SAFETY DATA SHEETS

This SDS packet was issued with item:

078947247

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

078947245 078947246 078947248 078947249 078947250



SAFETY DATA SHEET MOVODYL[™] Chewable Tablets (carprofen)

1. IDENTIFICATION

Product Name

Recommended use of the chemical and

restrictions on use Identified uses

Restrictions on Use Company Identification

Customer Information Number

Emergency Telephone Number

CHEMTREC Number
Other Emergency Number:

Other Emergency Number:

Issue Date Supersedes Date MOVODYL[™] Chewable Tablets (carprofen)

Veterinary product used as a non-steroidal, anti-

inflammatory drug (nsaid) for dogs only. Not for human use. Do not use in cats.

Virbac AH, Inc. P.O. Box 162059

Fort Worth, Texas 76161

(800) 338-3659

(800) 424-9300

Human Toll-free 833-224-2009 Animal Toll-free 833-224-2013

April 14, 2022 New document

Safety Data Sheet prepared in accordance with OSHA's Hazard Communication Standard (29 CFR 1910.1200) and the Globally Harmonized System of Classification and Labelling of Chemicals (GHS)

2. HAZARD IDENTIFICATION

Hazard Classification

Skin Sensitization - Category 1B

Reproductive toxicity (the unborn child) - Category 2

Specific target organ toxicity (Repeat Exposure) – Category 2 (digestive system)

Label Elements

Hazard Symbols





Signal Word: Warning

Hazard Statements

May cause an allergic skin reaction.

Suspected of damaging the unborn child.

Causes damage to organs through prolonged or repeated exposure. (ingestion)

Precautionary Statements

Prevention

Obtain special instructions before use. Do not handle until all safety precautions have been read and understood.

Do not breathe dusts.

Contaminated work clothing must not be allowed out of the workplace.

Wear protective gloves/protective clothing/face protection.

Wash hands thoroughly with soap and water after handling.

Wear protective gloves/protective clothing/eye protection/face protection.

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2. HAZARD IDENTIFICATION

Response

If exposed or concerned: Get medical advice/attention.

If on skin: Wash with plenty of soap and water.

If skin irritation or rash occurs: Get medical advice/attention.

Wash contaminated clothing before reuse.

Storage

Stoke locked up.

Disposal

Dispose of contents/container in accordance with local, regional, national and international regulations.

Other Hazards

None

3. COMPOSITION/INFORMATION ON INGREDIENTS

Synonyms:

This product is a mixture.

Component Name	CAS Number	Concentration
Carprofen	53716-49-7	***
Sodium Starch Glycolate	9063-38-1	*
Stearic Acid	57-11-4	*
Lactose Monohydrate	10039-26-6	*

Composition comments *** 25, 37.5, 50, 75, or 100 mg per tablet

* Designates that the specific chemical identify and/or percentage of composition has been withheld as a trade secret. In accordance with 29 CFR 1910.1200, the exact percentage composition of this mixture has been withheld as a trade secret.

4. FIRST - AID MEASURES

Description of necessary first-aid measures

Inhalation

Remove person to fresh air. Seek medical attention if symptoms develop or persist. For breathing difficulties, oxygen may be necessary.

Eves

Immediately flush with plenty of water for at least 15 minutes. If easy to do, remove contact lenses. Continue rinsing. Get medical attention if irritation develops and persists.

Skin

Wash off immediately with soap and plenty of water. If skin irritation or rash occurs: Get medical advice/attention. Take off contaminated clothing and wash before reuse.

Ingestion

Rinse mouth. Call a physician or poison control center immediately. Do not induce vomiting without advice from poison control center. Never give anything by mouth to a victim who is unconscious or is having convulsions



4. FIRST - AID MEASURES

Most important symptoms/effects, acute and delayed

Direct contact with eyes may cause temporary irritation. Exposed individuals may experience eye tearing, redness, and discomfort.

Mild skin irritation. Exposure may cause temporary irritation, redness, or discomfort. May cause an allergic skin reaction. Dermatitis. Rash.

If swallowed: Nausea, vomiting. Abdominal pain.

Chronic exposure to this material may cause serious gastrointestinal toxicity such as bleeding, ulceration, and perforation.

Indication of immediate medical attention and special treatment needed Notes to Physicians

Provide general supportive measures and treat symptomatically. Symptoms may be delayed.

