

SAFETY DATA SHEET

According to 29 CFR 1910.1200

Section 1. Identification

GHS product identifier : Progesterone
Product code: C01
Chemical name: Progesterone
Other means of identification: 4-Pregnene-3,20-dione
Product type: Powder
Relevant identified uses of the substance or mixture and uses advised against
Material uses: For Prescription Compounding
Supplier's details: Jiangsu Jiaerke Pharmaceuticals Group Corp., Ltd.
No. 302, Huzhuangtou, Sanhuangmiao, Zhenglu, Tianning,
Changzhou, Jiangsu 213111, China
Emergency phone number : 0086-519-88930785

Section 2. Hazards identification

OSHA/HCS status : This material is considered hazardous by the OSHA Hazard Communication Standard (29 CFR 1910.1200).

Classification of the substance or mixture:
COMBUSTIBLE DUSTS
CARCINOGENICITY-category 2

GHS label elements

Signal word : Warning

Hazard statements: No Code(s) - May form combustible dust concentrations in air.
H351 Suspected of causing cancer

Precautionary statements

Prevention : Obtain special instructions before use.
Use personal protective equipment as required.

Response: If exposed or concerned: Get medical advice/attention.

Storage : Not applicable.

Disposal: Not applicable.

Supplemental label elements: Keep container tightly closed. Keep away from heat, hot surfaces, sparks, open flames and other ignition sources. No smoking. Prevent dust accumulation.

Hazards not otherwise classified: Fine dust clouds may form explosive mixtures with air. Handling and/or processing of this material may generate a dust which can cause mechanical irritation of the eyes, skin, nose and throat.

Section 3. Composition/information on ingredients

Substance/mixture: Substance
Chemical name: Progesterone
Other means of identification: 4-Pregnene-3,20-dione

CAS number/other identifiers

CAS No.: 57-83-0

Ingredient name	%(w/w)	CAS number
Progesterone	97~103	57-83-0

Any concentration shown as a range is to protect confidentiality or is due to batch variation.

There are no additional ingredients present which, within the current knowledge of the supplier and in the concentrations applicable, are classified as hazardous to health or the environment and hence require reporting in this section.

Occupational exposure limits, if available, are listed in Section 8.

Section 4. First aid measures

Description of necessary first aid measures

Eye contact:

Immediately flush eyes with plenty of water, occasionally lifting the upper and lower eyelids. Check for and remove any contact lenses. Continue to rinse for at least 10 minutes. Get medical attention if irritation occurs.

Inhalation:

Remove victim to fresh air and keep at rest in a position comfortable for breathing. If not breathing, if breathing is irregular or if respiratory arrest occurs, provide artificial respiration or oxygen by trained personnel. It may be dangerous to the person providing aid to give mouth-to-mouth resuscitation. Get medical attention if adverse health effects persist or are severe. If unconscious, place in recovery position and get medical attention immediately. Maintain an open airway. Loosen tight clothing such as a collar, tie, belt or waistband.

Skin contact:

Flush contaminated skin with plenty of water. Remove contaminated clothing and shoes. Get medical attention if symptoms occur. Wash clothing before reuse. Clean shoes thoroughly before reuse.

Ingestion:

Wash out mouth with water. Remove dentures if any. Remove victim to fresh air and keep at rest in a position comfortable for breathing. If material has been swallowed and the exposed person is conscious, give small quantities of water to drink. Stop if the exposed person feels sick as vomiting may be dangerous. Do not induce vomiting unless directed to do so by medical personnel. If vomiting occurs, the head should be kept low so that vomit does not enter the lungs. Get medical attention if adverse health effects persist or are severe. Never give anything by mouth to an unconscious person. If unconscious, place in recovery position and get medical attention immediately. Maintain an open airway. Loosen tight clothing such as a collar, tie, belt or waistband.

Most important symptoms/effects, acute and delayed

Potential acute health effects

Eye contact: Exposure to airborne concentrations above statutory or recommended exposure limits may cause irritation of the eyes.

