## SECTION 1. PRODUCT AND COMPANY IDENTIFICATION

**Product name**: Etoricoxib Formulation

**Manufacturer or supplier’s details**

- **Company**: MSD
- **Address**: 26 Talavera Road, Talavera Corp Centre, Macquarie Park, New South Wales, 2113 Australia
- **Telephone**: (61)-02-8988-8000
- **Emergency telephone number**: (61)-02-8988-8000
- **E-mail address**: EHSDATASTEWARD@msd.com
- **Telefax**: 908-735-1496

**Recommended use of the chemical and restrictions on use**

- **Recommended use**: Pharmaceutical

## SECTION 2. HAZARDS IDENTIFICATION

**GHS Classification**

- **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**: ![Warning]
- **Signal word**: Warning
- **Hazard statements**: 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. P281 Use personal protective equipment as required.
Response:
P308 + P313 IF exposed or concerned: Get medical advice/attention.

Storage:
P405 Store locked up.

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

Other hazards which do not result in classification
Dust contact with the eyes can lead to mechanical irritation.
Contact with dust can cause mechanical irritation or drying of the skin.
May form explosive dust-air mixture during processing, handling or other means.

SECTION 3. COMPOSITION/INFORMATION ON INGREDIENTS

<table>
<thead>
<tr>
<th>Substance / Mixture</th>
<th>Components</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Chemical name</td>
</tr>
<tr>
<td></td>
<td>Cellulose</td>
</tr>
<tr>
<td></td>
<td>Etoricoxib</td>
</tr>
<tr>
<td></td>
<td>Titanium dioxide</td>
</tr>
</tbody>
</table>

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.
### SECTION 5. FIREFIGHTING MEASURES

| 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. |

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

#### Unsuitable extinguishing media:
- None known.

#### Specific hazards during firefighting:
- 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)
- Sulphur 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 firefighters:
- In the event of fire, wear self-contained breathing apparatus.
- Use personal protective equipment.

#### Hazchem Code:
- 2Z

### SECTION 6. ACCIDENTAL RELEASE MEASURES

| Personal precautions, protective equipment and emergency procedures: | Use personal protective equipment. Follow safe handling advice and personal protective equipment recommendations. |
| Environmental precautions: | Discharge into the environment must be avoided. 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 dis- |
posal 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.

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.

Conditions for safe storage: Keep in properly labelled 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

Components 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>AU OEL</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Further information: This value is for inhalable dust containing no asbestos and &lt; 1% crystalline silica</td>
<td></td>
</tr>
<tr>
<td>Etoricoxib</td>
<td>202409-33-4</td>
<td>TWA</td>
<td>400 ug/m³ (OEL 2)</td>
<td>Internal</td>
</tr>
<tr>
<td>Titanium dioxide</td>
<td>13463-67-7</td>
<td>TWA</td>
<td>10 mg/m³</td>
<td>AU OEL</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Further information: This value is for inhalable dust containing no asbestos and &lt; 1% crystalline silica</td>
<td></td>
</tr>
</tbody>
</table>
TWA 10 mg/m3 (Titanium dioxide) ACGIH

**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).

**Personal protective equipment**

**Respiratory protection**
If adequate local exhaust ventilation is not available or exposure assessment demonstrates exposures outside the recommended guidelines, use respiratory protection.

- **Filter type**: Particulates type
- **Hand protection**: Chemical-resistant gloves

**Remarks**
Choose gloves to protect hands against chemicals depending on the concentration and quantity of the hazardous substance and 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).

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**SECTION 9. PHYSICAL AND CHEMICAL PROPERTIES**

- **Appearance**: powder
- **Colour**: coloured
- **Odour**: odourless
- **Odour 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

Vapour pressure: No data available

Relative vapour density: No data available

Relative density: No data available

Solubility(ies)
Water solubility: No data available

Partition coefficient: n-octanol/water: No data available

Auto-ignition 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

Exposure routes: Inhalation, Skin contact, Ingestion, Eye contact

Acute toxicity
Not classified based on available information.

Product:
Acute oral toxicity: Acute toxicity estimate: > 2,000 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 sensitisation
Skin sensitisation
Not classified based on available information.

Respiratory sensitisation
Not classified based on available information.

Components:
Etoricoxib:
Test Type: Local lymph node assay (LLNA)
Exposure routes: Skin contact
Species: Mouse
Assessment: Did not cause sensitisation on laboratory animals.
Result: negative

Titanium dioxide:
Test Type: Local lymph node assay (LLNA)
Exposure routes: Skin contact
Species: Mouse
Result: negative

Chronic toxicity
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

**Titanium dioxide**

**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
**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>
</thead>
</table>

### 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.

### 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 foetal 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 foetal 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:**
- Exposure routes: 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: \( \geq 9,000 \) 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
# Eticoxib Formulation

## Species
- **Species**: Dog
- **LOAEL**: 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

## Aspiration toxicity
Not classified based on available information.

## Experience with human exposure

### Components:

**Eticoxib**
- **Ingestion**
  - Symptoms: upper respiratory tract infection, Headache, hypertension, Diarrhoea, urinary tract infection, flu-like symptoms, heartburn, Nausea, bronchitis, Dizziness, asthenia, Rash, Back pain, Cough, Abdominal pain, pharyngitis, Oedema

## 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

**Eticoxib**
- **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:
SAFETY DATA SHEET

Etoricoxib Formulation

Partition coefficient: n-octanol/water

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)
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.
National Regulations

**ADG**
- UN number: UN 3077
- Proper shipping name: ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID, N.O.S. (Etoricoxib)
- Class: 9
- Packing group: III
- Labels: 9
- Hazchem Code: 2Z

**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

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

**Prohibition/Licensing Requirements**
- There is no applicable prohibition or notification/licensing requirements, including for carcinogens under Commonwealth, State or Territory legislation.

**The components of this product are reported in the following inventories:**
- **AICS**: not determined
- **DSL**: not determined
- **IECSC**: not determined

### SECTION 16. OTHER INFORMATION

**Further information**
- **Revision Date**: 09/13/2019
- **Date format**: dd.mm.yyyy

**Full text of other abbreviations**
- **ACGIH**: USA. ACGIH Threshold Limit Values (TLV)
- **AU OEL**: Australia. Workplace Exposure Standards for Airborne Contaminants.
- **ACGIH / TWA**: 8-hour, time-weighted average
The information provided in this Safety Data Sheet is correct to the best of our knowledge, information and belief at the date of its publication. The information is designed only as a guidance for safe handling, use, processing, storage, transportation, disposal and release and shall not be considered a warranty or quality specification of any type. The information provided relates only to the specific material identified at the top of this SDS and may not be valid when the SDS material is used in combination with any other materials or in any process, unless specified in the text. Material users should review the information and recommendations in the specific context of their intended manner of handling, use, processing and storage, including an assessment of the appropriateness of the SDS material in the user’s end product, if applicable.

AU / EN