Product Name: REGULIN For Improved Joining Performance & Increased Ovulation Rates in Sheep

SAFETY DATA SHEET

Issued by: Ceva Animal Health Pty Ltd
11 Moores Rd
Glenorie NSW 2157
www.ceva.com.au

Phone: 02 9652 7000 (office hours)
Fax: 02 9652 7001

Section 1 - Identification of The Material and Supplier

Ceva Animal Health Pty Ltd
11 Moores Rd
Glenorie NSW 2157

Chemical nature: subcutaneous hormone implant for use in sheep.
Trade Name: REGULIN For Improved Joining Performance & Increased Ovulation Rates in Sheep
APVMA Code: 38233
Product Use: For improved joining performance and increased ovulation rates in sheep.
Creation Date: November, 2009
This version issued: August, 2016 and is valid for 5 years from this date.

Section 2 - Hazards Identification

Statement of Hazardous Nature
This product is classified as: Not classified as hazardous according to the criteria of SWA.
Not a Dangerous Good according to the Australian Dangerous Goods (ADG) Code.

Risk Phrases: Not Hazardous - No criteria found.
Safety Phrases: Not Hazardous - No criteria found.
SUSMP Classification: None allocated.
ADG Classification: None allocated. Not a Dangerous Good under the ADG Code.
UN Number: None allocated

GHS Signal word: NONE. Not hazardous.

PREVENTION
P102: Keep out of reach of children.

RESPONSE
P353: Rinse skin or shower with water.
P301+P330+P331: IF SWALLOWED: Rinse mouth. Do NOT induce vomiting.
P332+P313: If skin irritation occurs: Get medical advice.
P337+P313: If eye irritation persists: Get medical advice.
P370+P378: In case of fire, use carbon dioxide, dry chemical, foam, water fog.

STORAGE
P402+P404: Store in a dry place. Store in a closed container.

DISPOSAL
P501: Dispose of small quantities and empty containers by wrapping with paper and putting in garbage. For larger quantities, if recycling or reclaiming is not possible, use a commercial waste disposal service.

Emergency Overview
Physical Description & Colour: Pale yellow coated cylindrical implant about 4.2 mm long and 2.3 mm diameter.
Odour: No data; expected to be odourless.
Major Health Hazards: no significant risk factors have been found for this product.

Potential Health Effects

Inhalation:
Short Term Exposure: Available data indicates that this product is not harmful. In addition product is unlikely to cause any discomfort or irritation.
Long Term Exposure: No data for health effects associated with long term inhalation.

Skin Contact:
Short Term Exposure: Available data indicates that this product is not harmful. It should present no hazards in normal use. In addition product is unlikely to cause any discomfort in normal use.
Long Term Exposure: No data for health effects associated with long term skin exposure.
Eye Contact:
**Short Term Exposure:** This product is believed to be not irritating to eyes.
**Long Term Exposure:** No data for health effects associated with long term eye exposure.

Ingestion:
**Short Term Exposure:** Significant oral exposure is considered to be unlikely. This product is unlikely to cause any irritation problems in the short or long term.
**Long Term Exposure:** No data for health effects associated with long term ingestion.

Carcinogen Status:
SWA: No significant ingredient is classified as carcinogenic by SWA.
NTP: No significant ingredient is classified as carcinogenic by NTP.
IARC: No significant ingredient is classified as carcinogenic by IARC.

### Section 3 - Composition/Information on Ingredients

<table>
<thead>
<tr>
<th>Ingredients</th>
<th>CAS No</th>
<th>Conc,%</th>
<th>TWA (mg/m$^3$)</th>
<th>STEL (mg/m$^3$)</th>
</tr>
</thead>
<tbody>
<tr>
<td>melatonin</td>
<td>73-31-4</td>
<td>18mg/implant</td>
<td>not set</td>
<td>not set</td>
</tr>
<tr>
<td>Other non hazardous ingredients</td>
<td>secret to 100</td>
<td></td>
<td>not set</td>
<td>not set</td>
</tr>
</tbody>
</table>

This is a commercial product whose exact ratio of components may vary slightly. Minor quantities of other non hazardous ingredients are also possible.

