



<b>SECTION 1: IDENTIFICATION</b>	
<b>1.1 Product identifier</b>	
<b>Product name:</b>	Laxatract 667 mg/ml Syrup for Dogs and Cats
<b>Synonyms:</b>	None
<b>Proper Shipping name:</b>	Not applicable
<b>Other means of identification:</b>	None
<b>1.2 Relevant identified uses of the substances or mixture and uses advised against</b>	
<b>Recommended uses:</b>	Laxative for dogs and cats
<b>Uses advised against:</b>	<b>Not for human use.</b>
<b>1.3 Details of the supplier of the substance or mixture</b>	
<b>Registered company name (NL):</b>	Dechra Regulatory B.V.
<b>Address:</b>	Handelsweg 25 5531 AE Bladel The Netherlands
<b>Telephone:</b>	+31 (0) 497 544 300
<b>Fax:</b>	+31 (0) 497 544 302
<b>Website:</b>	<a href="http://www.dechra.com">www.dechra.com</a>
<b>Email:</b>	Not available
<b>1.4 Emergency Telephone Numbers</b>	
	+31 (0) 497 544 300



SECTION 2: HAZARDS IDENTIFICATION	
<b>2.1 Classification of the substance or mixture</b>	
<p><b>Not considered a hazardous mixture and is a product that is exempted from Regulation according to article 1(5) of Reg. (EC) No 1272/2008 and their amendments, because it is a veterinary medicinal product as defined in Directive 2001/82/EC, which is in the finished state, intended for the final user.</b></p> <p><b>Not classified as Dangerous Goods for transport purposes (EU).</b></p>	
<b>Classification according to regulation (EC) No 1272/2008 [CLP] (EU)<sup>1</sup>:</b>	Not applicable
<b>2.2 Label Elements</b>	
<b>Hazard Pictogram:</b>	Not applicable
<b>Signal Word:</b>	Not applicable
<b>Hazard statement(s):</b>	
	Not applicable
<b>Supplementary Statement(s) EU:</b>	
	Not applicable
<b>Precautionary Statement(s) Prevention:</b>	
	Not applicable
<b>Precautionary Statement(s) Response:</b>	
	Not applicable
<b>Precautionary Statement(s) Storage:</b>	
	Not applicable
<b>Precautionary Statement(s) Disposal:</b>	
	P501 Dispose of contents/ container in accordance with local regulations

<b>2.3 Other Hazard Information</b>
REACH (EU) Article 57-59: The mixture does not contain Substances of Very High Concern (SVHC) at the SDS print date.

<b>SECTION 3: INFORMATION ON THE INGREDIENTS</b>			
<b>3.1 Substances</b>			
See section below for composition of mixtures			
<b>3.2 Mixtures</b>			
1.CAS No 2.EC Number 3.Index Number 4.REACH Number	% Weight	Name	Classification according to regulations (EC) No 1272/2008 [CLP] (EU)
1.4618-18-2 2.225-027-7 3.Not Available 4.Not Available	>60	Lactulose	Not applicable
1.4618-18-2 2.225-027-7 3.Not Available 4.Not Available	<1	Benzylalcohol	Acute Toxicity (Oral) Category 4, Acute Toxicity (Inhalation) Category 4; H302, H332 [2]
Not available	Not specified	Ingredients determined not be hazardous	Not applicable
<b>Legend:</b>	1. Classified by Chemwatch; 2. Classification drawn from Regulation (EU) No 1272/2008 - Annex VI; 3. Classification drawn from C&L; * EU IOELVs available		

<b>SECTION 4: FIRST AID MEASURES</b>	
<b>4.1 Description of first aid measures</b>	
<b>Eye contact:</b>	If accidental eye contamination occurs, flush gently with fresh running water for 15 minutes. Medical advice should be sought if irritation persists.
<b>Skin contact:</b>	In the event of accidental skin contamination, flush skin with running water. Medical advice should be sought if irritation persists.
<b>Inhalation:</b>	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, remove the patient from the contaminated area. Seek medical advice if irritation persists and show the package leaflet or the label to the medical practitioner.
<b>Ingestion:</b>	If swallowed, do not induce vomiting and immediately give water. If discomfort persists, seek medical advice and show the package leaflet or the label to medical practitioner.



