



# SAFETY DATA SHEET

## 1. Identification

|                                                        |                                                                           |                 |
|--------------------------------------------------------|---------------------------------------------------------------------------|-----------------|
| Product identifier                                     | Dydrogesterone                                                            |                 |
| Other means of identification                          |                                                                           |                 |
| Catalog number                                         | 1231003                                                                   |                 |
| CAS number                                             | 152-62-5                                                                  |                 |
| Chemical name                                          | 9β,10α-Pregna-4,6-diene-3,20-dione                                        |                 |
| Recommended use                                        | For analytical laboratory use only.                                       |                 |
| Recommended restrictions                               | Not for use as a drug. Not for administration to humans or animals.       |                 |
| Manufacturer/Importer/Supplier/Distributor information |                                                                           |                 |
| Manufacturer                                           |                                                                           |                 |
| Company name                                           | U. S. Pharmacopeia                                                        |                 |
| Address                                                | 12601 Twinbrook Parkway<br>Rockville<br>MD<br>20852-1790<br>United States |                 |
| Telephone                                              | Technical Services                                                        | 301-816-8129    |
| Website                                                | www.usp.org                                                               |                 |
| E-mail                                                 | RSTECH@usp.org                                                            |                 |
| Emergency phone number                                 | CHEMTREC within US & Canada                                               | 1-800-424-9300  |
|                                                        | CHEMTREC outside US & Canada                                              | +1 703-527-3887 |

## 2. Hazard(s) identification

|                              |                                   |             |
|------------------------------|-----------------------------------|-------------|
| <b>Physical hazards</b>      | Not classified.                   |             |
| <b>Health hazards</b>        | Serious eye damage/eye irritation | Category 2B |
|                              | Carcinogenicity                   | Category 2  |
|                              | Reproductive toxicity             | Category 1  |
| <b>Environmental hazards</b> | Not classified.                   |             |
| <b>OSHA defined hazards</b>  | Not classified.                   |             |
| <b>Label elements</b>        |                                   |             |



|                                                  |                                                                                                                                                                                                                                                   |
|--------------------------------------------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <b>Signal word</b>                               | Danger                                                                                                                                                                                                                                            |
| <b>Hazard statement</b>                          | Causes eye irritation. Suspected of causing cancer. May damage fertility or the unborn child.                                                                                                                                                     |
| <b>Precautionary statement</b>                   |                                                                                                                                                                                                                                                   |
| <b>Prevention</b>                                | Obtain special instructions before use. Do not handle until all safety precautions have been read and understood. Wash thoroughly after handling. Wear protective gloves/protective clothing/eye protection/face protection.                      |
| <b>Response</b>                                  | If in eyes: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. If eye irritation persists: Get medical advice/attention. If exposed or concerned: Get medical advice/attention. |
| <b>Storage</b>                                   | Store locked up.                                                                                                                                                                                                                                  |
| <b>Disposal</b>                                  | Dispose of contents/container in accordance with local/regional/national/international regulations.                                                                                                                                               |
| <b>Hazard(s) not otherwise classified (HNOC)</b> | This product is supplied in a small quantity which does not constitute a combustible dust hazard. The physical properties of this material indicate that in large quantities accumulated dust may be hazardous.                                   |

### 3. Composition/information on ingredients

#### Substance

| Chemical name  | Common name and synonyms | CAS number | %   |
|----------------|--------------------------|------------|-----|
| Dydrogesterone |                          | 152-62-5   | 100 |