General Information

For personal protection, see section 8 of the SDS. If exposed or concerned: Get medical advice/attention. Ensure that medical personnel are aware of the material(s) involved, and take precautions to protect themselves. Show this safety data sheet to the doctor in attendance. Wash contaminated clothing before reuse.

5. FIRE - FIGHTING MEASURES

Extinguishing Media

Water spray. Foam. Powder. Carbon dioxide (CO₂).

Unsuitable extinguishing media

Do not use water jet as an extinguisher, as this will spread the fire.

Unusual Fire and Explosion Hazards

During fire, gases hazardous to health may be formed.

Protective Equipment for Fire-Fighting

Self-contained breathing apparatus and full protective clothing must be worn in case of fire.

Firefighting equipment/instructions

Use water spray to cool unopened containers

Specific methods hazards

Use standard firefighting procedures and consider the hazards of other involved materials.

General fire hazards

No unusual fire or explosion hazards noted.

6. ACCIDENTAL RELEASE MEASURES

Personal precautions, protective equipment and emergency procedures

Keep unnecessary personnel away. Ensure adequate ventilation. Wear appropriate protective equipment and clothing during clean-up. Do not touch damaged containers or spilled material unless wearing appropriate protective clothing. Avoid the generation of dusts during clean-up. Avoid inhalation of dust. Avoid contact with eyes, skin, and clothing. Local authorities should be advised if significant spillages cannot be contained. For personal protection, see section 8 of the SDS.



6. ACCIDENTAL RELEASE MEASURES

Environmental Precautions

Avoid discharge into drains, water courses or onto the ground.

Methods and materials for containment and cleaning up

Ensure adequate ventilation. Remove sources of ignition. Avoid release to the environment.

Large Spills: Stop the flow of material, if this is without risk. Absorb in vermiculite, dry sand or earth and place into containers. Following product recovery, flush area with water.

Small Spills: Wipe up with absorbent material (e.g. cloth, fleece). Clean surface thoroughly to remove residual contamination.

Never return spills to original containers for re-use. For waste disposal, see section 13 of the SDS.

7. HANDLING AND STORAGE

Precautions for safe handling

Do not taste or swallow. Avoid contact with eyes, skin, and clothing. If tablets or capsules are crushed and/or broken, avoid breathing dust and avoid contact with eyes. Avoid prolonged exposure. Minimize dust generation and accumulation. When using, do not eat, drink or smoke. Wash thoroughly after handling. Wear appropriate personal protective equipment. Avoid release to the environment..

Conditions for safe storage

Store in a well-ventilated place. Keep away from heat and sources of ignition. Store in original tightly closed container. @ 15-30°C (59-86°F). Store away from incompatible materials (see Section 10 of the SDS). Keep out of the reach of children. Protect from moisture.

8. EXPOSURE CONTROLS/PERSONAL PROTECTION

Occupational exposure limits: The following constituents are the only constituents of the product which have a PEL, TLV or other recommended exposure limit. At this time, the other constituents have no known exposure limits.

Components	Type	Value
Carprofen (CAS 53716-16-49-7)	TWA	1000 μg/m3

US. OSHA Table Z-1 Limits for Air Contaminants (29 CFR 1910.1000)

Components	Type	Value	Form
Sodium Starch Glycolate (CAS 9063-38-18)	PEL	5 mg/m3	Respirable fraction
		15 mg/m3	Total dust
Lactose Monohydrate (CAS 10039-26-6)	PEL	5 mg/m3	Respirable fraction
		15 mg/m3	Total dust
US. ACGIH Threshold Limit Values			
_			
Components	Type	Value	
Sodium Starch Glycolate (CAS 9063-38-18)	Type TWA	Value 10 mg/m3	
•			
Sodium Starch Glycolate (CAS 9063-38-18)	TWA	10 mg/m3	



8. EXPOSURE CONTROLS/PERSONAL PROTECTION

LIS	NIOSH:	Pocket	Guide to	Chemical	Hazards

Component	Type	Value	Form
Sodium Starch Glycolate (CAS 9063-38-18)	TWA	5 mg/m3	Respirable fraction
		10 mg/m3	Total dust
Lactose Monohydrate (CAS 10039-26-6)	TWA	5 mg/m3	Respirable fraction
		10 mg/m3	Total dust

Biological limit values

No biological exposure limits noted for the ingredients.

