

**Identification**

- **Product identifier**
- **Trade name:** ISE CONTROL II
- **Article number:** ISCT-47XX
- **Relevant identified uses of the substance or mixture and uses advised against**
- **Application of the substance / the mixture**  
Reagent for IN VITRO diagnostic  
Product included in kit(s) :  
- Kit composed of 1 control(s) : ISCT-0047
- **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.



**Hazard(s) identification**

- **Classification of the substance or mixture**
- **Classification according to Regulation (EC) No 1272/2008** The product is not classified according to the CLP regulation.
- **Label elements**
- **Labelling according to Regulation (EC) No 1272/2008 -**
- **Hazard pictograms -**
- **Signal word -**
- **Hazard statements -**
- **Additional information:**  
Safety data sheet available on request.

**Composition/information on ingredients**

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

· **Dangerous components:**

7647-14-5	sodium chloride	 Skin Irrit. 2, H315; Eye Irrit. 2, H319	2.5-10%
6131-90-4	sodium acetate 3-hydrate	 Skin Irrit. 2, H315; Eye Irrit. 2, H319; STOT SE 3, H335	2.5-10%

· **Additional information:**

Contains compounds of human origin potentially infectious.  
Contains compounds of animal origin.  
Each human donor unit used to manufacture this product was tested by FDA accepted methods and found non-reactive for Hepatite B Surface Antigen (HBsAg), antibody to Hepatitis C (HCV) and antibody to HIV-1/HIV-2.  
In accordance with good laboratory practice, all human source material should be considered potentially infectious and handled with the same precautions used with patient specimens.

**First-aid measures**

- **Description of first aid measures**
- **General information:** Show this safety data sheet to the doctor in attendance.
- **After inhalation:**  
Supply fresh air.  
Move out of dangerous area.  
If required, provide artificial respiration.  
If symptoms appear, seek medical advice.
- **After skin contact:**  
Immediately wash with water and soap and rinse thoroughly.  
Clean with a disinfectant.  
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.  
Seek advice from a doctor or a poison control center.

# Safety Data Sheet

## acc. to OSHA HCS

Printing date 09/19/2016

Reviewed on 09/19/2016

Trade name: ISE CONTROL II

(Contd. of page 1)

- **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* Data not available.

### Fire-fighting measures

- **Extinguishing media**
- **Suitable extinguishing agents:**  
CO<sub>2</sub>, 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** Dangerous decomposition products may be formed
- **Advice for firefighters**
- **Protective equipment:** As in any fire, wear a respiratory protective device, and full protective gear.

### 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/spray.  
Avoid breathing dust/spray.
- **Environmental precautions:**  
Keep contaminated washing water and dispose of appropriately.  
Do not allow to enter sewers/ surface or ground water.
- **Methods and material for containment and cleaning up:**  
Pick up mechanically.  
Clean the affected area carefully; suitable cleaners are:  
Water  
Disinfectant.  
Send for recovery or disposal in suitable receptacles.
- **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.

### 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.  
Avoid formation of dust/spray.  
Avoid breathing dust/spray.  
Observe the warnings on the label.
- **Information about protection against explosions and fires:** No special measures required.
- **Conditions for safe storage, including any incompatibilities**
- **Storage:**
- *Requirements to be met by storerooms and receptacles:* Store in a cool location.
- *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:* 2-8 °C
- **Specific end use(s)** Data not available.

### Exposure controls/personal protection

- **Additional information about design of technical systems:** Eyewash fountain and safety shower in the area of storage and use.
- **Control parameters**
- **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.
- **Exposure controls**
- **Personal protective equipment:**
- **General protective and hygienic measures:**  
The usual precautionary measures are to be adhered to when handling products potentially infectious.

(Contd. on page 3)

# Safety Data Sheet

acc. to OSHA HCS

Printing date 09/19/2016

Reviewed on 09/19/2016

Trade name: ISE CONTROL II

(Contd. of page 2)

The usual precautionary measures for handling chemicals should be followed.

Wash hands before breaks and at the end of work.

Keep away from foodstuffs, beverages and feed.

Disinfect workplace and hands after work.

Take off immediately all contaminated clothing and wash it before reuse.

Avoid physical contact with material.

Avoid formation of dust/spray.

Avoid breathing dust/spray.

The type of protective equipment must be selected according to the concentration and amount of the dangerous substance at the specific workplace.

· **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 equipment tested and approved under appropriate government standards such as NIOSH (US) or CEN (EU).

· **Protection of hands:**



Protective gloves

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

Use equipment tested and approved under appropriate government standards such as NIOSH (US) or CEN (EU).

· **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

Use equipment tested and approved under appropriate government standards such as NIOSH (US) or CEN (EU).

· **Body protection:** Protective work clothing

## Physical and chemical properties

· **Information on basic physical and chemical properties**

· **General Information**

· **Appearance:**

Form: Lyophilised material

Color: Light yellow

· **Odor:** Light

· **Odor threshold:** Data not available.

· **pH-value at 20 °C (68 °F):** 7.55-7.65

· **Change in condition**

Melting point/Melting range: Data not available.

Boiling point/Boiling range: Not applicable

· **Flash point:** Data not available.

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

· **Ignition temperature:** Data not available.

· **Decomposition temperature:** Data not available.

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

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

· **Vapor pressure:** Data not available.

· **Density:**

Relative density: Data not available.

Vapor density: Data not available.

Evaporation rate: Not applicable.

· **Solubility in / Miscibility with**

Water: Soluble.

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

· **Viscosity:**

Dynamic: Not applicable.