### 4. First-aid measures

|                                                                        |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                        |
|------------------------------------------------------------------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Inhalation                                                             | Move to fresh air. Call a physician if symptoms develop or persist.                                                                                                                                                                                                                                                                                                                                                                                                                                                                    |
| Skin contact                                                           | Wash off with soap and water. Get medical attention if irritation develops and persists.                                                                                                                                                                                                                                                                                                                                                                                                                                               |
| Eye contact                                                            | Immediately flush eyes with plenty of water for at least 15 minutes. Remove contact lenses, if present and easy to do. Continue rinsing. Get medical attention if irritation develops and persists.                                                                                                                                                                                                                                                                                                                                    |
| Ingestion                                                              | Rinse mouth. Get medical attention if symptoms occur.                                                                                                                                                                                                                                                                                                                                                                                                                                                                                  |
| Most important symptoms/effects, acute and delayed                     | Reproductive system effects. Potent pharmacologically active material. Occupational exposure to small amounts may cause physiological effects.                                                                                                                                                                                                                                                                                                                                                                                         |
| Indication of immediate medical attention and special treatment needed | Provide general supportive measures and treat symptomatically. Single acute overdose of progestins will seldom result in toxicity. Supportive treatment is adequate in most situations. In chronic toxicity, obtain a baseline CBC, hepatic and renal function tests, and treat symptomatically.                                                                                                                                                                                                                                       |
| General information                                                    | Remove from exposure. Remove contaminated clothing. For treatment advice, seek guidance from an occupational health physician or other licensed health-care provider familiar with workplace chemical exposures. In the United States, the national poison control center phone number is 1-800-222-1222. If person is not breathing, give artificial respiration. If breathing is difficult, give oxygen if available. Persons developing serious hypersensitivity (anaphylactic) reactions must receive immediate medical attention. |

### 5. Fire-fighting measures

|                                                               |                                                                                                                                                                                        |
|---------------------------------------------------------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Suitable extinguishing media                                  | Water. Foam. Dry chemical or CO2. Use fire-extinguishing media appropriate for surrounding materials.                                                                                  |
| Unsuitable extinguishing media                                | None known.                                                                                                                                                                            |
| Specific hazards arising from the chemical                    | Explosion hazard: 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.       |
| Special protective equipment and precautions for firefighters | Wear suitable protective equipment.                                                                                                                                                    |
| Fire fighting equipment/instructions                          | Use water spray to cool unopened containers. As with all fires, evacuate personnel to a safe area. Firefighters should use self-contained breathing equipment and protective clothing. |
| Specific methods                                              | Use standard firefighting procedures and consider the hazards of other involved materials.                                                                                             |
| General fire hazards                                          | No unusual fire or explosion hazards noted.                                                                                                                                            |

### 6. Accidental release measures

|                                                                     |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                          |
|---------------------------------------------------------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Personal precautions, protective equipment and emergency procedures | Keep unnecessary personnel away. 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. Wear appropriate protective equipment and clothing during clean-up. Avoid inhalation of dust from the spilled material. Do not touch damaged containers or spilled material unless wearing appropriate protective clothing. Ensure adequate ventilation. For personal protection, see section 8 of the SDS. |
| Methods and materials for containment and cleaning up               | Avoid the generation of dusts during clean-up. Sweep up or vacuum up spillage and collect in suitable container for disposal. Clean surface thoroughly to remove residual contamination. For waste disposal, see section 13 of the SDS.                                                                                                                                                                                                                                                                                  |
| Environmental precautions                                           | Avoid discharge into drains, water courses or onto the ground.                                                                                                                                                                                                                                                                                                                                                                                                                                                           |

## 7. Handling and storage

### Precautions for safe handling

As a general rule, when handling USP materials, avoid all contact and inhalation of dust, mists, and/or vapors associated with the material. Clean equipment and work surfaces with suitable detergent or solvent after use. After removing gloves, wash hands and other exposed skin thoroughly. Use of a designated area is recommended for handling of potent materials. Avoid significant deposits of material, especially on horizontal surfaces, which may become airborne and form combustible dust clouds and may contribute to secondary explosions. Combustible dust clouds may be created where operations produce fine material (dust). Select and use containment devices and personal protective equipment based on a risk assessment of material potency and exposure potential.

### Conditions for safe storage, including any incompatibilities

Store in tight container. This material should be handled and stored per label instructions to ensure product integrity.

## 8. Exposure controls/personal protection

### Occupational exposure limits

The following constituents are the only constituents of the product which have a PEL, TLV or other recommended exposure limit. At this time, the other constituents have no known exposure limits.

