

## SAFETY DATA SHEET


According to Regulation (EC) No1272/2008

Revision date: August 8, 2019 Version: 007

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

<p><b>1.1 Product identifiers</b>            Product name : Progesterone            Product Number : C01            Brand : JEK</p>
<p><b>1.2 Relevant identified uses of the substance or mixture and uses advised against</b>            Identified uses: For Prescription Compounding</p>
<p><b>1.3 Details of the supplier of the safety data sheet</b>            Company: Jiangsu Jiaerke Pharmaceuticals Group Corp., Ltd.            Address: No. 302, Huzhuangtou, Sanhuangmiao, Zhenglu, Tianning, Changzhou, Jiangsu 213111, China            E-mail: ehs@jiaerke.com</p>
<p><b>1.4 Emergency telephone number</b>            Emergency Phone #: 0086-519-88930785</p>

### SECTION 2 HAZARDS IDENTIFICATION

<p><b>2.1 Classification of the substance</b>            According to Regulation (EC) No1272/2008                Carcinogenicity (Category 2)                Reproductive toxicity (Category 1A)                Reproductive toxicity, Additional category, Effects on or via lactation</p>
<p><b>2.2 Label elements</b>  <b>Labeling according Regulation (EC) No 1272/2008</b></p> <div style="text-align: center; margin: 10px 0;">  </div> <p>Pictogram</p> <p>Signal word                      Danger</p> <p>Hazard statement(s)</p> <p>    H351              Suspected of causing cancer.          H360Fd          May damage fertility. Suspected of damaging the unborn child.          H362              May cause harm to breast-fed children.</p> <p>Precautionary statement(s)</p> <p>Prevention</p> <p>    P201              Obtain special instructions before use.          P263              Avoid contact during pregnancy/while nursing.          P280              Use protective clothing, protective gloves.</p>

**Response**

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

**Disposal**

P405 Store locked up.

P501 Dispose of contents/container in accordance with local/ regional/ national/international regulations.

**2.3 Other hazards - none****SECTION 3 COMPOSITION/INFORMATION ON INGREDIENTS****3.1 Substances**

Synonyms: 4-Pregnene-3,20-dione

Formula : C<sub>21</sub>H<sub>30</sub>O<sub>2</sub>

Molecular Weight : 314.47 g/mol

CAS No. : 57-83-0

EC No.: 200-350-6

For the full text of the H-Statements mentioned in this Section, see Section 2.

**SECTION 4 FIRST AID MEASURES****4.1 Description of first aid measures****General advice**

Consult a physician. Show this safety data sheet to the doctor in attendance.

**If inhaled**

If breathed in, move person into fresh air. If not breathing give artificial respiration

Consult a physician.

**In case of skin contact**

Wash off with soap and plenty of water. Consult a physician.

**In case of eye contact**

Rinse thoroughly with plenty of water for at least 15 minutes and consult a physician.

**If swallowed**

Never give anything by mouth to an unconscious person. Rinse mouth with water.

Consult a physician.

**4.2 Most important symptoms and effects, both acute and delayed**

Symptoms/effects after ingestion: If the quantity swallowed is significant: Nausea.

Headache. Affects the liver.

**4.3 Indication of any immediate medical attention and special treatment needed**

Treat symptomatically.

**SECTION 5 FIRE-FIGHTING MEASURES****5.1 Extinguishing media**

**Suitable extinguishing media:** Water spray, dry powder, Foam.

**Unsuitable extinguishing media:** Strong water jet.

<p><b>5.2 Special hazards arising from the substance or mixture</b> Fire may cause evolution of: Carbon monoxide, Carbon dioxide (CO<sub>2</sub>), nitrogen oxides (NO<sub>x</sub>),</p>
<p><b>5.3 Advice for firefighters</b> <b>Special protective equipment for fire-fighters</b> Wear self contained breathing apparatus for firefighting if necessary.</p>
<p><b>5.4 Further information</b> Do not allow run-off from fire fighting to enter drains or water courses.</p>

## SECTION 6 ACCIDENTAL RELEASE MEASURES

<p><b>6.1 Personal precautions, protective equipment and emergency procedures</b> <b>Personal protective equipment</b> Eye: Wear approved safety goggles. Skin: Wear approved clothing. Respiration: Wear approved full face respirator P3.</p>
<p><b>6.2 Environmental precautions</b> In case of accidental release or spill, keep away from drains, surface and ground water.</p>
<p><b>6.3 Methods and materials for containment and cleaning up</b> Contain spillage, and then collect with non-combustible absorbent material, (e.g. sand, earth, diatomaceous earth, vermiculite) and place in container for disposal according to local / national regulations (see section 13). If emergency, enforce internal emergency plan.</p>
<p><b>6.4 Reference to other sections</b> For disposal see section 13.</p>

