SAFETY DATA SHEET

Etoricoxib Formulation

SECTION 1. IDENTIFICATION

Product name : Etoricoxib Formulation

Manufacturer or supplier’s details
Company name of supplier : Merck & Co., Inc
Address : 2000 Galloping Hill Road
           Kenilworth - New Jersey - U.S.A. 07033
Telephone : 908-740-4000
Telefax : 908-735-1496
Emergency telephone : 1-908-423-6000
E-mail address : EHSDATASTEWARD@merck.com

Recommended use of the chemical and restrictions on use
Recommended use : Pharmaceutical

SECTION 2. HAZARDS IDENTIFICATION

GHS classification in accordance with the OSHA Hazard Communication Standard (29 CFR 1910.1200)

Combustible dust

Carcinogenicity (Inhalation) : Category 2

Reproductive toxicity : Category 2

Specific target organ toxicity - repeated exposure (Oral) : Category 2 (Kidney, Liver, Gastrointestinal tract)

GHS label elements
Hazard pictograms :

Signal Word : Warning

Hazard Statements : If small particles are generated during further processing, handling or by other means, may form combustible dust concentrations in air.
H351 Suspected of causing cancer if inhaled.
H361d Suspected of damaging the unborn child.
H373 May cause damage to organs (Kidney, Liver, Gastrointestinal tract) through prolonged or repeated exposure if swallowed.

Precautionary Statements : Prevention:
P201 Obtain special instructions before use.
P202 Do not handle until all safety precautions have been read and understood.
P260 Do not breathe dust.
P280 Wear protective gloves, protective clothing, eye protection and face protection.
Response:
P308 + P313 IF exposed or concerned: Get medical attention.

Storage:
P405 Store locked up.

Disposal:
P501 Dispose of contents and container to an approved waste disposal plant.

Other hazards
Dust contact with the eyes can lead to mechanical irritation.
Contact with dust can cause mechanical irritation or drying of the skin.

SECTION 3. COMPOSITION/INFORMATION ON INGREDIENTS

<table>
<thead>
<tr>
<th>Substance / Mixture</th>
<th>Components</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Chemical name</th>
<th>CAS-No.</th>
<th>Concentration (% w/w)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Cellulose</td>
<td>9004-34-6</td>
<td>&gt;= 30 - &lt; 50</td>
</tr>
<tr>
<td>Etoricoxib</td>
<td>202409-33-4</td>
<td>&gt;= 20 - &lt; 30</td>
</tr>
<tr>
<td>Titanium dioxide</td>
<td>13463-67-7</td>
<td>&gt;= 1 - &lt; 5</td>
</tr>
</tbody>
</table>

Actual concentration is withheld as a trade secret

SECTION 4. FIRST AID MEASURES

General advice:
In the case of accident or if you feel unwell, seek medical advice immediately. When symptoms persist or in all cases of doubt seek medical advice.

If inhaled:
If inhaled, remove to fresh air. Get medical attention.

In case of skin contact:
In case of contact, immediately flush skin with soap and plenty of water. Remove contaminated clothing and shoes. Get medical attention. Wash clothing before reuse. Thoroughly clean shoes before reuse.

In case of eye contact:
If in eyes, rinse well with water. Get medical attention if irritation develops and persists.

If swallowed:
If swallowed, DO NOT induce vomiting. Get medical attention. Rinse mouth thoroughly with water.

Most important symptoms and effects, both acute and delayed:
Suspected of causing cancer if inhaled. Suspected of damaging the unborn child. May cause damage to organs through prolonged or repeated exposure if swallowed. Contact with dust can cause mechanical irritation or drying of the skin. Dust contact with the eyes can lead to mechanical irritation.

Protection of first-aiders:
First Aid responders should pay attention to self-protection,
and use the recommended personal protective equipment when the potential for exposure exists (see section 8).

Notes to physician: Treat symptomatically and supportively.

SECTION 5. FIRE-FIGHTING MEASURES

Suitable extinguishing media: Water spray
- Alcohol-resistant foam
- Carbon dioxide (CO2)
- Dry chemical

Unsuitable extinguishing media: None known.

Specific hazards during fire fighting: Avoid generating dust; fine dust dispersed in air in sufficient concentrations, and in the presence of an ignition source is a potential dust explosion hazard. Exposure to combustion products may be a hazard to health.