### Exposure limit values

| Industrial Use Material | Type | Value |
|-------------------------|------|-------|
|-------------------------|------|-------|

|                               |     |                   |
|-------------------------------|-----|-------------------|
| Dydrogesterone (CAS 152-62-5) | TWA | 2.5 micrograms/m3 |
|-------------------------------|-----|-------------------|

### Biological limit values

No biological exposure limits noted for the ingredient(s).

### Appropriate engineering controls

No open handling. For laboratory operations, use approved ventilation or containment system (biological safety cabinet, ventilated balance enclosure, glovebox). Control exposures to below the occupational exposure level (if available). Select and use containment devices and personal protective equipment based on a risk assessment of exposure potential. Cover all containers for solutions and slurries while being transferred.

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

#### Eye/face protection

Wear safety glasses with side shields, chemical splash goggles, or full face shield, if necessary. Base the choice of protection on the job activity and potential for contact with eyes or face. An emergency eye wash station should be available.

#### Skin protection

##### Hand protection

Consider double gloves. Wear nitrile or other impervious gloves if skin contact is possible. When the material is dissolved or suspended in an organic solvent, wear gloves that provide protection against the solvent.

##### Other

Train employees in proper gowning and degowning practices. Wear disposable lab coat, disposable sleeve covers and two pair of gloves as appropriate for the task. Base the choice of skin protection on the job activity, potential for skin contact and solvents and reagents in use. Do not wear protective garments in common areas (e.g., cafeterias) or out-of-doors.

#### Respiratory protection

Use a powered air-purifying respirator (PAPR) with HEPA filters, disposable outerware and head cover for spill cleanup. Choose respiratory protection appropriate to the task and the level of existing engineering controls.

#### Thermal hazards

Wear appropriate thermal protective clothing, when necessary.

### General hygiene considerations

Pharmacological effects may be seen with occupational exposure. Handling practices in this SDS are recommendations for laboratory use of USP materials.

## 9. Physical and chemical properties

### Appearance

Appearance descriptions are general information and not specific to any USP lot.

#### Physical state

Solid.

#### Form

Solid.

#### Color

White. Off-white.

### Odor

Odorless or almost odorless.

### Odor threshold

Not available.

### pH

Not available.

### Melting point/freezing point

336.2 - 338 °F (169 - 170 °C)

### Initial boiling point and boiling range

Not available.

|                                                     |                                                                                                |
|-----------------------------------------------------|------------------------------------------------------------------------------------------------|
| <b>Flash point</b>                                  | Not available.                                                                                 |
| <b>Evaporation rate</b>                             | Not available.                                                                                 |
| <b>Flammability (solid, gas)</b>                    | Not available.                                                                                 |
| <b>Upper/lower flammability or explosive limits</b> |                                                                                                |
| <b>Flammability limit - lower (%)</b>               | Not available.                                                                                 |
| <b>Flammability limit - upper (%)</b>               | Not available.                                                                                 |
| <b>Explosive limit - lower (%)</b>                  | Not available.                                                                                 |
| <b>Explosive limit - upper (%)</b>                  | Not available.                                                                                 |
| <b>Vapor pressure</b>                               | 0.0000001 kPa (77 °F (25 °C))                                                                  |
| <b>Vapor density</b>                                | Not available.                                                                                 |
| <b>Relative density</b>                             | Not available.                                                                                 |
| <b>Solubility(ies)</b>                              |                                                                                                |
| <b>Solubility (water)</b>                           | Practically insoluble.                                                                         |
| <b>Solubility (other)</b>                           | Ethanol: Soluble.<br>Chloroform: Soluble.<br>Acetone: Soluble.<br>Methanol: Sparingly soluble. |
| <b>Partition coefficient (n-octanol/water)</b>      | 3.45                                                                                           |
| <b>Auto-ignition temperature</b>                    | Not available.                                                                                 |
| <b>Decomposition temperature</b>                    | Not available.                                                                                 |
| <b>Viscosity</b>                                    | Not available.                                                                                 |
| <b>Other information</b>                            |                                                                                                |
| <b>Chemical family</b>                              | Steroid.                                                                                       |
| <b>Dust explosion properties</b>                    |                                                                                                |
| <b>Kst</b>                                          | 326 bar.m/s                                                                                    |
| <b>St class</b>                                     | 3 Very strong explosion.                                                                       |
| <b>Minimum ignition energy (MIE) - dust cloud</b>   | 3 mJ                                                                                           |
| <b>Molecular formula</b>                            | C21-H28-O2                                                                                     |
| <b>Molecular weight</b>                             | 312.45 g/mol                                                                                   |
| <b>Potential for dust explosion</b>                 | Very strong dust deflagration hazard. Very sensitive to ignition by electrostatic discharge.   |

