

SAFETY DATA SHEETS

This SDS packet was issued with item:

078929403

The safety data sheets (SDS) in this packet apply to the individual products listed below. Please refer to invoice for specific item number(s).

078929400 078929401 078929402 078929404 078929405



SAFETY DATA SHEET

Galliprant Tablets

Section 1. Identification

GHS product identifier : Galliprant Tablets
Product code : Not available.
Other means of identification : CA5810; CA5811; CA5812; 20 mg Galliprant Tablet; 100 mg Galliprant Tablet; 60 mg Galliprant Tablet; Galliprant Tablets

Relevant identified uses of the substance or mixture and uses advised against

Identified uses : Veterinary pharmaceutical.
Uses advised against : None known.

Company Name : Elanco Animal Health
2500 Innovation Way
Greenfield, IN 46140
United States
Telephone number : 1-877 Elanco1 (1-877-352-6261)
Emergency telephone number : Elanco Product Technical Support / Human or Animal Exposure Reporting:
1-888-545-5973
Email : elanco_sds@elanco.com
Transportation Emergency telephone number : CHEMTREC: 1-800-424-9300
(Outside U.S. CHEMTREC International: 00 1-703-527-3887)

Section 2. Hazards identification

OSHA/HCS status : While this material is not considered hazardous by the OSHA Hazard Communication Standard (29 CFR 1910.1200), this SDS contains valuable information critical to the safe handling and proper use of the product. This SDS should be retained and available for employees and other users of this product.

Classification of the substance or mixture : Not classified.

GHS label elements

Signal word : No signal word.
Hazard statements : No known significant effects or critical hazards.

Precautionary statements

Prevention : Not applicable.
Response : Not applicable.
Storage : Not applicable.
Disposal : Not applicable.
Supplemental label elements : None known.
Hazards not otherwise classified : None known.

Section 3. Composition/information on ingredients

Substance/mixture : Mixture

Ingredient name	%	CAS number
sodium dodecyl sulphate	≤3	151-21-3

Any concentration shown as a range is to protect confidentiality or is due to batch variation.

There are no additional ingredients present which, within the current knowledge of the supplier and in the concentrations applicable, are classified as hazardous to health or the environment and hence require reporting in this section.

Occupational exposure limits, if available, are listed in Section 8.

Section 4. First aid measures

Description of necessary first aid measures

- Eye contact** : Immediately flush eyes with plenty of water, occasionally lifting the upper and lower eyelids. Check for and remove any contact lenses. Get medical attention if irritation occurs.
- Inhalation** : Remove victim to fresh air and keep at rest in a position comfortable for breathing. Get medical attention if symptoms occur. In case of inhalation of decomposition products in a fire, symptoms may be delayed. The exposed person may need to be kept under medical surveillance for 48 hours.
- Skin contact** : Flush contaminated skin with plenty of water. Remove contaminated clothing and shoes. Get medical attention if symptoms occur.
- Ingestion** : Wash out mouth with water. Remove victim to fresh air and keep at rest in a position comfortable for breathing. If material has been swallowed and the exposed person is conscious, give small quantities of water to drink. Do not induce vomiting unless directed to do so by medical personnel. Get medical attention if symptoms occur.

Most important symptoms/effects, acute and delayed

Potential acute health effects

- Eye contact** : No known significant effects or critical hazards.
- Inhalation** : No known significant effects or critical hazards.
- Skin contact** : No known significant effects or critical hazards.
- Ingestion** : No known significant effects or critical hazards.

Over-exposure signs/symptoms

- Eye contact** : No specific data.
- Inhalation** : No specific data.
- Skin contact** : No specific data.
- Ingestion** : No specific data.

Indication of immediate medical attention and special treatment needed, if necessary

- Notes to physician** : In case of inhalation of decomposition products in a fire, symptoms may be delayed. The exposed person may need to be kept under medical surveillance for 48 hours.
- Specific treatments** : No specific treatment.
- Protection of first-aiders** : No action shall be taken involving any personal risk or without suitable training.