Hazardous combustion products: Carbon oxides
- Nitrogen oxides (NOx)
- Sulfur oxides
- Chlorine compounds
- Metal oxides
- Oxides of phosphorus

Specific extinguishing methods: Use extinguishing measures that are appropriate to local circumstances and the surrounding environment.
- Use water spray to cool unopened containers.
- Remove undamaged containers from fire area if it is safe to do so.
- Evacuate area.

Special protective equipment for fire-fighters: In the event of fire, wear self-contained breathing apparatus. Use personal protective equipment.

SECTION 6. ACCIDENTAL RELEASE MEASURES

Personal precautions, protective equipment and emergency procedures: Use personal protective equipment.
- Follow safe handling advice (see section 7) and personal protective equipment recommendations (see section 8).

Environmental precautions: Avoid release to the environment.
- Prevent further leakage or spillage if safe to do so.
- Retain and dispose of contaminated wash water.
- Local authorities should be advised if significant spillages cannot be contained.

Methods and materials for containment and cleaning up: Sweep up or vacuum up spillage and collect in suitable container for disposal.
- Avoid dispersal of dust in the air (i.e., clearing dust surfaces with compressed air).
- Dust deposits should not be allowed to accumulate on surfaces, as these may form an explosive mixture if they are released into the atmosphere in sufficient concentration.
- Local or national regulations may apply to releases and disposal of this material, as well as those materials and items employed in the cleanup of releases. You will need to
determine which regulations are applicable. Sections 13 and 15 of this SDS provide information regarding certain local or national requirements.

SECTION 7. HANDLING AND STORAGE

Technical measures: Static electricity may accumulate and ignite suspended dust causing an explosion. Provide adequate precautions, such as electrical grounding and bonding, or inert atmospheres.

Local/Total ventilation: Use only with adequate ventilation.

Advice on safe handling: Do not breathe dust. Do not swallow. Avoid contact with eyes. Avoid prolonged or repeated contact with skin. Handle in accordance with good industrial hygiene and safety practice, based on the results of the workplace exposure assessment. Minimize dust generation and accumulation. Keep container closed when not in use. Keep away from heat and sources of ignition. Take precautionary measures against static discharges. Take care to prevent spills, waste and minimize release to the environment.

Conditions for safe storage: Keep in properly labeled containers. Store locked up. Store in accordance with the particular national regulations.

Materials to avoid: Do not store with the following product types: Strong oxidizing agents.

SECTION 8. EXPOSURE CONTROLS/PERSONAL PROTECTION

Ingredients with workplace control parameters

<table>
<thead>
<tr>
<th>Components</th>
<th>CAS-No.</th>
<th>Value type (Form of exposure)</th>
<th>Control parameters / Permissible concentration</th>
<th>Basis</th>
</tr>
</thead>
<tbody>
<tr>
<td>Cellulose</td>
<td>9004-34-6</td>
<td>TWA</td>
<td>10 mg/m³</td>
<td>ACGIH</td>
</tr>
<tr>
<td></td>
<td></td>
<td>TWA (Respirable)</td>
<td>5 mg/m³</td>
<td>NIOSH REL</td>
</tr>
<tr>
<td></td>
<td></td>
<td>TWA (total)</td>
<td>10 mg/m³</td>
<td>NIOSH REL</td>
</tr>
<tr>
<td></td>
<td></td>
<td>TWA (total dust)</td>
<td>15 mg/m³</td>
<td>OSHA Z-1</td>
</tr>
<tr>
<td></td>
<td></td>
<td>TWA (respirable fraction)</td>
<td>5 mg/m³</td>
<td>OSHA Z-1</td>
</tr>
<tr>
<td>Etoricoxib</td>
<td>202409-33-4</td>
<td>TWA</td>
<td>400 ug/m³ (OEB 2)</td>
<td>Internal</td>
</tr>
<tr>
<td>Titanium dioxide</td>
<td>13463-67-7</td>
<td>TWA (total dust)</td>
<td>15 mg/m³</td>
<td>OSHA Z-1</td>
</tr>
<tr>
<td></td>
<td></td>
<td>TWA</td>
<td>10 mg/m³ (Titanium dioxide)</td>
<td>ACGIH</td>
</tr>
</tbody>
</table>
Engineering measures:
Ensure adequate ventilation, especially in confined areas. Minimize workplace exposure concentrations. Apply measures to prevent dust explosions. Ensure that dust-handling systems (such as exhaust ducts, dust collectors, vessels, and processing equipment) are designed in a manner to prevent the escape of dust into the work area (i.e., there is no leakage from the equipment). Dust formation may be relevant in the processing of this product. In addition to substance-specific OELs, general limitations of concentrations of particulates in the air at workplaces have to be considered in workplace risk assessment. Relevant limits include: OSHA PEL for Particulates Not Otherwise Regulated of 15 mg/m³ - total dust, 5 mg/m³ - respirable fraction; and ACGIH TWA for Particles (insoluble or poorly soluble) Not Otherwise Specified of 3 mg/m³ - respirable particles, 10 mg/m³ - inhalable particles.

