

06.03.2013

Kit Components

Product code	Description
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CALI-0XXX	ELICAL 2 (kit) CALI-0031/0550/0580
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Components:

CALI-1XXX	ELICAL 2
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1 Identification of the substance/mixture and of the company/undertaking

- **Product identifier**
- **Trade name:** ELICAL 2
- **Article number:** CALI-1XXX
- **Application of the substance / the preparation** Reagent for IN VITRO diagnostic
- **Details of the supplier of the safety data sheet**
- **Manufacturer/Supplier:**
ELITech Clinical Systems SAS
Zone Industrielle
61500 Sées • France
Tel : +33 (0)2 33 81 21 00
Fax : +33 (0)2 33 28 77 51
www.elitechgroup.com
MSDS.ECS-SAS@elitechgroup.com
- **Information department:** Product safety department
- **Emergency telephone number:** Contact your distributor or poison control center in your country.

2 Composition/information on ingredients

- **Chemical characterization: Mixtures**
- **Description:**
Mixture of substances.
Human serum with chemical additives and material of biological origin.
- **Dangerous components:**

CAS NO.	Description	%
75-57-0	tetramethylammonium chloride	≤ 2.5%

3 Hazards identification

- **Classification of the substance or mixture**
- **Classification according to Directive 67/548/EEC or Directive 1999/45/EC** Not applicable.
- **Information concerning particular hazards for human and environment:**
The product does not have to be labelled due to the calculation procedure of international guidelines.
- **Classification system:**
The classification was made according to the latest editions of international substances lists, and expanded upon from company and literature data.
- **Additional information:**
Only blood of donors proven to have no antibodies against HIV1+2, HCV (Hepatitis C) and no HBsAG (Hepatitis B Surface Antigen), with FDA-licensed tests or CE-marked tests, is used in the manufacture of this product.
Since, nevertheless, risk of infection cannot be fully precluded the product must be handled as potentially infectious.

Label elements

- **Labelling according to EU guidelines:**
The product is not subject to identification regulations according to directives on hazardous materials.
Observe the general safety regulations when handling chemicals and/or products potentially infectious.

Classification system:

NFPA ratings (scale 0 - 4)



HMIS-ratings (scale 0 - 4)



4 First aid measures

- **General information:**
Immediately remove any clothing soiled by the product.
Show this safety data sheet to the doctor in attendance.
- **After inhalation:**
Supply fresh air.
If required, provide artificial respiration.
Seek immediate medical advice.
- **After skin contact:**
Immediately rinse with water.
Clean with a disinfectant.
Seek immediate medical advice.

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- **After eye contact:**
Protect unharmed eye.
Remove contact lenses, if present and easy to do.
Rinse opened eye for several minutes under running water.
Seek immediate medical advice.
- **After swallowing:**
Never give anything by mouth to an unconscious person.
Rinse out mouth.
Seek immediate advice from a doctor or a poison control center.
- **Information for doctor:**
- **Most important symptoms and effects, both acute and delayed** Data not available
- **Indication of any immediate medical attention and special treatment needed** Treat symptomatically.

5 Firefighting measures

- **Suitable extinguishing agents:**
Use fire fighting measures that suit the environment.
CO₂, extinguishing powder or water spray. Fight larger fire with alcohol resistant foam.
- **Special hazards arising from the substance or mixture** Formation of toxic gases is possible during heating or in case of fire.
- **Protective equipment:** As in any fire, wear a respiratory protective device, and full protective gear.

6 Accidental release measures

- **Personal precautions, protective equipment and emergency procedures**
Handle as potentially infectious.
Wear protective equipment. Keep unprotected persons away.
Ensure adequate ventilation
Avoid physical contact with material.
Avoid formation of dust.
- **Environmental precautions:** Do not allow to enter sewers/ surface or ground water.
- **Methods and material for containment and cleaning up:**
Take up dry.
Pick up mechanically.
Send for recovery or disposal in suitable receptacles.
Clean the affected area carefully; suitable cleaners are:
Warm water and cleansing agent
Disinfectant.
- **Reference to other sections**
See Section 7 for information on safe handling.
See Section 8 for information on personal protection equipment.
See Section 13 for disposal information.

