

MATERIAL SAFETY DATA SHEET

Dalmarelin

SECTION 1 – IDENTIFICATION OF THE MATERIAL AND SUPPLIER

IDENTIFICATION OF THE MIXTURE AND OF THE COMPANY

Product Identifier: Dalmarelin
ACVM Code: A010611
SUBSTANCE Number: SOS1000891
Relevant identified use of the mixture and uses advised against: Injectable solution for cattle and rabbits. For Veterinary Use only.
Details of the supplier of the safety data sheet: FATRO – Italy
Via Emilia, 285
40064 Ozzano dell’Emilia (BO)
ITALY
Tel: +051 651 2711
Fax: +051 651 2728
Email: info@fatro.it
Website: www.fatro.it
Emergency telephone number: Poisons Information Centre - New Zealand ph: 0800 POISONS (0800 764 766)

SECTION 2 – HAZARDS IDENTIFICATION

Classification of the mixture:

Main harmful effects: See sections from 9 to 12.

Label elements (NOTE: this chapter does not apply to veterinary medicinal products, it is only for information purposes)

Pictogram(s)	None
Signal word	None
Hazard statement(s)	None
Precautionary statement(s)	None
Hazard symbol(s)	None
R-phrases	None
S-phrases	None

Other hazards:

Special precautions to be adopted by the person administering the product to the animals.

Women of child bearing age must administer DALMARELIN carefully, because lecorelin has proved to be foetotoxic in rats. In case of accidental injection call a doctor. GnRH analogues may be absorbed through undamaged skin. In case of skin contact, a thorough cleaning with water and soap should be made immediately.

SECTION 3 – COMPOSITION/INFORMATION ON INGREDIENTS

Substances:

N/A

Mixtures

The following table shows the substances which are considered hazardous and their health classification, according to Regulation (EC) no. 1272/2008 and Directives EU 67/548/EEC and 1999/45/EC.

Component	CAS – no.
Benzyl alcohol	100-51-6
Lecirelin acetate	61012-19-9

As for the full text of R-phrases see section 16.

SECTION 4 – FIRST AID MEASURES

Description of first aid measures:**In case of skin contact:**

P302 + P352 – IF ON SKIN: wash with plenty of water and soap
 P333 + P313 – If skin irritation or rash occurs: get medical advice/attention:
 P101 – If medical advice is needed, have product container or label at hand.

In case of eye contact:

P305 + P351 + P 338 – IF IN EYES: wash carefully for many minutes. Rinse cautiously with water for several minutes. Remove contact lens, if present and easy to do. Continue rinsing.

If swallowed:

P301 + P330 – IF SWALLOWED: rinse mouth.
 P312 – Call a POISON CENTRE or doctor/physician if you feel unwell.

IF inhaled:

NA

First Aid in general:

P363 – Wash contaminated clothing before re-use

First Aid Measures:

Consult the National Poisons Centre on 0800 POISON (0800 764 766) or a doctor immediately in every case of suspected poisoning

Most important symptoms and effects, both acute and delayed:**In case of skin contact:**

ND

In case of eye contact:

ND

If swallowed:

ND

If inhaled: NA

Indication of any immediate medical attention and special treatment needed: see 4.1

SECTION 5 – FIREFIGHTING MEASURES

Extinguishing media:

Suitable: Powder, foam, carbon dioxide or water spray

Unsuitable: none

Special hazards arising from the mixture: The fumes might contain irritant and toxic gas, avoid breathing

Advice for firefighters: Wear self-contained breathing apparatus for firefighting and protective clothing and equipment.

SECTION 6 – ACCIDENTAL RELEASE MEASURES

Personal precautions, protective

equipment and emergency procedures: Wear personal protective equipment. Avoid ingestion or direct contact with spilled material.

Environmental precautions: Avoid any release into the environment

Methods and materials for containment and cleaning up:

Containment and cleaning up should be made through mechanical removal. Collect material in a tightly-closed container. Wash the affected area with soap and water.

Reference to other sections: None

SECTION 7 – HANDLING AND STORAGE

Precautions for safe handling: Avoid eyes, skin and clothing contact with the product. Wear personal protective equipment. Wash carefully hands, face and mouth after any contact with the product

Conditions for safe storage, including any incompatibilities: Store at a temperature not above 25°C

Specific end uses: This is a product for Veterinary use only

SECTION 8 – EXPOSURE CONTROLS/PERSONAL PROTECTION

Workplace control parameters for the mixture are not available. The following table shows the workplace control parameters referred to the main substances in the mixture and to the atmospheric contaminants which could generate during the employment of the mixture.

Control parameters:

Component	Work place parameters
Benzyl alcohol	Italian ND European ND
Lecirelin acetate	Italian ND European ND

Exposure controls:**Appropriate engineering controls:**

Handle according to good industrial hygiene and adequate safety practices. Wash hands before breaks and at the end of the workday.