Control banding approach

Not available

Appropriate engineering controls

Good general ventilation (typically 10 air changes per hour) should be used and is normally adequate. Ventilation rates should be matched to conditions. If applicable, use process enclosures, local exhaust ventilation, or other engineering controls to maintain airborne levels below recommended exposure limits. If exposure limits have not been established, maintain airborne levels to an acceptable level.

Individual protection measures

Respiratory Protection

No personal respiratory protective equipment normally required. In case of insufficient ventilation, wear suitable respiratory equipment. Respiratory protection should be provided in instances where exposure to dust, mists, aerosols or vapors are likely. If the applicable Occupational Exposure Limit (OEL) is exceeded, wear an appropriate respirator with a protection factor sufficient to control exposures to below the OEL.

Skin/Hand Protection

Wear appropriate chemical resistant gloves. Impervious gloves are recommended if skin contact with drug product is possible and for bulk processing operations

Eye/Face Protection

If contact is likely, safety glasses with side shields are recommended.

Body Protection

Wear suitable protective clothing. Use protective clothing (uniforms, lab coats, disposable coveralls, etc.) in both production and laboratory areas.

Thermal hazards

Not applicable

General hygiene considerations

Observe any medical surveillance requirements. Always observe good personal hygiene measures, such as washing after handling the material and before eating, drinking, and/or smoking. Routinely wash work clothing and protective equipment to remove contaminants.

Contaminated work clothing should not be allowed out of the workplace.

9. PHYSICAL AND CHEMICAL PROPERTIES

AppearanceTablet (chewable tablet)Physical StateSolidFormSolidColorLight brown

Color
Odor
Not available
Odor Threshold
Not available
Not available
Not available

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9. PHYSICAL AND CHEMICAL PROPERTIES

Density	Not available
Boiling Range/Point (°C/F)	Not available
Melting Point (°C/F)	Not available
Flash Point (PMCC) (°C/F)	Not available
Vapor Pressure	Not available
Evaporation Rate (BuAc=1)	Not available
Solubility in Water	Not available
Vapor Density (Air = 1)	Not available
Partition coefficient (n-	Not available
octanol/water)	
Viscosity	Not available
Auto-ignition Temperature	Not available
Decomposition Temperature	Not available
Upper explosive limit	Not available
Lower explosive limit	Not available
Flammability (solid, gas)	Not available
Other information	
Explosive properties	Not explosive
Oxidizing properties	Not oxidizing

10. STABILITY AND REACTIVITY

Reactivity

The product is stable and non-reactive under normal conditions of use, storage and transport.

Chemical Stability

Material is stable under normal conditions..

Possibility of hazardous reactions

No dangerous reaction known under conditions of normal use.

Conditions to Avoid

Contact with incompatible materials. Heat, flames and sparks. Moisture.

Incompatible Materials

Strong oxidizing agents. Acids.

Hazardous Decomposition Products

Irritating and/or toxic fumes and gases may be emitted upon the product's decomposition.

11. TOXICOLOGICAL INFORMATION

Information on likely routes of exposure

Inhalation: Under normal conditions of intended use, this material is not expected to be an

inhalation hazard.

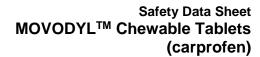
Skin contact: Prolonged skin contact may cause temporary irritation. There have been anecdotal

reports that workers handling this material have experienced skin irritation and/or

sensitivity reactions.

Carprofen Species: Rabbit Severity: Non-irritating

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11. TOXICOLOGICAL INFORMATION

Eye contact: Direct contact with eyes may cause temporary irritation

Carprofen Species: Rabbit Severity: Non-irritating

Ingestion: May be harmful if swallowed; however, ingestion is not likely to be a primary route of occupational exposure.

Symptoms related to the physical, chemical and toxicological characteristics

Direct contact with eyes may cause temporary irritation. Exposed individuals may experience eye tearing, redness, and discomfort.

Mild skin irritation. Exposure may cause temporary irritation, redness, or discomfort. May cause an allergic skin reaction. Dermatitis. Rash.

If swallowed: Nausea, vomiting. Abdominal pain. Chronic exposure to this material may cause serious gastrointestinal toxicity such as bleeding, ulceration, and perforation.

