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

1.1 IDENTIFICATION OF THE PRODUCT

Product name: ESR CONTROL
Product number: 10430 (4 x 9 mL)
10434 (2 x 9 mL)
Brand: DIESSE

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 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 319560/61
Fax: +39 0577 318763

1.4 EMERGENCY TELEPHONE NUMBER

Emergency number: Centro Antiveleni, Ospedale Niguarda Ca’ Granda - 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

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. Consult a physician immediately.

Eye contact: Immediately flush eyes with plenty of water for at least 15 minutes. Get medical attention if irritation develops or persists.

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

In case of fire 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, soil and the dispersion in the air.

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>
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</tr>
<tr>
<td>pH</td>
<td>No data available</td>
</tr>
<tr>
<td>Freezing/Melting point</td>
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</tr>
<tr>
<td>Initial boiling and melting point range</td>
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</tr>
<tr>
<td>Flash point</td>
<td>No data available</td>
</tr>
<tr>
<td>Evaporation rate</td>
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</tr>
<tr>
<td>Flammability (solid, gas)</td>
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</tr>
<tr>
<td>Upper/lower flammability or explosive limit</td>
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</tr>
<tr>
<td>Vapour pressure</td>
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</tr>
<tr>
<td>Vapour density</td>
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</tr>
<tr>
<td>Relative density</td>
<td>Soluble in water</td>
</tr>
<tr>
<td>Water solubility</td>
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</tr>
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</tr>
<tr>
<td>Autoignition temperature</td>
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<tr>
<td>Decomposition temperature</td>
<td>Not explosive</td>
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<tr>
<td>Viscosity</td>
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</tr>
<tr>
<td>Explosive properties</td>
<td>No data available</td>
</tr>
<tr>
<td>Oxidizing 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 are 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: No data available
- (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.