



SAFETY DATA SHEET

Revision Date 02-Oct-2018

Version 10

1. IDENTIFICATION OF THE SUBSTANCE/PREPARATION AND OF THE COMPANY/UNDERTAKING

Product identifier

Product Name Liletta

Other means of identification

Product Code FG00074

Synonyms Levonorgestrel Intrauterine Delivery System

Recommended use of the chemical and restrictions on use

Recommended Use Contraceptive Agent

This safety data sheet is written to provide health, safety and environmental information for people handling this formulated product in the workplace. It is not intended to provide information relevant to medicinal use of the product. In this instance patients should consult prescribing information/package insert/product label or consult their pharmacist or physician. For health and safety information for individual ingredients used during manufacturing, refer to the appropriate safety data sheet for each ingredient.

Details of the supplier of the safety data sheet

Manufacturer

Allergan plc
5 Giralda Farms
Madison, NJ USA 07940
+1-800-272-5525

E-mail address SDS@Allergan.com

Emergency telephone number

Emergency Telephone

Call CHEMTREC Day or Night
Within USA or Canada: 1-800-424-9300
Outside USA and Canada: +1-703-741-5970 (collect calls accepted)

2. HAZARDS IDENTIFICATION

Classification

OSHA Regulatory Status

This chemical is considered hazardous by the 2012 OSHA Hazard Communication Standard (29 CFR 1910.1200)

Carcinogenicity	Category 2
Reproductive toxicity	Category 1A
Effects on or via lactation	Yes

Label elements

Emergency Overview

Danger

Hazard statements

H351 - Suspected of causing cancer
H360 - May damage fertility or the unborn child
H362 - May cause harm to breast-fed children



Appearance Solid

Physical state Solid

Odor No information available

Chemical Name
Levonogestrel

Symptoms

Adverse reactions include: Ectopic pregnancy; Intrauterine Pregnancy; Group A Streptococcal Sepsis (GAS); Pelvic Inflammatory Disease or Endometritis; Perforation; Expulsion; Ovarian Cysts; Bleeding Pattern Alterations. Additional potential adverse effects include: nausea, vomiting, abdominal pain, tiredness, dizziness, changes in vaginal bleeding, breast tenderness, diarrhea, or headache. Androgenic side effects such as acne, hirsutism (increased body hair growth) and weight gain occur rarely. Increased concentrations of progestins increase the normal oral flora growth rate, leading to an increase in inflammation of the gingival tissues and increased bleeding. Fluid retention may be caused by some progestins, especially high doses, and may aggravate these conditions of asthma, significant cardiac insufficiency, epilepsy, hypertension, migraine headaches or significant renal dysfunction. Individuals who have had allergic reactions to products containing progestogens may experience allergic reactions to this material. Exposure to female hormones in men can also include testicular atrophy, increased risk of prostate cancer, loss of libido and potency, gynecomastia (the abnormal growth of breast tissue), increased risk of prostate cancer and infertility from decrease in FSH and subsequent effects on sperm maturation. Changes in FSH levels affect the ovulatory cycle in women which may lead to decreased fertility. These effects may be possible as a result of workplace exposure. Weight gain, fluid retention and swelling; High blood pressure, exacerbation of cardiovascular disorders; Headache.

Chemical Name
Levonogestrel

Medical Conditions Aggravated by Exposure

Current or recurrent pelvic inflammatory disease, current genital infection, endometritis, cervicitis, cervical dysplasia, uterine tumors, liver tumors, acute or severe liver disease, abnormal genital bleeding conditions with increased susceptibility to infections, severe arterial disease, such as stroke or myocardial infarction, hormone dependent tumor, acute malignancies affecting the blood, recent trophoblastic disease while hCG levels remain elevated, migraine with aura, severe or very frequent headache, jaundice, high blood pressure, history of ovarian cysts, risk factors for arterial disease, thrombotic arterial or embolic disease, may be aggravated.

Precautionary statements

P202 - Do not handle until all safety precautions have been read and understood
 P281 - Use personal protective equipment as required
 P405 - Store locked up
 P501 - Dispose of contents/ container to an approved waste disposal plant
 P280 - Wear protective gloves/protective clothing/eye protection/face protection
 P201 - Obtain special instructions before use
 P260 - Do not breathe dust/fume/gas/mist/vapors/spray
 P263 - Avoid contact during pregnancy/while nursing
 P264 - Wash face, hands and any exposed skin thoroughly after handling
 P270 - Do not eat, drink or smoke when using this product
 P308 + P313 - IF exposed or concerned: Get medical advice/attention

Other Information

Unknown Acute Toxicity

2% of the mixture consists of ingredient(s) of unknown toxicity

Over the counter drugs in their solid form are considered exempt under the criteria of the Federal OSHA Hazard Communication Standard 20 CFR 1910.1200. However, in an industrial setting where a component's occupational exposure limit may be

surpassed, than can be considered hazardous

3. COMPOSITION/INFORMATION ON INGREDIENTS

Chemical Name	CAS No.	EINECS	Weight-%
Silicon	7440-21-3	231-130-8	60 - 100*
Levonogestrel	797-63-7	212-349-8	1 - 5*

*The exact percentage (concentration) of composition has been withheld as a trade secret.