Inhalation: Exposure to airborne concentrations above statutory or recommended exposure limits may cause irritation of the nose, throat and lungs.

Skin contact: No known significant effects or critical hazards.

Ingestion: No known significant effects or critical hazards.

Over-exposure signs/symptoms

Eye contact: Adverse symptoms may include the following:
irritation
redness

Inhalation: Adverse symptoms may include the following:
respiratory tract irritation
coughing

Skin contact: No specific data.

Ingestion: No specific data.

Indication of immediate medical attention and special treatment needed, if necessary**Notes to physician:**

Treat symptomatically. Contact poison treatment specialist immediately if large quantities have been ingested or inhaled.

Specific treatments:

No specific treatment.

Protection of first-aiders:

No action shall be taken involving any personal risk or without suitable training. It may be dangerous to the person providing aid to give mouth-to-mouth resuscitation.

See toxicological information (Section 11)

Section 5. Fire-fighting measures**Extinguishing media****Suitable extinguishing media:**

Use dry chemical powder.

Unsuitable extinguishing media:

Do not use water jet.

Specific hazards arising from the chemical:

Fine dust clouds may form explosive mixtures with air.

Hazardous thermal decomposition products:

Decomposition products may include the following materials:

carbon dioxide

carbon monoxide

Special protective actions for fire-fighters:

Promptly isolate the scene by removing all persons from the vicinity of the incident if there is a fire. No action shall be taken involving any personal risk or without suitable training. Move

containers from fire area if this can be done without risk. Use water spray to keep fire-exposed containers cool.

Special protective equipment for fire-fighters:

Fire-fighters should wear appropriate protective equipment and self-contained breathing apparatus (SCBA) with a full face-piece operated in positive pressure mode.

Section 6. Accidental release measures

Personal precautions, protective equipment and emergency procedures

For non-emergency personnel:

No action shall be taken involving any personal risk or without suitable training. Evacuate surrounding areas. Keep unnecessary and unprotected personnel from entering. Do not touch or walk through spilled material. Shut off all ignition sources. No flares, smoking or flames in hazard area. Avoid breathing dust. Provide adequate ventilation. Wear appropriate respirator when ventilation is inadequate. Put on appropriate personal protective equipment.

For emergency responders:

If specialised clothing is required to deal with the spillage, take note of any information in Section 8 on suitable and unsuitable materials. See also the information in "For non-emergency personnel".

Environmental precautions:

Avoid dispersal of spilled material and runoff and contact with soil, waterways, drains and sewers. Inform the relevant authorities if the product has caused environmental pollution (sewers, waterways, soil or air).

Methods and materials for containment and cleaning up

Small spill:

Move containers from spill area. Use spark-proof tools and explosion-proof equipment. Vacuum or sweep up material and place in a designated, labeled waste container. Dispose of via a licensed waste disposal contractor.

Large spill:

Move containers from spill area. Use spark-proof tools and explosion-proof equipment. Approach release from upwind. Prevent entry into sewers, water courses, basements or confined areas. Vacuum or sweep up material and place in a designated, labeled waste container. Avoid creating dusty conditions and prevent wind dispersal. Dispose of via a licensed waste disposal contractor. Note: see Section 1 for emergency contact information and Section 13 for waste disposal.

Section 7. Handling and storage

Precautions for safe handling

Protective measures:

Put on appropriate personal protective equipment (see Section 8). Do not ingest. Avoid contact with eyes, skin and clothing. Avoid breathing dust. Avoid the creation of dust when handling and avoid all possible sources of ignition (spark or flame). Prevent dust accumulation. Use only with adequate ventilation. Wear appropriate respirator when ventilation is inadequate.

Keep in the original container or an approved alternative made from a compatible material, kept tightly closed when not in use. Electrical equipment and lighting should be protected to appropriate standards to prevent dust coming into contact with hot surfaces, sparks or other ignition sources. Take precautionary measures against electrostatic discharges. To avoid fire or explosion, dissipate static electricity during transfer by grounding and bonding containers and equipment before transferring material. Empty containers retain product residue and can be hazardous. Do not reuse container.

