




SECTION 1: IDENTIFICATION	
1.1 Product identifier	
Product name:	Myodine 25 mg/ml Solution for injection for dogs and cats (AT, BE, BG, CY, CZ, EL, ES, FR, HR, HU, IE, IT, LU, NL, PT, RO, SI, SK, UK)
Synonyms:	Myodine vet 25 mg/ml solution for injection for dogs and cats (DK, EE, FI, IS, LT, LV, NO, PL, SE) Nandrosol 25 mg/ml solution for injection for dogs and cats (DE)
Proper Shipping name:	Not applicable
Other means of identification:	None
1.2 Relevant identified uses of the substances or mixture and uses advised against	
Recommended uses:	Indicated for use in dogs and cats as an adjunctive treatment for conditions in which anabolic therapy is considered to be beneficial.
Uses advised against:	Do not use in pregnant animals. Do not use in animals with hypercalcaemia. Do not use in animals with androgenic dependent tumours. Do not use in breeding animals. Do not use in cases of hypersensitivity to the active substance or to any of the excipients. Not for human use.
1.3 Details of the supplier of the substance or mixture	
Registered company name	Le Vet Beheer B.V.
Address:	Wilgenweg 7 3421 TV Oudewater The Netherlands
Telephone:	+31 (0)348 565858
Fax:	+31 (0)348 565454+
Website:	www.dechra.com
Email:	Not available
Website:	www.dechra.com
Email:	Not available
1.4 Emergency Telephone Numbers	
Dechra (NL):	+31 (0)348 565858

SECTION 2: HAZARDS IDENTIFICATION	
2.1 Classification of the substance or mixture Considered a hazardous mixture according to Reg. (EC) No 1272/2008 and their amendments. Not classified as Dangerous Goods for transport purposes (EU).	
Classification according to regulation (EC) No 1272/2008 [CLP] (EU)!	H315 - Skin Corrosion/Irritation Category 2, H319 - Eye Irritation Category 2, H335 - Specific target organ toxicity - single exposure Category 3 (respiratory tract irritation), H412 - Chronic Aquatic Hazard Category 3
2.2 Label Elements	
Hazard Pictogram(:	
Signal Word:	WARNING
Hazard statement(s):	
	H315 Causes skin irritation H319 Causes serious eye irritation H412 Harmful to aquatic life with long lasting effects
Supplementary Statement(s) EU:	
	Not applicable
Precautionary Statement(s) Prevention:	
	Not applicable.
Precautionary Statement(s) Response:	
	Not applicable.
Precautionary Statement(s) Storage:	
	Not applicable.
Precautionary Statement(s) Disposal:	
	Not applicable.
2.3 Other Hazard Information REACH (EU) Article 57-59: The mixture does not contain Substances of Very High Concern (SVHC) at the SDS print date.	

SECTION 3: INFORMATION ON THE INGREDIENTS

3.1 Substances

See section below for composition of mixtures

3.2 Mixtures

1.CAS No 2.EC Number 3.Index Number 4.REACH Number	% Weight	Name	Classification according to regulations (EC) No 1272/2008 [CLP] (EU)
1. 8002-03-7 2. 232-296-4 3. Not Available 4. Not Available	Not Specified	Peanut oil	Skin Corrosion/Irritation Category 2, Eye Irritation Category 2, Specific target organ toxicity - single exposure Category 3 (respiratory tract irritation); H315, H319, H335, EUH019, EUH001 [1]
1. 100-51-6 2. 202-859-9 3. 603-057-00-5 4. 01-2119492630-38-XXXX[01-2120762094-56-XXXX	Not Specified	Benzyl Alcohol	Acute Toxicity (Oral) Category 4, Acute Toxicity (Inhalation) Category 4; H302, H332 [2]
1. 434-22-0 2. 207-101-0 3. Not Available 4. Not Available	Not Specified	Nandrolone	Acute Toxicity (Oral) Category 4, Acute Toxicity (Dermal) Category 4, Chronic Aquatic Hazard Category 1, Acute Aquatic Hazard Category 1, Acute Toxicity (Inhalation) Category 4; H302, H312, H410, H400, H332 [1]
Legend:	1. Classified by Chemwatch; 2. Classification drawn from Regulation (EU) No 1272/2008 - Annex VI; 3. Classification drawn from C&L; * EU IOELVs available		

