

PROGESTERONE

GHS Safety Data Sheet

Version No:4

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Section 1 - CHEMICAL PRODUCT AND COMPANY IDENTIFICATION

PRODUCT NAME

PROGESTERONE

OTHER NAMES

C21-H30-O2, "delta(sup 4)-pregnene-3, 20-dione", "delta(sup 4)-pregnene-3, 20-dione", "3, 20-pregnene-4", "3, 20-pregnene-4", pregnenedione, "pregnene-3, 20-dione", "pregnene-3, 20-dione", "pregn-4-ene-3, 20-dione", "pregn-4-ene-3, 20-dione", "4-pregnene-3, 20-dione", "4-pregnene-3, 20-dione", progesterol, beta-progesterone, progesteronum, progestin, progestone,

PRODUCT USE

Progesterone is the main hormone of the corpus luteum and the placenta. It acts upon the endometrium by converting the proliferative phase induced by oestrogen to a secretory phase ready for receipt of the fertilised ovum by the uterus. Also suppresses uterine motility and is responsible for enlargement of breasts. Used, therapeutically, in the treatment of functional uterine bleeding, for menstrual disorders (with oestrogen), for treatment of neoplasms of the breast and endometrium and for contraception. Usually administered by injection in oily solution or aqueous suspension, by implantation of pellets, as tablets for buccal administration and as pessaries or suppositories.

SUPPLIER

Company: S D FINE- CHEM LIMITED

Address:

315- 317, T.V. INDUSTRIAL ESTATE,

248, WORLI,

MUMBAI- 400030.INDIA.

technical@sdfine.com

Telephone: 91- 22- 24959898

Telephone: 91- 22- 24959899

Fax: 91- 22- 24937232

HAZARD RATINGS

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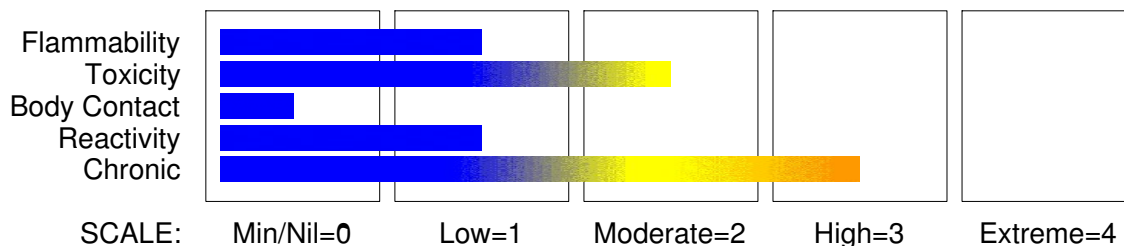
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Section 1 - CHEMICAL PRODUCT AND COMPANY IDENTIFICATION



Section 2 - HAZARDS IDENTIFICATION

GHS Classification

Reproductive Toxicity Category 1B
Reproductive Toxicity Category 2



EMERGENCY OVERVIEW

HAZARD

DANGER

Determined by using GHS criteria:

H360 H361

May damage the unborn child

Suspected of damaging fertility

PRECAUTIONARY STATEMENTS

Prevention

Do not handle until all safety precautions have been read and understood.

Use personal protective equipment as required.

Obtain special instructions before use.

Response

If exposed or concerned: Get medical attention advice.

Storage

Store locked up.

Disposal

Dispose of contents and container in accordance with relevant legislation.

Section 3 - COMPOSITION / INFORMATION ON INGREDIENTS

NAME	CAS RN	%
progesterone	57-83-0	100

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Section 4 - FIRST AID MEASURES

SWALLOWED

- If swallowed do NOT induce vomiting.
- If vomiting occurs, lean patient forward or place on left side (head-down position, if possible) to maintain open airway and prevent aspiration.
- Observe the patient carefully.
- Never give liquid to a person showing signs of being sleepy or with reduced awareness; i.e. becoming unconscious.
- Give water to rinse out mouth, then provide liquid slowly and as much as casualty can comfortably drink.
- Seek medical advice.