Personal protective equipment

Respiratory protection:
General and local exhaust ventilation is recommended to maintain vapor exposures below recommended limits. Where concentrations are above recommended limits or are unknown, appropriate respiratory protection should be worn. Follow OSHA respirator regulations (29 CFR 1910.134) and use NIOSH/MSHA approved respirators. Protection provided by air purifying respirators against exposure to any hazardous chemical is limited. Use a positive pressure air supplied respirator if there is any potential for uncontrolled release, exposure levels are unknown, or any other circumstance where air purifying respirators may not provide adequate protection.

Hand protection

Material:
Chemical-resistant gloves

Remarks:
Choose gloves to protect hands against chemicals depending on the concentration specific to place of work. Breakthrough time is not determined for the product. Change gloves often! For special applications, we recommend clarifying the resistance to chemicals of the aforementioned protective gloves with the glove manufacturer. Wash hands before breaks and at the end of workday.

Eye protection:
Wear the following personal protective equipment:
Safety goggles

Skin and body protection:
Select appropriate protective clothing based on chemical resistance data and an assessment of the local exposure potential. Skin contact must be avoided by using impervious protective clothing (gloves, aprons, boots, etc).

Hygiene measures:
If exposure to chemical is likely during typical use, provide eye flushing systems and safety showers close to the working place. When using do not eat, drink or smoke. Wash contaminated clothing before re-use.
SECTION 9. PHYSICAL AND CHEMICAL PROPERTIES

Appearance : powder
Color : colored
Odor : odorless
Odor Threshold : No data available
pH : No data available
Melting point/freezing point : No data available
Initial boiling point and boiling range : No data available
Flash point : No data available
Evaporation rate : No data available
Flammability (solid, gas) : May form explosive dust-air mixture during processing, handling or other means.
Flammability (liquids) : No data available
Upper explosion limit / Upper flammability limit : No data available
Lower explosion limit / Lower flammability limit : No data available
Vapor pressure : No data available
Relative vapor density : No data available
Relative density : No data available
Solubility(ies)
  Water solubility : No data available
Partition coefficient: n-octanol/water : No data available
Autoignition temperature : No data available
Decomposition temperature : No data available
Viscosity
  Viscosity, kinematic : No data available
Explosive properties : Not explosive
Oxidizing properties : The substance or mixture is not classified as oxidizing.
Molecular weight: No data available
Particle size: No data available

SECTION 10. STABILITY AND REACTIVITY

Reactivity: Not classified as a reactivity hazard.
Chemical stability: Stable under normal conditions.
Possibility of hazardous reactions:
- May form explosive dust-air mixture during processing, handling or other means.
  Can react with strong oxidizing agents.

Conditions to avoid:
- Heat, flames and sparks.
- Avoid dust formation.

Incompatible materials: Oxidizing agents

Hazardous decomposition products: No hazardous decomposition products are known.

SECTION 11. TOXICOLOGICAL INFORMATION

Information on likely routes of exposure

Inhalation
Skin contact
Ingestion
Eye contact

Acute toxicity
Not classified based on available information.