Information on toxicological effects

Acute toxicity:	May be harmful if swallowed.	
Product	Species	Test Results
Carprofen Chewable Tablets		
<u>Acute</u>		
Oral		
ATE		4545 mg/kg
Components	Species	Test Results
Carprofen (CAS 53716-49-7)		
<u>Acute</u>		
Intraperitoneal		
LD ₅₀	Rat	140 - 110 mg/kg (M/F)
Oral		
LD ₅₀	Mouse	282 mg/kg
	Rat	149 mg/kg
<u>Subcutaneous</u>		
LD ₅₀ Chronic	Rat	230 - 190 mg/kg (M/F)
Oral		
NOAEL	Dog	25 mg/kg/day, 2 years (Not carcinogenic; No effects at maximum dose)

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Safety Data Sheet MOVODYL[™] Chewable Tablets (carprofen)

11.	TOXICOLOGICAL INFORMATION	

Rat 10 mg/kg/day, 2 years

(Not carcinogenic, Gastrointestinal system effects)

Subchronic

Oral

NOAEL Dog 5 mg/kg/day, 13

weeks (Target organs: None identified)

Rat 5 mg/kg/day, 13

weeks (Target organs:

Gastrointestinal

System)

29.7 g/kg

Stearic Acid (CAS 57-11-4)

<u>Acute</u>

Inhalation

 LC_{50} Rat > 0.16 mg/l/4h

Oral

 LD_{50} Rat > 4600 mg/kg

Lactose Monohydrate (CAS 10039-26-6)

Acute

Oral

LD₅₀ Rat

Skin corrosion/irritation Prolonged skin contact may cause temporary irritation.

Corrosivity

Carprofen Rabbit Non-irritating

Serious eye damage/eye irritationDirect contact with eyes may cause temporary irritation.

Eye Contact

Carprofen Rabbit Non-irritating





11. TOXICOLOGICAL INFORMATION

Respiratory or skin sensitization

Respiratory sensitization Not a respiratory sensitizer.

Skin sensitization May cause an allergic skin reaction. Not a skin sensitizer in

experimental animals. However, workers handling Carprofen Chewable Tablets have developed red and

blotchy patches on their hands and faces.

Skin sensitization (GPMT)

Carprofen Guinea Pig Negative

Germ cell mutagenicityNo data available to indicate product or any components

present at greater than 0.1% are mutagenic or genotoxic.

Mutagenicity - Bacterial (Ames)

Carprofen Salmonella Negative

Mutagenicity - In Vivo Micronucleus

Carprofen Mouse Negative

Carcinogenicity This product is not considered to be a carcinogen by IARC,

ACGIH, NTP, or OSHA.

IARC Monographs. Overall Evaluation of Carcinogenicity

Not listed

OSHA Specifically Regulated Substances (29 CFR 1910.1001-1050) Not regulated.

US. National Toxicology Program (NTP) Report on Carcinogens Not listed.

Reproductive toxicity: Suspected of damaging the unborn child.

Developmental effects

Carprofen Rat 20 mg/kg/day Embryo/

Fetal Development, Not Teratogenic Result: NOAEL

Mouse 40 mg/kg/day Prenatal

& Postnatal
Development, Not
Teratogenic
Result: NOAEL



11. TOXICOLOGICAL INFORMATION

Rabbit 6 mg/kg/day Prenatal

& Postnatal Development,

Embryotoxicity, Early

embryonic development Result: NOAEL Organ: Oral

Reproductivity

Carprofen Rat 20 mg/kg/day

Reproductive & Fertility, Fetotoxicity, Maternal toxicity Result: NOAEL

Specific target organ

toxicity - single exposure

Not classified.

Specific target organ toxicity - repeated

exposure

May cause damage to organs (digestive system) through prolonged or

repeated ingestion

Aspiration hazard Not an aspiration hazard.

Further Information Anecdotal reports from facilities handling Carprofen Tablets have

indicated a potential for workers to develop rashes upon exposure to dusts

of the material.

12. ECOLOGICAL INFORMATION

Ecotoxicity

The product is not classified as environmentally hazardous. However, this does not exclude the possibility that large or frequent spills can have a harmful or damaging effect on the environment. Avoid release to the environment.

Mobility in soil

No relevant studies identified.

Persistence/Degradability

No data is available on the degradability of this product.

Bioaccumulative Potential

No data available for this product. Not expected to bioaccumulate.

Other adverse effects

No other adverse environmental effects (e.g. ozone depletion, photochemical ozone creation potential, endocrine disruption, global warming potential) are expected from this component.