See toxicological information (Section 11)

Section 5. Fire-fighting measures

Extinguishing media

- Suitable extinguishing media** : Use an extinguishing agent suitable for the surrounding fire.
- Unsuitable extinguishing media** : None known.

Specific hazards arising from the chemical : No specific fire or explosion hazard.

Hazardous thermal decomposition products : Decomposition products may include the following materials:
carbon dioxide
carbon monoxide
nitrogen oxides
sulfur oxides
metal oxide/oxides

Special protective actions for fire-fighters : Promptly isolate the scene by removing all persons from the vicinity of the incident if there is a fire. No action shall be taken involving any personal risk or without suitable training.

Special protective equipment for fire-fighters : Fire-fighters should wear appropriate protective equipment and self-contained breathing apparatus (SCBA) with a full face-piece operated in positive pressure mode.

Section 6. Accidental release measures

Personal precautions, protective equipment and emergency procedures

For non-emergency personnel : No action shall be taken involving any personal risk or without suitable training. Evacuate surrounding areas. Keep unnecessary and unprotected personnel from entering. Do not touch or walk through spilled material. Put on appropriate personal protective equipment.

For emergency responders : If specialized clothing is required to deal with the spillage, take note of any information in Section 8 on suitable and unsuitable materials. See also the information in "For non-emergency personnel".

Environmental precautions : Avoid dispersal of spilled material and runoff and contact with soil, waterways, drains and sewers. Inform the relevant authorities if the product has caused environmental pollution (sewers, waterways, soil or air).

Methods and materials for containment and cleaning up

Small spill : Move containers from spill area. Vacuum or sweep up material and place in a designated, labeled waste container. Dispose of via a licensed waste disposal contractor.

Large spill : Move containers from spill area. Prevent entry into sewers, water courses, basements or confined areas. Vacuum or sweep up material and place in a designated, labeled waste container. Dispose of via a licensed waste disposal contractor. Note: see Section 1 for emergency contact information and Section 13 for waste disposal.

Section 7. Handling and storage

Precautions for safe handling

Protective measures : Put on appropriate personal protective equipment (see Section 8).

Advice on general occupational hygiene : Eating, drinking and smoking should be prohibited in areas where this material is handled, stored and processed. Workers should wash hands and face before eating, drinking and smoking. Remove contaminated clothing and protective equipment before entering eating areas. See also Section 8 for additional information on hygiene measures.

Section 7. Handling and storage

Conditions for safe storage, including any incompatibilities : Store in accordance with local regulations. Store in original container protected from direct sunlight in a dry, cool and well-ventilated area, away from incompatible materials (see Section 10) and food and drink. Keep container tightly closed and sealed until ready for use. Containers that have been opened must be carefully resealed and kept upright to prevent leakage. Do not store in unlabeled containers. Use appropriate containment to avoid environmental contamination. See Section 10 for incompatible materials before handling or use.

Section 8. Exposure controls/personal protection

Control parameters

Occupational exposure limits

Ingredient name	Exposure limits
-----------------	-----------------

grapiprant

Limit values (ELANCO).

STEL: 90 µg/m³ 8 hours.

Appropriate engineering controls : Good general ventilation should be sufficient to control worker exposure to airborne contaminants.

Environmental exposure controls : Emissions from ventilation or work process equipment should be checked to ensure they comply with the requirements of environmental protection legislation. In some cases, fume scrubbers, filters or engineering modifications to the process equipment will be necessary to reduce emissions to acceptable levels.

Individual protection measures

Hygiene measures : Wash hands, forearms and face thoroughly after handling chemical products, before eating, smoking and using the lavatory and at the end of the working period. Appropriate techniques should be used to remove potentially contaminated clothing. Wash contaminated clothing before reusing. Ensure that eyewash stations and safety showers are close to the workstation location.

Eye/face protection : Safety eyewear complying with an approved standard should be used when a risk assessment indicates this is necessary to avoid exposure to liquid splashes, mists, gases or dusts. If contact is possible, the following protection should be worn, unless the assessment indicates a higher degree of protection: safety glasses with side-shields.

Skin protection

Hand protection : Chemical-resistant, impervious gloves complying with an approved standard should be worn at all times when handling chemical products if a risk assessment indicates this is necessary.

