SAFETY DATA SHEET
according to Regulation (EC) No. 1907/2006

Progesterone Formulation

SECTION 1: Identification of the substance/mixture and of the company/undertaking

1.1 Product identifier
   Trade name : Progesterone Formulation

1.2 Relevant identified uses of the substance or mixture and uses advised against
   Use of the Substance/Mixture : Pharmaceutical

1.3 Details of the supplier of the safety data sheet
   Company : MSD
             Shotton Lane
             NE23 3JU Cramlington NU - Great Britain
   Telephone : 44 1 670 59 30 00
   Telefax : 908-735-1496
   E-mail address of person responsible for the SDS : EHSDATASTEWARD@msd.com

1.4 Emergency telephone number
   1-908-423-6000

SECTION 2: Hazards identification

2.1 Classification of the substance or mixture
   Classification (REGULATION (EC) No 1272/2008)
   Carcinogenicity, Category 2 : H351: Suspected of causing cancer.
   Reproductive toxicity, Category 1A : H360: May damage fertility or the unborn child.
   Effects on or via lactation : H362: May cause harm to breast-fed children.

2.2 Label elements
   Labelling (REGULATION (EC) No 1272/2008)
   Hazard pictograms : 
   Signal word : Danger
   Hazard statements : H351 Suspected of causing cancer.
                      H360 May damage fertility or the unborn child.
                      H362 May cause harm to breast-fed children.
   Precautionary statements : Prevention:
                            P201 Obtain special instructions before use.
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P260 Do not breathe dust.
P263 Avoid contact during pregnancy and while nursing.
P264 Wash skin thoroughly after handling.
P280 Wear protective gloves/ protective clothing/ eye protection/ face protection.

Response:
P308 + P313 IF exposed or concerned: Get medical advice/ attention.

Hazardous components which must be listed on the label:
Progesterone

Additional Labelling
The following percentage of the mixture consists of ingredient(s) with unknown hazards to the aquatic environment: 27.777 %

2.3 Other hazards
Dust contact with the eyes can lead to mechanical irritation.
Contact with dust can cause mechanical irritation or drying of the skin.
May form explosive dust-air mixture if dispersed.

SECTION 3: Composition/information on ingredients

3.2 Mixtures

<table>
<thead>
<tr>
<th>Components</th>
<th>CAS-No.</th>
<th>Classification</th>
<th>Concentration (% w/w)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Progesterone</td>
<td>57-83-0 200-350-6</td>
<td>Carc. 2; H351 Repr. 1A; H360 Lact.H362</td>
<td>27.777</td>
</tr>
</tbody>
</table>

For explanation of abbreviations see section 16.

SECTION 4: First aid measures

4.1 Description of first aid measures

General advice: In the case of accident or if you feel unwell, seek medical advice immediately. When symptoms persist or in all cases of doubt seek medical advice.

Protection of first-aiders: First Aid responders should pay attention to self-protection, and use the recommended personal protective equipment when the potential for exposure exists (see section 8).

If inhaled: If inhaled, remove to fresh air. Get medical attention.

In case of skin contact: In case of contact, immediately flush skin with soap and plenty
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Wash with plenty of water. Remove contaminated clothing and shoes. Get medical attention. Wash clothing before reuse. Thoroughly clean shoes before reuse.

In case of eye contact: If in eyes, rinse well with water. Get medical attention if irritation develops and persists.

If swallowed: If swallowed, DO NOT induce vomiting. Get medical attention. Rinse mouth thoroughly with water.

4.2 Most important symptoms and effects, both acute and delayed

Risks: Suspected of causing cancer. May damage fertility or the unborn child. May cause harm to breast-fed children. Contact with dust can cause mechanical irritation or drying of the skin. Dust contact with the eyes can lead to mechanical irritation.

4.3 Indication of any immediate medical attention and special treatment needed

Treatment: Treat symptomatically and supportively.

