



Material Safety Data Sheet
ISO/DIS 11014 / 29 CFR 1910.1200 / ANSI Z400.1

Printing date 08/31/2004

Reviewed on 08/31/2004

1 Identification of substance

- **Product details**
- **Trade name:** **PREVICOX® Chewable Tablets for Dogs**
- **Manufacturer/Supplier:**
Merial Limited
3239 Satellite Blvd.
Duluth, Ga. 30096-4640
1-888-MERIAL 1 (1-888-637-4251)
- **Emergency information:**
Spill Information:
CHEMTREC® 1-800-424-9300
CHEMTREC® International 1+703-527-3887
International calls 011+703-527-3887
Reverse charges.

2 Composition/Data on components

- **Chemical characterization**
- **Components:**
189954-96-9 Firocoxib
Diluent
Binder 1
Flow Enhancer
Disintegrant
Binder 2
Lubricant
Other inactive ingredients
- **Additional information:** For the wording of the listed risk phrases refer to section 16.

3 Hazards identification

- **Hazard description:** Not applicable.
- **Information pertaining to particular dangers for man and environment:**
The product does not have to be labeled due to the calculation procedure of the "General Classification guideline for preparations of the EU" in the latest valid version.
- **Classification system:**
The classification was made according to the latest editions of international substances lists, and from company and regulatory data.
- **NFPA ratings (scale 0 - 4)**



Health = 1
Fire = 0
Reactivity = 0

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· **HMIS-ratings (scale 0 - 4)**

HEALTH	1	Health = 1
FIRE	0	Fire = 0
REACTIVITY	0	Reactivity = 0

4 First aid measures

- **General information:** No special measures required.
- **After inhalation:** Seek immediate medical advice.
- **After skin contact:** Immediately wash with water and soap and rinse thoroughly.
- **After eye contact:**
Rinse opened eye for a minimum of 15 minutes under running water. Get medical attention immediately.
- **After swallowing:** Immediately call a doctor.
- **After self injection** Not Applicable.
- **Information for doctor.**
The following symptoms may occur
In case of symptomatic effect provide treatment to maintain life functions.

5 Fire fighting measures

- **Suitable extinguishing agents:**
CO₂, extinguishing powder or water spray. Fight larger fires with water spray or alcohol resistant foam.
- **Protective equipment:** Self-contained breathing apparatus and full protective equipment.

6 Accidental release measures

- **Person-related safety precautions:** Not required.
- **Measures for environmental protection:**
Do not allow product to reach sewage system or any water course.
- **Measures for cleaning/collecting:**
Absorb with liquid-binding material (sand, diatomite, acid binders, universal binders, sawdust).
Dispose of contaminated material as waste according to section XIII.
- **Additional information:** No dangerous substances are released.

7 Handling and storage

- **Handling:**
- **Information for safe handling:**
Store in cool, dry place in tightly closed containers.
Handle with care. Avoid jolting and impact.
- **Information about protection against explosions and fires:** No special measures required.
- **Storage:**
- **Requirements to be met by storerooms and receptacles:** Store only in the original container.
- **Information about storage in one common storage facility:** Not required.

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- **Further information about storage conditions:** Store in a cool, dry, well ventilated place.

8 Exposure controls and personal protection

- **Additional information about design of technical systems:** No further data; see item 7.
- **Components with limit values that require monitoring at the workplace:**
The product does not contain any relevant quantities of materials with critical values that have to be monitored at the workplace.
- **Additional information:** The lists that were valid during the creation were used as basis.
- **Personal protective equipment:**
- **General protective and hygienic measures:**
Wash hands before breaks and at the end of work.
Avoid contact with the eyes and skin.
Do not eat, drink, smoke or inhale.
Do not store food in the working area.
- **Protection of hands:** Not required under normal conditions of use.
- **Eye protection:** Safety goggles.
- **Body protection:** Impervious protective clothing

9 Physical and chemical properties

· General Information

Form:	Solid tablets
Color:	Dark tan
Odor:	Smoked hickory

· Change in condition

Melting point/Melting range:	Undetermined.
Boiling point/Boiling range:	Undetermined.

· **Flash point:** Not applicable.

· **Auto igniting:** Product is not self-igniting.

· **Danger of explosion:** Product does not present an explosion hazard.

· **Specific gravity:** Not determined.

· Solubility in / Miscibility with Water:

Not miscible or difficult to mix.

