# 1. IDENTIFICATION OF THE SUBSTANCE/ MIXTURE AND THE COMPANY/ UNDERTAKING

## 1.1 IDENTIFICATION OF THE PRODUCT

<table>
<thead>
<tr>
<th>Product name:</th>
<th>ESR CONTROL CUBE</th>
</tr>
</thead>
<tbody>
<tr>
<td>Product number:</td>
<td>10435 (4 x 9 mL) 10436 (2 x 9 mL)</td>
</tr>
<tr>
<td>Brand:</td>
<td>DIESSE</td>
</tr>
</tbody>
</table>

## 1.2 IDENTIFIED USES OF THE SUBSTANCE OR MIXTURE AND USES ADVISED AGAINST

**Identified use:** Professional use as laboratory reagent. Control blood for Erythrocyte Sedimentation Rate (ESR) test/analysis, to be used with the instruments of VES-Matic Cube and Cube Next (MINI-CUBE e Cube 30 touch) series.

## 1.3 DETAILS OF THE SUPPLIER OF THE SAFETY DATA SHEET

**Company:** DIESSE Diagnostica Senese SpA  
**Registered office:** Via A. Solari 19, 20144 Milan, Italy  
**Tel:** +39 02 4859121  
**Fax:** +39 02 48008530  
**Production plant:** Via delle Rose, 10 – Loc. Tognazza 53035 Monteriggioni SI), Italy  
**Tel:** +39 0577 587111  
**Fax:** +39 0577 318690

## 1.4 EMERGENCY TELEPHONE NUMBER

**Emergency number:** Centro Antiveleni, Ospedale Niguarda Ca’ Granada - Milano  
**Tel:** +39 02 66101029  
Centro Antiveleni, Azienda Ospedaliera “S.G.Battista” - Molinette di Torino - Torino  
**Tel:** +39 011 6637637  
Centro Antiveleni - U.O. Tossicologia Medica, Azienda Ospedaliera Careggi - Firenze  
**Tel:** +39 055 4277238  
Centro Antiveleni, Policlinico A. Gemelli – Università Cattolica del Sacro Cuore - Roma  
**Tel:** +39 06 3054343  
Centro Antiveleni, Azienda Ospedaliera A. Cardarelli – Napoli  
**Tel:** +39 081 7472870  
**web:** [http://www.salute.gov.it/servizio/documenti/centri_antiveleni.pdf](http://www.salute.gov.it/servizio/documenti/centri_antiveleni.pdf)

# 2. HAZARDS IDENTIFICATION

## 2.1 CLASSIFICATION OF THE SUBSTANCES OR MIXTURE

**Classification according to Regulation (EC) No. 1272/2008:** The mixture is not classified as dangerous according to Regulation 1272/2008

**Dangerous components:** None

## 2.2 LABEL ELEMENTS

**Pictograms:** None  
**Signal word:** None  
**Hazard statement:** None  
**Precautionary statement:** None

## 2.3 OTHER HAZARDS

The mixture is composed of human blood. Handle as potentially infectious.

# 3. COMPOSITION/ INFORMATION ON INGREDIENTS

## 3.1 SUBSTANCES

Not applicable

## 3.2 MIXTURE

The mixture contains no substances classified as hazardous to health and/or the
environment in concentrations exceeding the limits according to Regulation 1272/2008.

4. FIRST AID MEASURES

4.1 DESCRIPTION OF FIRST AID MEASURES

General advice: Move the person from the exposure to open air. In case of severe condition consult a physician immediately and present this safety data sheet.

Skin contact: Take off the contaminated clothes and wash with copious amounts of water.

Eye contact: If present, remove immediately contact lenses. Wash with plenty of water at least 15 minutes, keeping eyelids opened.

Inhalation: In case of severe condition consult a physician.

Ingestion: Rinse the mouth with water and drink enough water.

4.2 MOST IMPORTANT SYMPTOMS AND EFFECTS

No data available

4.3 INDICATION OF ANY IMMEDIATE MEDICAL ATTENTION AND SPECIAL TREATMENT NEEDED

No data available

5. FIRE FIGHTING MEASURES

5.1 EXTINGUISH MEDIA

Suitable extinguishing media: Use extinguishing measures that are appropriate to local circumstances and the surrounding environment.