7 Handling and storage

- **Handling:**
- **Precautions for safe handling**
Handle as potentially infectious.
Ensure good ventilation/exhaustion at the workplace.
Open and handle receptacle with care.
Avoid physical contact with material.
Observe the warnings on the label.
- **Information about protection against explosions and fires:** No special measures required.
- **Storage:**
- **Requirements to be met by storerooms and receptacles:** No special requirements.
- **Information about storage in one common storage facility:** Not required.
- **Further information about storage conditions:** Protect the product from light. Avoid exposure to heat.
- **Recommended storage temperature:** 2-8 °C
- **Specific end use(s)** No further relevant information available.

8 Exposure controls/personal protection

- **Additional information about design of technical systems:** No further data; see item 7.
- **Components with limit values that require monitoring at the workplace:**
The product does not contain any relevant quantities of materials with critical values that have to be monitored at the workplace.
- **Additional information:** The lists that were valid during the creation were used as basis.
- **Personal protective equipment:**
- **General protective and hygienic measures:**
The usual precautionary measures are to be adhered to when handling products potentially infectious.
Keep away from foodstuffs, beverages and feed.
Disinfect workplace and hands after work.
Immediately remove all soiled and contaminated clothing.

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· **Breathing equipment:**

Under normal conditions, the use of these products should not require respiratory protection. If overexposure should occur and ventilation is not adequate to maintain airborne concentrations at acceptable levels, the use of respiratory protection should be evaluated by a qualified professional. Use respirators and components tested and approved under appropriate government standards such as NIOSH (US) or CEN (EU).

· **Protection of hands:**

The glove material has to be impermeable and resistant to the product/ the substance/ the preparation.

Due to missing tests no recommendation to the glove material can be given for the product/ the preparation/ the chemical mixture.

Selection of the glove material on consideration of the penetration times, rates of diffusion and the degradation

· **Material of gloves**

The selection of the suitable gloves does not only depend on the material, but also on further marks of quality and varies from manufacturer to manufacturer. As the product is a preparation of several substances, the resistance of the glove material can not be calculated in advance and has therefore to be checked prior to the application.

· **Penetration time of glove material** The exact break through time has to be found out by the manufacturer of the protective gloves and has to be observed.

· **Eye protection:** Safety glasses

· **Body protection:** Protective work clothing

9 Physical and chemical properties

· **General Information**

· **Appearance:**

Form: Freeze dried powder

Color: Yellow

· **Odor:** Odorless

· **pH-value:** 6.9

· **Change in condition**

Melting point/Melting range: Data not available

Boiling point/Boiling range: Not applicable

· **Flash point:** Not applicable.

· **Flammability (solid, gaseous):** Data not available

· **Ignition temperature:**

Decomposition temperature: Data not available

· **Auto igniting:** Product is not selfigniting.

· **Danger of explosion:** Product does not present an explosion hazard.

· **Vapor pressure:** Not applicable

· **Density:** Data not available

· **Vapour density** Data not available

· **Solubility in / Miscibility with**

Water: Soluble.

· **Partition coefficient (n-octanol/water):** Data not available

· **Viscosity:**

Dynamic: Not applicable.

· **Other information** No further relevant information available.

10 Stability and reactivity

· **Possibility of hazardous reactions** No dangerous reactions if used according to specifications.

· **Conditions to avoid** No further relevant information available.

· **Incompatible materials:**

Strong oxidizing agents.

Strong acids, strong bases.

· **Hazardous decomposition products:** Carbon oxides (COx)

· **Additional information:** Stable at the recommended storage temperature and if protected from light. Avoid exposure to heat.

11 Toxicological information

· **Acute toxicity:**

· **LD/LC50 values that are relevant for classification:**

Information on components:

75-57-0 tetramethylammonium chloride

Oral	LD50	50 mg/kg (rat)
Dermal	LD50	537 mg/kg (rat)

· **Primary irritant effect:**

· **on the skin:**

May cause irritating effect.

