Kit Components

Product code	Description
ALBU-0YYY	**ALBUMIN (Kit)** **ALBU-0201 / ALBU-0250**

Components:

ALBU-5XXX	ALBUMIN - R

Material Safety Data Sheet
acc. to ISO/DIS 11014

Printing date 01/17/2013 Reviewed on 01/17/2013

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1 Identification of the substance/mixture and of the company/undertaking

· **Product identifier**

· ***Trade name:*** **ALBUMIN - R**

· *Article number:* ALBU-5XXX
· *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.
Aqueous solution.
· ***Additional information:***
Each of the other components is present in less than 1% concentration for hazardous components (or 0.1% concentration for potential carcinogens, reproductive toxins, and mutagens).

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.

· **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.
· **Classification system:**
· ***NFPA ratings (scale 0 - 4)***

Health = 0
Fire = 0
Reactivity = 0

· ***HMIS-ratings (scale 0 - 4)***

Health = 0
Fire = 0
Reactivity = 0

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4 First aid measures

· **General information:** Show this safety data sheet to the doctor in attendance.
· **After inhalation:**
Supply fresh air; consult doctor in case of complaints.
If required, provide artificial respiration.
· **After skin contact:**
Rinse with water.
If symptoms appear, seek medical advice.
· **After eye contact:**
Protect unharmed eye.
Remove contact lenses, if present and easy to do.
Rinse opened eye for several minutes under running water. If symptoms appear, seek medical advice.
· **After swallowing:**
Never give anything by mouth to an unconscious person.
Rinse out mouth.
If symptoms appear, seek medical advice.
· **Information for doctor:**
· ***Most important symptoms and effects, both acute and delayed*** Data not available

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· ***Indication of any immediate medical attention and special treatment needed*** Data not available

5 Firefighting measures

· **Suitable extinguishing agents:**
CO2, extinguishing powder or water spray. Fight larger fires with water spray or alcohol resistant foam.
Use fire fighting measures that suit the environment.
· **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**
Wear protective clothing.
Ensure adequate ventilation
Avoid physical contact with material.
· **Environmental precautions:**
Dilute with plenty of water.
Do not allow to enter sewers/ surface or ground water.
· **Methods and material for containment and cleaning up:**
Absorb with liquid-binding material (sand, diatomite, universal binders, sawdust).
Clean the affected area carefully.
· **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***
Open and handle receptacle with care.
Ensure good ventilation/exhaustion at the workplace.
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:***
Keep container tightly closed.
Protect the product from light. Avoid exposure to heat.
· *Recommended storage temperature:* 2-25 °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 for handling chemicals should be followed.
Wash hands before breaks and at the end of work.
· ***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:*** Goggles recommended during refilling.

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· ***Body protection:*** Protective work clothing

9 Physical and chemical properties

· **General Information**	
· ***Appearance:***	
Form:	Liquid
Color:	Green
· ***Odor:***	Odorless
· **pH-value at 25°C (77 °F):**	~ 4.2
· **Change in condition**	
Melting point/Melting range:	Not applicable
Boiling point/Boiling range:	Undetermined.
Solidification point:	Not determined
· **Flash point:**	Not applicable.
· **Flammability (solid, gaseous):**	Not determined
· **Ignition temperature:**	Not determined
· ***Decomposition temperature:***	Not determined
· **Auto igniting:**	Product is not selfigniting.
· **Danger of explosion:**	Product does not present an explosion hazard.
· **Vapor pressure:**	Not determined
· **Density at 20°C (68 °F):**	1.003 g/cm³ (8.37 lbs/gal)
· ***Vapour density***	Not determined
· ***Evaporation rate***	Not determined
· **Solubility in / Miscibility with**	
Water:	Miscible
· **Partition coefficient (n-octanol/water):**	Not determined
· **Viscosity:**	
Dynamic:	Not determined
· **Other information**	No further relevant information available.

10 Stability and reactivity

· **Thermal decomposition / conditions to be avoided:** No decomposition if used according to specifications.
· **Possibility of hazardous reactions** No dangerous reactions known.
· **Conditions to avoid** No further relevant information available.
· **Incompatible materials:** Strong oxidizing agents, acids, bases.
· **Hazardous decomposition products:** Dangerous decomposition products may be formed.
· **Additional information:** Stable at the recommended storage temperature and if protected from light. Avoid exposure to heat.

11 Toxicological information

· **Acute toxicity:**
· ***Primary irritant effect:***
· *on the skin:* May cause irritating effect.
· *on the eye:* May cause irritating effect.
· *Inhalation:*
May cause irritating effect.
May be harmful by inhalation.
· *Ingestion:* May be harmful if swallowed.
· ***Sensitization:*** No sensitizing effects known.
· **Additional toxicological information:**
The product is not subject to classification according to internally approved calculation methods for preparations:
When used and handled according to specifications, the product does not have any harmful effects according to our experience and the information provided to us.

· ***Carcinogenic categories***
· *IARC (International Agency for Research on Cancer)* None of the ingredient is listed.
· *NTP (National Toxicology Program)* None of the ingredient is listed.

12 Ecological information

· ***Aquatic toxicity:*** At present there are no ecotoxicological assessments.
· **Persistence and degradability** Data not available

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

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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:*** Plastic vial (composed of polyethylene high density).

14 Transport information

· **UN-Number** · ***DOT, ADR, ADN, IMDG, IATA***	-
· **UN proper shipping name** · ***DOT, ADR, ADN, IMDG, IATA***	-
· **Transport hazard class(es)** · ***DOT, ADR, ADN, IMDG, IATA*** · *Class*	-
· **Packing group** · ***DOT, ADR, IMDG, IATA***	-
· **Environmental hazards:** · ***Marine pollutant:***	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.
· *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)* None of the ingredient is listed.
· *NIOSH-Ca (National Institute for Occupational Safety and Health)* None of the ingredient is listed.
· *OSHA-Ca (Occupational Safety & Health Administration)* None of the ingredient is listed.

· **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.
· **U. S. State Regulations:**
· ***PA-RTK*** None of the ingredient is listed.
· ***NJ-RTK*** None of the ingredient is listed.
· ***MA-RTK*** None of the ingredient is listed.
· ***RI-RTK*** None of the ingredient is listed.
· **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.***