keep in suitable, closed containers for disposal.

REFERENCE TO OTHER SECTIONS

For disposal see section 13.

SECTION 7: HANDLING AND STORAGE

PRECAUTIONS FOR SAFE HANDLING

Avoid contact with skin and eyes. Avoid formation of dust and aerosols. Further processing of solid materials may result in the formation of combustible dusts. The potential for combustible dust formation should be taken into consideration before additional processing occurs. Provide appropriate exhaust ventilation at places where dust is formed. For precautions see section 2.2.

CONDITIONS FOR SAFE STORAGE, INCLUDING ANY INCOMPATIBILITIES

Keep container tightly closed in a dry and well - ventilated place. Never allow product to get in contact with water during storage. Do not store near acids. Store in cool place.

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

CONTROL PARAMETERS

Component	CAS- No.	ValueForm of exposure	Control parameters	Basis	Remarks
Sodium azide	26628-22-8	TWA	0.1 mg/m^3	Europe. Commission Directive 2000/39/EC establishing a first list of indicative occupational exposure limit values	Identifies the possibility of significant uptake through the skin Indicative
		STEL	0.3 mg/m^3	Europe. Commission Directive 2000/39/EC establishing a first list of indicative occupational exposure limit values	Identifies the possibility of significant uptake through the skin Indicative
		TWA	0.1 mg/m^3	Limit value regulation	Can be absorbed through skin. The assigned substances are those for which there are concerns that dermal absorption will lead to systemic toxicity.
		KZW	0.3 mg/m^3	Limit value regulation	Can be absorbed through skin. The assigned substances are those for which there are concerns that dermal absorption will lead to systemic toxicity.

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

INFORMATION ON BASIC PHYSICAL AND CHEMICAL PROPERTIES

Properties	**Sodium Azide**	**EDTA**
Appearance	Form: crystalline Colour: white	Form: powder Colour: white
Odour	No data available	odourless
Odour Threshold	No data available	No data available
pH	10 at 65 g/l at 25°C	2.5 at 10 g/l at 23°C
Melting point/freezing point	275°C -	Melting point/range: 250°C - dec.
Initial boiling point and boiling range	No data available	No data available
Flash point	No data available	No data available
Evaporation rate	No data available	No data available
Flammability (solid, gas)	The product is not flammable. - Flammability (solids)	No data available
Upper/lower flammability or explosive limits	No data available	No data available
Vapour pressure	0.01 hPa at 20°C	No data available
Vapour density	No data available	No data available
Relative density	1.850 g/cm^3	1.46 g/cm3 at 20°C
Water solubility	65 g/l at 20°C - completely soluble	0.4 g/l at 20°C
Partition coefficient: n-octanol/water	No data available	log Pow: 8.85 - 10.44 at 20°C
Auto-ignition temperature	309°C at 1,013 hPa	> 400°C at 1,013 hPa
Decomposition temperature	300°C	No data available

Properties	Sodium Azide	EDTA
Viscosity	No data available	No data available
Explosive properties	Not explosive	No data available
Oxidizing properties	No data available	No data available

OTHER INFORMATION

Bulk density: 0.8 kg/m3

Dissociation constant 8.85 - 10.44 at 20 °C

SECTION 10: STABILITY AND REACTIVITY

REACTIVITY

No data available.

CHEMICAL STABILITY

Stable under recommended storage conditions.

POSSIBILITY OF HAZARDOUS REACTIONS

No data available.

CONDITIONS TO AVOID

An explosion occurred when a mixture of sodium azide, methylene chloride, dimethyl sulfoxide, and sulfuric acid were being concentrated on a rotary evaporator.

INCOMPATIBLE MATERIALS

Halogenated hydrocarbon, Metals, Acids, Acid chlorides, Hydrazine, Dimethyl sulfate, Inorganic acid chlorides. Strong oxidizing agents.

HAZARDOUS DECOMPOSITION PRODUCTS

Hazardous decomposition products formed under fire conditions. - Sodium oxides

Other decomposition products - No data available

In the event of fire: see section 5

SECTION 11: TOXICOLOGICAL INFORMATION

INFORMATION ON TOXICOLOGICAL EFFECTS

Toxicological effects	Sodium Azide	EDTA
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	IARC: No component of this product present at levels

Toxicological effects	Sodium Azide	EDTA
	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.	greater than or equal to 0.1% is identified as Sigma-Aldrich - EDS Page 6 of 7 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	

Additional Information
Repeated dose toxicity: Rat - male and female - Oral - LOAEL: 5 mg/kg,
Sodium Azide: RTECS: VY8050000
EDTA: RTECS: AH4025000
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., To the best of our knowledge, the chemical, physical, and toxicological properties have not been thoroughly investigated.

SECTION 12: ECOLOGICAL INFORMATION

TOXICITY

Toxicity	Sodium Azide	EDTA
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

PERSISTENCE AND DEGRADABILITY

No data available

BIOACCUMULATIVE POTENTIAL

Bioaccumulation Lepomis macrochirus - 28 d - 80 µg/l, Bioconcentration factor (BCF): 1.8

MOBILITY IN SOIL

No data available

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.

OTHER ADVERSE EFFECTS

Very toxic to aquatic life with long lasting effects.

SECTION 13: DISPOSAL CONSIDERATIONS

WASTE TREATMENT METHODS

Product
Offer surplus and non-recyclable solutions to a licensed disposal company. Dissolve or mix the material with a combustible solvent and burn in a chemical incinerator equipped with an afterburner and scrubber.

Contaminated packaging
Dispose of as unused product.

SECTION 14: TRANSPORT INFORMATIO

Section only relevant for sodium azide, not for EDTA.

UN NUMBER

ADR/RID: 1687 IMDG: 1687 IATA: 1687

UN PROPER SHIPPING NAME

ADR/RID: SODIUM AZIDE IMDG: SODIUM AZIDE IATA: Sodium azide

TRANSPORT HAZARD CLASS(ES)

ADR/RID: 6.1 IMDG: 6.1 IATA: 6.1

PACKAGING GROUP

ADR/RID: II IMDG: II IATA: II

ENVIRONMENTAL HAZARDS

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

SPECIAL PRECAUTIONS FOR USER

No data available

SECTION 15: REGULATORY INFORMATION

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.

CHEMICAL SAFETY ASSESSMENT

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

SECTION 16: OTHER INFORMATION

LIST OF H AND P STATEMENTS

H319 - Causes serious eye irritation

P305+P351+P338 - If in eyes: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing

TRAINING ADVICE

Regular safety training.

RECOMMENDED RESTRICTIONS ON USE

Only for professional users.

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. Macro Array 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, Macro Array Diagnostics will not be responsible for damages resulting from use of or reliance upon this information.