## SECTION 7 HANDLING AND STORAGE

<p><b>7.1 Precautions for safe handling</b> <b>Handling:</b> Keep away from heat and flames. Avoid powder dispersion. Avoid contact with incompatible substances. Avoid: direct contact with skin and eyes; inhalation of vapours and fumes. Wear appropriate PPE (See section 8). <b>Occupational hygiene:</b> Do not eat, drink or smoke in work areas. Wash hands after use. Remove contaminated clothing and protective equipment before entering eating areas.</p>
<p><b>7.2 Conditions for safe storage, including any incompatibilities</b> Store locked up. Preserve in tight, light-resistant containers. Store at 25 °C, excursion permitted between 15°C and 30°C.</p>
<p><b>7.3 Specific end uses</b> no data available</p>

## SECTION 8 EXPOSURE CONTROLS/PERSONAL PROTECTION

### 8.1 Control parameters

OEL: 1~10 $\mu$ g/m<sup>3</sup>

### 8.2 Exposure controls

Provide adequate exposition controls.

#### 8.2.1 Appropriate engineering controls

Provide adequate engineering control measures in confined plants or with local exhaust ventilation systems, to avoid powder dispersion.

#### 8.2.2. Individual protection measures, such as personal protective equipment

##### Respiratory protection:

Where risk assessment shows air-purifying respirators are appropriate use a full-face particle respirator type N100 (US) or type P3 (EN 143) respirator cartridges as a backup to engineering controls. If the respirator is the sole means of protection, use a full-face supplied air respirator. Use respirators and components tested and approved under appropriate government standards such as NIOSH (US) or CEN (EU).

##### Eye/face protection:

Safety glasses with side-shields conforming to EN166.

##### Hand protection:

The selected protective gloves have to satisfy the specifications of EU Directive 89/686/EEC and the standard EN 374 derived from it. Handle with gloves.

##### Body protection:

Choose body protection according to the amount and concentration of the dangerous substance at the work place.

#### 8.2.3 Environmental exposure controls

If necessary, adopt air emission treatment systems.

## SECTION 9 PHYSICAL AND CHEMICAL PROPERTIES

### 9.1 Information on basic physical and chemical properties

Appearance	Form: crystalline powder Color: white or almost-white
pH:	no data available
Melting point:	126- 131 °C.
Boiling point:	no data available
Flash point:	no data available
Ignition temperature:	no data available
Lower explosion limit:	no data available
Upper explosion limit:	no data available
Water solubility:	no data available
Log Pow:	3.87
Solubility:	Insoluble
Density	1.17g/cm <sup>3</sup>

### 9.2 Other safety information

no data available.

**SECTION 10 STABILITY AND REACTIVITY**

<b>10.1 Reactivity</b>
The product is non-reactive under normal conditions of use, storage and transport.
<b>10.2 Chemical stability</b>
The substance is stable in normal conditions of temperature and pressure and if stocked in closed containers in cold and ventilated area. Light sensitive.
<b>10.3 Possibility of hazardous reactions</b>
No dangerous reactions known under normal conditions of use.
<b>10.4 Conditions to avoid</b>
no data available
<b>10.5 Incompatible materials</b>
Strong oxidizing agents
<b>10.6 Hazardous decomposition products</b>
Hazardous decomposition products formed under fire conditions. - Carbon oxides

**SECTION 11 TOXICOLOGICAL INFORMATION**

<b>11.1 Information on toxicological effects</b>
<b>Acute toxicity</b>
LD50 Oral - rat – 5.000 mg/kg
<b>Skin corrosion/irritation</b>
no data available
<b>Serious eye damage/eye irritation</b>
no data available
<b>Respiratory or skin sensitization</b>
Causes photosensitivity. Exposure to light can result in allergic reactions resulting in dermatologic lesions, which can vary from sunburnlike responses to edematous, vesiculated lesions, or bullae.
<b>Germ cell mutagenicity</b>
Genotoxicity in vitro - rat - Embryo Morphological transformation. Genotoxicity in vivo - rat - Oral Micronucleus test
<b>Carcinogenicity</b>
This product is or contains a component that has been reported to be possibly carcinogenic based on its IARC, ACGIH, NTP, or EPA classification. Limited evidence of carcinogenicity in animal studies
<b>Reproductive toxicity</b>
Suspected human reproductive toxicant. Overexposure may cause reproductive disorder(s) based on tests with laboratory animals.
<b>Specific target organ toxicity - single exposure</b>
no data available
<b>Specific target organ toxicity - repeated exposure</b>