Personal protective equipment:

- **Eye/Face protection:** Protective gloves during production
- **Skin/Body protections:** Overalls during production
- **Hand Protection:** latex or vinyl protective gloves
- **Breathing protection:** N/A
- **Thermal hazards:** ND
- **Environment:** N/A

SECTION 9 – PHYSICL AND CHEMICAL PROPERTIES

Information on basic physical and chemical properties:

- | | |
|---|-----------------------------|
| a) Appearance | Colourless clear solution |
| b) Odour | ND |
| c) Odour threshold | ND |
| d) pH | 4,5 - 5,5 |
| e) Melting point/Freezing point | ND |
| f) Initial boiling point and boiling Range | ND |
| g) Flash point | ND |
| h) Evaporation rate | ND |
| i) Flammability (solid, gas) | ND |
| j) Upper/Lower flammability or explosive limits | ND |
| k) Vapour pressure | ND |
| l) Vapour density | ND |
| m) Relative density | 1,000 |
| n) Water solubility | Completely soluble in water |
| o) Partition coefficient (n-Octanol/water) | ND |
| p) Autoignition temperature | ND |
| q) Decomposition temperature | ND |
| r) Viscosity | ND |
| s) Explosive properties | No |
| t) Oxidizing properties | No |

Other Information:

ND

SECTION 10 – STABILITY AND REACTIVITY

Reactivity:	No
Chemical stability:	Stable at the normal conditions of storage and handling
Possibility of hazardous reactions:	None
Conditions to avoid:	Keep away from any heat and from direct sunlight exposure.
Incompatible materials:	ND
Hazardous decomposition products:	ND. In case of fire see section 5

SECTION 11 – TOXICOLOGICAL INFORMATION

Information on toxicological effects

Acute Toxicity:	LD50 Dermal
Irritation:	ND- Rat > 2000 mg/kg Relevant LD/LC50 values for classification

Component	Type	Species	Value
Lecirelin acetate	ND	ND	ND
Benzyl alcohol	LD50 oral LD50 dermal	Rat Rabbit	1230 mg/kg 2000 mg/kg

Irritation:	ND
Skin corrosion/irritation:	ND
Serious eye damage/eye irritation:	ND
Respiratory or skin sensitization:	ND
Germ cell mutagenicity:	ND
Carcinogenity:	ND
Reproductivity toxicity:	ND
Specific target organ toxicity – single expose:	ND
Specific target organ toxicity – repeated expose:	ND
Aspiration hazard:	NA
Potential health effects:	
• Inhalation:	NA
• Ingestion:	ND
• Skin:	ND
• Eyes:	ND
Further toxicological information:	ND

SECTION 12 – ECOLOGICAL INFORMATION

Ecological information on the mixture is not available, the table shows the ecological information referred to the main substances in the mixture

Toxicity:

<i>Component</i>	<i>Data</i>
Lecirelin acetate	ND
Benzyl alcohol	<u>Fish Toxicity</u> LC50 10mg/l (96h, Lepomis macrochirus) <u>Daphnia and other aquatic invertebrates Toxicity</u> EC50 55 mg/l (24h, Daphnia magna)

Persistence and degradability:	ND
Bio accumulative potential:	ND
Mobility in soil:	ND
Results of PBT and vPvB assessment:	ND
Other adverse effects	ND

SECTION 13 – DISPOSAL CONSIDERATIONS

Waste Treatment Methods: Waste classification (product and container): special.

P501 – Dispose of contents/container in accordance with official local/regional/national/international Regulations.

It is recommended to make the disposal at an authorized disposal centre.

SECTION 14 – TRANSPORT INFORMATION

UN Number:	NA
UN Proper shipping /Name:	NA
Transport hazard class(es):	
IMDG (sea)	Not classified
ADR (road) 94/55/EC:	Not classified
RID (railway) 96/49/EC:	Not classified
ICATO/IATA (air):	Not classified
Packing group:	ND
Environmental hazards:	
IMDG (sea):	Not Classified
ADR (road) 94/55/EC:	Not Classified
RID (railway):	Not Classified
ICAO/IATA (air):	Not Classified
Special precautions for user:	NA
Transport in bulk according to Annex II of MORPOL 73/78 and the IBC code:	NA

SECTION 15 – REGULATORY INFORMATION

Safety, health and environmental regulations/legislation specific for the mixture:

Regulation (EC) no. 1272/2008 (CLP):	NA
Others:	NA
Chemical safety assessment:	ND

SECTION 16– OTHER INFORMATION

Main bibliographical sources	MSDS of suppliers of raw materials Sax 11 th edition ACGIH TLV E BEI di Federchimica, ed. 2010 “Dalmarelin acute Dermal toxicity (Limit) test in rats” – Inveresk Report 19591/2001”
Text – H – code (S) mentioned in Section 3:	H302 – Harmful if swallowed H332 – Harmful if inhaled H360F – May damage fertility
Text – R – phrase (s) mentioned in Section 3:	R20/22 – Harmful by inhalation and if swallowed R60 – May impair fertility
Revision change control:	06U New lay-out of the MSDS according to Regulation (EC) no. 1907/2006
Acronyms:	
ACGIH:	American Conference of Government Industrial /Hygienists
ADR:	Accord européen relative au transport international Des marchandises dangereuses par Route
BEI:	Biological Exposure Indices
CAS:	Chemical Abstracts Service
CLP:	Classification, Labelling and Packaging
DNEL:	Derived No Effect Level
EC50:	Effective Concentration 50
EINECS:	European Inventory of Existing Commercial Chemical Substances
IARC:	International Agency for Research on Cancer
IATA:	International Air Transport Association
ICAO:	International Civil Aviation Organisation
IMDG Code:	International Maritime Dangerous Goods code
LC50:	Lethal Concentration 50
LD50:	Lethal Dose 50
PBT:	Persistent, Bio accumulative and Toxic
PNEC:	Predict No Effect Concentration
RID:	Règlement concernant le transport International ferroviaire des marchandises Dangereuses

VPVB: very Persistent, very Bio accumulative
TLV: Threshold Limit Value

THIS SDS 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 SDS 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.