<b>4.2 Most important symptoms and effects, both acute and delayed</b>	
<b>Ingestion:</b>	This veterinary medicinal product may cause flatulence and diarrhoea. Accidental ingestion should be avoided, especially by a child. To avoid accidental ingestion, the veterinary medicinal product must be used and kept out of reach of children. Always replace the cap after use.
See Section 11 for more detailed information	
<b>4.3 Indication of immediate medical attention and special treatment needed</b>	
Treat symptomatically	

<b>SECTION 5: FIRE FIGHTING MEASURES</b>	
<b>5.1 Extinguishing media</b>	
<b>Suitable:</b>	Select extinguishing media suitable for surrounding area
<b>Unsuitable:</b>	There is no restriction on the type of extinguisher which may be used
<b>5.2 Special hazards arising from the substance or mixture</b>	
<b>Fire incompatibility:</b>	None known
<b>5.3 Special protective actions for fire-fighters:</b>	
<b>Firefighting:</b>	Use water delivered as a fine spray to control fire and cool adjacent area. 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.
<b>Fire / explosion hazard:</b>	Non-combustible.

<b>SECTION 6: ACCIDENTAL RELEASE MEASURES</b>	
<b>6.1 Personal precautions, protective equipment and emergency procedures</b>	
For information on protective equipment, see section 8	
<b>6.2 Environmental Precautions</b>	
See section 12	



<b>6.3 Methods and material for containment and cleaning up</b>	
Spills are unlikely due to the nature of the product and how it is packaged	
<b>Minor Spills:</b>	Clean up all spills immediately. Avoid breathing vapours and contact with skin and eyes. Control personal contact with the substance, by using protective equipment. Place in a suitable, labelled container for waste disposal.
<b>Major Spills:</b>	Clear area of personnel and move upwind. Alert Fire Brigade and tell them location and nature of the hazard.. Prevent, by any means available, spillage from entering drains or water course.

**SECTION 7: HANDLING AND STORAGE**

**7.1 Precautions for safe handling**

<b>Safe Handling:</b>	When handling, <b>DO NOT</b> eat, drink or smoke. Always wash hands with water after handling. Observe manufacturer's storage and handling recommendations.
<b>Other Information:</b>	This veterinary medicinal product does not require any special temperature storage conditions. Keep out of the reach and sight of children.

**7.2 Conditions for safe storage, including any incompatibilities**

<b>Suitable Container:</b>	50 ml and 125 ml: HDPE bottle closed with a (LDPE) syringe inlay and a (HDPE) cap. 325 ml: HDPE bottle closed with a (LDPE) syringe inlay and a cap (PP). Oral syringe (5 and 10 ml): Polypropylene (PP) barrel and plunger, graduated per 0.2 ml.  Cardboard box of 1 bottle of 50 ml with a 5ml oral syringe Cardboard box of 1 bottle of 125 ml with a 5ml oral syringe Cardboard box of 1 bottle of 325 ml with a 10ml oral syringe  Not all pack sizes may be marketed.
<b>Storage incompatibility:</b>	Avoid contamination of water or food stuffs.