SECTION 4: FIRST AID MEASURES

4.1 Description of first aid measures

Eye contact:	Accidental spillage on the eyes should be washed off with plenty of water. If pain or irritation occurs, seek medical advice and show the package leaflet or the label to the medical practitioner.
Skin contact:	Accidental spillage on the skin should be washed off with plenty of water. If irritation occurs, seek medical advice and show the package leaflet or the label to the medical practitioner.

Inhalation:	Inhalation is highly unlikely due to the nature of the product and how it is packaged and administered. If irritation or difficulty in breathing occurs, seek urgent medical advice and show the package leaflet or the label to the medical practitioner. Remove the patient from the contaminated area. Lay the patient down, keep warm and rested.
Ingestion:	Ingestion is highly unlikely due to the nature of the product and how it is packaged and administered. If swallowed, do not induce vomiting. Seek medical advice and show the package leaflet or the label to the medical practitioner. Remove material and give water to rinse out mouth, then provide liquid slowly and as much as the casualty can comfortably drink.
4.2 Most important symptoms and effects, both acute and delayed	
Eye contact:	May eye irritation.
Skin contact:	May cause skin irritation.
Ingestion:	May cause discomfort if ingested in large quantities
See Section 11 for more detailed information	
4.3 Indication of immediate medical attention and special treatment needed	
Treat symptomatically. For acute massive ingestions of androgenic-anabolic steroids, decontamination of the gastrointestinal tract with oral administration of activated charcoal may reduce absorption within 1-2 hours of ingestion.	
SECTION 5: FIRE FIGHTING MEASURES	
5.1 Extinguishing media	
Suitable:	Select extinguishing media suitable for surrounding area
Unsuitable:	There is no restriction on the type of extinguisher which may be used
5.2 Special hazards arising from the substance or mixture	
Fire incompatibility:	Avoid contamination with oxidising agents.
5.3 Special protective actions for fire-fighters:	
Firefighting:	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.
Fire / explosion hazard:	Combustible. Slight fire hazard when exposed to heat or flame. On combustion, may emit toxic fumes of carbon monoxide.




SECTION 6: ACCIDENTAL RELEASE MEASURES	
6.1 Personal precautions, protective equipment and emergency procedures	
For information on protective equipment, see section 8	
6.2 Environmental Precautions	
See section 12	
6.3 Methods and material for containment and cleaning up	
Spills are unlikely due to the nature of the product and how it is packaged	
Minor Spills:	Clean up all spills immediately. Avoid breathing vapours and contact with skin and eyes. Control personal contact with the substance, by using protective equipment. Contain and absorb spill with sand, earth, inert material or vermiculite. Wipe up. Place in a suitable, labelled container for waste disposal.
Major Spills:	Clear area of personnel and move upwind. Alert Fire Brigade and tell them location and nature of the hazard. Contain and absorb spill with sand, earth, inert material or vermiculite. Prevent, by any means available, spillage from entering drains or water course.

SECTION 7: HANDLING AND STORAGE	
7.1 Precautions for safe handling	
Safe Handling:	Wear suitable protection gloves and clothing when handling the product. Do not allow clothing wet with material to stay in contact with skin. When handling, DO NOT eat, drink or smoke. Always wash hands with water after handling. Observe manufacturer's storage and handling recommendations.
Other Information:	Keep the vial in the outer carton in order to protect from light. At low temperatures the product may become viscous and turbid. Warming the vial in the hand will return the contents to the normal state. Keep out of the reach and sight of children.
7.2 Conditions for safe storage, including any incompatibilities	
Suitable Container:	Type I/ Type II colourless glass vial with FM259/0 coated bromobutyl rubber stopper (20mm) and an aluminium cap (20mm) Check that containers are clearly labelled.

