


MATERIAL SAFETY DATA SHEET

According to Regulation (EC) No1272/2008

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

1.1 Product identifiers
Product name : Progesterone
Product Number : C01
Brand : JEK
1.2 Relevant identified uses of the substance or mixture and uses advised against
Identified uses: For Prescription Compounding
1.3 Details of the supplier of the safety data sheet
Company: Jiangsu Jiaerke Pharmaceuticals Group Corp., Ltd.
Address: Sanhuangmiao, Zhenglu, Wujin, Changzhou, Jiangsu 213111, China
E-mail: ehs@jiaerke.com
1.4 Emergency telephone number
Emergency Phone #: 0086-519-88930785

SECTION 2 HAZARDS IDENTIFICATION

2.1 Classification of the substance
According to Regulation (EC) No1272/2008
Carcinogenicity (Category 2)
2.2 Label elements
Labelling according Regulation (EC) No 1272/2008
<div style="display: flex; align-items: center;"> <div style="margin-right: 10px;">Pictogram</div>  </div>
Signal word Danger
Hazard statement(s)
H351 Suspected of causing cancer
H360 May damage fertility or the unborn child
H362 May cause harm to breast-fed children
Precautionary statement(s)
Prevention
P201 Obtain special instructions before use.
P202 Do not handle until all safety precautions have been read and understood.
P263 Avoid contact during pregnancy/while nursing.
P281 Use personal protective equipment as required.
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 ₂₁ H ₃₀ O ₂
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 The most important known symptoms and effects are described in the labelling (see section 2.2) and/or in section 11
4.3 Indication of any immediate medical attention and special treatment needed no data available

SECTION 5 FIRE-FIGHTING MEASURES

5.1 Extinguishing media Suitable extinguishing media: Use water spray, alcohol-resistant foam, dry chemical or carbon dioxide. Unsuitable extinguishing media: None
5.2 Special hazards arising from the substance or mixture Fire may cause evolution of: Carbon monoxide, Carbon dioxide (CO ₂), nitrogen oxides (NO _x),
5.3 Advice for firefighters Special protective equipment for fire-fighters

Wear self contained breathing apparatus for fire fighting if necessary.

5.4 Further information

no data available

SECTION 6 ACCIDENTAL RELEASE MEASURES

6.1 Personal precautions, protective equipment and emergency procedures

Personal protective equipment

Eye: Wear approved safety goggles.

Skin: Wear approved clothing.

Respiration: Wear approved full face respirator P3.

6.2 Environmental precautions

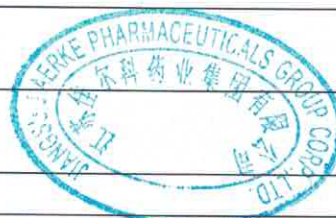
In case of accidental release or spill, keep away from drains, surface and ground water.

6.3 Methods and materials for containment and cleaning up

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.

6.4 Reference to other sections

For disposal see section 13.



SECTION 7 HANDLING AND STORAGE

7.1 Precautions for safe handling

Handling: 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).

Occupational hygiene: Do not eat, drink or smoke in work areas. Wash hands after use. Remove contaminated clothing and protective equipment before entering eating areas.

7.2 Conditions for safe storage, including any incompatibilities

Store in cool place. Keep container tightly closed in a dry and well-ventilated place. Store locked up.

7.3 Specific end uses

no data available

SECTION 8 EXPOSURE CONTROLS/PERSONAL PROTECTION

8.1 Control parameters

OEL: 1~10µg/m³

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
Colour: 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

9.2 Other safety information

no data available.



SECTION 10 STABILITY AND REACTIVITY

10.1 Reactivity

no data available

10.2 Chemical stability

The substance is stable in normal conditions of temperature and pressure and if stocked in closed containers in cold and ventilated area.

10.3 Possibility of hazardous reactions

no data available

10.4 Conditions to avoid

no data available

10.5 Incompatible materials

Strong oxidizing agents

10.6 Hazardous decomposition products

Hazardous decomposition products formed under fire conditions. - Carbon oxides

SECTION 11 TOXICOLOGICAL INFORMATION**11.1 Information on toxicological effects****Acute toxicity**

LD50 Oral - rat – 5.000 mg/kg

Skin corrosion/irritation

no data available

Serious eye damage/eye irritation

no data available

Respiratory or skin sensitization

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.

Germ cell mutagenicity

Genotoxicity in vitro - rat - Embryo

Morphological transformation.

Genotoxicity in vivo - rat - Oral

Micronucleus test

Carcinogenicity

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

Reproductive toxicity

Suspected human reproductive toxicant.

Overexposure may cause reproductive disorder(s) based on tests with laboratory animals.

Specific target organ toxicity - single exposure

no data available

Specific target organ toxicity - repeated exposure

no data available

Aspiration hazard

no data available

Potential health effects

Inhalation May be harmful if inhaled. Causes respiratory tract irritation.

Ingestion May be harmful if swallowed.

Skin May be harmful if absorbed through skin. Causes skin irritation.

Eyes Causes eye irritation.

Signs and Symptoms of Exposure

To the best of our knowledge, the chemical, physical, and toxicological properties



have not been thoroughly investigated.

Additional Information

RTECS: TW0175000

SECTION 12 ECOLOGICAL INFORMATION

12.1 Toxicity

no data available

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 PBT and vPvB assessment

no data available

12.6 Other adverse effects

no data available

SECTION 13 DISPOSAL CONSIDERATIONS

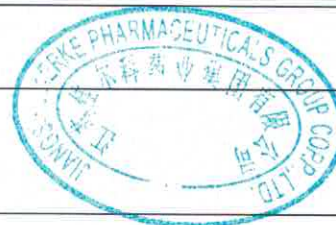
13.1 Waste treatment methods

Product

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.

Contaminated packaging

Dispose of as unused product.



SECTION 14 TRANSPORT INFORMATION

14.1 UN number

ADR/RID: -

IMDG: -

IATA: -

14.2 UN proper shipping name

ADR/RID/ADN: Not dangerous goods

IMDG: Not dangerous goods

IATA/ICAO: Not dangerous goods

14.3 Transport hazard class(es)

ADR/RID: -

IMDG: -

IATA: -

14.4 Packaging group

ADR/RID: -

IMDG: -

IATA: -

14.5 Environmental hazards

ADR/RID/ADN: no

IMDG: no

IATA/ICAO: no

14.6 Special precautions for user

no data available

SECTION 15 REGULATORY INFORMATION**15.1 Safety, health and environmental regulations/legislation specific for the substance or mixture**

This safety datasheet complies with the requirements of Regulation (EC) No. 1272/2008.

SECTION 16 OTHER INFORMATION**Further information**

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 Material 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 MSDS. 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.

Effective date: Jan.20, 2016