EYE

- If this product comes in contact with the eyes:
- Wash out immediately with fresh running water.
 - Ensure complete irrigation of the eye by keeping eyelids apart and away from eye and moving the eyelids by occasionally lifting the upper and lower lids.
 - If pain persists or recurs seek medical attention.
 - Removal of contact lenses after an eye injury should only be undertaken by skilled personnel.

SKIN

- If skin or hair contact occurs:
- Flush skin and hair with running water (and soap if available).
 - Seek medical attention in event of irritation.

INHALED

- If fumes or combustion products are inhaled remove from contaminated area.
- Other measures are usually unnecessary.

NOTES TO PHYSICIAN

Treat symptomatically.

Section 5 - FIRE FIGHTING MEASURES

EXTINGUISHING MEDIA

- Foam.
- Dry chemical powder.
- BCF (where regulations permit).
- Carbon dioxide.
- Water spray or fog - Large fires only.

FIRE FIGHTING

- Alert Fire Brigade and tell them location and nature of hazard.
- Wear breathing apparatus plus protective gloves.
- Prevent, by any means available, spillage from entering drains or water courses.
- Use water delivered as a fine spray to control fire and cool adjacent area.
- DO NOT approach containers suspected to be hot.
- Cool fire exposed containers with water spray from a protected location.
- If safe to do so, remove containers from path of fire.
- Equipment should be thoroughly decontaminated after use.

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Section 5 - FIRE FIGHTING MEASURES

FIRE/EXPLOSION HAZARD

- Combustible solid which burns but propagates flame with difficulty.
- Avoid generating dust, particularly clouds of dust in a confined or unventilated space as dusts may form an explosive mixture with air, and any source of ignition, i.e. flame or spark, will cause fire or explosion. Dust clouds generated by the fine grinding of the solid are a particular hazard; accumulations of fine dust may burn rapidly and fiercely if ignited.
- Dry dust can be charged electrostatically by turbulence, pneumatic transport, pouring, in exhaust ducts and during transport.
- Build-up of electrostatic charge may be prevented by bonding and grounding.
- Powder handling equipment such as dust collectors, dryers and mills may require additional protection measures such as explosion venting.
- All movable parts coming in contact with this material should have a speed of less than 1-meter/sec.

Combustion products include: carbon monoxide (CO), carbon dioxide (CO₂), other pyrolysis products typical of burning organic material.
May emit poisonous fumes.

FIRE INCOMPATIBILITY

Avoid contamination with oxidising agents i.e. nitrates, oxidising acids, chlorine bleaches, pool chlorine etc. as ignition may result.

Section 6 - ACCIDENTAL RELEASE MEASURES

EMERGENCY PROCEDURES

MINOR SPILLS

- Clean up waste regularly and abnormal spills immediately.
- Avoid breathing dust and contact with skin and eyes.
- Wear protective clothing, gloves, safety glasses and dust respirator.
- Use dry clean up procedures and avoid generating dust.
- Vacuum up or sweep up. NOTE: Vacuum cleaner must be fitted with an exhaust micro filter (HEPA type) (consider explosion-proof machines designed to be grounded during storage and use).
- Dampen with water to prevent dusting before sweeping.
- Place in suitable containers for disposal.

MAJOR SPILLS

Moderate hazard.

- CAUTION: Advise personnel in area.
- Alert Emergency Services and tell them location and nature of hazard.
- Control personal contact by wearing protective clothing.
- Prevent, by any means available, spillage from entering drains or water courses.
- Recover product wherever possible.
- IF DRY: Use dry clean up procedures and avoid generating dust. Collect residues and place in sealed plastic bags or other containers for disposal. IF WET: Vacuum/shovel up and place in labelled containers for disposal.
- ALWAYS: Wash area down with large amounts of water and prevent runoff into drains.
- If contamination of drains or waterways occurs, advise Emergency Services.

Personal Protective Equipment advice is contained in Section 8 of the MSDS.