Storage incompatibility:	Avoid reaction with oxidizing agents.
7.3 Specific end uses	
Not available	

SECTION 8: EXPOSURE CONTROLS / PERSONAL PROTECTION				
8.1 Control parameters				
DERIVED NO EFFECT LEVEL – DNEL (EU)				
Not Available				
PREDICTED NO EFFECT LEVEL – PNEC (EU)				
Not Available				
OCCUPATIONAL EXPOSURE LIMITS (OEL)				
INGREDIENT DATA				
Not Available				
EMERGENCY LIMITS (EU/US):				
Ingredient	Material Name	TEEL-1	TEEL-2	TEEL-3
Benzyl alcohol	Benzyl alcohol	30ppm	52ppm	740ppm
Ingredient		Original IDLH		Revised IDLH
Peanut oil		Not Available		Not Available
Benzyl alcohol		Not Available		Not Available
Nandrolone		Not Available		Not Available

8.2 Exposure controls	
Appropriate engineering controls:	The basic types of engineering controls are: Process controls which involve changing the way a job activity or process is done to reduce the particular risk.
Personal protection:	
Eye and face protection:	Safety glasses with side shields / chemical goggles
Skin protection:	See hand protection below



Hands/ feet protection:	No special equipment needed when handling small quantities. OTHERWISE: Wear chemical protective gloves and safety footwear
Body protection:	Wear appropriate clothing
Other protection:	No special equipment needed when handling small quantities
Thermal hazards:	Not applicable
Respiratory protection:	Not applicable
8.3 Environmental exposure controls See Section 12	

SECTION 9: PHYSICAL AND CHEMICAL PROPERTIES

9.1 Information on basic physical and chemical properties

Appearance: Product: Solution for injection
Container: Type 1/ Type II colourless glass vials
Physical state: Clear yellowish oily solution
Odour: Not available
Melting point / freezing point (degrees C): API: ~47°C
Initial boiling point and boiling range: Not applicable
Flash Point: Not applicable
Evaporation rate Not applicable
Flammability: Not available
Upper/lower flammability or explosive limits: Not available
Vapour pressure: Not applicable
Specific Gravity: Not available
Solubility in water and solvents (mg/l): API: white to creamy white crystalline powder
Auto ignition temperature (degrees C): Not available
Decomposition temperature (degrees C): Not available
Viscosity: (degrees C): Not available
Explosive properties: Not available
Oxidising properties: Not available
Partition Coefficient: Not available
Taste: Not applicable
Surface tension: Not available
Volatile component: Not available
Gas group: Not applicable
pH: Not applicable
VOC g/L: Not applicable

9.2 Other information
Not Available



SECTION 10: STABILITY AND REACTIVITY	
10.1 Reactivity:	See Section 7.
10.2 Chemical stability:	Unstable in the presence of incompatible materials. Product is considered stale otherwise. Hazardous polymerisation will not occur.
10.3 Possibility of hazardous reactions:	The product is not considered to be hazardous if used as per instructions.
10.4 Conditions to avoid:	Protect from light.
10.5 Incompatible materials:	See section 7.
10.6 Hazardous decomposition:	See Section 5.

SECTION 11: TOXICOLOGICAL INFORMATION		
Inhalation:	May cause respiratory irritation in some persons. Due to the nature of the product, this is however, unlikely to occur.	
Ingestion:	May cause discomfort if ingested in large quantities	
Skin contact:	May cause skin irritation. In the event of accidental self-injection, transient painful, local reactions may occur. People with known hypersensitivity to nandrolone or any of the excipients should avoid contact with the veterinary medicinal product.	
Eye contact:	May cause eye irritation	
Chronic:	Long term exposure is not thought to produce chronic effects	
Myodine 25 mg/ml Solution for injection for dogs and cats:	Toxicity	Irritation
	Not available	Not available
Peanut oil	Toxicity	Irritation
	>2000 mg/kg (oral rat)	Skin (human): 300 mg/3d I – mild Skin (rabbit): 100 mg/ 24hr moderate
Benzyl alcohol	Acute toxicity	Irritation
	Dermal (rabbit) LD50: 2000 mg/kg ² Inhalation (rat) LC50; >4.178 mg/l/4h ² Oral (rat) LD50: 1230 mg/kg ²	Eye (rabbit): 0.75 mg open SEVERE Skin (man): 16 mg/48h mild Skin (rabbit): 10 mg/24 open mild