Product:
Acute oral toxicity: Acute toxicity estimate: > 5,000 mg/kg
  Method: Calculation method

Components:

Cellulose:
Acute oral toxicity: LD50 (Rat): > 5,000 mg/kg
Acute inhalation toxicity: LC50 (Rat): > 5.8 mg/l
  Exposure time: 4 h
  Test atmosphere: dust/mist
Acute dermal toxicity: LD50 (Rabbit): > 2,000 mg/kg

Etoricoxib:
Acute oral toxicity: LD50 (Rat): 1,499 mg/kg
  LD50 (Mouse): 1,499 mg/kg
Acute toxicity (other routes of administration): LD50 (Rat): 238 mg/kg
  Application Route: Intraperitoneal
  LD50 (Mouse): 599 mg/kg
Application Route: Intraperitoneal

**Titanium dioxide:**
Acute oral toxicity : LD50 (Rat): > 5,000 mg/kg
Acute inhalation toxicity : LC50 (Rat): > 6.82 mg/l
  Exposure time: 4 h
  Test atmosphere: dust/mist
  Assessment: The substance or mixture has no acute inhalation toxicity

**Skin corrosion/irritation**
Not classified based on available information.

**Components:**

**Etoricoxib:**
Species : Rabbit
Result : No skin irritation

**Titanium dioxide:**
Species : Rabbit
Result : No skin irritation

**Serious eye damage/eye irritation**
Not classified based on available information.

**Components:**

**Etoricoxib:**
Species : Rabbit
Result : Mild eye irritation

**Titanium dioxide:**
Species : Rabbit
Result : No eye irritation

**Respiratory or skin sensitization**

**Skin sensitization**
Not classified based on available information.

**Respiratory sensitization**
Not classified based on available information.

**Components:**

**Etoricoxib:**
Test Type : Local lymph node assay (LLNA)
Routes of exposure : Skin contact
Species : Mouse
Assessment : Did not cause sensitization on laboratory animals.
Titanium dioxide:

- **Test Type**: Local lymph node assay (LLNA)
- **Routes of exposure**: Skin contact
- **Species**: Mouse
- **Result**: negative

Germ cell mutagenicity

Not classified based on available information.

**Components:**

**Cellulose:**

- **Genotoxicity in vitro**: Test Type: Bacterial reverse mutation assay (AMES)
  - Result: negative
  - Test Type: In vitro mammalian cell gene mutation test
  - Result: negative

- **Genotoxicity in vivo**: Test Type: Mammalian erythrocyte micronucleus test (in vivo cytogenetic assay)
  - **Species**: Mouse
  - **Application Route**: Ingestion
  - Result: negative

**Etoricoxib:**

- **Genotoxicity in vitro**: Test Type: reverse mutation assay
  - Result: negative
  - Test Type: In vitro mammalian cell gene mutation test
  - Test system: human lymphoblastoid cells
  - Result: negative
  - Test Type: Chromosomal aberration
  - Test system: Chinese hamster ovary cells
  - Result: negative
  - Test Type: Alkaline elution assay
  - Result: negative

- **Genotoxicity in vivo**: Test Type: Chromosomal aberration
  - **Species**: Rat
  - **Cell type**: Bone marrow
  - **Application Route**: Oral
  - Result: negative
  - Test Type: Alkaline elution assay
  - **Species**: Rat
  - **Application Route**: Oral
  - Result: negative
Genotoxicity in vitro: Test Type: Bacterial reverse mutation assay (AMES)  
Result: negative

Genotoxicity in vivo: Test Type: In vivo micronucleus test  
Species: Mouse  
Result: negative

Carcinogenicity  
Suspected of causing cancer if inhaled.

Components:

Cellulose:
Species: Rat  
Application Route: Ingestion  
Exposure time: 72 weeks  
Result: negative

Etoricoxib:
Species: Rat, male and female  
Application Route: oral (gavage)  
Exposure time: 2 Years  
Result: positive

Species: Mouse, male and female  
Application Route: oral (gavage)  
Exposure time: 2 Years  
Result: negative

Titanium dioxide:
Species: Rat  
Application Route: inhalation (dust/mist/fume)  
Exposure time: 2 Years  
Method: OECD Test Guideline 453  
Result: positive  
Remarks: The mechanism or mode of action may not be relevant in humans.

Carcinogenicity - Assessment: Limited evidence of carcinogenicity in inhalation studies with animals.

IARC  
Group 2B: Possibly carcinogenic to humans  
Titanium dioxide  
13463-67-7

OSHA  
No component of this product present at levels greater than or equal to 0.1% is on OSHA’s list of regulated carcinogens.

NTP  
No ingredient of this product present at levels greater than or equal to 0.1% is identified as a known or anticipated carcinogen by NTP.