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Section 7 - HANDLING AND STORAGE

PROCEDURE FOR HANDLING

- Avoid all personal contact, including inhalation.
- Wear protective clothing when risk of exposure occurs.
- Use in a well-ventilated area.
- Prevent concentration in hollows and sumps.
- DO NOT enter confined spaces until atmosphere has been checked.
- DO NOT allow material to contact humans, exposed food or food utensils.
- Avoid contact with incompatible materials.
- When handling, DO NOT eat, drink or smoke.
- Keep containers securely sealed when not in use.
- Avoid physical damage to containers.
- Always wash hands with soap and water after handling.
- Work clothes should be laundered separately. Launder contaminated clothing before re-use.
- Use good occupational work practice.
- Observe manufacturer's storing and handling recommendations.
- Atmosphere should be regularly checked against established exposure standards to ensure safe working conditions are maintained.

SUITABLE CONTAINER

- Glass container.
- Polyethylene or polypropylene container.
 - Check all containers are clearly labelled and free from leaks.

STORAGE INCOMPATIBILITY

Avoid reaction with oxidising agents.

STORAGE REQUIREMENTS

Observe manufacturer's storing and handling recommendations.

SAFE STORAGE WITH OTHER CLASSIFIED CHEMICALS



+ + + + + +

+: May be stored together

O: May be stored together with specific preventions

X: Must not be stored together

Section 8 - EXPOSURE CONTROLS / PERSONAL PROTECTION

EXPOSURE CONTROLS

The following materials had no OELs on our records

- progesterone: CAS:57- 83- 0

MATERIAL DATA

Airborne particulate or vapour must be kept to levels as low as is practicably achievable given access to modern engineering controls and monitoring hardware. Biologically active

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Section 8 - EXPOSURE CONTROLS / PERSONAL PROTECTION

compounds may produce idiosyncratic effects which are entirely unpredictable on the basis of literature searches and prior clinical experience (both recent and past).

PERSONAL PROTECTION



EYE

For laboratory, larger scale or bulk handling or where regular exposure in an occupational setting occurs:

- Chemical goggles
- Face shield. Full face shield may be required for supplementary but never for primary protection of eyes
- Contact lenses may pose a special hazard; soft contact lenses may absorb and concentrate irritants. A written policy document, describing the wearing of lens or restrictions on use, should be created for each workplace or task. This should include a review of lens absorption and adsorption for the class of chemicals in use and an account of injury experience. Medical and first-aid personnel should be trained in their removal and suitable equipment should be readily available. In the event of chemical exposure, begin eye irrigation immediately and remove contact lens as soon as practicable. Lens should be removed at the first signs of eye redness or irritation - lens should be removed in a clean environment only after workers have washed hands thoroughly. [CDC NIOSH Current Intelligence Bulletin 59].

HANDS/FEET

Suitability and durability of glove type is dependent on usage. Factors such as:

- frequency and duration of contact,
 - chemical resistance of glove material,
 - glove thickness and
 - dexterity,
- are important in the selection of gloves.
- Rubber gloves (nitrile or low-protein, powder-free latex). Employees allergic to latex gloves should use nitrile gloves in preference.
 - Double gloving should be considered.
 - PVC gloves.
 - Protective shoe covers.
 - Head covering.

OTHER

- For quantities up to 500 grams a laboratory coat may be suitable.
- For quantities up to 1 kilogram a disposable laboratory coat or coverall of low permeability is recommended. Coveralls should be buttoned at collar and cuffs.
- For quantities over 1 kilogram and manufacturing operations, wear disposable coverall of low permeability and disposable shoe covers.
- For manufacturing operations, air-supplied full body suits may be required for the provision of advanced respiratory protection.
- Eye wash unit.
- Ensure there is ready access to an emergency shower.
- For Emergencies: Vinyl suit.

RESPIRATOR

Protection Factor
10 x ES

Half- Face Respirator
P1 Air- line*

Full- Face Respirator
- -

Powered Air Respirator
PAPR- P1 -

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Section 8 - EXPOSURE CONTROLS / PERSONAL PROTECTION

50 x ES	Air- line**	P2	PAPR- P2
100 x ES	-	P3	-
		Air- line*	-
100+ x ES	-	Air- line**	PAPR- P3

* - Negative pressure demand ** - Continuous flow.

