



SECTION 1: IDENTIFICATION	
1.1 Product identifier	
Product name:	Apovomin 3 mg/ml Solution for Injection for Dogs
Synonyms:	None
Proper Shipping name:	Not Available
Other means of identification:	None
1.2 Relevant identified uses of the substances or mixture and uses advised against	
Recommended uses:	Induction of emesis in dogs
Uses advised against:	Not for human use.
1.3 Details of the supplier of the substance or mixture	
Registered company name:	Dechra Regulatory B.V.
Address:	Handelsweg 25 5531 AE Bladel The Netherlands
Telephone:	+31 (0) 497 544 300
Fax:	+31 (0) 497 544 302
Website	www.dechra.com
1.4 Emergency Telephone Numbers	
	+31 (0) 497 544 300
SECTION 2: HAZARDS IDENTIFICATION	
2.1 Classification of the substance or mixture	
<p>Not considered a hazardous mixture according to Reg. (EC) No 1272/2008 and their amendments. This product is exempted from Regulation according to article 1(5) of Reg. (EC) No 1272/2008 and their amendments, because it is a veterinary medicinal products as defined in Directive 2001/82/EC, which is in the finished state, intended for the final user. Not classified as Dangerous Goods for transport purposes (EU).</p>	
DSD Classification (EU):	Not Available
DPD Classification (EU):	Not Available
Classification according to regulation (EC) No 1272/2008 [CLP] (EU)¹:	Not applicable
2.2 Label Elements	
Signal Word:	Not applicable



Hazard Statement(s): Not applicable	
H301	Toxic if swallowed
H302	Harmful if swallowed.
H312	Harmful in contact with skin
H361	Suspected of damaging fertility of the unborn child
Precautionary Statement(s) Prevention: Not applicable	
P270	Do not eat, drink or smoke when using this product.
P280	Wear protective gloves/protective clothing/eye protection/face protection.
Precautionary Statement(s) Response: Not applicable	
Precautionary Statement(s) Storage:	
P405	Store locked up
P403 + P233	Store in a well-ventilated place. Keep container tightly closed.
Precautionary Statement(s) Disposal:	
P501	Dispose of contents / packaging according to local regulations
2.3 Other Hazard Information Apomorphine has been shown to have teratogenic effects in laboratory animals and is excreted in human milk. Pregnant or lactating women should avoid handling the veterinary medicinal product.	

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. 41372-20-7 2. 206-243-0 200-360-0 3. Not Available 4. Not Available	0-1	Apomorphine hydrochloride	Reproductive Toxicity Category 2, Acute Toxicity (Inhalation) Category 4, Skin Sensitizer Category 1, Respiratory Sensitizer Category 1, Chronic Aquatic Hazard Category 2, Acute Toxicity (Oral) Category 4, Acute Toxicity (Dermal) Category 4;



N/a/	Proprietary	Other ingredients determined not to be hazardous	N/A
SECTION 4: FIRST AID MEASURES			
4.1 Description of first aid measures			
Eye contact:	In cases of accidental eye contact, immediately rinse the affected area with large amounts of clean water until advised to stop by a doctor or for at least 15 minutes. Seek medical advice.		
Skin contact:	In the event of eye or skin contact, remove contaminated clothing, rinse the affected area with large amounts of clean water and if irritation occurs, seek medical attention.		
Inhalation:	If fumes or combustion products are inhaled, remove from contaminated area. Other measures are usually unnecessary.		
Ingestion:	If accidentally swallowed, seek medical aid immediately and show the package leaflet or SDS to the medical practitioner.		
Self-injection:	In case of accidental self-injection, seek medical advice immediately and show the package leaflet or the label to the physician. DO NOT DRIVE, as sedation may occur.		
4.2 Most important symptoms and effects, both acute and delayed			
See Section 11.			
4.3 Indication of immediate medical attention and special treatment needed			
Treat symptomatically			



