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
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

<table>
<thead>
<tr>
<th>Chemical Name</th>
<th>CAS No.</th>
<th>EINECS</th>
<th>Weight-%</th>
</tr>
</thead>
<tbody>
<tr>
<td>Silicon</td>
<td>7440-21-3</td>
<td>231-130-8</td>
<td>60 - 100*</td>
</tr>
<tr>
<td>Levonogestrel</td>
<td>797-63-7</td>
<td>212-349-8</td>
<td>1 - 5*</td>
</tr>
</tbody>
</table>

*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, Congential or acquired uterine anomaly that distorts the uterine cavity, Acture 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**

<table>
<thead>
<tr>
<th>Sensitivity to Mechanical Impact</th>
<th>Sensitivity to Static Discharge</th>
</tr>
</thead>
<tbody>
<tr>
<td>Not impact sensitive.</td>
<td>Fine dust dispersed in air, in sufficient concentrations, and in the presence of an ignition source is a potential dust explosion hazard.</td>
</tr>
</tbody>
</table>
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

<table>
<thead>
<tr>
<th>Chemical Name</th>
<th>ACGIH TLV</th>
<th>OSHA PEL</th>
<th>NIOSH IDLH</th>
<th>Allergen OEL (ug/m³)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Silicon 7440-21-3</td>
<td>N/A</td>
<td>TWA: 15 mg/m³ total dust TWA: 5 mg/m³ respirable fraction (vacated) TWA: 10 mg/m³ total dust (vacated) TWA: 5 mg/m³ respirable fraction</td>
<td>TWA: 10 mg/m³ total dust TWA: 5 mg/m³ respirable dust</td>
<td>N/A</td>
</tr>
<tr>
<td>Levonorgestrel 797-63-7</td>
<td>N/A</td>
<td>N/A</td>
<td>N/A</td>
<td>0.03 ug/m³</td>
</tr>
</tbody>
</table>

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
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**

<table>
<thead>
<tr>
<th>Property</th>
<th>Values</th>
</tr>
</thead>
<tbody>
<tr>
<td>Physical state</td>
<td>Solid</td>
</tr>
<tr>
<td>Color</td>
<td>No information available</td>
</tr>
<tr>
<td>Odor threshold</td>
<td>No information available</td>
</tr>
<tr>
<td>Appearance</td>
<td>Solid</td>
</tr>
<tr>
<td>Odor</td>
<td>No information available</td>
</tr>
</tbody>
</table>

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

**Other Information**
- Molecular weight
- VOC Content (%)
- Density
- 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

<table>
<thead>
<tr>
<th>Chemical Name</th>
<th>Inhalation</th>
<th>Eye contact</th>
<th>Skin Contact</th>
<th>Ingestion</th>
</tr>
</thead>
<tbody>
<tr>
<td>Levonogestrel</td>
<td>Inhalation of airborne dusts generated by this product may slightly irritate the nose, throat, and lungs. Symptoms are generally alleviated upon breathing fresh air.</td>
<td>Contact with the eyes of airborne dusts generated by this product may cause mild to moderate irritation, redness, and tearing.</td>
<td>Prolonged contact may cause redness and irritation.</td>
<td>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.</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Chemical Name</th>
<th>Oral LD50</th>
<th>Dermal LD50</th>
<th>Inhalation LC50</th>
</tr>
</thead>
<tbody>
<tr>
<td>Silicon</td>
<td>= 3160 mg/kg (Rat)</td>
<td>N/A</td>
<td>N/A</td>
</tr>
</tbody>
</table>

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

<table>
<thead>
<tr>
<th>Chemical Name</th>
<th>Germ cell mutagenicity</th>
<th>Carcinogenicity</th>
<th>Reproductive toxicity</th>
<th>Effects on or via lactation</th>
</tr>
</thead>
<tbody>
<tr>
<td>Levonogestrel</td>
<td>Not mutagenic in the standard battery of tests.</td>
<td>There is no evidence of increased risk of cancer with short-term use of progestins. There was no increase in tumorigenicity following administration of levonorgestrel 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 levonorgestrel at 0.5 mg/kg/day did increase the number of mammary adenomas in treated dogs compared to controls. There were no malignancies.</td>
<td>Chronic exposure can cause temporary infertility.</td>
<td>Small amounts of progestins pass into the breast milk of nursing mothers, resulting in detectable steroid levels in infant plasma.</td>
</tr>
</tbody>
</table>

**Chronic toxicity**
Avoid repeated exposure. Contains a known or suspected reproductive toxin.

**Target Organ Effects**
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 components(s) of unknown hazards to the aquatic environment

<table>
<thead>
<tr>
<th>Chemical Name</th>
<th>Persistence and degradability</th>
<th>Bioaccumulation</th>
<th>Mobility</th>
<th>Partition coefficient</th>
</tr>
</thead>
<tbody>
<tr>
<td>Levonorgestrel 797-63-7</td>
<td>This compound has not been tested for persistence or biodegradability</td>
<td>This product has not been tested for bio-accumulation potential</td>
<td>This product has not been tested for mobility in soil</td>
<td>Log P = 3.368</td>
</tr>
</tbody>
</table>

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

<table>
<thead>
<tr>
<th>International Inventories</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>TSCA</td>
<td>Not Listed</td>
</tr>
<tr>
<td>DSL/NDSL</td>
<td>Not Listed</td>
</tr>
<tr>
<td>EINECS/ELINCS</td>
<td>Listed</td>
</tr>
</tbody>
</table>
**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).

<table>
<thead>
<tr>
<th>Chemical Name</th>
<th>ACGIH</th>
<th>IARC</th>
<th>NTP</th>
<th>OSHA</th>
</tr>
</thead>
<tbody>
<tr>
<td>Levonogestrel</td>
<td>-</td>
<td>Group 2B</td>
<td>-</td>
<td>X</td>
</tr>
</tbody>
</table>

*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:

<table>
<thead>
<tr>
<th>Chemical Name</th>
<th>California Proposition 65</th>
</tr>
</thead>
<tbody>
<tr>
<td>Levonogestrel</td>
<td>Female Reproductive</td>
</tr>
</tbody>
</table>

**U.S. State Right-to-Know Regulations**

<table>
<thead>
<tr>
<th>Chemical Name</th>
<th>New Jersey</th>
<th>Massachusetts</th>
<th>Pennsylvania</th>
</tr>
</thead>
<tbody>
<tr>
<td>Silicon</td>
<td>X</td>
<td>X</td>
<td>X</td>
</tr>
<tr>
<td>7440-21-3</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

**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