4. FIRST AID MEASURES

First aid measures

General advice	If symptoms persist, call a physician. Do not breathe dust/fume/gas/mist/vapors/spray. Do not get in eyes, on skin, or on clothing.
Eye contact	Immediately flush with plenty of water. After initial flushing, remove any contact lenses and continue flushing for at least 15 minutes. Keep eye wide open while rinsing. If symptoms persist, call a physician.
Skin Contact	Consult a physician if necessary. Wash off immediately with soap and plenty of water while removing all contaminated clothes and shoes. Wash contaminated clothing before reuse. Wash off immediately with plenty of water. If skin irritation persists, call a physician. Immediate medical attention is not required.
Inhalation	Remove to fresh air. Call a physician. If breathing is irregular or stopped, administer artificial respiration. Avoid direct contact with skin. Use barrier to give mouth-to-mouth resuscitation. Immediate medical attention is not required. Move to fresh air in case of accidental inhalation of vapors. If symptoms persist, call a physician.
Ingestion	Do NOT induce vomiting. Rinse mouth. Drink plenty of water. If symptoms persist, call a physician. Clean mouth with water and drink afterwards plenty of water. Never give anything by mouth to an unconscious person. Call a physician.

Chemical Name
Levonogestrel

Note to physicians

This material is contraindicated in: Pregnancy or suspected pregnancy, use for post-coital contraception, Congenital or acquired uterine anomaly that distorts the uterine cavity, Acute pelvic inflammatory disease (PID) or a history of PID unless there has been a subsequent intrauterine pregnancy, postpartum endometritis or infected abortion in the past 3 months, known or suspected uterine or cervical neoplasia, known or suspected breast cancer or other progestin-sensitive cancer, uterine bleeding of unknown etiology.

5. FIRE-FIGHTING MEASURES

Suitable extinguishing media

Use extinguishing measures that are appropriate to local circumstances and the surrounding environment.

Unsuitable extinguishing media

None known.

Specific hazards arising from the chemical

Fire may produce irritating, corrosive and/or toxic gases.

Explosion data

Sensitivity to Mechanical Impact
Sensitivity to Static Discharge

Not impact sensitive.

Fine dust dispersed in air, in sufficient concentrations, and in the presence of an ignition source is a potential dust explosion hazard.

Protective equipment and precautions for firefighters

As in any fire, wear self-contained breathing apparatus pressure-demand, MSHA/NIOSH (approved or equivalent) and full protective gear.

6. ACCIDENTAL RELEASE MEASURES

Personal precautions	Use personal protective equipment as required. Evacuate personnel to safe areas. Keep people away from and upwind of spill/leak.
Environmental precautions	Prevent entry into waterways, sewers, basements or confined areas. Do not flush into surface water or sanitary sewer system. Prevent further leakage or spillage if safe to do so. Prevent product from entering drains. See Section 12 for additional ecological information.
Methods for containment	Prevent further leakage or spillage if safe to do so.
Methods for cleaning up	Use personal protective equipment as required. Cover powder spill with plastic sheet or tarp to minimize spreading and keep powder dry. Take up mechanically, placing in appropriate containers for disposal. Avoid creating dust. Clean contaminated surface thoroughly. Soak up with inert absorbent material. Dam up. Pick up and transfer to properly labeled containers. Sweep up and shovel into suitable containers for disposal. After cleaning, flush away traces with water. Take precautionary measures against static discharges.

7. HANDLING AND STORAGE

Advice on safe handling	Use personal protective equipment as required. Avoid contact with skin, eyes or clothing. Wash contaminated clothing before reuse. Do not breathe dust/fume/gas/mist/vapors/spray. Do not eat, drink or smoke when using this product. Use with local exhaust ventilation.
Storage Conditions	Keep container tightly closed in a dry and well-ventilated place. Keep out of the reach of children. Keep containers tightly closed in a cool, well-ventilated place. Keep in properly labeled containers.
Incompatible materials	None known based on information supplied.