SECTION 11: TOXICOLOGICAL INFORMATION

Nandrolone	Acute toxicity	Irritation
	Not Available	Not Available

1. Value obtained from Europe ECHA Registered Substances - Acute toxicity 2. Value obtained from manufacturer's SDS. Unless otherwise specified data extracted from RTECS - Register of Toxic Effect of chemical Substances*

Skin corrosion/irritation:

May cause any skin corrosion/ irritation.

Serious eye damage/irritation:

May cause irritation

Respiratory or skin sensitization:

May cause respiratory irritation. People with known hypersensitivity to nandrolone or any of the excipients should avoid contact with the veterinary medicinal product.

Germ cell mutagenicity:

Not available

Carcinogenicity:

Not expected to be carcinogenic.

Reproductive toxicity:

Virilisation of the foetus may occur if pregnant women are exposed to the product. Therefore, the veterinary medicinal product should not be administered by pregnant women or women trying to conceive.

STOT – single exposure:

Not available

STOT–repeated exposure:

Not available

Aspiration hazard:

Not available

SECTION 12: ECOLOGICAL INFORMATION					
12.1 Toxicity					
Ingredient	Endpoint	Test duration (hr)	Species	Value	Source
Myodine 25 mg/ml Solution for injection for dogs and cats	Not available	Not available	Not available	Not available	Not available
Peanut oil	Not available	Not available	Not available	Not available	Not available
Benzyl alcohol	LC50 EC50 EC50 NOEC	96 48 96 336	Fish Crustacea Algae or other aquatic plants Fish	10 mg/l 230 mg/l 76.828 mg/l 5.1 mg/l	1 1 1 1
Nandrolone	LC50 EX50	96 96	Fish Algae or other aquatic plants	11.743 mg/l 13.064 mg/l	2 2
Legend: <i>Extracted from 1. Europe ECHA Registered Substances - Ecotoxicological Information - Aquatic Toxicity 2. EPIWIN Suite V3.12 (QSAR) - Aquatic Toxicity Data (Estimated)</i>					
DO NOT discharge into sewer or waterways.					
12.2 Persistence and degradability					
Ingredient	Persistence: Water/Soil		Persistence: Air		
Benzyl alcohol	LOW		LOW		
Nandrolone	HIGH		HIGH		
12.3 Bioaccumulative potential					
Ingredient	Bioaccumulative Potential				
Benzyl alcohol	LOW (LogKOW = 1.1)				
Nandrolone	LOW (LogKOW = 2.62)				
12.4 Mobility in Soil					
Ingredient	Mobility				
Benzyl alcohol	LOW (KOC = 15.66)				
Nandrolone	LOW (KOC = 906.3)				



<p>12.5 Results of PBT and vPvB assessment Not Available</p>
<p>12.6 Other adverse effects Not Available</p>

SECTION 13: DISPOSAL CONSIDERATIONS

13.1 Waste treatment methods	
Product / packaging disposal:	<p>Any unused veterinary medicinal product or waste material derived from such veterinary medicinal products should be disposed of in accordance with national requirements.</p> <p>Legislation addressing waste disposal requirements may differ by country, state and/or territory. Each user must refer to laws operating in their area.</p> <p>Recycle wherever possible or consult manufacturer for recycling options. Consult State Land Waste Management Authority for disposal. Bury residue in an authorised landfill. Recycle containers if possible, or dispose of in an authorised landfill.</p> <p>Shelf life considerations should also be applied in making decisions of this type. Note that properties of a material may change in use, and recycling or reuse may not always be appropriate. Where in doubt contact the responsible authority.</p>
Waste Treatment Options:	Not Available
Sewage Disposal Options:	Not Available