Reproductive toxicity  
Suspected of damaging the unborn child.
Components:

Cellulose:
Effects on fertility: Test Type: One-generation reproduction toxicity study
Species: Rat
Application Route: Ingestion
Result: negative

Effects on fetal development: Test Type: Fertility/early embryonic development
Species: Rat
Application Route: Ingestion
Result: negative

Etoricoxib:
Effects on fertility: Test Type: Fertility/early embryonic development
Species: Rat, female
Application Route: Oral
General Toxicity Parent: NOAEL: 10 mg/kg body weight
Result: positive

Test Type: Fertility/early embryonic development
Species: Rat, male
Application Route: Oral
Result: negative

Effects on fetal development: Species: Rat
Application Route: Oral
Result: positive

Species: Rabbit
Application Route: Oral
Result: positive

Reproductive toxicity - Assessment: Some evidence of adverse effects on development, based on animal experiments.

STOT-single exposure
Not classified based on available information.

STOT-repeated exposure
May cause damage to organs (Kidney, Liver, Gastrointestinal tract) through prolonged or repeated exposure if swallowed.

Components:

Etoricoxib:
Routes of exposure: Ingestion
Target Organs: Kidney, Liver, Gastrointestinal tract
Assessment: May cause damage to organs through prolonged or repeated exposure.
Repeated dose toxicity

**Components:**

**Cellulose:**
- **Species:** Rat
- **NOAEL:** >= 9,000 mg/kg
- **Application Route:** Ingestion
- **Exposure time:** 90 Days

**Etoricoxib:**
- **Species:** Rat
- **LOAEL:** 30 mg/kg
- **Application Route:** oral (gavage)
- **Exposure time:** 27 Weeks
- **Target Organs:** Gastrointestinal tract, Kidney

- **Species:** Rat
- **NOAEL:** 30 mg/kg
- **Application Route:** oral (gavage)
- **Exposure time:** 53 Weeks
- **Target Organs:** Liver

- **Species:** Dog
- **NOAEL:** 50 mg/kg
- **Application Route:** oral (gavage)
- **Exposure time:** 53 Weeks
- **Target Organs:** Liver

- **Species:** Dog
- **NOAEL:** 200 mg/kg
- **Application Route:** oral (gavage)
- **Exposure time:** 14 Weeks
- **Target Organs:** Gastrointestinal tract, Kidney

**Titanium dioxide:**
- **Species:** Rat
- **NOAEL:** 24,000 mg/kg
- **Application Route:** Ingestion
- **Exposure time:** 28 Days

- **Species:** Rat
- **NOAEL:** 10 mg/m³
- **Application Route:** inhalation (dust/mist/fume)
- **Exposure time:** 2 y

Aspiration toxicity
Not classified based on available information.

Experience with human exposure

**Components:**

**Etoricoxib:**
SECTION 12. ECOLOGICAL INFORMATION

Ecotoxicity

**Components:**

**Cellulose:**
- Toxicity to fish: LC50 (Oryzias latipes (Japanese medaka)): > 100 mg/l
  - Exposure time: 48 h
  - Remarks: Based on data from similar materials

**Etoricoxib:**
- Toxicity to fish: LC50 (Pimephales promelas (fathead minnow)): > 30 mg/l
  - Exposure time: 96 h
  - Method: OECD Test Guideline 203
- Toxicity to daphnia and other aquatic invertebrates: EC50 (Daphnia magna (Water flea)): > 30 mg/l
  - Exposure time: 48 h
  - Method: OECD Test Guideline 202
- Toxicity to algae/aquatic plants: EC50 (Pseudokirchneriella subcapitata (green algae)): > 10 mg/l
  - Exposure time: 72 h
  - Method: OECD Test Guideline 201
- Toxicity to fish (Chronic toxicity): NOEC (Pimephales promelas (fathead minnow)): 7.93 mg/l
  - Exposure time: 32 d
  - Method: OECD Test Guideline 210
- Toxicity to daphnia and other aquatic invertebrates (Chronic toxicity): NOEC (Daphnia magna (Water flea)): 0.75 mg/l
  - Exposure time: 21 d
  - Method: OECD Test Guideline 211
- Toxicity to microorganisms: EC50: > 1,000 mg/l
  - Exposure time: 3 h
  - Test Type: Respiration inhibition
  - Method: OECD Test Guideline 209
  - NOEC: 1,000 mg/l
  - Exposure time: 3 h
  - Test Type: Respiration inhibition
  - Method: OECD Test Guideline 209