Advice on general occupational hygiene:

Eating, drinking and smoking should be prohibited in areas where this material is handled, stored and processed. Workers should wash hands and face before eating, drinking and smoking. Remove contaminated clothing and protective equipment before entering eating areas. See also Section 8 for additional information on hygiene measures.

Conditions for safe storage, including any incompatibilities

Store in accordance with local regulations. Store in a segregated and approved area. Preserve in tight, light-resistant containers. Store at 25 °C, excursion permitted between 15°C and 30°C. Away from incompatible materials (see Section 10) and food and drink. Eliminate all ignition sources. Separate from oxidizing materials. Keep container tightly closed and sealed until ready for use. Containers that have been opened must be carefully resealed and kept upright to prevent leakage. Do not store in unlabeled containers. Use appropriate containment to avoid environmental contamination.

Section 8. Exposure controls/personal protection

Control parameters

Occupational exposure limits

None.

Appropriate engineering controls

Use only with adequate ventilation. If user operations generate dust, fumes, gas, vapor or mist, use process enclosures, local exhaust ventilation or other engineering controls to keep worker exposure to airborne contaminants below any recommended or statutory limits. The engineering controls also need to keep gas, vapor or dust concentrations below any lower explosive limits. Use explosion-proof ventilation equipment.

Environmental exposure controls

Emissions from ventilation or work process equipment should be checked to ensure they comply with the requirements of environmental protection legislation. In some cases, fume scrubbers, filters or engineering modifications to the process equipment will be necessary to reduce emissions to acceptable levels.

Individual protection measures

Hygiene measures

Wash hands, forearms and face thoroughly after handling chemical products, before eating, smoking and using the lavatory and at the end of the working period. Appropriate techniques should be used to remove potentially contaminated clothing. Wash contaminated clothing before reusing. Ensure that eyewash stations and safety showers are close to the workstation location.

Eye/face protection

Safety eyewear complying with an approved standard should be used when a risk assessment indicates this is necessary to avoid exposure to liquid splashes, mists, gases or dusts. If contact is possible, the following protection should be worn, unless the assessment indicates a higher degree of protection: safety glasses with side-shields. If operating conditions cause high dust concentrations to be produced, use dust goggles.

Skin protection**Hand protection**

Chemical-resistant, impervious gloves complying with an approved standard should be worn at all times when handling chemical products if a risk assessment indicates this is necessary. Considering the parameters specified by the glove manufacturer, check during use that the gloves are still retaining their protective properties. It should be noted that the time to breakthrough for any glove material may be different for different glove manufacturers. In the case of mixtures, consisting of several substances, the protection time of the gloves cannot be accurately estimated.

Body protection

Personal protective equipment for the body should be selected based on the task being performed and the risks involved and should be approved by a specialist before handling this product.

Other skin protection

Appropriate footwear and any additional skin protection measures should be selected based on the task being performed and the risks involved and should be approved by a specialist before handling this product.

Respiratory protection

Use a properly fitted, particulate filter respirator complying with an approved standard if a risk assessment indicates this is necessary. Respirator selection must be based on known or anticipated exposure levels, the hazards of the product and the safe working limits of the selected respirator.

Section 9. Physical and chemical properties**Appearance**

Physical state:	Solid. [Powder.]
Color :	White or almost-white.
Odor:	Characteristic.
Odor threshold:	Not available.
pH :	Not available.
Melting point:	126 to131 °C
Boiling point :	Not available.
Flash point:	Closed cup >93.3°C (>199.9°F)
Evaporation rate:	Not available.
Flammability (solid, gas):	Not available.
Lower and upper explosive (flammable) limits:	Not available.

Vapor pressure:	Not available.
Vapor density:	Not available.
Relative density:	Not available.
Solubility:	Soluble in acetone. Insoluble in cold water, hot water.
Partition coefficient:	
n-octanol/water :	Not available.
Auto-ignition temperature:	Not available.
Decomposition temperature:	Not available.
Viscosity:	Not available.

