

SECTION 1: Identification of the substance/mixture and of the company/undertaking**1.1 Product identifier**

- **Product Name:** Creatinine

Reference Numbers						
A2160N	A2160B10	HT2161	S2161	R2161	K2161	M2160
A2161N	DM2160	T2160	EC10	BY2160	L2160	M2161
A2162N	N2160	T2161	EC11	BY2161	L2161	RD2160
A2160B5	HT2160	S2160	R2160	K2160	LM246	M3160

- **Brand:** ARCHEM Diagnostics
- **CAS-No:** N/A
- **Product Use:** For invitro quantitative determination of creatinine in serum, plasma and urine.

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

For in vitro diagnostic use.

1.3 Details of the supplier of the safety data sheet

- **Company:** Archem Diagnostics Industry LTD. ŞTİ. İkitelli Organize Sanayi Bölgesi, MUTSAN Sanayi Sitesi M8 Blok No: 48 34490 İstanbul TURKEY
- **Telephone:** +90 212 444 08 92
- **Fax:** +90 212 629 98 89

1.4. Emergency telephone number

- Emergency phone: +(90) 212 444 0 892

REACH Registration Number: A registration number is not available for this mixture as the mixture or its use are exempted from registration according to Article 2 REACH Regulation (EC) No 1907/2006, the annual tonnage does not require a registration or the registration is envisaged for a later registration deadline.

SECTION 2: Hazards identification**2.1. Classification of the substance or mixture**

Product definition : Mixture

Classification according to Regulation (EC) No 1272/2008 (CLP/GHS):

This product has been evaluated per the classification criteria in Regulation (EC) No 1272/2008 (CLP) and the Globally Harmonized System of Classification and Labelling of Chemicals (GHS).

This product does not meet the criteria for classification in accordance with either CLP or GHS.

- **Classification according to Directive 67/548/EEC or Directive 1999/45/EC:**
- **Classification:**
- **Classification system:**
- The classification is in alignment with current European regulations.

2.2. Label elements

- **Labelling according to Regulation (EC) No 1272/2008(CLP):** None
- **Hazard pictograms:** None
- **Signal word:** None
- **Hazard statements:** None
- **Additional information:** Refer to section 15 for labelling per Directives 67/548/EEC or 1999/45/EC.
- **Labelling according to Directives 67/548/EEC or 1999/45/EC**
- **Hazard-determining components of labelling:** None

Routes of Exposure:

Skin: No adverse effects expected when used as directed.

Eye: No adverse effects expected when used as directed.

Inhalation: No adverse effects expected when used as directed.

Ingestion: No adverse effects expected when used as directed.

NOTE: All blood products should be treated as potentially infectious. Source material from which this product was derived was found negative when tested in accordance with current FDA required tests. No known test methods can offer assurance that products derived from human blood will not transmit infectious agents.

Emergency Phone Number: In emergency situation please contact the National Poison Solidarity Center (Turkey) for information in Turkish :(114) (24 hours/7 days). Please contact with Archem **for information in English: +(90) 212 444 0 892 (Turkey) (8:30-18:30/ except Sundays)**

2.3. Other Hazards

- **Hazards nor otherwise classified (HNOC) or not covered by GHS:** None
- **Results of PBT and vPvB assessment:**
- **PBT:** Not applicable
- **vPvB:** Not applicable

SECTION 3: Composition/information on ingredients

3.1. Substances: N/A

3.2. Chemical characterization: Mixtures

Hazardous components according to EC criteria: N/A

Classification according to Regulation (EC) No 1272/2008:

May damage to unborn child: H360D

Skin Corr. 1C, H314;

Acute Tox. 4, H302

Additional Information: For the full text of the H statements mentioned in this section, see Section 16.

Warnings: For in vitro diagnostic use only. Do not pipette by mouth. Perform the test according to the general "Good Laboratory Practice" (GLP) guidelines.

This product is made to be used in professional laboratories and by professional operators.

SECTION 4: FIRST AID MEASURES

4.1. Description of first aid measures

General advice: Consult a doctor. Show this safety data sheet to the doctor in attendance.

Emergency First Aid: Call an internal First Aider where available or else contact a doctor immediately.

Direction for First Aider:

Inhalation: If inhaled, remove to fresh air. If breathing becomes difficult, call a doctor.

Ingestion: If inhaled, remove to fresh air. If breathing becomes difficult, call a doctor.

Skin contact: In case of skin contact immediately wash skin with soap and copious quantities of water.

Eye contact: Flush with copious amounts of water for at least 15 minutes. Assure adequate flushing by separating eyelids with fingers. Call a doctor.

4.2. Most important symptoms and effects, both acute and delayed: None expected.

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

No additional relevant information available.