**Titanium dioxide:**
- Toxicity to fish: LC50 (Oncorhynchus mykiss (rainbow trout)): > 100 mg/l
  - Exposure time: 96 h
  - Method: OECD Test Guideline 203
Toxicity to daphnia and other aquatic invertebrates: EC50 (Daphnia magna (Water flea)): > 100 mg/l
Exposure time: 48 h

Toxicity to algae/aquatic plants: EC50 (Skeletonema costatum (marine diatom)): > 10,000 mg/l
Exposure time: 72 h

Toxicity to microorganisms: EC50: > 1,000 mg/l
Exposure time: 3 h
Method: OECD Test Guideline 209

Persistence and degradability

Components:
Cellulose: Biodegradability: Result: Readily biodegradable.

Etoricoxib: Biodegradability: Result: not rapidly degradable
Biodegradation: 0.2 %
Exposure time: 28 d

Bioaccumulative potential

Components:
Etoricoxib: Partition coefficient: n-octanol/water: log Pow: 2.3

Mobility in soil
No data available

Other adverse effects
No data available

SECTION 13. DISPOSAL CONSIDERATIONS

Disposal methods
Waste from residues: Dispose of in accordance with local regulations.
Contaminated packaging: Empty containers should be taken to an approved waste handling site for recycling or disposal.
If not otherwise specified: Dispose of as unused product.

SECTION 14. TRANSPORT INFORMATION

International Regulations
UNRTDG
UN number: UN 3077
Proper shipping name: ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID, N.O.S. (Etoricoxib)
# SAFETY DATA SHEET

## Etoricoxib Formulation

<table>
<thead>
<tr>
<th>Version</th>
<th>Revision Date</th>
<th>SDS Number</th>
<th>Date of last issue</th>
<th>Date of first issue</th>
</tr>
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<tbody>
<tr>
<td>7.3</td>
<td>10/02/2020</td>
<td>26559-00018</td>
<td>03/23/2020</td>
<td>10/29/2014</td>
</tr>
</tbody>
</table>

- **Class**: 9
- **Packing group**: III
- **Labels**: 9

### IATA-DGR
- **UN/ID No.**: UN 3077
- **Proper shipping name**: Environmentally hazardous substance, solid, n.o.s. (Etoricoxib)
- **Class**: 9
- **Packing group**: III
- **Labels**: Miscellaneous
- **Packing instruction (cargo aircraft)**: 956
- **Packing instruction (passenger aircraft)**: 956
- **Environmentally hazardous**: yes

### IMDG-Code
- **UN number**: UN 3077
- **Proper shipping name**: ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID, N.O.S. (Etoricoxib)
- **Class**: 9
- **Packing group**: III
- **Labels**: 9
- **EmS Code**: F-A, S-F
- **Marine pollutant**: yes

**Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code**
Not applicable for product as supplied.

**Domestic regulation**

**49 CFR**
- **UN/ID/NA number**: UN 3077
- **Proper shipping name**: Environmentally hazardous substance, solid, n.o.s. (Etoricoxib)
- **Class**: 9
- **Packing group**: III
- **Labels**: CLASS 9
- **ERG Code**: 171
- **Marine pollutant**: yes(Etoricoxib)
- **Remarks**: Above applies only to containers over 119 gallons or 450 liters., Shipment by ground under DOT is non-regulated; however it may be shipped per the applicable hazard classification to facilitate multi-modal transport involving ICAO (IATA) or IMO.

**Special precautions for user**
The transport classification(s) provided herein are for informational purposes only, and solely based upon the properties of the unpackaged material as it is described within this Safety Data Sheet. Transportation classifications may vary by mode of transportation, package sizes, and variations in regional or country regulations.
SECTION 15. REGULATORY INFORMATION

CERCLA Reportable Quantity
This material does not contain any components with a CERCLA RQ.

SARA 304 Extremely Hazardous Substances Reportable Quantity
This material does not contain any components with a section 304 EHS RQ.

SARA 302 Extremely Hazardous Substances Threshold Planning Quantity
This material does not contain any components with a section 302 EHS TPQ.

SARA 311/312 Hazards
- Combustible dust
- Carcinogenicity
- Reproductive toxicity
- Specific target organ toxicity (single or repeated exposure)

SARA 313
- This material does not contain any chemical components with known CAS numbers that exceed the threshold (De Minimis) reporting levels established by SARA Title III, Section 313.