SECTION 5: Firefighting measures

5.1 Extinguishing media

Suitable extinguishing media: Water spray  Alcohol-resistant foam  Carbon dioxide (CO2)  Dry chemical

Unsuitable extinguishing media: High volume water jet

5.2 Special hazards arising from the substance or mixture

Specific hazards during firefighting: Avoid generating dust; fine dust dispersed in air in sufficient concentrations, and in the presence of an ignition source is a potential dust explosion hazard. Do not use a solid water stream as it may scatter and spread fire. Exposure to combustion products may be a hazard to health.

Hazardous combustion products: Carbon oxides  Nitrogen oxides (NOx)

5.3 Advice for firefighters

Special protective equipment: In the event of fire, wear self-contained breathing apparatus.
for firefighters

Specific extinguishing methods:

Use personal protective equipment.

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

Use water spray to cool unopened containers.

Remove undamaged containers from fire area if it is safe to do so.

Evacuate area.

SECTION 6: Accidental release measures

6.1 Personal precautions, protective equipment and emergency procedures

Personal precautions:

Use personal protective equipment.

Follow safe handling advice and personal protective equipment recommendations.

6.2 Environmental precautions

Environmental precautions:

Discharge into the environment must be avoided.

Prevent further leakage or spillage if safe to do so.

Retain and dispose of contaminated wash water.

Local authorities should be advised if significant spillages cannot be contained.

6.3 Methods and material for containment and cleaning up

Methods for cleaning up:

Sweep up or vacuum up spillage and collect in suitable container for disposal.

Avoid dispersal of dust in the air (i.e., clearing dust surfaces with compressed air).

Dust deposits should not be allowed to accumulate on surfaces, as these may form an explosive mixture if they are released into the atmosphere in sufficient concentration.

Local or national regulations may apply to releases and disposal of this material, as well as those materials and items employed in the cleanup of releases. You will need to determine which regulations are applicable.

Sections 13 and 15 of this SDS provide information regarding certain local or national requirements.

6.4 Reference to other sections

See sections: 7, 8, 11, 12 and 13.

SECTION 7: Handling and storage

7.1 Precautions for safe handling

Technical measures:

Static electricity may accumulate and ignite suspended dust causing an explosion.

Provide adequate precautions, such as electrical grounding and bonding, or inert atmospheres.

Local/Total ventilation:

If sufficient ventilation is unavailable, use with local exhaust ventilation.
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Advice on safe handling: Do not get on skin or clothing.
Do not breathe dust.
Do not swallow.
Avoid contact with eyes.
Handle in accordance with good industrial hygiene and safety practice, based on the results of the workplace exposure assessment
Keep container tightly closed.
Minimize dust generation and accumulation.
Keep container closed when not in use.
Keep away from heat and sources of ignition.
Take care to prevent spills, waste and minimize release to the environment.

Hygiene measures: If exposure to chemical is likely during typical use, provide eye flushing systems and safety showers close to the working place. When using do not eat, drink or smoke. Wash contaminated clothing before re-use.
The effective operation of a facility should include review of engineering controls, proper personal protective equipment, appropriate degowning and decontamination procedures, industrial hygiene monitoring, medical surveillance and the use of administrative controls.

7.2 Conditions for safe storage, including any incompatibilities
Requirements for storage areas and containers: Keep in properly labelled containers. Store locked up. Keep tightly closed. Store in accordance with the particular national regulations.