SECTION 14: TRANSPORT INFORMATION

Labels required:

Marine pollutant: NO

Hazchem: Not Applicable

Land transport (EU: ADR / US: DOT): NOT REGULATED FOR TRANSPORT OF DANGEROUS GOODS

14.1 UN Number N/a

14.2 UN Proper Shipping Name N/a

14.3 Transport hazard class(es)	Class	N/a
	Sub risk	N/a

14.4 Packing group N/a

14.5 Environmental hazards N/a

14.6 Special precautions for user	Special provisions	N/a
	Limited quantity	N/a

14.7 Transport in bulk according to Annex II of MARPOL73/78 and the IBC Code N/a

Air transport (ICAO-IATA / DGR): NOT REGULATED FOR TRANSPORT OF DANGEROUS GOODS

14.1 UN Number N/a

14.2 UN Proper Shipping Name N/a

14.3 Transport hazard class(es)	ICAO/IATA Class	N/a
	ICAO / IATA Sub risk	N/a
	ERG Code	N/a

14.4 Packing group N/a

14.5 Environmental hazards N/a



14.6 Special precautions for user	Special provisions	N/a
	Cargo only packing instructions	N/a
	Cargo only maximum qty/pack	N/a
	Passenger and cargo packaging instructions	N/a
	Passenger and cargo maximum qty/pack	N/a
	Passenger and cargo limited quantity packing instructions	N/a
	Passenger and cargo limited maximum qty/pack	N/a
14.7 Transport in bulk according to Annex II of MARPOL73/78 and the IBC Code	N/a	
Sea transport (IMDG-Code / GGVSee): NOT REGULATED FOR TRANSPORT OF DANGEROUS GOODS		
14.1 UN Number	N/a	
14.2 UN Proper Shipping Name	N/a	
14.3 Transport hazard class(es)	IMDG Class	N/a
	IMDG Sub risk	N/a
14.4 Packing group	N/a	
14.5 Environmental hazards	N/a	
14.6 Special precautions for user	EMS Number	N/a
	Special provisions	N/a
	Limited quantities	N/a
14.7 Transport in bulk according to Annex II of MARPOL73/78 and the IBC Code	N/a	



Inland waterways transport (ADN): NOT REGULATED FOR TRANSPORT OF DANGEROUS GOODS		
14.1 UN Number	N/a	
14.2 UN Proper Shipping Name	N/a	
14.3 Transport hazard class(es)	N/a	N/a
14.4 Packing group	N/a	
14.5 Environmental hazard	N/a	
14.6 Special precautions for user	Classification Code	N/a
	Special provisions	N/a
	Limited quantity	N/a
	Equipment required	N/a
	Fire cones number	N/a
14.7 Transport in bulk according to Annex II of MARPOL73/78 and the IBC Code	N/a	

SECTION 15: REGULATORY INFORMATION

15.1 Safety, health and environmental regulations / legislation specific for the substance or mixture

Peanut oil (8002-03-7)

Europe EC inventory
ECHA Classification and labelling inventory
EINECS
GESAMP/ EHS Composite list
IMO IBC Code Chapter 17: Summary of minimum requirements
IMO MARPOL (Annex II)

Benzyl alcohol (100-51-6)

ADN – European agreement concerning the International Carriage of Dangerous goods by inland waterways
ECHA CoRAP list of substances
Europe EC inventory
ECHA Classification and labelling inventory
ADR 2011 - European agreement concerning the International Carriage of Dangerous goods by road
EINECS
GESAMP/ EHS Composite list
IMO IBC Code Chapter 17: Summary of minimum requirements
IMO MARPOL (Annex II)
IATA Dangerous Goods Regulations
IMDG Code
RID 2017
UN Recommendations on the transport of dangerous goods model regulations

Nandrolone (434-22-0)

