1. Identification of the Product and Company

Product Name: PHENOBARBITONE ELIXIR 15mg/5mL
Product Code: PHE00479F
Other Names: None allocated
Use: Long acting barbiturate with sedative, hypnotic and anticonvulsant properties.

Company Name & Contact Details
Medical Information Associate
Distributed by Perrigo Australia
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Other Information
All reasonable care has been taken to ensure information and advice contained in this data sheet is accurate at time of printing. However, Orion accepts no liability for any loss or damages suffered as a consequence of reliance on the information contained herein.

2. Hazards Identification

Hazard Classification
This product is not hazardous under normal conditions of use. This product is not dangerous for the purposes of transport and storage.

Risk phrase(s) No component is present at sufficient concentration to require a hazardous classification

Safety phrase(s) This medication may cause drowsiness. If affected do not drive a vehicle or operate machinery. Avoid alcohol

3. Composition/Information on Ingredients

<table>
<thead>
<tr>
<th>Chemical Entity</th>
<th>CAS No:</th>
<th>Proportion</th>
</tr>
</thead>
<tbody>
<tr>
<td>Phenobarbitone</td>
<td>50-06-6</td>
<td>0.3% w/v</td>
</tr>
<tr>
<td>Ethanol</td>
<td>64-17-5</td>
<td>9.6% v/v</td>
</tr>
<tr>
<td>Glycerol</td>
<td>56-81-5</td>
<td>&gt; 60% v/v</td>
</tr>
<tr>
<td>Sorbitol solution 70%</td>
<td>50-70-4</td>
<td>30 - 60% w/v</td>
</tr>
<tr>
<td>Flavour</td>
<td>-</td>
<td>&lt; 10% v/v</td>
</tr>
<tr>
<td>Purified water</td>
<td>7732-18-5</td>
<td>100%</td>
</tr>
</tbody>
</table>

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Review September 2015
4. First Aid Measures

Inhalation: If necessary, take patient to fresh air.

Ingestion: Contact a doctor or Poisons Information Centre.

Skin: Remove contaminated clothing and launder before use. Wash off with water.

Eye: Hold eyes open and gently flush with running water for 15 minutes. Seek medical attention.

Advice to Doctor: Treatment of overdosage is primarily supportive including maintenance of an adequate airway and assisted respiration and oxygen administration if needed. Standard treatment for shock should be administered if necessary. Activated charcoal is an effective barbiturate absorbent when administered within 30 minutes following ingestion of the drug. Multiple dose, nasogastric administration of activated charcoal has been used effectively to treat phenobarbitone overdose: activated charcoal enhances the elimination of the drug and shortens the duration of the coma. The patient's vital signs and fluid intake should be monitored closely. Analeptic drugs should not be administered because these may produce paroxysmal cerebral activity which may result in generalized seizures. In addition, it has been demonstrated that analeptics are incapable of stimulating respiration and exerting an arousal effect in patients with severe barbiturate poisoning and CNS depression. If renal function is normal forced diuresis may be of benefit. In addition, alkalinisation of the urine increases renal excretion of phenobarbitone. Peritoneal dialysis or haemodialysis may be useful in severe barbiturate intoxication and/or if the patient is anuric or in shock.

5. Fire Fighting Measures

Extinguishing Media Carbon dioxide, dry chemical powder or water jets/spray

Hazards from Combustion products On burning, may emit toxic fumes of carbon monoxide, carbon dioxide and nitrogen oxides.

Precautions & Equipment for Fire Fighters Firefighters should wear self-contained breathing apparatus as exposure to vapour or combustion products is likely.

Hazchem Code None allocated

6. Accidental Release Measure

Contain using an absorbent (sand, vermiculite) where appropriate. Collect and seal in properly labelled containers for disposal. Wash area down with excess water. Waste material may be incinerated under controlled conditions where permitted. Refer to local Waste Management Authority Regulations for other approved methods.

7. Handling and Storage

Safe Handling Practices Not hazardous for the purposes of transport and storage.

Storage Store below 30°C.

Other Information No data available
8. Exposure Controls; Personal Protection

**Exposure Limits:**
Exposure standards for Phenobarbitone Elixir 15mg/5mL have not been established.

**Engineering Controls:**
Precautions are not usually required.

**Personal Protection:**
Maintain adequate ventilation at all times.

**Personal Protection:**
Not usually required.

9. Physical and Chemical Properties

**Appearance / Odour:**
Clear, colourless syrup which has a butterscotch essence and flavour.

**pH:**
Not known

**Vapour Pressure:**
Not known

**Vapour Density:**
Not known

**Boiling Point:**
Not known

**Freezing/Melting Point:**
Not known

**Percent Volatiles:**
Approximately 10% v/v

**Solubility:**
Miscible @20°C

**Specific Gravity or Density:**
1.21 - 1.23g/mL @20°C

10. Chemical Stability and Reactivity Information

**Conditions Contributing to Instability:**
This product is stable.

11. Toxicological Information

**Inhalation:**
Not expected to be hazardous.

**Ingestion:**
Overdosage of barbiturates produce CNS depression ranging from sleep to profound coma to death: respiratory depression which may progress to Cheyne-Stokes respiration, central hypoventilation and cyanosis: cold, clammy skin and/or hypothermia or later fever, areflexia, tachycardia, hypotension and decreased urine formation. Pupils are usually slightly constricted but may be dilated in severe poisoning. Patients with severe overdosage often experience typical shock syndrome: apnoea, circulatory collapse, respiratory arrest and death may occur. Complications such as pneumonia, pulmonary oedema or renal failure may also prove fatal. Other complications which may occur are congestive heart failure, cardiac arrhythmias and urinary tract infections. Some patients have developed bullous cutaneous lesions which heal slowly.

**Skin:**
May irritate skin.

**Eye:**
May be irritating, causing redness.

**Carcinogenicity and Mutagenisity:**
Phenobarbitone is carcinogenic in mice and rats after lifetime administration. In mice it produced benign and malignant liver cell tumours. In rats, benign liver cell tumours were observed. Phenobarbitone was negative in a 26 week bioassay in p53 heterozygous mice. Genotoxicity studies for gene mutations and chromosome aberrations have given mixed results, however tests for DNA damage or repair have been negative.

12. Ecological Information

**Mobility:**
No data available

**Persistence and Degradability:**
No data available

**Ecotoxicity:**
No data available
13. Disposal Considerations

Disposal Methods & Containers: Containers may be rinsed with water & re-cycled. Waste material may be incinerated under controlled conditions where permitted.

Special Disposal for Landfill or Incineration: Waste material may be incinerated under controlled conditions where permitted. Refer to local Waste Management Authority Regulations for other approved methods.

14. Transport Information

UN Number: None allocated

UN Proper Shipping Name: None allocated

DG Class & Subsidiary Risk: None allocated

Packing Group: None allocated

Hazchem Code: None allocated

15. Regulatory Information

Classified as Prescription Only Medicine (Schedule 4) using the criteria in the Standard Uniform Schedule for Medicines and Poisons.

16. Other Information

References:
- MSDS Phenobarbital P1636 version 3.2 date 07.09.2011, Sigma-Aldrich
- PI Phenobarbitone Elixir 15mg/5mL PHE00479_4_PI, Orion Laboratories
- CMI Phenobarbitone Elixir 15mg/5mL PHE00479_3_CMI Orion Laboratories

END OF MSDS