Unsuitable extinguishing media: None

5.2 SPECIAL HAZARDS ARISING FROM THE SUBSTANCE OR MIXTURE

The mixture is not flammable.

5.3 ADVICE FOR FIRE FIGHTERS

If necessary wear self-contained breathing apparatus. Avoid that fire extinguishing water contaminates surface water and/or groundwater.

6. ACCIDENTAL RELEASE MEASURES

6.1 PERSONAL PRECAUTIONS, PROTECTIVE EQUIPMENT AND EMERGENCY PROCEDURES

Keep people not involved in the intervention operations away. Ensure an adequate ventilation of the affected area. Do not handle damaged containers or the leaked product before wearing appropriate protective outfit.

6.2 ENVIRONMENTAL PRECAUTIONS

Avoid the contamination of surface water and soil.

6.3 METHODS AND MATERIALS FOR CONTAINMENT AND CLEANING UP

Absorb on inert material such as sand or earth. Collect the spilled material with mechanical means avoiding raising of dust and store it in suitable containers for disposal. Use water only to remove residuals, to avoid the danger of spill of product into the sewers and put in appropriate disposal containers.

6.4 REFERENCE TO OTHER SECTIONS

For disposal see section 13

7. HANDLING AND STORAGE

7.1 PRECAUTION FOR SAFE HANDLING

Ensure an adequate ventilation of the working area and avoid contact with eyes and skin.

7.2 CONDITION FOR SAFE STORAGE, INCLUDING ANY INCOMPATIBILITIES

Keep the unopened product at 2-10°C.

Keep the containers tightly closed and labeled in a cool, well-ventilated area, away from heat sources.
7.3 SPECIFIC END USE

None

8. EXPOSURE CONTROL/PERSONAL PROTECTION

8.1 CONTROL PARAMETERS

Applicable exposure limits: None

8.2 EXPOSURE CONTROLS

Work and handle according to the usual precautionary measures for handling chemicals. Avoid aerosol creation. Treat as potentially infectious material.

Do not eat, drink or smoke while handling the product; wash hands thoroughly with soap and water before meals and after the work shift.

Appropriate engineering controls: Ensure an adequate ventilation of the working area.

Personal Protective Equipment

Suggestions on the use of specific PPE are indicated below. Their choice should be made according to the use of the product and the instructions given by the supplier of the device.

Hand protections: Protective gloves

Eye protections: Safety goggles

Body protections: Work outfits

Respiratory protections: Not necessary for the normal working activities.

8.3 ENVIRONMENTAL EXPOSURE CONTROLS:

Do not discard residuals in the environment.

9. PHYSICAL AND CHEMICAL PROPERTIES

9.1 INFORMATION ON BASIC PHYSICAL AND CHEMICAL PROPERTIES

<table>
<thead>
<tr>
<th>Property</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Form</td>
<td>Liquid</td>
</tr>
<tr>
<td>Odour</td>
<td>Odourless</td>
</tr>
<tr>
<td>Odour Threshold</td>
<td>Not pertinent</td>
</tr>
<tr>
<td>pH</td>
<td>No data available</td>
</tr>
<tr>
<td>Freezing/Melting point</td>
<td>No data available</td>
</tr>
<tr>
<td>Initial boiling and melting point range</td>
<td>No data available</td>
</tr>
<tr>
<td>Flash point</td>
<td>Not pertinent</td>
</tr>
<tr>
<td>Evaporation rate</td>
<td>No data available</td>
</tr>
<tr>
<td>Flammability (solid, gas)</td>
<td>Not pertinent</td>
</tr>
<tr>
<td>Upper/lower flammability or explosive limit</td>
<td>Not pertinent</td>
</tr>
<tr>
<td>Vapour pressure</td>
<td>No data available</td>
</tr>
<tr>
<td>Vapour density</td>
<td>No data available</td>
</tr>
<tr>
<td>Relative density</td>
<td>No data available</td>
</tr>
<tr>
<td>Water solubility</td>
<td>Soluble in water</td>
</tr>
<tr>
<td>Partition coefficient: n-octano/water</td>
<td>No data available</td>
</tr>
<tr>
<td>Autoignition temperature</td>
<td>Not pertinent</td>
</tr>
<tr>
<td>Decomposition temperature</td>
<td>No data available</td>
</tr>
<tr>
<td>Viscosity</td>
<td>No data available</td>
</tr>
<tr>
<td>Explosive properties</td>
<td>Not explosive</td>
</tr>
<tr>
<td>Oxidazing properties</td>
<td>No data available</td>
</tr>
</tbody>
</table>

9.2 OTHER SAFETY INFORMATION

None

10. STABILITY AND REACTIVITY

10.1 REACTIVITY

No hazardous reaction
10.2 **CHEMICAL STABILITY**
Stable under the recommended transport, handling and storage conditions.