## 10. Stability and reactivity

|                                           |                                                                                                                           |
|-------------------------------------------|---------------------------------------------------------------------------------------------------------------------------|
| <b>Reactivity</b>                         | The product is stable and non-reactive under normal conditions of use, storage and transport.                             |
| <b>Chemical stability</b>                 | Stable at normal conditions.                                                                                              |
| <b>Possibility of hazardous reactions</b> | No dangerous reaction known under conditions of normal use.                                                               |
| <b>Conditions to avoid</b>                | Heat, flames and sparks. Avoid temperatures exceeding the decomposition temperature. Contact with incompatible materials. |
| <b>Incompatible materials</b>             | Oxidizing agents.                                                                                                         |
| <b>Hazardous decomposition products</b>   | Irritating and/or toxic fumes or gases. Emits toxic fumes under fire conditions.                                          |

## 11. Toxicological information

### Information on likely routes of exposure

|                     |                                                                                        |
|---------------------|----------------------------------------------------------------------------------------|
| <b>Inhalation</b>   | Knowledge about health hazard is incomplete.                                           |
| <b>Skin contact</b> | Based on information from therapeutic use, this material may cause: Endocrine effects. |
| <b>Eye contact</b>  | Causes eye irritation.                                                                 |
| <b>Ingestion</b>    | Based on information from therapeutic use, this material may cause: Endocrine effects. |

**Symptoms related to the physical, chemical and toxicological characteristics**

For progestins: Breast enlargement, pain, or tenderness. Hot flashes. Mood or mental changes. Headache. Gastrointestinal disturbances. Joint pain.

**Information on toxicological effects****Acute toxicity**

| Product                       | Species | Test Results |
|-------------------------------|---------|--------------|
| Dydrogesterone (CAS 152-62-5) |         |              |
| <b>Oral</b>                   |         |              |
| LD50                          | Rat     | > 4600 mg/kg |

**Skin corrosion/irritation**

Based on available data, the classification criteria are not met.

**Serious eye damage/eye irritation**

Causes eye irritation.

**Local effects**

Eye irritation  
Result: Irritant, reversible after 48 hours.  
Species: Rabbit  
Severity: Mild.  
Skin irritation  
Result: Negative.  
Species: Rabbit

**Respiratory or skin sensitization****Respiratory sensitization**

Knowledge about health hazard is incomplete.

**Skin sensitization**

Knowledge about health hazard is incomplete.

**Germ cell mutagenicity**

Knowledge about mutagenicity is incomplete.

**Carcinogenicity**

Suspected of causing cancer. Progestins are suspected to be a human carcinogen based on evidence from animal studies.

**IARC Monographs. Overall Evaluation of Carcinogenicity**

Dydrogesterone (CAS 152-62-5) 2B Possibly carcinogenic to humans.

**OSHA Specifically Regulated Substances (29 CFR 1910.1001-1053)**

Not listed.

**US. National Toxicology Program (NTP) Report on Carcinogens**

Not listed.

**Reproductive toxicity**

May damage fertility or the unborn child. Progestins may inhibit male and female fertility.

**Specific target organ toxicity - single exposure**

Knowledge about health hazard is incomplete.

**Specific target organ toxicity - repeated exposure**

Knowledge about health hazard is incomplete.