SECTION 5: FIRE FIGHTING MEASURES	
5.1 Extinguishing media	
Suitable:	There is no restriction on the type of extinguisher which may be used.
Unsuitable:	None.
5.2 Special hazards arising from the substance or mixture	
Fire incompatibility:	Avoid contamination with oxidising agents i.e. nitrates, oxidising acids, chlorine bleaches, pool chlorine etc. as ignition may result.
5.3 Special protective actions for fire-fighters:	
Firefighting:	Alert Fire Brigade and tell them location and nature of hazard. Wear full breathing apparatus and self-contained breathing apparatus. Prevent, by any means available, spillage from entering drains or water courses.
Fire / explosion hazard:	No combustible. May decompose to produce toxic fumes of sulfur oxides (SOx)

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	
For information on environmental precautions, see section 12.	
6.3 Methods and material for containment and cleaning up	
Minor Spills:	Clean up all spills immediately. Avoid breathing vapours and contact with skin and eyes. Wear protective clothing, gloves, safety glasses and dust respirator. Use dry clean up procedures and avoid generating dust.
Major Spills:	Clear area of personnel and move upwind. Alert Fire Brigade and tell them location and nature of the hazard. Control personal contact by wearing protective clothing.

SECTION 7: HANDLING AND STORAGE

7.1 Precautions for safe handling

Safe Handling:	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 out of the reach and sight of children.

7.2 Conditions for safe storage, including any incompatibilities

Suitable Container:	Clear Type I glass vials containing 5, 10 or 20 ml, closed with a coated bromobutyl rubber stopper and sealed with an aluminium cap. Each vial is packed into a cardboard box.
Storage incompatibility:	None known

7.3 Specific end uses

see section 1.2

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:

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:	Protective gloves
Body protection:	Wear appropriate clothing
Other protection:	Not applicable
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: Clear solution practically free from particles
Container: Solution for Injection, vials with stopper
Physical state: Liquid
Odour: Not available
Odour Threshold: Not available
pH (as supplied): Not available
Melting point / freezing point (degrees C): Not available
Initial boiling point and boiling range: Not available
Flash Point: Not available
Evaporation rate: Not available
Flammability: Not available
Upper/lower flammability or explosive limits: Not available
Vapour pressure: Not available
Relative Density (at degrees C): Not available
Solubility in water and solvents (mg/l): Not available
Vapour density: Not available
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
Molecular weight: Not available
Taste: Not available
Surface tension: Not available
Volative component: Not available
Gas group: Not available
pH as a solution: 2.5-5
VOC g/L: Not available

9.2 Other information
 Not Available



10: REACTIVITY AND STABILITY	
10.1 Reactivity:	See Section 7
10.2 Chemical stability:	Product is considered stable. Hazardous polymerisation will not occur.
10.3 Possibility of hazardous reactions:	See Section 7..
10.4 Conditions to avoid:	See Section 7.
10.5 Incompatible materials:	See section 7.
10.6 Hazardous decomposition:	See Section 5.
SECTION 11: TOXICOLOGICAL INFORMATION	
Inhalation:	Not expected to cause adverse health effects or respiratory irritation
Ingestion:	Not expected to be harmful for ingestion
Skin contact:	May cause skin irritation and hypersensitivity.
Eye contact:	May cause eye irritation.
Chronic:	May cause hypersensitivity

Apovomin 3 mg/ml Solution for Injection:	Toxicity	Irritation
	Not Available	May cause irritation
Apomorphine hydrochloride:	Toxicity	Irritation
	Oral (mouse) LD50: 300 mg/kg ²	May cause irritation
<i>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</i>		
Skin corrosion/ irritation:		
May cause skin irritation.		
Serious eye damage/ irritation:		
May cause serious eye irritation.		
Respiratory or skin sensitization:		
Hypersensitivity may occur.		



