SAFETY DATA SHEET



1. Identification

Product identifier Desogestrel Related Compound A

Other means of identification

Catalog number 1173246 201360-82-9 **CAS** number

Synonyms Desogestrel delta-3 isomer

Chemical name 13-Ethyl-11-methylene-18,19-dinor-5alpha, 17alpha-pregn-3-en-20-yn-17-ol

Recommended use Specified quality tests and assay use only.

Not for use as a drug. Not for administration to humans or animals. **Recommended restrictions**

Manufacturer/Importer/Supplier/Distributor information

Manufacturer

Company name U. S. Pharmacopeia **Address** 12601 Twinbrook Parkway

> Rockville MD 20852-1790 **United States**

Telephone RS Technical Services 301-816-8129

Website www.usp.org E-mail RSTECH@usp.org

Emergency phone number CHEMTREC within US & 1-800-424-9300

Canada

CHEMTREC outside US & +1 703-527-3887

Canada

2. Hazard(s) identification

Physical hazards Not classified.

Health hazards Carcinogenicity Category 2 Reproductive toxicity Category 1

Environmental hazards Not classified. **OSHA** defined hazards Not classified.

Label elements



Signal word

Hazard statement Suspected of causing cancer. May damage fertility or the unborn child.

Precautionary statement

Prevention Obtain special instructions before use. Do not handle until all safety precautions have been read

and understood. Wear protective gloves/protective clothing/eye protection/face protection.

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

Store locked up. Storage

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

Hazard(s) not otherwise

classified (HNOC)

None known.

Supplemental information Pharmaceutical related compound of unknown potency.

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3. Composition/information on ingredients

Substance

Chemical name	Common name and synonyms	CAS number	%
Desogestrel Related Compound A	Desogestrel delta-3 isomer	201360-82-9	100

4. First-aid measures

Inhalation Move to fresh air. Call a physician if symptoms develop or persist.

Wash off with soap and water. Get medical attention if irritation develops and persists. Skin contact

Eye contact Rinse with water. Get medical attention if irritation develops and persists.

Rinse mouth. Get medical attention if symptoms occur. Ingestion

Most important symptoms/effects, acute and

delayed

Indication of immediate

Provide general supportive measures and treat symptomatically.

if occupational exposure may cause physiological effects.

medical attention and special treatment needed

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.

Endocrine system effects. Pharmaceutical related compound of unknown potency. It is not known

5. Fire-fighting measures

Water. Foam. Dry chemical or CO2. Use fire-extinguishing media appropriate for surrounding Suitable extinguishing media

materials

Unsuitable extinguishing

media

None known.

Specific hazards arising from

the chemical

No unusual fire or explosion hazards noted.

Special protective equipment and precautions for firefighters

Wear suitable protective equipment.

Fire fighting

equipment/instructions

Specific methods

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.

Use standard firefighting procedures and consider the hazards of other involved materials.

No unusual fire or explosion hazards noted. General fire hazards

6. Accidental release measures

Personal precautions, protective equipment and emergency procedures

Keep unnecessary personnel away. Wear appropriate personal protective equipment. 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 Reference Standards, 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. 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 as defined in the USP-NF. This material should be handled and stored per label instructions to ensure product integrity.

8. Exposure controls/personal protection

Occupational exposure limits **Biological limit values**

No exposure limits noted for ingredient(s).

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

Material name: Desogestrel Related Compound A

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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

Consider double gloves. Wear nitrile or other impervious gloves if skin contact is possible. When Hand protection

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.

Use a powered air-purifying respirator (PAPR) with HEPA filters, disposable outerware and head Respiratory protection

cover for spill cleanup. Choose respiratory protection appropriate to the task and the level of

existing engineering controls.

Wear appropriate thermal protective clothing, when necessary. Thermal hazards

General hygiene considerations

Pharmacological effects may be seen with occupational exposure. Handling practices in this SDS are recommendations for laboratory use of reference standards. Procedures for any other uses or quantities should be determined after an appropriate assessment.

9. Physical and chemical properties

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

Solid. Physical state Powder. **Form** Color White.