The local concentration of material, quantity and conditions of use determine the type of personal protective equipment required.

For further information consult your Occupational Health and Safety Advisor.

ENGINEERING CONTROLS

Enclosed local exhaust ventilation is required at points of dust, fume or vapour generation.

HEPA terminated local exhaust ventilation should be considered at point of generation of dust, fumes or vapours.

Barrier protection or laminar flow cabinets should be considered for laboratory scale handling.

When handling quantities up to 500 gram in either a standard laboratory with general dilution ventilation (e.g. 6-12 air changes per hour) is preferred. Quantities up to 1 kilogram may require a designated laboratory using fume hood, biological safety cabinet, or approved vented enclosures. Quantities exceeding 1 kilogram should be handled in a designated laboratory or containment laboratory using appropriate barrier/ containment technology.

Manufacturing and pilot plant operations require barrier/ containment and direct coupling technologies.

Barrier/ containment technology and direct coupling (totally enclosed processes that create a barrier between the equipment and the room) typically use double or split butterfly valves and hybrid unidirectional airflow/ local exhaust ventilation solutions (e.g. powder containment booths). Glove bags, isolator glove box systems are optional. HEPA filtration of exhaust from dry product handling areas is required.

Fume-hoods and other open-face containment devices are acceptable when face velocities of at least 1 m/s (200 feet/minute) are achieved. Partitions, barriers, and other partial containment technologies are required to prevent migration of the material to uncontrolled areas. For non-routine emergencies maximum local and general exhaust are necessary. Air contaminants generated in the workplace possess varying "escape" velocities which, in turn, determine the "capture velocities" of fresh circulating air required to effectively remove the contaminant.

Type of Contaminant:	Air Speed:
solvent, vapours, etc. evaporating from tank (in still air)	0.25- 0.5 m/s (50- 100 f/min.)
aerosols, fumes from pouring operations, intermittent container filling, low speed conveyer transfers (released at low velocity into zone of active generation)	0.5- 1 m/s (100- 200 f/min.)
direct spray, drum filling, conveyer loading, crusher dusts, gas discharge (active generation into zone of rapid air motion)	1- 2.5 m/s (200- 500 f/min.)

Within each range the appropriate value depends on:

Lower end of the range
1: Room air currents minimal or favourable to capture

Upper end of the range
1: Disturbing room air currents

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Section 8 - EXPOSURE CONTROLS / PERSONAL PROTECTION

2: Contaminants of low toxicity or of nuisance value only.

3: Intermittent, low production.

4: Large hood or large air mass in motion

2: Contaminants of high toxicity

3: High production, heavy use

4: Small hood- local control only

Simple theory shows that air velocity falls rapidly with distance away from the opening of a simple extraction pipe. Velocity generally decreases with the square of distance from the extraction point (in simple cases). Therefore the air speed at the extraction point should be adjusted, accordingly, after reference to distance from the contaminating source. The air velocity at the extraction fan, for example, should be a minimum of 1-2.5 m/s (200-500 f/min.) for extraction of gases discharged 2 meters distant from the extraction point. Other mechanical considerations, producing performance deficits within the extraction apparatus, make it essential that theoretical air velocities are multiplied by factors of 10 or more when extraction systems are installed or used.

The need for respiratory protection should also be assessed where incidental or accidental exposure is anticipated: Dependent on levels of contamination, PAPR, full face air purifying devices with P2 or P3 filters or air supplied respirators should be evaluated.

The following protective devices are recommended where exposures exceed the recommended exposure control guidelines by factors of:

10; high efficiency particulate (HEPA) filters or cartridges

10-25; loose-fitting (Tyvek or helmet type) HEPA powered-air purifying respirator.

25-50; a full face-piece negative pressure respirator with HEPA filters

50-100; tight-fitting, full face-piece HEPA PAPR

100-1000; a hood-shroud HEPA PAPR or full face-piece supplied air respirator operated in pressure demand or other positive pressure mode.