Emergency Phone Number: In emergency situation please contact the National Poison Solidarity Center (Turkey) for information in Turkish: (114) (24 hours/7 days). Please contact with Archem **for information in English: +(90) 212444 0 892 (Turkey) (8:30-18:30/ except Sundays)**

SECTION 5: FIREFIGHTING MEASURES**5.1 Extinguishing Media****Suitable Extinguishing Media**

Use water spray, regular foam, dry chemical or carbon dioxide.

5.2 Special hazards arising from the substance or mixture

There are no unique chemical or reactivity hazards that would impact firefighting decisions due to the chemicals in this product.

5.3 Advice for firefighters**Protective equipment**

For large fires, wear appropriate heat and flame-resistant personal protective equipment and an approved positive-pressure, self-contained breathing apparatus.

5.4 Other Information

Flash point:	NOT FLAMMABLE MATERIAL
Flammable limits:	NOT FLAMMABLE, NOT EXPLOSIVE
Extinguishing media:	Use water spray, regular foam, dry chemical or carbon dioxide.
Special Fire Fighting Procedures:	Wear self-contained breathing apparatus and protective clothing to prevent contact with skin and eyes.
Unusual Fire and Explosion Hazards:	May emit toxic fumes under fire conditions
Thermal decomposition:	Not determined

SECTION 6: ACCIDENTAL RELEASE MEASURES**6.1. Personal precautions, protective equipment and emergency procedures**

Use appropriate spill absorbent kit as instructed by the manufacturer. Alternatively, mop up with an absorbent material and hold for waste disposal. Avoid breathing vapours, mist or gas. Ensure adequate ventilation. Remove all sources of ignition. Evacuate personnel to safe areas. Beware of vapours accumulating to form explosive concentrations. Vapours can accumulate in low areas.

For personal protection see section 8.

Clean the affected area. Suitable cleaners are:

- Warm water and detergent or similar cleansing agent.

6.2. Environmental precautions

Prevent liquid and vapour from entering sewage system, storm drains, surface waters and soil.

6.3. Methods and materials for containment and cleaning up

Contain spillage and then collect with an electrically protected vacuum cleaner or by wet-brushing and place in container for disposal according to local regulations (see section 13).

6.4. Reference to other sections

For disposal see section 13.

For personal protection see section 8.

SECTION 7: HANDLING AND STORAGE

7.1. Precautions for safe handling: Wash thoroughly after handling. Do not use if skin is cut or scratched. Avoid contact with eyes, skin and clothing.

7.2. Conditions for safe storage, including any incompatibilities

- **Storage:**
Requirements to be met by storerooms and containers:
Store only in the original container.
- **Information about storage in one common storage facility:** Store in original packaging.
- **Further information about storage conditions:** Protect from heat and direct sunlight.

7.3. Specific end use(s)

- **Specific use(s):** No information available.
- **Exposure scenario:** No information available.

SECTION 8: EXPOSURE CONTROLS / PERSONAL PROTECTION

8.1. Control Parameters

8.2. Exposure Controls

- **Personal protective equipment**

General protective and hygienic measures

Handle in accordance with good industrial hygiene and safety practice. Wash hands before breaks and at the end of workday.

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 gloves' 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.

Body protection

Protect personal clothing from spatters and small spills. The type of protective equipment must be selected according to the concentration and amount of the dangerous substance at the specific workplace.

Breathing equipment

No special protective equipment required.

SECTION 9: PHYSICAL AND CHEMICAL PROPERTIES

9.1. Information on basic physical and chemical properties

General information ARCHEM ALP

- **Appearance:**

Form:	Liquid
Odour:	Odourless

- Change in condition:	
Melting point/Melting range:	Not determined
Boiling point/Boiling range:	Not determined
Flash point:	Not applicable
Inflammability (solid, gaseous):	Not applicable
Auto igniting:	Product is not self-igniting.
- Danger of explosion:	Product does not present an explosion hazard.
- Explosion limits	
Lower:	Not determined
Upper:	Not determined
- Density	Not determined
Relative density:	Not determined
Evaporation rate:	Not determined
- Solubility in / Miscibility with Water:	Fully miscible
- Viscosity:	
Dynamic:	Not determined
9.2. Other information: No further relevant information available.	

SECTION 10: STABILITY AND REACTIVITY

- 10.1. Reactivity:** No specific data.
- 10.2. Chemical stability:** Not determined.
- 10.3. Possibility of hazardous reactions:** Not determined.
- 10.4. Conditions to be avoided:** No decomposition if used and stored according to specifications.
- 10.5. Incompatible materials:** Strong oxidizing agents, also acids.
- 10.6. Hazardous decomposition products:** Not determined.