13. DISPOSAL INFORMATION

Disposal Instructions

Avoid release to the environment. Do not discharge into drains, water courses or onto the ground. Do not contaminate ponds, waterways or ditches with chemical or used container. Considering the relevant known environmental and human health hazards of the material, review and implement appropriate technical and procedural waste water and waste disposal measures to prevent occupational exposure and environmental release. It is recommended that waste minimization be practiced. The best available technology should be utilized to prevent environmental releases. This may include destructive techniques for waste and wastewater. Dispose of contents/container in accordance with local/regional/international regulations.

Local disposal regulations

Dispose of in accordance with applicable regulations.

Hazardous waste code

None known

Waste from residues / unused products

Dispose of in accordance with local regulations. Empty containers or liners may retain some product residues. This material and its container must be disposed of in a safe manner (see: Disposal instructions).

Contaminated packaging

Since emptied containers may retain product residue, follow label warnings even after container is emptied.

14. TRANSPORTATION INFORMATION

DOT – Not regulated as dangerous goods

IATA - Not regulated as dangerous goods

IMDG – Not regulated as dangerous goods

Transport in bulk to Annex II of MARPOL 7/78 and the IBC Code – Not applicable

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15. REGULATORY INFORMATION

US Federal Regulations

This product is a "Hazardous Chemical" as defined by the OSHA Hazard Communication Standard, 29 CFR 1910.1200.

TSCA Section 12(b) Export Notification (40 CFR 707, Subpt. D)

Not regulated.

CERCLA Hazardous Substance List (40 CFR 302.4)

Not listed.

SARA 304 Emergency release notification Not regulated.

OSHA Specifically Regulated Substances (29 CFR 1910.1001-1050) Not regulated.

Superfund Amendments and Reauthorization Act of 1986 (SARA)

Hazard categories

Immediate Hazard - Yes

Delayed Hazard - Yes

Fire Hazard - No

Pressure Hazard - No

Reactivity Hazard - No

SARA 302 Extremely hazardous substance Not listed.

SARA 311/312 Hazardous chemical None

SARA 313 (TRI reporting) Not regulated.

Other federal regulations

Clean Air Act (CAA) Section 112 Hazardous Air Pollutants (HAPs) List Not regulated.

Clean Air Act (CAA) Section 112(r) Accidental Release Prevention (40 CFR 68.130) Not regulated.

Safe Drinking Water Act (SDWA) Not regulated.

US state regulations

California Safe Drinking Water and Toxic Enforcement Act of 1986 (Proposition 65): This material is not known to contain any chemicals currently listed as carcinogens or reproductive toxins.

International Inventories

Country(s) or region	Inventory name	On inventory (yes/no)*
Australia	Australian Inventory of Chemical Substances (AICS)	No
Canada	Domestic Substances List (DSL)	No
Canada	Non-Domestic Substances List (NDSL)	No
China	Inventory of Existing Chemical Substances in China (IECSC)	No
Europe	European Inventory of Existing Commercial Chemical Substances (EINECS)	No
Europe	European List of Notified Chemical Substances (ELINCS)	No
Japan	Inventory of Existing and New Chemical Substances (ENCS)	No
Korea	Existing Chemicals List (ECL)	No
New Zealand	New Zealand Inventory	No
Philippines	Philippine Inventory of Chemicals and Chemical Substances (PICCS)	No

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15. REGULATORY INFORMATION

United States and Puerto Rico Inventories

Country(s) or region Inventory name On inventory (yes/no)*

United States & Puerto Rico Toxic Substances Control Act (TSCA) Inventory No

* A "Yes" indicates that all components of this product comply with the inventory requirements administered by the governing country(s)

* A "No" indicates that one or more components of the product are not listed or exempt from listing on the inventory

16. OTHER INFORMATION

Legend

ACGIH: American Conference of Governmental Industrial Hygienists

ATE: Acute Toxicity Estimate according to REGULATION (EC) No 1272/2008 (CLP)

BOD: Biological Oxygen Demand

CAS#: Chemical Abstracts Service Number

ECHA: European Chemicals Agency

FIFRA: Federal Insecticide, Fungicide and Rodenticide Act

IARC: International Agency for Research on Cancer

LC50: Lethal Concentration 50%

LD50: Lethal Dose 50%

N/A: Denotes no applicable information found or available

NTP: National Toxicology Program

OSHA: Occupational Safety and Health Administration

PEL: Permissible Exposure Limit STEL: Short Term Exposure Limit

TLV: Threshold Limit Value

TSCA: Toxic Substance Control Act

Revision Date: April 14, 2022 Replaces: New document

Information Source and References

This SDS is prepared by Virbac Corporation based on information provided by internal and external references.

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