Body protection : Personal protective equipment for the body should be selected based on the task being performed and the risks involved and should be approved by a specialist before handling this product.

Other skin protection : Appropriate footwear and any additional skin protection measures should be selected based on the task being performed and the risks involved and should be approved by a specialist before handling this product.

Respiratory protection : Based on the hazard and potential for exposure, select a respirator that meets the appropriate standard or certification. Respirators must be used according to a respiratory protection program to ensure proper fitting, training, and other important aspects of use.

Section 9. Physical and chemical properties

Appearance

Physical state : Solid. [Tablet.]

Color : Brown.

Odor : Not available.

Odor threshold : Not available.

pH : Not available.

Section 9. Physical and chemical properties

Melting point	: Not available.
Boiling point	: Not available.
Flash point	: Not available.
Evaporation rate	: Not available.
Flammability (solid, gas)	: Not available.
Lower and upper explosive (flammable) limits	: Not available.
Vapor pressure	: Not available.
Vapor density	: Not available.
Relative density	: Not available.
Solubility	: Not available.
Solubility in water	: Not available.
Partition coefficient: n-octanol/water	: Not available.
Auto-ignition temperature	: Not available.
Decomposition temperature	: Not available.
Viscosity	: Not available.
Flow time (ISO 2431)	: Not available.

Section 10. Stability and reactivity

Reactivity	: No specific test data related to reactivity available for this product or its ingredients.
Chemical stability	: The product is stable.
Possibility of hazardous reactions	: Under normal conditions of storage and use, hazardous reactions will not occur.
Conditions to avoid	: No specific data.
Incompatible materials	: No specific data.
Hazardous decomposition products	: Under normal conditions of storage and use, hazardous decomposition products should not be produced.

Section 11. Toxicological information

Information on toxicological effects

Acute toxicity

Product/ingredient name	Result	Species	Dose	Exposure
sodium dodecyl sulphate	LD50 Oral	Rat	1288 mg/kg	-

Irritation/Corrosion

Product/ingredient name	Result	Species	Score	Exposure	Observation
sodium dodecyl sulphate	Eyes - Mild irritant	Rabbit	-	250 ug	-
	Eyes - Moderate irritant	Rabbit	-	24 hours 100 mg	-
	Eyes - Moderate irritant	Rabbit	-	10 mg	-
	Skin - Mild irritant	Dog	-	24 hours 25 mg	-
	Skin - Mild irritant	Guinea pig	-	24 hours 25 mg	-
	Skin - Mild irritant	Human	-	2 hours 2 %	-
	Skin - Mild irritant	Human	-	504 hours 0.3	-

Section 11. Toxicological information

	Skin - Mild irritant	Human	-	% 24 hours 0.06	-
	Skin - Mild irritant	Human	-	% 22 hours 10	-
	Skin - Mild irritant	Human	-	% 47 hours 0.5	-
	Skin - Mild irritant	Human	-	% 18 hours 2 %	-
	Skin - Moderate irritant	Human	-	48 hours 3 %	-
	Skin - Moderate irritant	Human	-	24 hours 0.1	-
	Skin - Moderate irritant	Mouse	-	% 24 hours 25	-
	Skin - Mild irritant	Pig	-	mg 24 hours 25	-
	Skin - Mild irritant	Rabbit	-	mg 24 hours 50	-
	Skin - Moderate irritant	Rabbit	-	mg 24 hours 25	-

Sensitization

Not available.

Mutagenicity

Not available.

Carcinogenicity

Not available.

Reproductive toxicity

Not available.

Teratogenicity

Not available.

Specific target organ toxicity (single exposure)

Not available.

Specific target organ toxicity (repeated exposure)

Not available.

Aspiration hazard

Not available.

Information on the likely routes of exposure : Not available.

Potential acute health effects

Eye contact : No known significant effects or critical hazards.

Inhalation : No known significant effects or critical hazards.

Skin contact : No known significant effects or critical hazards.

Ingestion : No known significant effects or critical hazards.