Germ cell mutagenicity:
Not available
Carcinogenicity:
Not available
Reproductive toxicity:
Apomorphine has been shown to have teratogenic effects in laboratory animals and is excreted in human milk. Pregnant or lactating women should avoid handling the veterinary medicinal product.
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
Apovomin 3 mg/ml Solution for Injection	Not Available	Not Available	Not Available	Not Available	Not Available
Apomorphine hydrochloride	LC50	96	Fish	12.989mg/L	3
Extracted from 3. EPIWIN Suite V3.12 (QSAR) - Aquatic Toxicity Data (Estimated)					
DO NOT discharge into sewer or waterways.					
12.2 Persistence and degradability					
Ingredient	Persistence: Water/Soil		Persistence: Air		
Apomorphine hydrochloride	HIGH		HIGH		
12.3 Bioaccumulative potential					
Ingredient	Bioaccumulation				
Apomorphine hydrochloride	LOW (LogKOW = 2.3)				



12.4 Mobility in Soil	
Ingredient	Mobility
Apomorphine hydrochloride	LOW (KOC = 245300)
12.5 Results of PBT and vPvB assessment Not Applicable	
12.6 Other adverse effects Not Available	
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>Ensure that the disposal of material is carried out in accordance with Hazardous Substances (Disposal) Regulations 2001.</p> <p>DO NOT allow wash water from cleaning or process equipment to enter drains.</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 (ADR): NOT REGULATED FOR TRANSPORT OF DANGEROUS GOODS	
Air transport (ICAO-IATA / DGR): NOT REGULATED FOR TRANSPORT OF DANGEROUS GOODS	
Sea transport (IMDG-Code / GGVSee): NOT REGULATED FOR TRANSPORT OF DANGEROUS GOODS	
Inland waterways transport (ADN): NOT REGULATED FOR TRANSPORT OF DANGEROUS GOODS	



SECTION 15: REGULATORY INFORMATION

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

APOMORPHINE HYDROCHLORIDE IS FOUND ON THE FOLLOWING REGULATORY LISTS:

- Europe EC Inventory
- Europe European Customs Inventory of Chemical Substances
- EINECS

15.2 Chemical Safety Assessment

ECHA SUMMARY

Ingredient	CAS number	Index Number	ECHA Dossier
Apomorphine hydrochloride	41372-20-7	Not Available	Not Available

Harmonization (C&L Inventory)	Hazard Class and Category Code(s)	Pictograms Signal Word Code(s)	Hazard Statement Code(s)
1	Acute Tox. 4; Acute Tox 3 ; Skin Sens 1 ;	GHS08, GHS06; Dgr	H301, H312, H317, H332, H334
Harmonization Code 1 = The most prevalent classification. Harmonization Code 2 = The most severe classification			

National Inventory	Status
Australia - AICS	Y
Canada - DSL	N (apomorphine hydrochloride)
Canada - NDSL	Y
China - IECSC	N (apomorphine hydrochloride)
Europe - EINEC / ELINCS /NLP	Y
Japan - ENCS	N (apomorphine hydrochloride)
Korea - KECI	N (apomorphine hydrochloride)
New Zealand - NZIoC	Y
Philippines - PICCS	N (apomorphine hydrochloride)
USA - TSCA	Y
Taiwan - TCSI	Y
Mexico - INSQ	N (apomorphine hydrochloride)
Vietnam - NCI	N (apomorphine hydrochloride)
Russia - ARIPS	N (apomorphine hydrochloride)



Legend:	<i>Y = All ingredients are on the inventory N = 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

Full text Risk and Hazard codes:

H301	Toxic if swallowed
H302	Harmful if swallowed.
H312	Harmful in contact with skin
H361	Suspected of damaging fertility of the unborn child

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

The information provided in this Safety Data Sheet has been compiled by Dechra Ltd using a number of different sources, and is correct to the best of its knowledge, information and belief as at the date of its publication. However, Dechra Ltd makes no warranties, express or implied, in relation to the information set out in this Safety Data Sheet, including, without limitation, as to its accuracy or completeness.

The information provided is not a quality specification, and is prepared by way of guidance as to the safe handling, use, processing, storage, transportation, disposal and release of the relevant products referred to. The user is responsible for determining whether or not the product is fit for any particular purpose and/or suitable for the user's proposed method of use and application.

Copyright, 2020, Dechra Ltd. All rights reserved.

Copying and/or downloading of this information for the purpose of properly utilizing Dechra Ltd products is permitted provided that: (1) the information is copied in full with no changes unless prior written agreement is obtained from Dechra Ltd, and (2) neither the copy nor the original is resold or otherwise distributed for the purposes of making a profit thereon.