10.3 **POSSIBILITY OF HAZARDOUS REACTIONS**
No data available

10.4 **CONDITIONS TO AVOID**
No data available

10.5 **INCOMPATIBLE MATERIALS**
No data available

10.6 **HAZARDOUS DECOMPOSITION PRODUCTS**
No data available

### 11. TOXICOLOGICAL INFORMATION

11.1 **INFORMATION ON TOXICOLOGICAL EFFECTS**
There is no known information on toxicological effects from exposure to the mixture.
In any case, it must be handled in accordance with the rules of good laboratory practice.

- **Acute toxicity:** No data available
- **Skin irritation:** No data available
- **Eye irritation:** No data available
- **Subcutaneous sensitization:** No data available
- **Germ cell mutagenesis:** No data available
- **Carcinogenicity:** No data available
- **Reproduction toxicity:** No data available
- **Organ specific toxicity**
  - (on single or repeated exposure): No data available
- **Acute inhalation toxicity:** No data available
- **Other information:** No data available

### 12. ECOLOGICAL INFORMATION

12.1 **TOXICITY**
Use according to the good working practices, avoiding the disposal in the environment. In case the product reach waterways or sewers or contaminate soil or vegetation, inform the competent authorities.

12.2 **PERSISTENCE AND DEGRADABILITY**
No data available

12.3 **BIOACCUMULATIVE POTENTIAL**
No data available

12.4 **MOBILITY IN SOIL**
No data available

12.5 **RESULTS OF PBT AND vPvB ASSESSMENT**
No data available

12.6 **OTHER ADVERSE EFFECTS**
No data available

### 13. DISPOSAL CONSIDERATIONS

13.1 **WASTE TREATMENT METHODS**
The product and its containers should be considered special waste.
Their transport and disposal should be performed by authorized specialized companies according to the law.

### 14. TRANSPORT INFORMATION
The substance/mixture is not classified hazardous under transport regulations.
15. REGULATORY INFORMATION

15.1  SAFETY, HEALTH AND ENVIRONMENTAL REGULATIONS/LEGISLATION SPECIFIC FOR THE SUBSTANCE OR MIXTURE

The classification and labeling of all the components in the mixture are done in accordance with the directives 1272/2008 (EC) and its subsequent amendments

Legislative Decree 81/2008 and s.m.i:
The use of this chemical entails the obligation of "Risk Assessment" by the employer in accordance with the provisions of the Decree April 9, 2008 n. 81 and subsequent amendments. Workers exposed to this chemical agent must not undergo health checks whether the results of the risk assessment show that, depending on the type and quantity of chemical agent and the method and frequency of exposure to this agent, there is only one "Low risk to the safety and irrelevant to the health" of the workers and the measures provided for in the same Decree are sufficient to reduce the risk.

European Standards: 1907/2006/EC:
Not applicable

Directive 96/82/EC (Seveso Directive):
Not applicable

15.2  CHEMICAL SAFETY ASSESSMENT

Not performed for the product

16. OTHER INFORMATION

This product has to be used for diagnostic use only by personnel who is qualified and trained on the hazards shown in this safety sheet.

REFERENCES:
1. Regulation (EC) 1907/2006 of the European Parliament (REACH) as amended
5. The Merck Index.
6. Handling Chemical Safety
7. NIOSH - Registry of Toxic Effects of Chemical Substances
8. INRS - Fiche Toxicologique

DIESSE Diagnostica Senese SpA declares that the information contained in this data sheet is based on the knowledge available to us on the date of the last version. Users must verify the suitability and accuracy of the provided information according to the specific use of the product. The document has not be accepted as a guarantee of any specific product property. Because of the use of this product is not subject to our direct control, the users, under their own responsibility, must observe the laws and regulations relating to health and safety. We accept no responsibility for improper use.

This data sheet supersedes the previous edition.