**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**

Source	Ingredient	Material name	TWA	STEL	Peak	Notes
Not available						

**EMERGENCY LIMITS (EU):**

Ingredient	Material Name	TEEL-1	TEEL-2	TEEL-3
Benzylalcohol	Benzylalcohol	30 ppm	52 ppm	740 ppm

Ingredient	Original IDLH	Revised IDLH
Lactulose	Not available	Not Available
Benzylalcohol	Not available	Not Available

**8.2 Exposure controls**

<b>Appropriate engineering controls:</b>	Engineering controls are used to remove a hazard or place a barrier between the worker and the hazard. Well-designed engineering controls can be highly effective in protecting workers and will typically be independent of worker interactions to provide this high level of protection. The basic types of engineering controls are: Process controls which involve changing the way a job activity or process is done to reduce the risk. Enclosure and/or isolation of emission source which keeps a selected hazard "physically" away from the worker and ventilation that strategically "adds" and "removes" air in the work environment.
<b>Personal protection:</b>	
<b>Eye and face protection:</b>	Not required
<b>Skin protection:</b>	See hand protection below



<b>Hands/ feet protection:</b>	Wear chemical protective gloves
<b>Body protection:</b>	Wear appropriate clothing
<b>Other protection:</b>	Wear appropriate clothing
<b>Thermal hazards:</b>	Not applicable
<b>Respiratory protection:</b>	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, slightly yellow viscous liquid

**Container:** 50 ml and 125 ml: HDPE bottle closed with a (LDPE) syringe inlay and a (HDPE) cap.

325 ml: HDPE bottle closed with a (LDPE) syringe inlay and a cap (PP).

Oral syringe (5 and 10 ml): Polypropylene (PP) barrel and plunger, graduated per 0.2 ml.

Cardboard box of 1 bottle of 50 ml with a 5ml oral syringe

Cardboard box of 1 bottle of 125 ml with a 5ml oral syringe

Cardboard box of 1 bottle of 325 ml with a 10ml oral syringe

Not all pack sizes may be marketed.

**Physical state:** Viscous Liquid

**Odour:** Not available

**Melting point / freezing point (degrees C):** Not available

**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):** Miscible in water

**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 available

**VOC g/L:** Not applicable

### 9.2 Other information

Not Available



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

<b>SECTION 11: TOXICOLOGICAL INFORMATION</b>	
<b>Inhalation:</b>	Due to the nature of the product, the material is not thought to produce either adverse health effects or irritation of the respiratory tract following inhalation.
<b>Ingestion:</b>	Accidental ingestion of the material in large quantities may cause discomfort.
<b>Skin contact:</b>	This veterinary medicinal product contains benzyl alcohol. This preservative may cause hypersensitivity (allergic) reactions. People with known hypersensitivity to benzyl alcohol should avoid contact with the veterinary medicinal product. Wash hands after use. In case direct contact with skin or eyes should occur, rinse with clean water. If irritation persists, seek medical advice.
<b>Eye contact:</b>	This material is not expected to be an irritant.
<b>Chronic:</b>	This veterinary medicinal product may cause flatulence and diarrhoea. Accidental ingestion should be avoided, especially by a child. To avoid accidental ingestion, the veterinary medicinal product must be used and kept out of reach of children. Always replace the cap after use.



<b>Laxatract 667 mg/ml Syrup for Dogs and Cats</b>	<b>Toxicity</b>	<b>Irritation</b>
	Not available	Not available
Lactulose	<b>Toxicity</b>	<b>Irritation</b>
	Oral (rat) LD50: 18160 mg/kg <sup>2</sup>	Not available
Benzylalcohol	<b>Toxicity</b>	<b>Irritation</b>
	Not available	Skin: not irritating <sup>1</sup>
<p><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></p>		
<b>Skin corrosion/irritation:</b>		
Not expected to cause skin corrosion/ irritation.		
<b>Serious eye damage/irritation:</b>		
Not expected to cause eye damage/ irritation		
<b>Respiratory or skin sensitization:</b>		
Due to nature of product, not expected to cause respiratory sensitization. May cause hypersensitisation.		
<b>Germ cell mutagenicity:</b>		
Not available		
<b>Carcinogenicity:</b>		
Not available.		
<b>Reproductive toxicity:</b>		
Not available		
<b>STOT – single exposure:</b>		
Not available		
<b>STOT–repeated exposure:</b>		
Not available		
<b>Aspiration hazard:</b>		
Not available		