Advice on common storage: Do not store with the following product types:
- Strong oxidizing agents
- Organic peroxides
- Explosives

7.3 Specific end use(s)
Specific use(s): No data available

SECTION 8: Exposure controls/personal protection

8.1 Control parameters

<table>
<thead>
<tr>
<th>Components</th>
<th>CAS-No.</th>
<th>Value type (Form of exposure)</th>
<th>Control parameters</th>
<th>Basis</th>
</tr>
</thead>
<tbody>
<tr>
<td>Progesterone</td>
<td>57-83-0</td>
<td>TWA</td>
<td>5 μg/m³ (OEB 4)</td>
<td>Internal</td>
</tr>
<tr>
<td>Further information</td>
<td>DSEN</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Glycerine</td>
<td>56-81-5</td>
<td>TWA (Mist)</td>
<td>10 mg/m³</td>
<td>GB EH40</td>
</tr>
<tr>
<td>Further information</td>
<td></td>
<td>Wipe limit</td>
<td>50 μg/100 cm²</td>
<td>Internal</td>
</tr>
</tbody>
</table>

Derived No Effect Level (DNEL) according to Regulation (EC) No. 1907/2006:
Substance name | End Use | Exposure routes | Potential health effects | Value |
--- | --- | --- | --- | --- |
Glycerine | Workers | Inhalation | Long-term local effects | 56 mg/m^3 |
| Consumers | Ingestion | Long-term systemic effects | 229 mg/kg bw/day |
| Consumers | Inhalation | Long-term local effects | 33 mg/m^3 |

### Predicted No Effect Concentration (PNEC) according to Regulation (EC) No. 1907/2006:

<table>
<thead>
<tr>
<th>Substance name</th>
<th>Environmental Compartment</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Glycerine</td>
<td>Fresh water</td>
<td>0.885 mg/l</td>
</tr>
<tr>
<td></td>
<td>Marine water</td>
<td>0.0885 mg/l</td>
</tr>
<tr>
<td></td>
<td>Intermittent use/release</td>
<td>8.85 mg/l</td>
</tr>
<tr>
<td></td>
<td>Sewage treatment plant</td>
<td>1000 mg/l</td>
</tr>
<tr>
<td></td>
<td>Fresh water sediment</td>
<td>3.3 mg/kg dry weight (d.w.)</td>
</tr>
<tr>
<td></td>
<td>Marine sediment</td>
<td>0.33 mg/kg dry weight (d.w.)</td>
</tr>
<tr>
<td></td>
<td>Soil</td>
<td>0.141 mg/kg dry weight (d.w.)</td>
</tr>
</tbody>
</table>

#### 8.2 Exposure controls

**Engineering measures**

Containment technologies suitable for controlling compounds are required to control at source and to prevent migration of the compound to uncontrolled areas (e.g., vacuum conveying from a closed system, packout head with inflatable seal from stationary container, ventilated enclosure, etc.).

All engineering controls should be implemented by facility design and operated in accordance with GMP principles to protect products, workers, and the environment.

Essentially no open handling permitted.

Use closed processing systems or containment technologies.

**Personal protective equipment**

**Eye protection**

Wear safety glasses with side shields or goggles.

If the work environment or activity involves dusty conditions, mists or aerosols, wear the appropriate goggles.

Wear a faceshield or other full face protection if there is a potential for direct contact to the face with dusts, mists, or aerosols.

**Hand protection**

- **Material**: Chemical-resistant gloves
- **Remarks**: Consider double gloving.

**Skin and body protection**

- **Material**: Work uniform or laboratory coat.
- **Remarks**: Additional body garments should be used based upon the task being performed (e.g., sleevelets, apron, gauntlets, disposable suits) to avoid exposed skin surfaces.
- **Remarks**: Use appropriate degowning techniques to remove potentially contaminated clothing.

**Respiratory protection**

If adequate local exhaust ventilation is not available or exposure assessment demonstrates exposures outside the rec-
SECTION 9: Physical and chemical properties