Section 10. Stability and reactivity

Reactivity

No specific test data related to reactivity available for this product or its ingredients.

Chemical stability

The product is stable.

Possibility of hazardous reactions

Under normal conditions of storage and use, hazardous reactions will not occur.

Conditions to avoid

Avoid the creation of dust when handling and avoid all possible sources of ignition (spark or flame). Take precautionary measures against electrostatic discharges. To avoid fire or explosion, dissipate static electricity during transfer by grounding and bonding containers and equipment before transferring material. Prevent dust accumulation.

Incompatible materials

Reactive or incompatible with the following materials:

Strong oxidizing agents

Hazardous decomposition products

Under normal conditions of storage and use, hazardous decomposition products should not be produced.

Section 11. Toxicological information

Information on toxicological effects

Acute toxicity

Product/ingredient name	Result	Species	Dose	Exposure
Progesterone	LD50 Oral	Rat	5,000mg/kg	-

Irritation/Corrosion

Not available.

Sensitization

Not available.

Mutagenicity

Not available.

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

Not available.

Teratogenicity

Not available.

Specific target organ toxicity (single exposure)

Not available.

Specific target organ toxicity (repeated exposure)

Not available.

Aspiration hazard

Not available.

Information on the likely routes of exposure:

Not available.

Potential acute health effects**Eye contact**

Exposure to airborne concentrations above statutory or recommended exposure limits may cause irritation of the eyes.

Inhalation

Exposure to airborne concentrations above statutory or recommended exposure limits may cause irritation of the nose, throat and lungs.

Skin contact

No known significant effects or critical hazards.

Ingestion

No known significant effects or critical hazards.

Symptoms related to the physical, chemical and toxicological characteristics

Eye contact: Adverse symptoms may include the following:
irritation
redness

Inhalation: Adverse symptoms may include the following:
respiratory tract irritation
coughing

Skin contact: No specific data.

Ingestion: No specific data.

Delayed and immediate effects and also chronic effects from short and long term exposure**Short term exposure**

Potential immediate effects: Not available.

Potential delayed effects: Not available.

Long term exposure

Potential immediate effects: Not available.

Potential delayed effects: Not available.

Potential chronic health effects

Not available.

General: Repeated or prolonged inhalation of dust may lead to chronic respiratory irritation.

Carcinogenicity: No known significant effects or critical hazards.

Mutagenic: No known significant effects or critical hazards.

Teratogenicity: No known significant effects or critical hazards.

Developmental effects: No known significant effects or critical hazards.

Fertility effects: No known significant effects or critical hazards.

Numerical measures of toxicity

Acute toxicity estimates

Not available.

Section 12. Ecological information

Toxicity

Not available.

Persistence and degradability

Not available.

Bioaccumulative potential

Not available.

Mobility in soil

Soil/water partition coefficient (K_{OC}): Not available.

Other adverse effects: No known significant effects or critical hazards.

Section 13. Disposal considerations

Disposal methods

The generation of waste should be avoided or minimized wherever possible. Disposal of this product, solutions and any by-products should at all times comply with the requirements of environmental protection and waste disposal legislation and any regional local authority requirements. Dispose of surplus and non-recyclable products via a licensed waste disposal contractor. Waste should not be disposed of untreated to the sewer unless fully compliant with the requirements of all authorities with jurisdiction. Waste packaging should be recycled. Incineration or landfill should only be considered when recycling is not feasible. This material and its container must be disposed of in a safe way. Care should be taken when handling emptied containers that have not been cleaned or rinsed out. Empty containers or liners may retain some product residues. Avoid dispersal of spilled material and runoff and contact with soil, waterways, drains and sewers.