**Aspiration hazard**

Based on available data, the classification criteria are not met.

**Further information**

Potent pharmacologically active material. Occupational exposure to small amounts may cause physiological effects.

**12. Ecological information****Ecotoxicity**

Toxic to aquatic organisms.

| Product                       | Species            | Test Results       |
|-------------------------------|--------------------|--------------------|
| Dydrogesterone (CAS 152-62-5) |                    |                    |
| <b>Aquatic</b>                |                    |                    |
| Crustacea                     | EC50 Daphnia magna | 5.2 mg/l, 48 hours |

**Persistence and degradability**

Not readily biodegradable.

**Bioaccumulative potential****Octanol/water partition coefficient log Kow**

3.45

**Mobility in soil**

No data available.

**Other adverse effects**

No other adverse environmental effects (e.g. ozone depletion, photochemical ozone creation potential, endocrine disruption, global warming potential) are expected from this component.

### 13. Disposal considerations

|                                              |                                                                                                                                                                                                                            |
|----------------------------------------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <b>Disposal instructions</b>                 | Dispose in accordance with all applicable regulations. Under RCRA, it is the responsibility of the user of the product to determine, at the time of disposal, whether the product meets RCRA criteria for hazardous waste. |
| <b>Local disposal regulations</b>            | Dispose in accordance with all applicable regulations.                                                                                                                                                                     |
| <b>Hazardous waste code</b>                  | The waste code should be assigned in discussion between the user, the producer and the waste disposal company.                                                                                                             |
| <b>Waste from residues / unused products</b> | Empty containers or liners may retain some product residues. This material and its container must be disposed of in a safe manner (see: Disposal instructions).                                                            |
| <b>Contaminated packaging</b>                | Since emptied containers may retain product residue, follow label warnings even after container is emptied.                                                                                                                |

### 14. Transport information

#### DOT

|                                   |                                                                     |
|-----------------------------------|---------------------------------------------------------------------|
| <b>UN number</b>                  | UN3077                                                              |
| <b>UN proper shipping name</b>    | Environmentally hazardous substance, solid, n.o.s. (Dydrogesterone) |
| <b>Transport hazard class(es)</b> |                                                                     |
| <b>Class</b>                      | 9                                                                   |
| <b>Subsidiary risk</b>            | -                                                                   |
| <b>Packing group</b>              | III                                                                 |

#### IATA

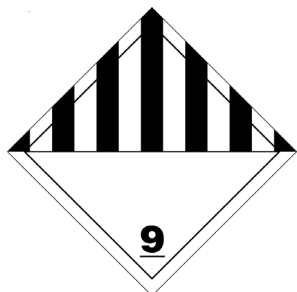
|                                   |                                                                     |
|-----------------------------------|---------------------------------------------------------------------|
| <b>UN number</b>                  | UN3077                                                              |
| <b>UN proper shipping name</b>    | Environmentally hazardous substance, solid, n.o.s. (Dydrogesterone) |
| <b>Transport hazard class(es)</b> |                                                                     |
| <b>Class</b>                      | 9                                                                   |
| <b>Subsidiary risk</b>            | -                                                                   |
| <b>Packing group</b>              | III                                                                 |
| <b>Other information</b>          |                                                                     |

**Passenger and cargo aircraft**      Allowed with restrictions.

**Cargo aircraft only**              Allowed with restrictions.

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

#### DOT; IATA



**General information**      It is the shipper's responsibility to determine the correct transport classification at the time of shipment.

### 15. Regulatory information

**US federal regulations**      This product is a "Hazardous Chemical" as defined by the OSHA Hazard Communication Standard, 29 CFR 1910.1200.

#### Toxic Substances Control Act (TSCA)

##### TSCA Section 12(b) Export Notification (40 CFR 707, Subpt. D)

Not regulated.

#### CERCLA Hazardous Substance List (40 CFR 302.4)

Not listed.

#### SARA 304 Emergency release notification

Not regulated.