Symptoms related to the physical, chemical and toxicological characteristics

Eye contact : No specific data.

Inhalation : No specific data.

Skin contact : No specific data.

Ingestion : No specific data.

Section 11. Toxicological information

Delayed and immediate effects and also chronic effects from short and long term exposure

Short term exposure

Potential immediate effects : Not available.

Potential delayed effects : Not available.

Long term exposure

Potential immediate effects : Not available.

Potential delayed effects : Not available.

Potential chronic health effects

Not available.

General : No known significant effects or critical hazards.

Carcinogenicity : No known significant effects or critical hazards.

Mutagenicity : No known significant effects or critical hazards.

Teratogenicity : No known significant effects or critical hazards.

Developmental effects : No known significant effects or critical hazards.

Fertility effects : No known significant effects or critical hazards.

Numerical measures of toxicity

Acute toxicity estimates

Product/ingredient name	Oral (mg/kg)	Dermal (mg/kg)	Inhalation (gases) (ppm)	Inhalation (vapors) (mg/l)	Inhalation (dusts and mists) (mg/l)
Galliprant Tablets sodium dodecyl sulphate	21040.3 1288	N/A N/A	N/A N/A	N/A N/A	N/A N/A

Section 12. Ecological information

Toxicity

Product/ingredient name	Result	Species	Exposure
sodium dodecyl sulphate	Acute EC50 1200 µg/l Marine water	Algae - Skeletonema costatum	96 hours
	Acute LC50 900 µg/l Marine water	Crustaceans - Artemia salina - Adult	48 hours
	Acute LC50 1400 µg/l Fresh water	Daphnia - Daphnia pulex - Neonate	48 hours
	Acute LC50 590 µg/l Fresh water	Fish - Cirrhinus mrigala - Larvae	96 hours
	Chronic NOEC 1.25 mg/l Marine water	Algae - Ulva fasciata - Zoea	96 hours
	Chronic NOEC 1 mg/l Fresh water	Crustaceans - Pseudosida ramosa - Neonate	21 days
	Chronic NOEC 3.2 mg/l Fresh water	Daphnia - Daphnia magna - Neonate	21 days
	Chronic NOEC >1357 µg/l Fresh water	Fish - Pimephales promelas	42 days

Persistence and degradability

Bioaccumulative potential

Product/ingredient name	LogP _{ow}	BCF	Potential
sodium dodecyl sulphate	-2.03	-	low

Mobility in soil

Soil/water partition coefficient (K_{oc}) : Not available.











Section 12. Ecological information

Other adverse effects : No known significant effects or critical hazards.

Section 13. Disposal considerations

Disposal methods : The generation of waste should be avoided or minimized wherever possible. Disposal of this product, solutions and any by-products should at all times comply with the requirements of environmental protection and waste disposal legislation and any regional local authority requirements. Dispose of surplus and non-recyclable products via a licensed waste disposal contractor. Waste should not be disposed of untreated to the sewer unless fully compliant with the requirements of all authorities with jurisdiction. Waste packaging should be recycled. Incineration or landfill should only be considered when recycling is not feasible. This material and its container must be disposed of in a safe way. Empty containers or liners may retain some product residues. Avoid dispersal of spilled material and runoff and contact with soil, waterways, drains and sewers.

Section 14. Transport information

	DOT Classification	TDG Classification	Mexico Classification	IMDG	IATA
UN number	UN3077	UN3077	UN3077	UN3077	UN3077
UN proper shipping name	ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID, N.O.S. (grapiprant)	ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID, N.O.S. (grapiprant)	ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID, N.O.S. (grapiprant)	ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID, N.O.S. (grapiprant)	ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID, N.O.S. (grapiprant)
Transport hazard class(es)	9  	9  	9  	9  	9  
Packing group	III	III	III	III	III
Environmental hazards	Yes.	Yes.	Yes.	Yes.	Yes.