ADN – European agreement concerning the International Carriage of Dangerous goods by inland waterways
ECHA DSD-DPD
Europe EC inventory
ECHA Classification and labelling inventory
ECICS
ADR 2011 - European agreement concerning the International Carriage of Dangerous goods by road
EINECS
GESAMP/ EHS Composite list
IMO IBC Code Chapter 17: Summary of minimum requirements
IMO MARPOL (Annex II)
IATA Dangerous Goods Regulations
IMDG Code
RID 2017
UN Recommendations on the transport of dangerous goods model regulations

Safety Data Sheet

Product Name: Myodine 25 mg/ml Solution for injection for
dogs and cats

Issue Date: 03/2019

Version No: 1

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This safety data sheet is in compliance with the following EU legislation and its adaptations - as far as applicable: 98/24/EC, 92/85/EC, 94/33/EC, 91/689/EEC, 1999/13/EC, Commission Regulation (EU) 2015/830, Regulation (EC) No 1272/2008 and their amendments.



15.2 Chemical Safety Assessment

ECHA SUMMARY

Ingredient	CAS number	Index Number	ECHA Dossier
Peanut oil	8002-03-7	Not available	Not available

Harmonization (C&L Inventory)	Hazard Class and Category Code(s)	Pictograms Signal Word Code(s)	Hazard Statement Code(s)
1	Not classified	Not available	Not available
Harmonisation Code 1 = the most prevalent classification			

Ingredient	CAS number	Index Number	ECHA Dossier
Benzyl alcohol	100-51-6	603-057-00-5	01-2119492630-38-XXXX 01-2120762094-56-XXXX

Harmonization (C&L Inventory)	Hazard Class and Category Code(s)	Pictograms Signal Word Code(s)	Hazard Statement Code(s)
1	Acute Tox. 4; Acute Tox. 4 GHS07; Wng H302; H332	Acute Tox. 4; Acute Tox. 4 GHS07; Wng H302; H332	Acute Tox. 4; Acute Tox. 4 GHS07; Wng H302; H332
Harmonisation Code 1 = the most prevalent classification			

Ingredient	CAS number	Index Number	ECHA Dossier
Nandrolone	434-22-0	Not available	Not available

Harmonization (C&L Inventory)	Hazard Class and Category Code(s)	Pictograms Signal Word Code(s)	Hazard Statement Code(s)
1	Acute Tox. 4; Acute Tox. 4; Acute Tox. 4 GHS07; Wng H302; H312; H332	Acute Tox. 4; Acute Tox. 4; Acute Tox. 4 GHS07; Wng H302; H312; H332	Acute Tox. 4; Acute Tox. 4; Acute Tox. 4 GHS07; Wng H302; H312; H332
Harmonisation Code 1 = the most prevalent classification			



National Inventory	Status
Australia – AICS	No (nandrolone)
Canada – DSL	No (nandrolone)
Canada – NDSL	No (benzyl alcohol, peanut oil, nandrolone)
China – IECSC	No (nandrolone)
Europe - EINEC / ELINCS / NLP	Yes
Japan – ENCS	No (peanut oil)
Korea – KECI	No (nandrolone)
New Zealand - NZIoC	No (nandrolone)
Philippines – PICCS	No (nandrolone)
USA – TSCA	No (nandrolone)
Legend:	<i>Yes = All ingredients are on the inventory No = Not determined or one or more ingredients are not on the inventory and are not exempt from listing(see specific ingredients in brackets)</i>



SECTION 16: OTHER INFORMATION

The SDS is written in accordance to guidelines specified by REACH, GHS and ECHA.

Other Information

For detailed advice on Personal Protective Equipment, refer to the following EU CEN Standards:

- EN 166 Personal eye-protection
- EN 340 Protective clothing
- EN 374 Protective gloves against chemicals and micro-organisms
- EN 13832 Footwear protecting against chemicals
- EN 133 Respiratory protective devices

Definitions and abbreviations

- PC—TWA: Permissible Concentration-Time Weighted Average
- PC—STEL: Permissible Concentration-Short Term Exposure Limit
- STEL: Short Term Exposure Limit
- TEEL: Temporary Emergency Exposure Limit
- IDLH: Immediately Dangerous to Life or Health Concentrations

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