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

1.1 Product Identification

**Trade name:** GONADOTROPHIN, PREGNANT MARE SERUM (PMSG)

**Synonyms**
Gonadotrophin, Equine serum for veterinary use (according to European Pharmacopeia)
Serum Gonadotrophin (according to Japanese Pharmacopeia)

1.2 Application of the substance / the preparation

PMSG has follicle stimulating (FSH-like) and luteinizing (LH-like) activities. It is used for the stimulation of ovarian function and activity, improvement of fertility in estrus-synchronized animals and the induction of super ovulation. For veterinary use only. **It is not for human consumption.**

1.3 Manufacturer / Supplier

SYNTEX S.A.
Luis de Sarro 501 – Luis Guillón
Buenos Aires – Argentina
Tel. / Fax: 005411 4290-0609
http://www.syntexar.com
bulk@syntexar.com

1.4 Information in case of emergency

In case of Emergency call (005411) 4290 0609 (ARGENTINA)

2 Hazards identification

2.1 Classification/ 2.2 Labeling:

<table>
<thead>
<tr>
<th>pictograms</th>
<th>hazard statements</th>
<th>safety phrases</th>
</tr>
</thead>
<tbody>
<tr>
<td><img src="image" alt="danger" /></td>
<td>Toxic if swallowed</td>
<td>Muta. Cat. 2 Carc. Cat 2</td>
</tr>
<tr>
<td><img src="image" alt="warning" /></td>
<td>Toxic by inhalation</td>
<td>May damaged fertility or the unborn child.</td>
</tr>
<tr>
<td><img src="image" alt="mutagens" /></td>
<td>Toxic if swallowed</td>
<td>May impaired fertility or cause harm to the unborn child</td>
</tr>
</tbody>
</table>

**Information concerning particular hazards for human and environment:**

**Risk phrases:**

- R48/23/25 Toxic: danger of serious damage to health by prolonged exposure through inhalation and if swallowed
- R36/37 Irritating to eyes and respiratory system
- R42/43 May cause sensitization by inhalation and skin contact
- R45/48 May cause cancer by prolonged exposure
- R47 May cause birth defects
- R60/61 May impair fertility or cause harm to the unborn child

**Safety phrases:**
### 3 Composition / information on ingredients

<table>
<thead>
<tr>
<th>Chemical characterization</th>
<th>Glycoprotein hormone</th>
</tr>
</thead>
</table>

<table>
<thead>
<tr>
<th>Identification number(s)</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>CAS. Nº Description</strong></td>
</tr>
<tr>
<td><strong>EINECS Number:</strong></td>
</tr>
<tr>
<td><strong>RTECS Number</strong></td>
</tr>
<tr>
<td><strong>ATC Code</strong></td>
</tr>
<tr>
<td><strong>Merck Index number:</strong></td>
</tr>
</tbody>
</table>

### 4 First aid measures

**After excessive inhalation:**
If inhales remove to fresh air and keep at rest in a position comfortable for breathing. If not breathing, give artificial respiration. If breathing is difficult, give oxygen. Get medical attention.

**After skin contact:**
In case of contact, immediately flush skin with plenty of water for at least 15 minutes while removing contaminated clothing and shoes. Cold water may be used. Wash clothing before reuse. Thoroughly clean shoes before reuse. Get medical attention.

**After eye contact:**
Check for and remove any contact lenses. In case of contact, immediately flush eyes with plenty of water for at least 15 minutes. Cold water may be used. Get medical attention.

**After swallowing:**
Do not induce vomiting. Unless directed to do so by medical personnel. Never give anything by mouth to an unconscious person. Wash mouth. If large quantities of this material are swallowed, call a physician immediately. Loosen tight clothing such as collar, tie, belt or waistband.

### 5 First-fighting measures

**5.1 Suitable extinguishing agents**
For small fire use DRY chemical powder. For large fire use water spray, fog or foam.

**5.2 For safety reasons unsuitable extinguishing agents:**
Do not use water jet.

**5.3 Protective equipment:**
Be sure to use an approved/certified respirator or equivalent.
### 6 Accidental release measures
#### 6.1 Person-related safety precautions:
Be sure to use an approved/certified respirator or equivalent. Wear suitable protective clothing, gloves and eye protection.

#### 6.2 Measures for environmental protection
Small spill and leak: Use appropriate tools to put the spilled solid in a convenient waste disposal container.
Large spill and leak: Use a shovel to put the material into a convenient waste disposal container.

#### 6.3 Measures for cleaning / collecting:
Avoid dust elevation. Finish cleaning by spreading water on the contaminated surface and dispose of according to local and regional authority requirements.

### 7 Handling and storage
#### 7.1 Information for safe handling
Do not breathe dust. Avoid prolonged or repeated contact with skin. Keep container closed. Use only with adequate ventilation. Wash thoroughly after handling. Wear suitable protective clothing, gloves and eye protection. Do not eat, drink or smoke when using this product.