The SWA TWA exposure value is the average airborne concentration of a particular substance when calculated over a normal 8 hour working day for a 5 day working week. The STEL (Short Term Exposure Limit) is an exposure value that may be equalled (but should not be exceeded) for no longer than 15 minutes and should not be repeated more than 4 times per day. There should be at least 60 minutes between successive exposures at the STEL. The term "peak" is used when the TWA limit, because of the rapid action of the substance, should never be exceeded, even briefly.

### Section 4 - First Aid Measures

**General Information:**
You should call The Poisons Information Centre if you feel that you may have been poisoned, burned or irritated by this product. The number is 13 1126 from anywhere in Australia (0800 764 766 in New Zealand) and is available at all times. Have this MSDS with you when you call.

Melatonin is a naturally occurring bodily hormone produced by the pineal gland. Occasional brief exposure to this product is unlikely to cause any significant effects. However as with all hormone products, contact should be minimised by careful use.

**Contact or Poisoning:** From the available evidence, this product would appear to offer no significant health hazard by any exposure route. Consequently, First Aid is not generally required.
If major contact (eg swallowing) has occurred or if an accidental implant has been made to a person, seek medical advice.
If in doubt, contact a Poisons Information Centre or a doctor.

### Section 5 - Fire Fighting Measures

**Fire and Explosion Hazards:** There is no risk of an explosion from this product under normal circumstances if it is involved in a fire.

Fire decomposition products from this product may be toxic if inhaled. Take appropriate protective measures.

**Extinguishing Media:** Suitable extinguishing media are carbon dioxide, dry chemical, foam, water fog.

**Fire Fighting:** If a significant quantity of this product is involved in a fire, call the fire brigade.

**Flash point:** No data

**Upper Flammability Limit:** No data.

**Lower Flammability Limit:** No data.

**Autoignition temperature:** No data.

**Flammability Class:** No data.

### Section 6 - Accidental Release Measures

**Accidental release:** This product is sold in small packages, and the accidental release from one of these is not usually a cause for concern. For minor spills, clean up, rinsing to sewer and put empty container in garbage. Although no special protective clothing is normally necessary because of occasional minor contact with this product, it is good practice to use disposable gloves.

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**Poisons Information Centre:** 13 1126 from anywhere in Australia, (0800 764 766 in New Zealand)
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Section 7 - Handling and Storage

Handling: Keep exposure to this product to a minimum, and minimise the quantities kept in work areas. Check Section 8 of this MSDS for details of personal protective measures, and make sure that those measures are followed. The measures detailed below under "Storage" should be followed during handling in order to minimise risks to persons using the product in the workplace. Also, avoid contact or contamination of product with incompatible materials listed in Section 10.

Storage: Store packages of this product in a cool place. Make sure that containers of this product are kept tightly closed. Keep containers dry and away from water. Make sure that the product does not come into contact with substances listed under "Incompatibilities" in Section 10. Check packaging - there may be further storage instructions on the label.

Section 8 - Exposure Controls and Personal Protection

The following Australian Standards will provide general advice regarding safety clothing and equipment:
- Respiratory equipment: AS/NZ 1715
- Protective Gloves: AS 2161
- Occupational Protective Clothing: AS/NZS 4501
- Industrial Eye Protection: AS1336 and AS/NZS 1337
- Occupational Protective Footwear: AS/NZS2210.

SWA Exposure Limits

TWA (mg/m$^3$) STEL (mg/m$^3$)

Exposure limits have not been established by SWA for any of the significant ingredients in this product.

No special equipment is usually needed when occasionally handling small quantities. The following instructions are for bulk handling or where regular exposure in an occupational setting occurs without proper containment systems.

Ventilation: No special ventilation requirements are normally necessary for this product. However make sure that the work environment remains clean and that dusts are minimised.

Eye Protection: Eye protection is not normally necessary when this product is being used. However, if in doubt, wear suitable protective glasses or goggles.

Skin Protection: The information at hand indicates that this product is not harmful and that normally no special skin protection is necessary. However, we suggest that you routinely avoid contact with all chemical products and that you wear suitable gloves (preferably elbow-length) when skin contact is likely.

Protective Material Types: There is no specific recommendation for any particular protective material type.

Respirator: If there is a significant chance that dusts are likely to build up in the area where this product is being used, we recommend that you use a suitable Dust Mask.

Section 9 - Physical and Chemical Properties:

Physical Description & colour: Pale yellow coated cylindrical implant about 4.2 mm long and 2.3 mm diameter.