no data available	
<b>Aspiration hazard</b>	
no data available	
<b>Potential health effects</b>	
<b>Inhalation</b>	May be harmful if inhaled. Causes respiratory tract irritation.
<b>Ingestion</b>	May be harmful if swallowed.
<b>Skin</b>	May be harmful if absorbed through skin. Causes skin irritation.
<b>Eyes</b>	Causes eye irritation.
<b>Signs and Symptoms of Exposure</b>	
To the best of our knowledge, the chemical, physical, and toxicological properties have not been thoroughly investigated.	
<b>Additional Information</b>	
RTECS: TW0175000	

**SECTION 12 ECOLOGICAL INFORMATION**

<b>12.1 Toxicity</b>	
no data available	
<b>12.2 Persistence and degradability</b>	
no data available	
<b>12.3 Bioaccumulative potential</b>	
Bioconcentration factor (BCF REACH):	170
Log Pow:	3.87
Bioaccumulative potential:	Based on the n-octanol/water partition coefficient accumulation in organisms is possible.
<b>12.4 Mobility in soil</b>	
no data available	
<b>12.5 PBT and vPvB assessment</b>	
no data available	
<b>12.6 Other adverse effects</b>	
no data available	

**SECTION 13 DISPOSAL CONSIDERATIONS**

<b>13.1 Waste treatment methods</b>
<b>Product</b>
Observe all federal, state, and local environmental regulations. Contact a licensed professional waste disposal service to dispose of this material. Dissolve or mix the material with a combustible solvent and burn in a chemical incinerator equipped with an afterburner and scrubber.
<b>Contaminated packaging</b>
Dispose of as unused product.
<b>European List of Waste (LoW) code</b>
07 05 13*-solid wastes containing dangerous substances

**HP Code**

HP10-"Toxic for reproduction:"waste which has adverse effects on sexual function and fertility in adult males and females, as well as developmental toxicity in the offspring.  
 HP7-"Carcinogenic:"waste which induces cancer or increases its incidence.

**SECTION 14 TRANSPORT INFORMATION**

<b>14.1 UN number</b>		
ADR/RID: -	IMDG: -	IATA: -
<b>14.2 UN proper shipping name</b>		
ADR/RID/ADN: Not dangerous goods		
IMDG: Not dangerous goods		
IATA/ICAO: Not dangerous goods		
<b>14.3 Transport hazard class(es)</b>		
ADR/RID: -	IMDG: -	IATA: -
<b>14.4 Packaging group</b>		
ADR/RID: -	IMDG: -	IATA: -
<b>14.5 Environmental hazards</b>		
ADR/RID/ADN: no		
IMDG: no		
IATA/ICAO: no		
<b>14.6 Special precautions for user</b>		
no data available		

**SECTION 15 REGULATORY INFORMATION**

<b>15.1 Safety, health and environmental regulations/legislation specific for the substance or mixture</b>
<b>15.1.1 EU-Regulations</b>
This safety datasheet complies with the requirements of Regulation (EC) No. 1272/2008.
No REACH Annex XVII restrictions.
Progesterone is not on the REACH Candidate List.
<b>15.1.2 National regulations</b>
No additional information available.
<b>15.2 Chemical safety assessment</b>
No chemical safety assessment has been carried out.

**SECTION 16 OTHER INFORMATION**

<b>Further information</b>
The above information is believed to be correct but does not purport to be all inclusive and shall be used only as a guide. All chemicals may pose unknown hazards and should be used with caution. This Safety Data Sheet applies only to the material as packaged. If this product is combined with other materials, deteriorates, or becomes

contaminated, it may pose hazards not mentioned in this SDS. It shall be the user's responsibility to develop proper methods of handling and personal protection based on the actual conditions of use.

The information in this document is based on the present state of our knowledge and is applicable to the product with regard to appropriate safety precautions. It does not represent any guarantee of the properties of the product. Jiangsu Jiaerke Pharma., shall not be held liable for any damage resulting from handling or from contact with the above product.