#### 7.2 Information about storage:
Keep container tightly closed. Keep container in a cool, well ventilated area. Do not store above 25 °C.

### 8 Exposure control / personal protection
#### 8.1 Control Parameters:

**Information about design of technical facilities:**
Use process enclosures, local exhaust ventilation, or other engineering controls to keep airborne levels below recommended exposure limits. If user operations generate dust, fume or mist, use ventilation to keep exposure to airborne contaminants below the exposure limit.

#### 8.2 Exposure control:

**Personal protective equipment:**

- **Eye and Respiratory protection**
- **Protection of hands**
- **Full suit**

**In case of spill**
Splash goggles. Dust respirator. Boots. Gloves. A self contained breathing apparatus should be used to avoid inhalation of the product.
## 9 Physical and chemical properties

### General Information

<table>
<thead>
<tr>
<th>Property</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Form:</td>
<td>Solid powder</td>
</tr>
<tr>
<td>Color:</td>
<td>A white or pale grey, amorphous powder</td>
</tr>
<tr>
<td>Odor:</td>
<td>Odorless</td>
</tr>
</tbody>
</table>

### Change in condition

<table>
<thead>
<tr>
<th>Property</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Melting point / range</td>
<td>Not Apply</td>
</tr>
<tr>
<td>Boiling point / range</td>
<td>Not Apply</td>
</tr>
<tr>
<td>Flash point</td>
<td>Not Available</td>
</tr>
<tr>
<td>Ignition temperature</td>
<td>Not Available</td>
</tr>
<tr>
<td>Danger of explosion</td>
<td>Not Available</td>
</tr>
<tr>
<td>Explosion limits</td>
<td>Not found</td>
</tr>
<tr>
<td>Vapor pressure at 20 °C</td>
<td>Not Available</td>
</tr>
<tr>
<td>Density at 20 °C</td>
<td>Not Available</td>
</tr>
<tr>
<td>Solubility in / Miscibility with water at 20 °C</td>
<td>Soluble</td>
</tr>
<tr>
<td>Viscosity</td>
<td>Not Available</td>
</tr>
</tbody>
</table>

## 10 Stability and reactivity

### 10.1 Reactivity

Not Available

### 10.2 Chemical stability

Stable at recommended storage conditions.

### 10.3 Dangerous reactions / 10.4 Conditions to be avoid

Avoid extremely oxidizing agents

### 10.5 Incompatibles materials:

Not Available

### 10.6 Dangerous decomposition products:

Carbon oxide, Carbon dioxide.

## 11 Toxicological information

### Acute toxicity:

<table>
<thead>
<tr>
<th>Route</th>
<th>LD/LC50 values relevant for classification</th>
</tr>
</thead>
<tbody>
<tr>
<td>Oral</td>
<td>LD50… 120 mg / kg (mouse)</td>
</tr>
</tbody>
</table>

Primary irritant effect
Hazardous in case of skin contact (sensitizer), of inhalation (lung sensitizer)

May cause congenital malformations in the fetus.

CMR effects (carcinogenetic, mutagenicity and toxicity for reproduction):
Teratogenic Cat.2, Mutagenic Cat.2 ; May cause damaged to the following organs: the reproductive system, gastrointestinal tract.

### 12 Ecological information
**General notes:**
Not Available

### 13 Disposal considerations:
**13.1 Waste treatment**
Waste must be disposed of in accordance with federal, state and local environmental control regulations for special wastes.

### 14 Transport information
**14.1 ONU Number:** 2811

**14.2 Proper shipping name:** Gonadotrophin, Pregnant Mare Serum (PMSG) / Toxic solids, organic, n.o.s.

**14.3 Hazard class for transportation** 6.1

**14.4 Packaging group:** III

**14.5 Hazard for the media:** Toxic substances

### 15 Regulatory information
**15.1 International regulations:** Not Apply

**15.2 Security evaluation / NFPA Classification**

<table>
<thead>
<tr>
<th>Category</th>
<th>Value</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>HEALTH</td>
<td>3</td>
<td>Toxic. Avoid skin contact or inhalation.</td>
</tr>
<tr>
<td>FLAMABILITY</td>
<td>0</td>
<td>Not combustible</td>
</tr>
<tr>
<td>REACTIVITY</td>
<td>0</td>
<td>Stable. Not reactive when mixed with water</td>
</tr>
<tr>
<td>PERSONAL PROTECTION</td>
<td>K</td>
<td>Required</td>
</tr>
</tbody>
</table>

### 16 Other information – Change Control
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.

<table>
<thead>
<tr>
<th>Version</th>
<th>Description of the change</th>
</tr>
</thead>
<tbody>
<tr>
<td>02</td>
<td>Item 1.2, veterinary use only. Item 2.1/2.2, harmful in contact with skin. Minor changes for EU compliance with the Regulation No 453/2010</td>
</tr>
</tbody>
</table>