Odour: No data; expected to be odourless.

Boiling Point: Not available.

Freezing/Melting Point: No specific data. Solid at normal temperatures.

Vapour Pressure: No specific data. Expected to be low at 100°C.

Vapour Density: Negligible at normal ambient temperatures.

Specific Gravity: No data.

Water Solubility: No data.

pH: No data.

Volatility: Negligible at normal ambient temperatures.

Autoignition temp: No data.

Section 10 - Stability and Reactivity

Reactivity: This product is unlikely to react or decompose under normal storage conditions. However, if you have any doubts, contact the supplier for advice on shelf life properties.

Conditions to Avoid: This product should be kept in a cool place, preferably below 30°C. Keep containers tightly closed. Containers should be kept dry.

Incompatibilities: acids, bases, strong oxidising agents.

Fire Decomposition: Carbon dioxide, and if combustion is incomplete, carbon monoxide and smoke. Nitrogen and its compounds, and under some circumstances, oxides of nitrogen. Occasionally hydrogen cyanide gas in reducing

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atmospheres. Water. Carbon monoxide poisoning produces headache, weakness, nausea, dizziness, confusion, dimness of vision, disturbance of judgment, and unconsciousness followed by coma and death.

**Polymerisation:** This product will not undergo polymerisation reactions.

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**Section 11 - Toxicological Information**

**Local Effects:**

**Target Organs:** There is no data to hand indicating any particular target organs.

**Classification of Hazardous Ingredients**

**Ingredient** | **Risk Phrases**
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No ingredient mentioned in the HSIS Database is present in this product at hazardous concentrations.

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**Section 12 - Ecological Information**

Insufficient data to be sure of status. Expected to not be an environmental hazard.

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**Section 13 - Disposal Considerations**

**Disposal:** Dispose of small quantities and empty containers by wrapping with paper and putting in garbage. For larger quantities, if recycling or reclaiming is not possible, use a commercial waste disposal service.

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**Section 14 - Transport Information**

**ADG Code:** This product is not classified as a Dangerous Good. No special transport conditions are necessary unless required by other regulations.

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**Section 15 - Regulatory Information**

**AICS:** All of the significant ingredients in this formulation are compliant with NICNAS regulations.

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**Section 16 - Other Information**

This MSDS contains only safety-related information. For other data see product literature.

**Acronyms:**

- **ADG Code**
- **AICS**
- **SWA**
- **CAS number**
- **IARC**
- **NOS**
- **NTP**
- **R-Phrase**
- **SUSMP**
- **UN Number**

Australian Code for the Transport of Dangerous Goods by Road and Rail (7th edition)
Australian Inventory of Chemical Substances
Safe Work Australia, formerly ASCC and NOHSC
Chemical Abstracts Service Registry Number
International Agency for Research on Cancer
Not otherwise specified
National Toxicology Program (USA)
Risk Phrase
Standard for the Uniform Scheduling of Medicines & Poisons
United Nations Number

THIS MSDS SUMMARISES OUR BEST KNOWLEDGE OF THE HEALTH AND SAFETY HAZARD INFORMATION OF THE PRODUCT AND HOW TO SAFELY HANDLE AND USE THE PRODUCT IN THE WORKPLACE. EACH USER MUST REVIEW THIS MSDS IN THE CONTEXT OF HOW THE PRODUCT WILL BE HANDLED AND USED IN THE WORKPLACE.

IF CLARIFICATION OR FURTHER INFORMATION IS NEEDED TO ENSURE THAT AN APPROPRIATE RISK ASSESSMENT CAN BE MADE, THE USER SHOULD CONTACT THIS COMPANY SO WE CAN ATTEMPT TO OBTAIN ADDITIONAL INFORMATION FROM OUR SUPPLIERS.

OUR RESPONSIBILITY FOR PRODUCTS SOLD IS SUBJECT TO OUR STANDARD TERMS AND CONDITIONS, A COPY OF WHICH IS SENT TO OUR CUSTOMERS AND IS ALSO AVAILABLE ON REQUEST.

Please read all labels carefully before using product.

This MSDS is prepared in accord with the SWA document “Preparation of Safety Data Sheets for Hazardous Chemicals - Code of Practice” (December 2011)

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