Section 14. Transport information

	DOT Classification	TDG Classification	Mexico Classification	ADR/RID	IMDG	IATA
UN number	Not regulated.	Not regulated.	Not regulated.	Not regulated.	Not regulated.	Not regulated.
UN proper shipping name	-	-	-	-	-	-
Transport hazard class(es)	-	-	-	-	-	-
Packing group	-	-	-	-	-	-
Environmental hazards	NO.	NO.	NO.	NO.	NO.	NO.
Additional information	-	-	-	-	-	-

Special precautions for user

Transport within user's premises: always transport in closed containers that are upright and secure. Ensure that persons transporting the product know what to do in the event of an accident or spillage.

Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code
Not available.

Section 15. Regulatory information

U.S. Federal regulations:

TSCA 8(a) CDR Exempt/Partial exemption: Not determined.

United States inventory (TSCA 8b): Progesterone

Clean Air Act Section 112(b) Hazardous Air Pollutants (HAPs): Not listed.

Clean Air Act Section 602 Class I Substances: Not listed.

Clean Air Act Section 602 Class II Substances: Not listed.

DEA List I Chemicals (Precursor Chemicals) : Not listed.

DEA List II Chemicals (Essential Chemicals) : Not listed.

SARA 302/304

Composition/information on ingredients

No products were found.

SARA 304 RQ: Not applicable.

SARA 311/312

Classification: Fire hazard

Composition/information on ingredients

Name	%(w/w)	Fire hazard	Sudden release of	Reactive	Immediate (acute)	Delayed (chronic)

			pressure		health hazard	health hazard
Progesterone	97~103	Yes.	No.	No.	No.	No.

State regulations**Massachusetts:** Progesterone**New York:** Not determined.**New Jersey:** Progesterone**Pennsylvania:** Progesterone**International regulations****Chemical Weapon Convention List Schedules I, II & III Chemicals**

Not listed.

Montreal Protocol (Annexes A, B, C, E)

Not listed.

Stockholm Convention on Persistent Organic Pollutants

Not listed.

Rotterdam Convention on Prior Inform Consent (PIC)

Not listed.

UNECE Aarhus Protocol on POPs and Heavy Metals

Not listed.

International lists**National inventory****Australia:** Not determined.**Canada :** Not controlled under WHMIS.**China :** Not determined.**Europe:** This product is on the European Inventory of Existing Commercial Chemical Substances.**Japan:** Not determined.**Malaysia:** Not determined.**New Zealand:** Not determined.**Philippines:** Not determined.**Republic of Korea:** Not determined.**Taiwan:** Not determined.**Section 16. Other information****Hazardous Material Information System (U.S.A.)**

Health Hazard	1
Fire Hazard	1
Reactivity	0
Personal Protection	E

Caution: HMIS® ratings are based on a 0-4 rating scale, with 0 representing minimal hazards or risks, and 4 representing significant hazards or risks. Although HMIS® ratings are not required on SDSs under 29 CFR 1910.1200, the preparer may choose to provide them. HMIS® ratings are to be used with a fully implemented HMIS® program. HMIS® is a registered mark of the National Paint & Coatings Association (NPCA).

National Fire Protection Association (U.S.A.)



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Procedure used to derive the classification

Classification	Justification
Comb.Dusts CARCINOGENICITY-category 2	On basis of test data. Some evidence.

Key to abbreviations

ATE = Acute Toxicity Estimate

BCF = Bioconcentration Factor

GHS = Globally Harmonized System of Classification and Labelling of Chemicals

IATA = International Air Transport Association

IBC = Intermediate Bulk Container

IMDG = International Maritime Dangerous Goods

LogPow = logarithm of the octanol/water partition coefficient

MARPOL 73/78 = International Convention for the Prevention of Pollution From Ships, 1973 as modified by the Protocol of 1978. ("Marpol" = marine pollution)

UN = United Nations

Notice to reader

To the best of our knowledge, the information contained herein is accurate. However, neither the above-named supplier, nor any of its subsidiaries, assumes any liability whatsoever for the accuracy or completeness of the information contained herein.

Final determination of suitability of any material is the sole responsibility of the user. All materials may present unknown hazards and should be used with caution. Although certain hazards are described herein, we cannot guarantee that these are the only hazards that exist.

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