· **Solvent content:**

Organic solvents: 0.0 %

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

USA

(Contd. on page 4)

# Safety Data Sheet

acc. to OSHA HCS

Printing date 09/19/2016

Reviewed on 09/19/2016

Trade name: ISE CONTROL II

(Contd. of page 3)

## Stability and reactivity

- **Reactivity** See § Possibility of hazardous reactions.
- **Chemical stability** Stable under recommended storage conditions.
- **Thermal decomposition / conditions to be avoided:** No decomposition if used according to specifications.
- **Possibility of hazardous reactions** No dangerous reactions if used according to specifications.
- **Conditions to avoid** No further relevant information available.
- **Incompatible materials:** No further relevant information available.
- **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.

## Toxicological information

- **Information on toxicological effects**
- **Acute toxicity:**
- **LD/LC50 values that are relevant for classification:**  
ATE (Acute Toxicity Estimates) : data not available  
Information on components:

### 7647-14-5 sodium chloride

Oral	LD50	3000 mg/kg (rat)
Dermal	LD50	> 10000 mg/kg (rabbit)

- **Primary irritant effect:**
- *on the skin:* Data not available.
- *on the eye:* Data not available.
- **Sensitization:** Data not available.
- **Additional toxicological information:**  
Contains compounds of human origin potentially infectious.  
Contains compounds of animal origin.  
Each human donor unit used to manufacture this product was tested by FDA accepted methods and found non-reactive for Hepatite B Surface Antigen (HBsAg), antibody to Hepatitis C (HCV) and antibody to HIV-1/HIV-2.  
In accordance with good laboratory practice, all human source material should be considered potentially infectious and handled with the same precautions used with patient specimens.

- **IARC (International Agency for Research on Cancer)**

57-88-5	cholesterol	3
103-90-2	paracetamol	3
50-06-6	phenobarbital	2B
58-55-9	theophylline	3

- **NTP (National Toxicology Program)**

630-93-3	Phenytoinnatrium	R
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## Ecological information

- **Toxicity**
- **Aquatic toxicity:**  
At present there are no ecotoxicological assessments.  
Information on components:

### 7647-14-5 sodium chloride

EC50/48h	1000 mg/l (Daphnia)
LC50/96h	7650 mg/l (Pimephales promelas)

- **Persistence and degradability** Data not available.
- **Behavior in environmental systems:**
- **Bioaccumulative potential** Data not available.
- **Mobility in soil** Data not available.
- **Additional ecological information:**
- **General notes:**  
Water hazard class 2 (Self-assessment): hazardous for water  
Do not allow product to reach ground water, water course or sewage system.  
Disposal procedures have to be respected, see Section 13.
- **Other adverse effects** No further relevant information available.

## 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.

(Contd. on page 5)

USA

# Safety Data Sheet

acc. to OSHA HCS

Printing date 09/19/2016

Reviewed on 09/19/2016

Trade name: ISE CONTROL II

(Contd. of page 4)

· **Primary packaging:** Glass bottle

## Transport information

· <b>UN-Number</b> · <i>DOT, ADR, ADN, IMDG, IATA</i>	Not applicable. -
· <b>UN proper shipping name</b> · <i>DOT, ADR, ADN, IMDG, IATA</i>	-
· <b>Transport hazard class(es)</b> · <i>DOT, ADR, ADN, IMDG, IATA</i> · <i>Class</i>	-
· <b>Packing group</b> · <i>DOT, ADR, IMDG, IATA</i>	-
· <b>Environmental hazards:</b>	Not applicable.
· <b>Special precautions for user</b>	Not applicable.
· <b>Transport in bulk according to Annex II of MARPOL73/78 and the IBC Code</b>	Not applicable.
· <b>UN "Model Regulation":</b>	-

## Regulatory information

· **SARA**· *Section 302/304 (40CFR355.30 / 40CFR355.40):*

20830-75-5 | digoxin

· *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:*

50-06-6 | phenobarbital

630-93-3 | Phenytoinnatrium

· *Chemicals known to cause reproductive toxicity for females:* Available information lists none.· *Chemicals known to cause reproductive toxicity for males:* Available information lists none.· *Chemicals known to cause developmental toxicity:*

298-46-4 | Carbamazepin

· **Carcinogenic categories**· *EPA (Environmental Protection Agency)*

57-13-6 | urea

II

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

## 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.

· **Relevant phrases**

H315 Causes skin irritation.

H319 Causes serious eye irritation.

H335 May cause respiratory irritation.

· **Department issuing SDS:** Product safety department· **Contact:** Product safety department· **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

DOT: US Department of Transportation

IATA: International Air Transport Association

GHS: Globally Harmonised System of Classification and Labelling of Chemicals

ACGIH: American Conference of Governmental Industrial Hygienists

EINECS: European Inventory of Existing Commercial Chemical Substances

(Contd. on page 6)

-USA-

**Safety Data Sheet**  
acc. to OSHA HCS

Printing date 09/19/2016

Reviewed on 09/19/2016

**Trade name: ISE CONTROL II**

(Contd. of page 5)

ELINCS: European List of Notified Chemical Substances  
CAS: Chemical Abstracts Service (division of the American Chemical Society)  
LC50: Lethal concentration, 50 percent  
LD50: Lethal dose, 50 percent  
NOEC : No Observed Effect Concentration  
EC50: Effective concentration, 50 percent  
IC50 : Inhibitory concentration, 50 percent.  
Skin Irrit. 2: Skin corrosion/irritation – Category 2  
Eye Irrit. 2: Serious eye damage/eye irritation – Category 2  
STOT SE 3: Specific target organ toxicity (single exposure) – Category 3

· ***\* Data compared to the previous version altered.***

—USA—