Additional information

- DOT Classification** : Non-bulk packages of this product are not regulated as hazardous materials unless transported by inland waterway. This product is not regulated as a hazardous material when transported in sizes of ≤5 L or ≤5 kg, provided the packagings meet the general provisions of §§ 173.24 and 173.24a.
- TDG Classification** : Product classified as per the following sections of the Transportation of Dangerous Goods Regulations: 2.43-2.45 (Class 9), 2.7 (Marine pollutant mark). Non-bulk packages of this product are not regulated as dangerous goods when transported by road or rail.
- Mexico Classification** : The environmentally hazardous substance mark is not required when transported in sizes of ≤5 L or ≤5 kg.
- IMDG** : This product is not regulated as a dangerous good when transported in sizes of ≤5 L or ≤5 kg, provided the packagings meet the general provisions of 4.1.1.1, 4.1.1.2 and 4.1.1.4 to 4.1.1.8.
- IATA** : This product is not regulated as a dangerous good when transported in sizes of ≤5 L or ≤5 kg, provided the packagings meet the general provisions of 5.0.2.4.1, 5.0.2.6.1.1 and 5.0.2.8.
- Special provisions** A197

Special precautions for user : **Transport within user's premises:** always transport in closed containers that are upright and secure. Ensure that persons transporting the product know what to do in the event of an accident or spillage.

Section 14. Transport information

Transport in bulk according to Annex II of MARPOL and the IBC Code : Not available.

Section 15. Regulatory information

U.S. Federal regulations : TSCA 8(a) CDR Exempt/Partial exemption: Not determined

Clean Air Act Section 112 (b) Hazardous Air Pollutants (HAPs) : Not listed

Clean Air Act Section 602 Class I Substances : Not listed

Clean Air Act Section 602 Class II Substances : Not listed

DEA List I Chemicals (Precursor Chemicals) : Not listed

DEA List II Chemicals (Essential Chemicals) : Not listed

SARA 302/304

Composition/information on ingredients

No products were found.

SARA 304 RQ : Not applicable.

SARA 311/312

Classification : Not applicable.

Composition/information on ingredients

Name	%	Classification
grapiprant	≤10	COMBUSTIBLE DUSTS
sodium dodecyl sulphate	≤3	COMBUSTIBLE DUSTS ACUTE TOXICITY (oral) - Category 4 SKIN IRRITATION - Category 2 SERIOUS EYE DAMAGE - Category 1
magnesium distearate	≤3	COMBUSTIBLE DUSTS

State regulations

Massachusetts : The following components are listed: CELLULOSE

New York : None of the components are listed.

New Jersey : The following components are listed: CELLULOSE

Pennsylvania : The following components are listed: CELLULOSE

California Prop. 65

This product does not require a Safe Harbor warning under California Prop. 65.

Inventory list

United States : Not determined.

Section 16. Other information

History

Date of issue/Date of revision : 8/26/2020

Date of previous issue : No previous validation

Version : 0.01

Section 16. Other information

Key to abbreviations

: ATE = Acute Toxicity Estimate
BCF = Bioconcentration Factor
GHS = Globally Harmonized System of Classification and Labelling of Chemicals
IATA = International Air Transport Association
IBC = Intermediate Bulk Container
IMDG = International Maritime Dangerous Goods
LogPow = logarithm of the octanol/water partition coefficient
MARPOL = International Convention for the Prevention of Pollution From Ships, 1973
as modified by the Protocol of 1978. ("Marpol" = marine pollution)
N/A = Not available
SGG = Segregation Group
UN = United Nations

References

: Not available.

📌 Indicates information that has changed from previously issued version.

Notice to reader

As of the date of issuance, we are providing available information relevant to the handling of this material in the workplace. All information contained herein is offered with the good faith belief that it is accurate. **THIS SAFETY DATA SHEET SHALL NOT BE DEEMED TO CREATE ANY WARRANTY OF ANY KIND (INCLUDING WARRANTY OF MERCHANT ABILITY OR FITNESS FOR A PARTICULAR PURPOSE).** In the event of an adverse incident associated with this material, this safety data sheet is not intended to be a substitute for consultation with appropriately trained personnel. Nor is this safety data sheet intended to be a substitute for product literature which may accompany the finished product.

For additional information contact:

Elanco Animal Health

0011+1-877-352-6261

0011+1-800-428-4441