**OSHA Specifically Regulated Substances (29 CFR 1910.1001-1053)**

Not listed.

**Superfund Amendments and Reauthorization Act of 1986 (SARA)****SARA 302 Extremely hazardous substance**

Not listed.

**SARA 311/312 Hazardous chemical**

|                                     |                                      |
|-------------------------------------|--------------------------------------|
| <b>Classified hazard categories</b> | Yes                                  |
|                                     | Serious eye damage or eye irritation |
|                                     | Carcinogenicity                      |
|                                     | Reproductive toxicity                |

**SARA 313 (TRI reporting)**

Not regulated.

**Other federal regulations****Clean Air Act (CAA) Section 112 Hazardous Air Pollutants (HAPs) List**

Not regulated.

**Clean Air Act (CAA) Section 112(r) Accidental Release Prevention (40 CFR 68.130)**

Not regulated.

**Safe Drinking Water Act (SDWA)**

Not regulated.

**US state regulations****California Proposition 65**

California Safe Drinking Water and Toxic Enforcement Act of 1986 (Proposition 65): This material is not known to contain any chemicals currently listed as carcinogens or reproductive toxins. For more information go to [www.P65Warnings.ca.gov](http://www.P65Warnings.ca.gov).

**International Inventories**

| Country(s) or region        | Inventory name                                                         | On inventory (yes/no)* |
|-----------------------------|------------------------------------------------------------------------|------------------------|
| Australia                   | Australian Inventory of Chemical Substances (AICS)                     | No                     |
| Canada                      | Domestic Substances List (DSL)                                         | No                     |
| Canada                      | Non-Domestic Substances List (NDSL)                                    | No                     |
| China                       | Inventory of Existing Chemical Substances in China (IECSC)             | No                     |
| Europe                      | European Inventory of Existing Commercial Chemical Substances (EINECS) | Yes                    |
| Europe                      | European List of Notified Chemical Substances (ELINCS)                 | No                     |
| Japan                       | Inventory of Existing and New Chemical Substances (ENCS)               | Yes                    |
| Korea                       | Existing Chemicals List (ECL)                                          | No                     |
| New Zealand                 | New Zealand Inventory                                                  | No                     |
| Philippines                 | Philippine Inventory of Chemicals and Chemical Substances (PICCS)      | No                     |
| Taiwan                      | Taiwan Chemical Substance Inventory (TCSI)                             | No                     |
| United States & Puerto Rico | Toxic Substances Control Act (TSCA) Inventory                          | No                     |

\*A "Yes" indicates that all components of this product comply with the inventory requirements administered by the governing country(s)

A "No" indicates that one or more components of the product are not listed or exempt from listing on the inventory administered by the governing country(s).

**16. Other information, including date of preparation or last revision**

|                            |                                                                                                                                                                                   |
|----------------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <b>Issue date</b>          | 12-21-2004                                                                                                                                                                        |
| <b>Revision date</b>       | 07-19-2021                                                                                                                                                                        |
| <b>Version #</b>           | 03                                                                                                                                                                                |
| <b>Further information</b> | Refer to NFPA 654, Standard for the Prevention of Fire and Dust Explosions from the Manufacturing, Processing, and Handling of Combustible Particulate Solids, for safe handling. |

**Disclaimer**

USP materials are sold for analytical laboratory use only, and NOT for human consumption. The information contained herein is applicable solely to the chemical substance when used for analytical laboratory use and does not necessarily relate to any other use of the substance described, (i.e. at different concentrations, in drug dosage forms, or in bulk quantities). USP materials are intended for use by persons having technical skill and at their own discretion and risk. This information has been developed by USP staff from sources considered reliable but has not been independently verified by the USP. Therefore, the USP Convention cannot guarantee the accuracy of the information in these sources nor should the statements contained herein be considered an official expression. NO REPRESENTATION OR WARRANTY, EXPRESS OR IMPLIED, INCLUDING THE WARRANTIES OF MERCHANTABILITY AND FITNESS FOR A PARTICULAR PURPOSE is made with respect to the information contained herein.