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- May be harmful if absorbed through skin.
- *on the eye*: May cause irritating effect.
- *Inhalation*: May cause irritating effect.
- May be harmful by inhalation.
- *Ingestion*: May be harmful if swallowed.
- **Sensitization**: Data not available
- **Additional toxicological information**:
Only blood of donors proven to have no antibodies against HIV1+2, HCV (Hepatitis C) and no HBsAG (Hepate B Surface Antigen), with FDA-licenced tests or CE-marked tests, is used in the manufacture of this product.
Since, nevertheless, risk of infection cannot be fully precluded the product must be handled as potentially infectious.
The product is not subject to classification according to internally approved calculation methods for preparations:
- **Carcinogenic categories**
 - *IARC (International Agency for Research on Cancer)* Available information lists no component.
 - *NTP (National Toxicology Program)* Available information lists no component.

12 Ecological information

- **Aquatic toxicity**:
Information on components:

75-57-0 tetramethylammonium chloride
LC50/96h 462 mg/l (Pimephales promelas)

- **Persistence and degradability** Data not available
- **Behavior in environmental systems**:
- **Bioaccumulative potential** Data not available
- **Additional ecological information**:
- **General notes**:
Do not allow product to reach ground water, water course or sewage system.
Water hazard class 1 (Self-assessment): slightly hazardous for water
Disposal procedures have to be respected, see Section 13.

13 Disposal considerations

- **Waste treatment methods**
- **Recommendation**: Disposal must be made according to official regulations.
- **Uncleaned packagings**:
- **Recommendation**: Disposal must be made according to official regulations.
- **Primary packaging**: Glass bottle

14 Transport information

· UN-Number · <i>DOT, ADR, ADN, IMDG, IATA</i>	-
· UN proper shipping name · <i>DOT, ADR, ADN, IMDG, IATA</i>	-
· Transport hazard class(es) · <i>DOT, ADR, ADN, IMDG, IATA</i> · <i>Class</i>	-
· Packing group · <i>DOT, ADR, IMDG, IATA</i>	-
· Environmental hazards : · <i>Marine pollutant</i> :	No
· Special precautions for user	Not applicable.
· Transport in bulk according to Annex II of MARPOL73/78 and the IBC Code	Not applicable.

15 Regulatory information

- **SARA**
- *Section 302/304 (40CFR355.30 / 40CFR355.40)*: None of the ingredients is listed.
- *Section 313 (Specific toxic chemical listings)*: Not regulated.
- **TSCA (Toxic Substances Control Act)**: This product is regulated by the Food and Drug Administration; it is exempt from requirements of TSCA.
- **Proposition 65**
- *Chemicals known to cause cancer*: None of the ingredients is listed.
- *Chemicals known to cause reproductive toxicity for females*: None of the ingredients is listed.

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- *Chemicals known to cause reproductive toxicity for males:* None of the ingredients is listed.
- *Chemicals known to cause developmental toxicity:* None of the ingredient is listed.
- **Carcinogenic categories**
- *EPA (Environmental Protection Agency)* None of the ingredient is listed.
- *TLV (Threshold Limit Value established by ACGIH)* Available information lists none.
- *NIOSH-Ca (National Institute for Occupational Safety and Health)* Available information lists none.
- *OSHA-Ca (Occupational Safety & Health Administration)* Available information lists none.
- **Product related hazard informations:**
The product is not subject to identification regulations according to directives on hazardous materials.
Observe the general safety regulations when handling chemicals and/or products potentially infectious.
- **U. S. State Regulations:**
- **PA-RTK** Available information lists none.
- **NJ-RTK** Available information lists none.
- **MA-RTK** Available information lists none.
- **RI-RTK** Available information lists none.
- **US Federal Regulation** This preparation is a component of an FDA-regulated IN VITRO diagnostic medical device.

16 Other information

This information is based on our present knowledge. However, this shall not constitute a guarantee for any specific product features and shall not establish a legally valid contractual relationship.

- **Department issuing MSDS:** Product safety department
- **Contact:** Product safety department
- *** Data compared to the previous version altered.**

USA