SECTION 12: ECOLOGICAL INFORMATION					
12.1 Toxicity					
Ingredient	Endpoint	Test duration (hr)	Species	Value	Source
Lactulose	Not available	Not available	Not available	Not available	Not available
Benzylalcohol	LC50	96	Fish	10 mg/l	2
	EC50	48	Crustacea	230 mg/l	2
	EC50	96	Algae or other aquatic plants	76.828 mg/l	2
	NOEC	336	Fish	5.1 mg/l	2
<p>Legend: <i>Extracted from 1. IUCLID Toxicity Data 2. Europe ECHA Registered Substances - Ecotoxicological Information - Aquatic Toxicity 3. EPIWIN Suite V3.12 (QSAR) - Aquatic Toxicity Data (Estimated) 4. US EPA, Ecotox database - Aquatic Toxicity Data 5. ECETOC Aquatic Hazard Assessment Data 6. NITE (Japan) - Bioconcentration Data 7. METI (Japan) - Bioconcentration Data 8. Vendor Data</i></p>					
<p><b>DO NOT discharge into sewer or waterways.</b></p>					

12.2 Persistence and degradability		
Ingredient	Persistence: Water/Soil	Persistence: Air
Lactulose	LOW	LOW
Benzylalcohol	LOW	LOW
12.3 Bioaccumulative potential		
Ingredient	Bioaccumulative Potential	
Lactulose	LOW (LogKOW = -3.3194)	
Benzylalcohol	LOW (LogKOW = 1.1)	
12.4 Mobility in Soil		
Ingredient	Mobility	
Lactulose	LOW (KOC = 10)	
Benzylalcohol	LOW (KOC = 15.66)	



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

**SECTION 13: DISPOSAL CONSIDERATIONS**

<b>13.1 Waste treatment methods</b>	
<b>Product / packaging disposal:</b>	<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>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> <p>Disposal of this product is controlled by the Misuse of Drugs Regulations 2001.</p>
<b>Waste Treatment Options:</b>	Not Available
<b>Sewage Disposal Options:</b>	Not Available

**SECTION 14: TRANSPORT INFORMATION**

<b>Labels required:</b> None	
<b>Marine pollutant:</b>	NO
<b>Hazchem:</b>	Not applicable
<b>Land transport (EU: ADR): NOT REGULATED FOR TRANSPORT OF DANGEROUS GOODS</b>	
<b>Air transport (ICAO-IATA / DGR): NOT REGULATED FOR TRANSPORT OF DANGEROUS GOODS</b>	
<b>Sea transport (IMDG-Code / GGVSee): NOT REGULATED FOR TRANSPORT OF DANGEROUS GOODS</b>	
<b>Inland waterways transport (ADN): NOT REGULATED FOR TRANSPORT OF DANGEROUS GOODS</b>	



**SECTION 15: REGULATORY INFORMATION**

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

**Lactulose**

Europe EC Inventory / EINECS

**Benzylalcohol**

Europe EC Inventory / ECHA / EINECS

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
Lactulose	4618-18-2	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. Harmonisation Code 2 = The most severe classification

Ingredient	CAS number	Index Number	ECHA Dossier
Benzylalcohol	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	GHS07; Wng	H302

Harmonisation Code 1 = the most prevalent classification. Harmonisation Code 2 = The most severe classification



<b>National Inventory</b>	<b>Status</b>
Australia – AICS	Yes
Canada – DSL	No (lactulose)
Canada – NDSL	No (benzylalcohol)
China – IECSC	No (lactulose)
Europe - EINEC / ELINCS / NLP	Yes
Japan – ENCS	No (lactulose)
Korea – KECI	Yes
New Zealand – NZIoC	Yes
Philippines – PICCS	No (lactulose)
USA – TSCA	Yes
Taiwan – TCSI	Yes
Mexico – INSQ	No (lactulose)
Vietnam – NCI	No (lactulose)
Russia – ARIPS	No (lactulose)
<b>Legend:</b>	<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 and ECHA.

### Hazard codes

H302 Harmful if swallowed

### 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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