8. EXPOSURE CONTROLS/PERSONAL PROTECTION

Control parameters

Exposure Guidelines

Chemical Name	ACGIH TLV	OSHA PEL	NIOSH IDLH	Allergan OEL (ug/m ³)
Silicon 7440-21-3	N/A	TWA: 15 mg/m ³ total dust TWA: 5 mg/m ³ respirable fraction (vacated) TWA: 10 mg/m ³ total dust (vacated) TWA: 5 mg/m ³ respirable fraction	TWA: 10 mg/m ³ total dust TWA: 5 mg/m ³ respirable dust	N/A
Levonogestrel 797-63-7	N/A	N/A	N/A	0.03 ug/m ³

NIOSH IDLH *Immediately Dangerous to Life or Health*

Other Information Vacated limits revoked by the Court of Appeals decision in AFL-CIO v. OSHA, 965 F.2d 962 (11th Cir., 1992).

Appropriate engineering controls

Engineering Controls The health hazard risks of handling this material are dependent on factors, such as physical form and quantity. Site specific risk assessments should be conducted to determine the appropriate exposure control measures. Good general ventilation should be used. Ventilation rates should be matched to conditions. If applicable, use process enclosures, local exhaust ventilation, or other engineering controls to maintain airborne levels below

recommended exposure limits. If exposure limits have not been established, maintain airborne levels as low as reasonably achievable.

Individual protection measures, such as personal protective equipment

Eye/face protection	No eye protection is normally needed during medical administration of this product. During operations in which dusts of the product may be generated, safety glasses should be considered.
Skin and body protection	During medical administration of this product, medical latex or nitrile gloves should be worn to avoid absorption of the product. Use appropriate protective clothing for the task (e.g., lab coat, etc.).
Respiratory protection	Respiratory protection is generally not needed during routine conditions of use of this product. If respiratory protection is needed, use only respiratory protection authorized under appropriate regional regulations.

9. PHYSICAL AND CHEMICAL PROPERTIES

Information on basic physical and chemical properties

Physical state	Solid	Appearance	Solid
Color	No information available	Odor	No information available
Odor threshold	No information available		

<u>Property</u>	<u>Values</u>
pH	No information available
Melting point/freezing point	No information available
Boiling point / boiling range	No information available
Flash point	No information available
Evaporation rate	No information available
Flammability (solid, gas)	No information available
Flammability Limit in Air	
Upper flammability limit:	No information available
Lower flammability limit:	No information available
Vapor pressure	No information available
Vapor density	No information available
Specific Gravity	No information available
Water solubility	No information available
Solubility in other solvents	No information available
Partition coefficient	No information available
Autoignition temperature	No information available
Decomposition temperature	No information available
Explosive properties	No information available
Oxidizing properties	No information available

Other Information

Molecular weight	No information available
VOC Content (%)	No information available
Density	No information available
Bulk density	No information available

10. STABILITY AND REACTIVITY

Reactivity
Not defined As Reactive substance

Chemical stability
Stable under normal conditions.
Possibility of Hazardous Reactions

None under normal processing.

Conditions to avoid

Aerosol formation.

Incompatible materials

None known based on information supplied.

Hazardous Decomposition Products

None known based on information supplied.

11. TOXICOLOGICAL INFORMATION

Information on likely routes of exposure

Acute toxicity

Chemical Name	Inhalation	Eye contact	Skin Contact	Ingestion
Levonogestrel	Inhalation of airborne dusts generated by this product may slightly irritate the nose, throat, and lungs. Symptoms are generally alleviated upon breathing fresh air.	Contact with the eyes of airborne dusts generated by this product may cause mild to moderate irritation, redness, and tearing.	Prolonged contact may cause redness and irritation.	If this compound is swallowed, CALL PHYSICIAN OR POISON CONTROL CENTER FOR MOST CURRENT INFORMATION. If professional advice is not available, do not induce vomiting. Rinse mouth with water immediately. Victim should drink large quantities of water. If milk is available, victim should drink it after drinking water. Never induce vomiting or give diluents (milk or water) to someone who is unconscious, having convulsions, or unable to swallow.

Chemical Name	Oral LD50	Dermal LD50	Inhalation LC50
Silicon	= 3160 mg/kg (Rat)	N/A	N/A

Delayed and immediate effects as well as chronic effects from short and long-term exposure

Chemical Name	Germ cell mutagenicity	Carcinogenicity	Reproductive toxicity	Effects on or via lactation
Levonogestrel	Not mutagenic in the standard battery of tests.	There is no evidence of increased risk of cancer with short-term use of progestins. There was no increase in tumorigenicity following administration of levonogestrel to rats for 2 years at approximately 5 µg/day, to dogs for 7 years at up to 0.125 mg/kg/day, or to rhesus monkeys for 10 years at up to 250 µg/kg/day. In another 7 year dog study, administration of levonogestrel at 0.5 mg/kg/day did increase the number of mammary adenomas in treated dogs compared to controls. There were no malignancies.	Chronic exposure can cause temporary infertility.	Small amounts of progestins pass into the breast milk of nursing mothers, resulting in detectable steroid levels in infant plasma.

