SAFETY DATA SHEET

Print date December 15, 2021

Section 1. Identifications

Product name: Drospirenone Impurity 14
TLC ID: D-128
Product Use: For laboratory use only. Not for use in humans or animals, drug, household or other use.
Supplier/Manufacturer:

TLC Pharmaceutical Standards Ltd.
130 Pony Drive
Newmarket, ON, L3Y 7B6, Canada
Telephone: (905)-898-3645 Fax: (905)-898-0595
Website: www.tlcstandards.com

Section 2. Hazards identifications

Physical state: Solid
Warning: Harmful if swallowed, inhaled or in contact with skin.
Routes of entry: Inhalation, skin, eyes

GHS classification:

Skin irritation (Category 2)
Serious eye damage/eye irritation (Category 2)
Acute toxicity, oral (Category 4)
Acute toxicity, dermal (Category 4)
Acute toxicity, inhalation (Category 4)

GHS Label elements, including precautionary statements

Pictogram(s):

Signal word: Warning

Hazards statements:
H302 +H312 +H332 Harmful if swallowed, in contact with skin or if inhaled.
H315 Causes skin irritation.
H319 Causes serious eye irritation.

Precautionary statements:
P261 Avoid breathing dust/fume/gas/mist/vapours/spray.
P271 Use only outdoors or in a well-ventilated area.
P280 Wear protective gloves/protective clothing/eye protection/face protection.
P302+P352 IF ON SKIN: wash with plenty of soap and water.
P305+P351+P338 IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.

Section 3. Composition/ Information on Ingredients

CAS No.: 863329-71-9
Molecular Formula: C24H32O3
Molecular Weight: 368.52
Synonyms: (4aR,4bS,6aS,7S,7aS,8aS,8bS,8cR,8dR,9aR)-5'-hydroxy-4a,6a-dimethyl-4,4a,4b,4',5,5',6,6a,7a,8,8a,8b,8c,8d,9,9a-hexadecahydro-3'H-spiro[cyclopropa[4,5]cyclopenta[1,2-a]cyclopropa[l]phenanthrene-7,2'-furan]-2(3H)-one

Section 4. First-aid measures

General
Consult a physician. Show this safety data sheet to the doctor in attendance. Move out of dangerous area.

If inhaled
If breathed in, move person into fresh air. If not breathing, give artificial respiration. Consult a physician.

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

In case of skin contact
Wash off with soap and plenty of water. Consult a physician.

If swallowed
Do NOT induce vomiting. Never give anything by mouth to an unconscious person. Rinse mouth with water. Consult a physician.

Section 5. Firefighting measures

Conditions of flammability
Not flammable or combustible.

Suitable extinguishing media
Use water spray, alcohol-resistant foam, dry chemical or carbon dioxide.

Hazardous combustion products
Hazardous decomposition products formed under fire conditions: carbon oxides, sodium oxides, nitrogen oxides

Special firefighting procedures
Wear self-contained breathing apparatus and protective clothing.

Section 6. Accidental release measures

Personal precautions
Wear respiratory protection. Avoid dust formation. Avoid breathing vapours, mist or gas. Ensure adequate ventilation. Evacuate personnel to safe areas. Avoid breathing dust.

Environmental precautions
Prevent further leakage or spillage if safe to do so. Do not let product enter drains. Method and materials for containment and cleaning up

Method and materials for containment and cleaning up
Pick up and arrange disposal without creating dust. Sweep up and shovel. Keep in suitable, closed containers for disposal.

Section 7. Handling and storage

Handling
Avoid contact with skin and eyes. Avoid formation of dust and aerosols. Provide appropriate exhaust ventilation at places where dust is formed. Keep away from sources of ignition. Take measures to prevent the buildup of electrostatic charge.

Storage
Keep refrigerated as specification of Certificate of Analysis. Keep container tightly closed in a dry and well-ventilated place.

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Section 8. Exposure controls/personal protection

Engineering controls
Use mechanical exhaust or laboratory fumehood to avoid exposure.

Personal protective equipment
Respiratory protection
Where risk assessment shows air-purifying respirators are appropriate use a full-face respirator with multi-purpose combination (US) or type ABEK (EN 14387) 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)

Hand Protection
Handle with chemical-resistant gloves, solvent-resistant gloves. Gloves must be inspected prior to use. Dispose of contaminated gloves after use in accordance with applicable laws and good laboratory practices. Wash and dry hands.

Eye Protection
Face shield and safety glasses Use equipment for eye protection tested and approved under appropriate government standards such as NIOSH (US) or EN 166(EU).

Skin and body protection
Complete suit protecting against chemicals, flame retardant antistatic protective clothing. The type of protective equipment must be selected according to the concentration and amount of the dangerous substance at the specific workplace.

Section 9. Physical and chemical properties

Physical property: Solid
Colour: White to off-white
Odour: No data available
Density: No data available
Melting Point/Freezing Point(°C): No data available
Flash Point (°C): No data available
Explosive Properties: No data available
Oxidizing Properties: No data available
Water solubility: No data available
Solubility (other solvents): Methanol, DMSO

Section 10. Stability and reactivity

Reactivity: No data available.
Chemical stability: Stable under recommended storage conditions.
Conditions to avoid: Heat, flames and sparks. Extremes of temperature and direct sunlight.
Materials to avoid: oxidizing agents.
Hazardous decomposition products: possible products formed under fire conditions: Carbon oxides.

Section 11. Toxicological information

Acute toxicity
Oral LD50: No data available. Inhalation**.**
LC50: No data available.
Dermal LD50: No data available.
Skin Corrosion/Irritation: Toxic if absorbed through skin. May cause skin irritation.
Eyes: May cause eye irritation.

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Acute and Chronic Health hazards: TLV: None verified.
Effects of Overexposure: May causes eye, respiratory, and skin irritation. May be harmful by inhalation, ingestion, or skin absorption.
To the best of our knowledge, the chemical, physical, and toxicological properties have not been thoroughly investigated

Section 12. Ecological information

No data available**.**

Section 13. Disposal considerations

Product
Burn in a chemical incinerator equipped with an afterburner and scrubber but exert extra care in igniting as this material is highly flammable. Offer surplus and non-recyclable solutions to a licensed disposal company. Contact a licensed professional waste disposal service to dispose of this material.

Contaminated packaging
Dispose of as unused product.

Section 14. Transport information

Non-hazardous for transport. IATA - Not regulated

Section 15. Regulatory information

TLV: None verified

Section 16. Other information

This product is not bioactive, not radioactive. It is for R&D use only. Not for drug, household or other uses.
The above information is believed to be correct but does not purport to be all inclusive and shall be used only as a guide. TLC Pharmaceutical Standards Ltd. extends no warranties with respect hereto and disclaims all liabilities from reliance thereon. All judgments as to the suitability of the data presented with respect to the use of this product are the responsibility of the purchaser and intended user.

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