Section 9 - PHYSICAL AND CHEMICAL PROPERTIES

APPEARANCE

White odourless, tasteless crystals or crystalline powder; does not mix with water. Soluble in alcohol (1:8), chloroform (1:1), ether (1:16).

Two forms exist with different melting points; the so-called beta-progesterone melts at 121 deg C.

PHYSICAL PROPERTIES

Solid.

Does not mix with water.

Molecular Weight: 314.5

Melting Range (°C): 126- 131; 121 (b)

Solubility in water (g/L): Immiscible

pH (1% solution): Not applicable.

Volatile Component (%vol): Negligible

Relative Vapour Density (air=1): Not applicable

Lower Explosive Limit (%): Not available.

Autoignition Temp (°C): Not available.

State: Divided solid

Boiling Range (°C): Not available.

Specific Gravity (water=1): Not available.

pH (as supplied): Not applicable

Vapour Pressure (kPa): Negligible

Evaporation Rate: Not applicable

Flash Point (°C): Not Available

Upper Explosive Limit (%): Not available.

Decomposition Temp (°C): Not available.

Viscosity: Not Applicable

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Section 10 - CHEMICAL STABILITY AND REACTIVITY INFORMATION

CONDITIONS CONTRIBUTING TO INSTABILITY

- Presence of incompatible materials.
- Product is considered stable.
- Hazardous polymerisation will not occur.

Section 11 - TOXICOLOGICAL INFORMATION

POTENTIAL HEALTH EFFECTS

ACUTE HEALTH EFFECTS

SWALLOWED

Accidental ingestion of the material may be damaging to the health of the individual. Oral contraceptives may produce side-effects as a result of altering the normal balance of oestrogenic and progestogenic effects. Such effects may include nausea, vomiting, chloasma and other skin and hair changes, headache, oedema, weight gain and breast tenderness. Spotting, breakthrough bleeding, or amenorrhoea may occur following withdrawal. Intolerance to contact lens has been reported. Mental changes, including depression, may also occur at clinical doses. Hypertension is associated with combined oral contraceptives and there may be changes in carbohydrate and lipid metabolism. Liver function may become impaired although jaundice is rare.

EYE

Although the material is not thought to be an irritant (as classified by EC Directives), direct contact with the eye may cause transient discomfort characterised by tearing or conjunctival redness (as with windburn). Slight abrasive damage may also result. The material may produce foreign body irritation in certain individuals.

SKIN

The material is not thought to produce adverse health effects or skin irritation following contact (as classified by EC Directives using animal models). Nevertheless, good hygiene practice requires that exposure be kept to a minimum and that suitable gloves be used in an occupational setting.

Entry into the blood-stream, through, for example, cuts, abrasions or lesions, may produce systemic injury with harmful effects. Examine the skin prior to the use of the material and ensure that any external damage is suitably protected.

INHALED

The material is not thought to produce either adverse health effects or irritation of the respiratory tract following inhalation (as classified by EC Directives using animal models). Nevertheless, adverse systemic effects have been produced following exposure of animals by at least one other route and good hygiene practice requires that exposure be kept to a minimum and that suitable control measures be used in an occupational setting.

CHRONIC HEALTH EFFECTS

The use of oral contraceptives has been associated with an increased risk of thrombo-embolic and cardiovascular disease, related, at least in part, to the oestrogen content of combined oral contraceptives.

An increased risk of the incidence of benign liver tumours, though marked, is thought to be rare.

Long term exposure to high dust concentrations may cause changes in lung function (i.e. pneumoconiosis) caused by particles less than 0.5 micron penetrating and remaining in the lung. A prime symptom is breathlessness. Lung shadows show on X-ray.

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Section 11 - TOXICOLOGICAL INFORMATION

There is some evidence that human exposure to the material may result in developmental toxicity. This evidence is based on animal studies where effects have been observed in the absence of marked maternal toxicity, or at around the same dose levels as other toxic effects but which are not secondary non-specific consequences of the other toxic effects. Exposure to the material may cause concerns for human fertility, on the basis that similar materials provide some evidence of impaired fertility in the absence of toxic effects, or evidence of impaired fertility occurring at around the same dose levels as other toxic effects, but which are not a secondary non-specific consequence of other toxic effects.