Not available. Odor **Odor threshold** Not available. Not available. Ha Melting point/freezing point Not available. Not available. Initial boiling point and boiling

range

Not available. Flash point **Evaporation rate** Not available. Flammability (solid, gas) Not available. Upper/lower flammability or explosive limits

Flammability limit - lower

(%)

Not available.

Flammability limit - upper

Not available.

Not available.

Explosive limit - lower (%) Not available. Explosive limit - upper (%) Vapor pressure Not available. Not available. Vapor density Relative density Not available.

Solubility(ies)

Not available. Solubility (water) Not available. **Auto-ignition temperature** Not available. **Decomposition temperature Viscosity** Not available.

Other information

Molecular formula C22H30O

USP SDS US

Molecular weight 310.48

10. Stability and reactivity

Reactivity The product is stable and non-reactive under normal conditions of use, storage and transport.

Material is stable under normal conditions. Chemical stability

Possibility of hazardous

reactions

No dangerous reaction known under conditions of normal use.

Conditions to avoid Contact with incompatible materials.

Incompatible materials Strong oxidizing agents.

Hazardous decomposition

products

Irritating and/or toxic fumes or gases. Emits toxic fumes under fire conditions.

11. Toxicological information

Information on likely routes of exposure

Inhalation Knowledge about health hazard is incomplete.

Skin contact Based on a related compound, this material may cause: Endocrine effects.

Eye contact Knowledge about health hazard is incomplete.

Based on a related compound, this material may cause: Endocrine effects. Ingestion

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. It is not known if this material causes the

same effects.

Information on toxicological effects

Not known. **Acute toxicity**

Knowledge about health hazard is incomplete. Skin corrosion/irritation Knowledge about health hazard is incomplete. Serious eye damage/eye

irritation

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

Not listed.

OSHA Specifically Regulated Substances (29 CFR 1910.1001-1053)

Not listed.

US. National Toxicology Program (NTP) Report on Carcinogens

Not listed.

May damage fertility or the unborn child. For progestins: Exposure during early pregnancy may Reproductive toxicity

lead to chromosomal abnormalities and congenital malformations, including genital abnormalities.

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 Pharmaceutical related compound of unknown potency. It is not known if occupational exposure

may cause physiological effects.

12. Ecological information

Ecotoxicity The product is not classified as environmentally hazardous. However, this does not exclude the

possibility that large or frequent spills can have a harmful or damaging effect on the environment.

No data is available on the degradability of this substance. Persistence and degradability

Bioaccumulative potential No data available. 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

Disposal instructions

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.

Local disposal regulations

Hazardous waste code

Dispose in accordance with all applicable regulations.

The waste code should be assigned in discussion between the user, the producer and the waste

disposal company.

Waste from residues / unused

products

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).

Contaminated packaging Since emptied containers may retain product residue, follow label warnings even after container is

emptied.

14. Transport information

DOT

UN number

UN3077

9

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UN proper shipping name Transport hazard class(es)

nsport hazard class(es) Class

Subsidiary risk
Packing group

IATA

UN number

UN3077

UN proper shipping name Transport hazard class(es) Environmentally hazardous substance, n.o.s. (Desogestrel delta-3 isomer)

Environmentally hazardous substance, n.o.s. (Desogestrel delta-3 isomer)

Class 9
Subsidiary risk Packing group III

Other information

Passenger and cargo

aircraft

Cargo aircraft only

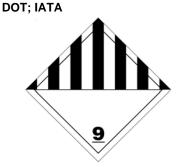
Transport in bulk according to Annex II of MARPOL 73/78 and

the IBC Code

Allowed with restrictions.

Allowed with restrictions.

Not applicable.



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.

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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

Yes

chemical

Carcinogenicity Classified hazard Reproductive toxicity categories

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

Not regulated.

(SDWA)

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.

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)	No
Europe	European List of Notified Chemical Substances (ELINCS)	No
Japan	Inventory of Existing and New Chemical Substances (ENCS)	No
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)

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

Issue date 02-02-2005 12-14-2020 **Revision date**

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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).

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