· Solvent content:

Organic solvents: 0.0 %

· **Solids content:** 100 %

10 Stability and reactivity

- **Thermal decomposition / conditions to be avoided:**
No decomposition if used according to specifications.

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- **Dangerous reactions** No dangerous reactions known.
- **Dangerous products of decomposition:** No dangerous decomposition products known.

11 Toxicological information

- **Acute toxicity:**

- **LD/LC50 values that are relevant for classification:**

189954-96-9 Firocoxib

Oral	LD50	>2000 mg/kg (rat)
Dermal	LD50	>2000 mg/kg (rabbit)

- **Primary irritant effect:**
- **on the skin:** No irritating effect known.
- **on the eye:** No irritating effect known.
- **Sensitization:** No sensitizing effects known.
- **Other information (about experimental toxicology):**

SUBCHRONIC TOXICITY DATA:

In a 90-day oral toxicity study in rats, the NOAEL was 60 mg/kg/day, the highest dose tested. Non-adverse changes in liver, thyroid and kidney were reversible (resolved after treatment termination).

CARCINOGENICITY:

This mixture is not expected to cause carcinogenic effects.

MUTAGENICITY:

Firocoxib tested negative in bacterial and mammalian genetic toxicity tests with and without metabolic activation: tests included Ames Test, mouse lymphoma assay, CHO cell assay and micronucleus assay.

REPRODUCTIVE EFFECTS:

In a one-generation reproductive oral toxicity study in rats, the Parental NOAEL was 3 mg/kg bw/day. The LOEL for reproduction and fetotoxicity was 1 mg/kg bw/day.

TERATOGENICITY/DEVELOPMENTAL EFFECTS:

In a developmental oral toxicity study in rats, a Maternal and Developmental NOEL of 3 mg/kg bw was observed. In rabbits, a Maternal NOEL of 10 mg/kg bw was observed, whereas the Developmental LOEL was 1 mg/kg bw.

- **Additional toxicological information:**

The product is not subject to classification according to internally approved calculation methods for preparations:

When used and handled according to specifications, the product does not have any harmful effects according to our experience and the information provided to us.

12 Ecological information

- **General notes:**

Water hazard class 1 (Self-assessment): slightly hazardous for water

Do not allow undiluted product or large quantities of it to reach ground water, water course or sewage system.

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13 Disposal considerations

- **Product:**
- **Recommendation:**
Must not be disposed of together with household garbage. Do not allow product to reach sewage system.
- **Uncleaned packagings:**
- **Recommendation:** *Disposal must be made according to official regulations.*

14 Transport information

- **DOT regulations:**
- **Hazard class:** *Not Regulated*
- **Land transport ADR/RID (cross-border):**
- **ADR/RID class:** *-*
- **Maritime transport IMDG:**
- **IMDG Class:** *-*
- **Marine pollutant:** *No*
- **Air transport ICAO-TI and IATA-DGR:**
- **ICAO/IATA Class:** *-*

15 Regulations

- **Sara**
- **Section 355 (extremely hazardous substances):**
None of the ingredients are listed.
- **Section 313 (Specific toxic chemical listings):**
None of the ingredients are listed.
- **TSCA (Toxic Substances Control Act):**
None of the ingredients are listed.
- **CA Proposition 65**
- **Chemicals known to cause cancer:**
None of the ingredients are listed.
- **Chemicals known to cause reproductive toxicity:**
None of the ingredients are listed.
- **Carcinogenesis potential categories**
- **EPA (Environmental Protection Agency)**
None of the ingredients is listed.
- **IARC (International Agency for Research on Cancer)**
None of the ingredients is listed.
- **NTP (National Toxicology Program)**
None of the ingredients is listed.

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· TLV (Threshold Limit Value established by ACGIH)

None of the ingredients is listed.

· MAK (German Maximum Workplace Concentration)

None of the ingredients is listed.

· NIOSH-Ca (National Institute for Occupational Safety and Health)

None of the ingredients is listed.

· OSHA-Ca (Occupational Safety & Health Administration)

None of the ingredients is listed.

· Product related hazard informations:

Observe the general safety regulations when handling chemicals.

The product is not subject to identification regulations according to directives on hazardous materials.

· Safety phrases:

29 Do not empty into drains.

· Water hazard class: Water hazard class 1 (Self-assessment): slightly hazardous for water.

16 Other information

This information is based on our present knowledge. However, this shall not constitute a guarantee for any specific product features and shall not establish a legally valid contractual relationship.

· Contact: MSDS Coordinator, msds@merial.com

USA