Exposure to the material for prolonged periods may cause physical defects in the developing embryo (teratogenesis).

Some progestogens have been associated with an increase in congenital abnormalities. Repeated intake of progesterones may produce headache, nausea, vomiting, diarrhoea, ulcerative stomatitis, oedema, weight change, pyrexia, fatigue, somnolence or insomnia, mental depression, allergic rashes including urticaria and pruritis, acne, photosensitisation, pigmented skin, alopecia or hirsutism, thrombophlebitis, cholestatic jaundice, and precipitation of porphyria. Other symptoms may include menstrual disorders, breast changes, effects on the cervix, vaginal candidiasis, loss of libido, and inhibition of spermatogenesis. Exposure during the first trimester may produce mild masculinisation of the external genitalia of the female foetus or hypospadias in the male foetus. Exposure to female sex hormones during the first trimester has also been linked to various congenital anomalies especially of the cardiovascular and skeletal systems; this association is still controversial.

Side-effects of progestogens include gastrointestinal disturbances, acne, fluid retention or oedema, weight gain, allergic skin rashes or urticaria, mental depression, breast changes, including discomfort or occasionally gynaecomastia, changes in libido, and altered menstrual cycles or irregular menstrual bleeding. Alterations in liver function tests with occasional jaundice have also been reported.

TOXICITY AND IRRITATION

unless otherwise specified data extracted from RTECS - Register of Toxic Effects of Chemical Substances. Animal Sufficient Evidence of Carcinogenicity -International Agency for Research on Cancer (IARC).

Exposure to the material for prolonged periods may cause physical defects in the developing embryo (teratogenesis).

Section 12 - ECOLOGICAL INFORMATION

DO NOT discharge into sewer or waterways.

Section 13 - DISPOSAL CONSIDERATIONS

- Recycle wherever possible.
- Consult manufacturer for recycling options or consult local or regional waste management authority for disposal if no suitable treatment or disposal facility can be identified.
- Dispose of by: Burial in a licenced land-fill or Incineration in a licenced apparatus (after admixture with suitable combustible material)
- Decontaminate empty containers. Observe all label safeguards until containers are cleaned and destroyed.

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Section 14 - TRANSPORTATION INFORMATION

HAZCHEM: None

NOT REGULATED FOR TRANSPORT OF DANGEROUS GOODS:UN, IATA,
IMDG

Section 15 - REGULATORY INFORMATION

REGULATIONS

progesterone (CAS: 57-83-0) is found on the following regulatory lists;
International Agency for Research on Cancer (IARC) Carcinogens

Section 16 - OTHER INFORMATION

MSDS SECTION CHANGES

The following table displays the version number of and date on which each section was last changed.

Section Name	Version	Date	Section Name	Version	Date	Section Name	Version	Date
First Aid (eye)	4	29- May- 2006	Handling Procedure	4	29- May- 2006	Acute Health (skin)	4	29- May- 2006
First Aid (inhaled)	4	29- May- 2006	Storage (storage requirement)	4	29- May- 2006	Acute Health (swallowed)	4	29- May- 2006
First Aid (swallowed)	4	29- May- 2006	Storage (suitable container)	4	29- May- 2006	Chronic Health	4	29- May- 2006
Fire Fighter (fire fighting)	4	29- May- 2006	Appearance	4	29- May- 2006	Toxicity and Irritation (Other)	4	29- May- 2006
Fire Fighter (fire/explosion hazard)	4	29- May- 2006	Physical Properties	4	29- May- 2006	Environmental	4	29- May- 2006
Spills (major)	4	29- May- 2006	Acute Health (eye)	4	29- May- 2006	Disposal	4	29- May- 2006
Spills (minor)	4	29- May- 2006	Acute Health (inhaled)	4	29- May- 2006			

The above information is believed to be accurate and represent the best information currently available to us, but does not represent any warranty expressed or implied of the properties of the product. User should make their own investigation to determine the suitability of the information for their particular purpose.

Issue Date: 29-May-2018