US State Regulations

Pennsylvania Right To Know

- Cellulose 9004-34-6
- Calcium hydrogenorthophosphate 7757-93-9
- Etoricoxib 202409-33-4
- Titanium dioxide 13463-67-7

California Prop. 65
WARNING: This product can expose you to chemicals including Titanium dioxide, which is/are known to the State of California to cause cancer. For more information go to www.P65Warnings.ca.gov.

California Permissible Exposure Limits for Chemical Contaminants

- Cellulose 9004-34-6
- Titanium dioxide 13463-67-7

The ingredients of this product are reported in the following inventories:

- AICS: not determined
- DSL: not determined
- IECSC: not determined

SECTION 16. OTHER INFORMATION

Further information
NFPA 704:

- Flammability: 0
- Health: 1
- Special hazard: 0
- Instability: 0

HMIS® IV:

- HEALTH: 2
- FLAMMABILITY: 3
- PHYSICAL HAZARD: 0

HMIS® ratings are based on a 0-4 rating scale, with 0 representing minimal hazards or risks, and 4 representing significant hazards or risks. The "*" represents a chronic hazard, while the "/" represents the absence of a chronic hazard.

Full text of other abbreviations:

- ACGIH: USA. ACGIH Threshold Limit Values (TLV)
- NIOSH REL: USA. NIOSH Recommended Exposure Limits
- OSHA Z-1: USA. Occupational Exposure Limits (OSHA) - Table Z-1 Limits for Air Contaminants
- ACGIH / TWA: 8-hour, time-weighted average
- NIOSH REL / TWA: Time-weighted average concentration for up to a 10-hour workday during a 40-hour workweek
- OSHA Z-1 / TWA: 8-hour time weighted average

AIIC - Australian Inventory of Industrial Chemicals; ASTM - American Society for the Testing of Materials; bw - Body weight; CERCLA - Comprehensive Environmental Response, Compensation, and Liability Act; CMR - Carcinogen, Mutagen or Reproductive Toxicant; DIN - Standard of the German Institute for Standardisation; DOT - Department of Transportation; DSL - Domestic Substances List (Canada); ECx - Concentration associated with x% response; EHS - Extremely Hazardous Substance; ELx - Loading rate associated with x% response; EmS - Emergency Schedule; ENCS - Existing and New Chemical Substances (Japan); ErCx - Concentration associated with x% growth rate response; ERG - Emergency Response Guide; GHS - Globally Harmonized System; GLP - Good Laboratory Practice; HMIS - Hazardous Materials Identification System; IARC - International Agency for Research on Cancer; IATA - International Air Transport Association; IBC - International Code for the Construction and Equipment of Ships carrying Dangerous Chemicals in Bulk; IC50 - Half maximal inhibitory concentration; ICAO - International Civil Aviation Organization; IECSC - Inventory of Existing Chemical Substances in China; IMDG - International Maritime Dangerous Goods; IMO - International Maritime Organization; ISHL - Industrial Safety and Health Law (Japan); ISO - International Organisation for Standardization; KECl - Korea Existing Chemicals Inventory; LC50 - Lethal Concentration to 50% of a test population; LD50 - Lethal Dose to 50% of a test population (Median Lethal Dose); MARPOL - International Convention for the Prevention of Pollution from Ships; MSHA - Mine Safety and Health Administration; n.o.s. - Not Otherwise Specified; NFPA - National Fire Protection Association; NO(A)EC - No Observed (Adverse) Effect Concentration; NO(A)EL - No Observed (Adverse) Effect Level; NOELR - No Observable Effect Loading Rate; NTP - National Toxicology Program; NZIoC - New Zealand Inventory of Chemicals; OECD - Organization for Economic Co-operation and Development; OPPTS - Office of Chemical Safety and Pollution Prevention; PBT - Persistent, Bioaccumulative and Toxic substance; PICCS - Philippines Inventory of Chemicals and Chemical Substances; (Q)SAR - (Quantitative) Structure-Activity Relationship; USEPA - United States Environmental Protection Agency; WHO - World Health Organization; Z-1 - OSHA Z-1 Limits for Air Contaminants.
SAFETY DATA SHEET

Etoricoxib Formulation

Revision Date: 10/02/2020

SDS Number: 26559-00018

Date of last issue: 03/23/2020

Date of first issue: 10/29/2014

Sources of key data used to compile the Material Safety Data Sheet:

Revision Date: 10/02/2020

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