9.1 Information on basic physical and chemical properties

- **Appearance**: Crystalline powder
- **Colour**: white to off-white
- **Odour**: odourless
- **Odour Threshold**: No data available
- **pH**: No data available
- **Melting point/freezing point**: 126 °C
- **Initial boiling point and boiling range**: No data available
- **Flash point**: Not applicable
- **Evaporation rate**: Not applicable
- **Flammability (solid, gas)**: No data available
- **Upper explosion limit / Upper flammability limit**: No data available
- **Lower explosion limit / Lower flammability limit**: No data available
- **Vapour pressure**: Not applicable
- **Relative vapour density**: Not applicable
- **Relative density**: No data available
- **Density**: No data available
- **Solubility(ies)**: 
  - **Water solubility**: practically insoluble
- **Partition coefficient: n-octanol/water**: Not applicable
- **Auto-ignition temperature**: No data available
- **Decomposition temperature**: No data available
- **Viscosity**: 
  - **Viscosity, kinematic**: Not applicable
- **Explosive properties**: Not explosive
- **Oxidizing properties**: The substance or mixture is not classified as oxidizing.

9.2 Other information
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Molecular weight : No data available
Particle size : No data available

SECTION 10: Stability and reactivity

10.1 Reactivity
Not classified as a reactivity hazard.

10.2 Chemical stability
Stable under normal conditions.

10.3 Possibility of hazardous reactions
Hazardous reactions : Dust can form an explosive mixture in air.
Can react with strong oxidizing agents.

10.4 Conditions to avoid
Conditions to avoid : Avoid dust formation.

10.5 Incompatible materials
Materials to avoid : Oxidizing agents

10.6 Hazardous decomposition products
No hazardous decomposition products are known.

SECTION 11: Toxicological information

11.1 Information on toxicological effects

Information on likely routes of exposure : Inhalation
Skin contact
Ingestion
Eye contact

Acute toxicity
Not classified based on available information.

Components:

Progesterone:
Acute oral toxicity : LD50 (Rat): > 5,000 mg/kg

Skin corrosion/irritation
Not classified based on available information.

Serious eye damage/eye irritation
Not classified based on available information.

Respiratory or skin sensitisation
Skin sensitisation
Not classified based on available information.
Respiratory sensitisation
Not classified based on available information.

Germ cell mutagenicity
Not classified based on available information.

Components:

Progesterone:

Genotoxicity in vitro: Test Type: DNA damage and repair, unscheduled DNA synthesis in mammalian cells (in vitro)
Method: OECD Test Guideline 482
Result: negative

Genotoxicity in vivo: Test Type: Mammalian erythrocyte micronucleus test (in vivo cytogenetic assay)
Species: Monkey
Application Route: Subcutaneous
Result: negative

Carcinogenicity
Suspected of causing cancer.

Components:

Progesterone:

Species: Mouse
Application Route: Subcutaneous
Exposure time: 19 weeks
Result: positive

Carcinogenicity - Assessment: Limited evidence of carcinogenicity in animal studies

Reproductive toxicity
May damage fertility or the unborn child.
May cause harm to breast-fed children.

Components:

Progesterone:

Effects on fertility: Test Type: Fertility
Species: Rat
Application Route: Subcutaneous
Result: positive

Effects on foetal development: Test Type: Embryo-foetal development
Species: Rat
Application Route: Skin contact
Result: positive

Reproductive toxicity - Assessment: Positive evidence of adverse effects on sexual function, fertility and/or development from human epidemiological studies. Studies indicating a hazard to babies during the lactation period
STOT - single exposure
Not classified based on available information.

STOT - repeated exposure
Not classified based on available information.

Aspiration toxicity
Not classified based on available information.

SECTION 12: Ecological information

12.1 Toxicity

Components:

Progesterone:

Ecotoxicology Assessment
Acute aquatic toxicity : Toxic effects cannot be excluded
Chronic aquatic toxicity : Toxic effects cannot be excluded

12.2 Persistence and degradability
No data available

12.3 Bioaccumulative potential

Components:

Progesterone:
Partition coefficient: n-octanol/water : Pow: 3.65

12.4 Mobility in soil
No data available

12.5 Results of PBT and vPvB assessment
Not relevant

12.6 Other adverse effects
No data available

SECTION 13: Disposal considerations

13.1 Waste treatment methods

Product : Dispose of in accordance with local regulations. According to the European Waste Catalogue, Waste Codes are not product specific, but application specific. Waste codes should be assigned by the user, preferably in discussion with the waste disposal authorities.