**Chronic toxicity
Target Organ Effects**

Avoid repeated exposure. Contains a known or suspected reproductive toxin. Central nervous system, Endocrine System, Eyes, Reproductive System, Respiratory system, Skin.

Numerical measures of toxicity - Product Information

Unknown Acute Toxicity 2% of the mixture consists of ingredient(s) of unknown toxicity

The following values are calculated based on chapter 3.1 of the GHS document .

ATEmix (oral)	3224 mg/kg
ATEmix (dermal)	4622
ATEmix (inhalation-dust/mist)	177

12. ECOLOGICAL INFORMATION**Ecotoxicity**

Very toxic to aquatic life with long lasting effects

99% of the mixture consists of component(s) of unknown hazards to the aquatic environment

Chemical Name	Persistence and degradability	Bioaccumulation	Mobility	Partition coefficient
Levonogestrel 797-63-7	This compound has not been tested for persistence or biodegradability	This product has not been tested for bio-accumulation potential	This product has not been tested for mobility in soil	Log P = 3.368

Other adverse effects No information available

13. DISPOSAL CONSIDERATIONS**Waste treatment methods**

Disposal of wastes Disposal should be in accordance with applicable regional, national and local laws and regulations.

Contaminated packaging Do not reuse container. Dispose of contents/containers in accordance with local regulations.

This product contains one or more substances that are listed with the State of California as a hazardous waste.

14. TRANSPORT INFORMATION

DOT Not regulated

TDG Not regulated

ICAO (air) Not regulated

IATA Not regulated

IMDG Not regulated

ADR Not regulated

ADN Not regulated

15. REGULATORY INFORMATION**International Inventories**

TSCA	Not Listed
DSL/NDSL	Not Listed
EINECS/ELINCS	Listed

Legend:

TSCA - United States Toxic Substances Control Act Section 8(b) Inventory

DSL/NDSL - Canadian Domestic Substances List/Non-Domestic Substances List

EINECS/ELINCS - European Inventory of Existing Chemical Substances/European List of Notified Chemical Substances

US Federal Regulations**Carcinogenicity**

The table below indicates whether each agency has listed any ingredient as a carcinogen. This product contains one or more substances which are classified by IARC as carcinogenic to humans (Group I), probably carcinogenic to humans (Group 2A) or possibly carcinogenic to humans (Group 2B).

Chemical Name	ACGIH	IARC	NTP	OSHA
Levonogestrel 797-63-7	-	Group 2B	-	X

IARC (International Agency for Research on Cancer)

Group 2B - Possibly Carcinogenic to Humans

Not classifiable as a human carcinogen

OSHA (Occupational Safety and Health Administration of the US Department of Labor)

X - Present

SARA 313

Section 313 of Title III of the Superfund Amendments and Reauthorization Act of 1986 (SARA). This product does not contain any chemicals which are subject to the reporting requirements of the Act and Title 40 of the Code of Federal Regulations, Part 372

SARA 311/312 Hazard Categories

Acute health hazard	Yes
Chronic Health Hazard	No
Fire hazard	No
Sudden release of pressure hazard	No
Reactive Hazard	No

CWA (Clean Water Act)

This product contains the following substances which are regulated pollutants pursuant to the Clean Water Act (40 CFR 122.21 and 40 CFR 122.42)

CERCLA

This material, as supplied, contains one or more substances regulated as a hazardous substance under the Comprehensive Environmental Response Compensation and Liability Act (CERCLA) (40 CFR 302)

US State Regulations**California Proposition 65**

This product contains the following Proposition 65 chemicals

Chemical Name	California Proposition 65
Levonogestrel - 797-63-7	Female Reproductive

U.S. State Right-to-Know Regulations

Chemical Name	New Jersey	Massachusetts	Pennsylvania
Silicon 7440-21-3	X	X	X

16. OTHER INFORMATION

Revision Date 02-Oct-2018

Revision Note No information available

Disclaimer

The information provided in this Material Safety Data Sheet is correct to the best of our knowledge, information and belief at the date of its publication. The information given is designed only as a guidance for safe handling, use, processing, storage, transportation, disposal and release and is not to be considered a warranty or quality specification. The information relates only to the specific material designated and may not be valid for such material used in combination with any other materials or in any process, unless specified in the text.

End of Safety Data Sheet