SECTION 11: TOXICOLOGICAL INFORMATION

11.1. Information on toxicological effects
Acute toxicity

Result	
LD50 oral	Not determined
LD50 intraperitoneal	Not determined
LD50 skin	Not determined
LD50 inhalation	Not determined

11.2. Primary irritant effect

On the skin: No irritant effect.

On the eye: No irritant effect.

11.3. Sensitization: No sensitizing effects known.

11.4. Additional toxicological information: None

11.5. Target organs/systems: Unknown

SECTION 12: ECOLOGICAL INFORMATION

- 12.1. Toxicity**
 - **Aquatic toxicity** : No further relevant information available.
- 12.2. Persistence and degradability:** No further relevant information available.
- 12.3. Bioaccumulative potential** : No further relevant information available.
- 12.4. Mobility in soil:** No further relevant information available.
- 12.5. Results of PBT and vPvB assessment:**
PBT : Not applicable

vPvB : Not applicable
- 12.6. Other adverse effects:** No further relevant information available.
- 12.7. Additional ecological information**
 - **General notes:** Do not allow undiluted product or large quantities of it to reach ground water, water bodies or sewage system.

SECTION 13: DISPOSAL CONSIDERATIONS

13.1. Waste treatment methods

There are no uniform EU regulations for the disposal of laboratory waste. In general, laboratory waste is under special supervision of the authorities.

- **Recommendation for disposal of unused product:** Dispose in accordance with national, state and local regulations.
- **European waste catalogue:** Consult the responsible regulatory body for the assignment of disposal codes according to the European Waste Catalogue.
- **The following waste disposal key numbers are possible:** 18 01 06: chemicals consisting of or containing dangerous substance.

13.2. Uncleaned packagings

For disposal of contaminated packaging, refer to applicable local regulations and institutional policies.

- **Recommended cleaning agent:** Water with cleansing agents, if necessary.

SECTION 14: TRANSPORT INFORMATION

This product is not subject to current regulations for transportation of dangerous goods.

- 14.1. UN-Number**
 - **ADR, ADN, IMDG, IATA:** None
- 14.2. UN proper shipping name**
 - **ADR, ADN, IMDG, IATA:** None
- 14.3. Transport hazard class(es)**
 - **ADR, ADN, IMDG, IATA**
 - **Class:** None
- 14.4. Packing group**
 - **ADR, IMDG, IATA:** None
- 14.5. Environmental hazards:**
 - **Marine pollutant:** No
- 14.6. Special precautions for user:** Not applicable

14.7. Transport/Additional information

- **ADR**
 - **Remarks:** Not regulated as dangerous goods.
- **IMDG**
 - **Remarks:** Not regulated as dangerous goods.
- **IATA**
 - **Remarks:** Not regulated as dangerous goods.

SECTION 15: REGULATORY INFORMATION

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

- **Labelling according to Directives 67/548/EEC or 1999/45/EC**
 - **Hazard-determining components of labelling:**

None

15.2. Chemical safety assessment: A Chemical Safety Assessment has not been carried out.

SECTION 16: OTHER INFORMATION

The information herein is believed to be correct as of the date hereof but is provided without warranty of any kind. The recipient of our products is responsible for observing any national laws and guidelines applicable.

- **REACH Registration Number:** A registration number is not available for this mixture as the mixture or its use are exempted from registration according to Article 2 REACH Regulation (EC) No 1907/2006, the annual tonnage does not require a registration or the registration is envisaged for a later registration deadline.
- **Material Safety Data Sheet was prepared in accordance with:**
- **Classification according to Regulation (EC) No 1272/2008,** The EC Directive Nr UE2001/58/WE, the EC Directive 67/548 EEC or the EC Directive 91/155/EEC (Dangerous Product Regulations incl. EC Guidelines).
- **Hazard Statement Codes According to Regulation (EC) No 1272/2008**
 - H360D May damage the unborn child.
 - H302 Harmful if swallowed.
 - H314 Causes severe skin burns and eye damage.
- **Contact supplier:**
 - Tel.:** +90 212 444 08 92
- **Abbreviations and acronyms:**
 - ADR: Accord européen sur le transport des marchandises dangereuses par Route (European Agreement concerning the International Carriage of Dangerous Goods by Road)
 - IMDG: International Maritime Code for Dangerous Goods
 - IATA: International Air Transport Association
 - GHS: Globally Harmonized System of Classification and Labelling of Chemicals
 - CAS: Chemical Abstracts Service (Division of the American Chemical Society)
 - LD50: Lethal dose, 50 percent
 - PBT: persistent, bioaccumulative and toxic
 - vPvB: very persistent and very bioaccumulative