Contaminated packaging : Empty containers should be taken to an approved waste handling site for recycling or disposal.
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SECTION 14: Transport information

14.1 UN number
Not regulated as a dangerous good

14.2 UN proper shipping name
Not regulated as a dangerous good

14.3 Transport hazard class(es)
Not regulated as a dangerous good

14.4 Packing group
Not regulated as a dangerous good

14.5 Environmental hazards
Not regulated as a dangerous good

14.6 Special precautions for user
Not applicable

14.7 Transport in bulk according to Annex II of Marpol and the IBC Code
Remarks : Not applicable for product as supplied.

SECTION 15: Regulatory information

15.1 Safety, health and environmental regulations/legislation specific for the substance or mixture

<table>
<thead>
<tr>
<th>Regulation</th>
<th>Applicability</th>
</tr>
</thead>
<tbody>
<tr>
<td>REACH - Candidate List of Substances of Very High Concern for Authorisation (Article 59).</td>
<td>Not applicable</td>
</tr>
<tr>
<td>REACH - List of substances subject to authorisation (Annex XIV)</td>
<td>Not applicable</td>
</tr>
<tr>
<td>Regulation (EC) No 1005/2009 on substances that deplete the ozone layer</td>
<td>Not applicable</td>
</tr>
<tr>
<td>Regulation (EC) No 850/2004 on persistent organic pollutants</td>
<td>Not applicable</td>
</tr>
<tr>
<td>Regulation (EC) No 649/2012 of the European Parliament and the Council concerning the export and import of dangerous chemicals</td>
<td>Not applicable</td>
</tr>
</tbody>
</table>

Other regulations:
Take note of Directive 92/85/EEC regarding maternity protection or stricter national regulations, where applicable.
Take note of Directive 94/33/EC on the protection of young people at work or stricter national regulations, where applicable.
The components of this product are reported in the following inventories:

<table>
<thead>
<tr>
<th>Inventory</th>
<th>Status</th>
</tr>
</thead>
<tbody>
<tr>
<td>IECSC</td>
<td>not determined</td>
</tr>
<tr>
<td>AICS</td>
<td>not determined</td>
</tr>
<tr>
<td>DSL</td>
<td>not determined</td>
</tr>
</tbody>
</table>

15.2 Chemical safety assessment
A Chemical Safety Assessment has not been carried out.

SECTION 16: Other information

Other information: Items where changes have been made to the previous version are highlighted in the body of this document by two vertical lines.

Full text of H-statements

H351 : Suspected of causing cancer.
H360 : May damage fertility or the unborn child.
H362 : May cause harm to breast-fed children.

Full text of other abbreviations

Carc.: Carcinogenicity  
Lact.: Effects on or via lactation  
Repr.: Reproductive toxicity  
GB EH40: UK. EH40 WEL - Workplace Exposure Limits  
GB EH40 / TWA: Long-term exposure limit (8-hour TWA reference period)
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Further information
Sources of key data used to compile the Safety Data Sheet:

Classification of the mixture:
| Carc. 2 | H351 | Calculation method |
| Repr. 1A | H360 | Calculation method |
| Lact. | H362 | Calculation method |

The information provided in this Safety Data Sheet is correct to the best of our knowledge, information and belief at the date of its publication. The information is designed only as a guidance for safe handling, use, processing, storage, transportation, disposal and release and shall not be considered a warranty or quality specification of any type. The information provided relates only to the specific material identified at the top of this SDS and may not be valid when the SDS material is used in combination with any other materials or in any process, unless specified in the text. Material users should review the information and recommendations in the specific context of their intended manner of handling, use, processing and storage, including an assessment of the appropriateness of the SDS material in the user’s end product, if applicable.

GB / EN