SAFETY DATA SHEET  
according to Regulation (EC) No. 1907/2006

Etoricoxib Granulation Formulation

SECTION 1: Identification of the substance/mixture and of the company/undertaking

1.1 Product identifier

<table>
<thead>
<tr>
<th>Trade name</th>
<th>Etoricoxib Granulation Formulation</th>
</tr>
</thead>
<tbody>
<tr>
<td>Product code</td>
<td>ETORICOXIB GRANULATION</td>
</tr>
</tbody>
</table>

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

| Use of the Substance/Mixture | Pharmaceutical                       |

1.3 Details of the supplier of the safety data sheet

<table>
<thead>
<tr>
<th>Company</th>
<th>MSD</th>
</tr>
</thead>
<tbody>
<tr>
<td>Address</td>
<td>Innishannon County Cork - Ireland</td>
</tr>
<tr>
<td>Telephone</td>
<td>353 214329300</td>
</tr>
<tr>
<td>Telefax</td>
<td>908-735-1496</td>
</tr>
<tr>
<td>E-mail address</td>
<td><a href="mailto:EHSDATASTEWARD@msd.com">EHSDATASTEWARD@msd.com</a></td>
</tr>
</tbody>
</table>

1.4 Emergency telephone number

1-908-423-6000

SECTION 2: Hazards identification

2.1 Classification of the substance or mixture

<table>
<thead>
<tr>
<th>Classification (REGULATION (EC) No 1272/2008)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Reproductive toxicity, Category 2</td>
</tr>
<tr>
<td>Specific target organ toxicity - repeated exposure, Category 2</td>
</tr>
<tr>
<td>Long-term (chronic) aquatic hazard, Category 2</td>
</tr>
</tbody>
</table>

2.2 Label elements

<table>
<thead>
<tr>
<th>Labelling (REGULATION (EC) No 1272/2008)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Hazard pictograms</td>
</tr>
<tr>
<td>Signal word</td>
</tr>
<tr>
<td>Hazard statements</td>
</tr>
<tr>
<td></td>
</tr>
</tbody>
</table>
H411  Toxic to aquatic life with long lasting effects.

Precautionary statements:

**Prevention:**
P201  Obtain special instructions before use.
P260  Do not breathe dust.
P273  Avoid release to the environment.
P280  Wear protective gloves/ protective clothing/ eye protection/ face protection.

**Response:**
P308 + P313  IF exposed or concerned: Get medical advice/ attention.
P391  Collect spillage.

Hazardous components which must be listed on the label:
Etoricoxib

### 2.3 Other hazards
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

#### 3.2 Mixtures

<table>
<thead>
<tr>
<th>Components</th>
</tr>
</thead>
<tbody>
<tr>
<td>Chemical name: Etoricoxib</td>
</tr>
<tr>
<td>CAS-No. 202409-33-4</td>
</tr>
<tr>
<td>EC-No. H302</td>
</tr>
<tr>
<td>Index-No. H361d</td>
</tr>
<tr>
<td>Registration number: STOT RE 2; H373 Aquatic Chronic 2; H411</td>
</tr>
<tr>
<td>Classification: Acute Tox. 4;</td>
</tr>
<tr>
<td>Concentration: &gt;= 25 - &lt; 30</td>
</tr>
</tbody>
</table>

For explanation of abbreviations see section 16.

### SECTION 4: First aid measures

#### 4.1 Description of 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.

**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).

**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.

4.2 Most important symptoms and effects, both acute and delayed

Risks:
- Suspected of damaging the unborn child.
- May cause damage to organs through prolonged or repeated exposure.
- Contact with dust can cause mechanical irritation or drying of the skin.
- Dust contact with the eyes can lead to mechanical irritation.

4.3 Indication of any immediate medical attention and special treatment needed

Treatment:
- Treat symptomatically and supportively.

SECTION 5: Firefighting measures

5.1 Extinguishing media

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

Unsuitable extinguishing media:
- None known.

5.2 Special hazards arising from the substance or mixture

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
- Metal oxides
- Oxides of phosphorus
- Nitrogen oxides (NOx)
- Sulphur oxides
CLORINE COMPOUNDS

5.3 Advice for firefighters

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

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.

SECTION 6: Accidental release measures

6.1 Personal precautions, protective equipment and emergency procedures

Personal precautions: Use personal protective equipment.
Follow safe handling advice and personal protective equipment recommendations.

6.2 Environmental precautions

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.

6.3 Methods and material for containment and cleaning up

Methods for 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.

6.4 Reference to other sections

See sections: 7, 8, 11, 12 and 13.

SECTION 7: Handling and storage

7.1 Precautions for safe handling

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.

7.2 Conditions for safe storage, including any incompatibilities
Requirements for storage areas and containers: Keep in properly labelled containers. Store locked up. Store in accordance with the particular national regulations.
Advice on common storage: Do not store with the following product types:
Strong oxidizing agents

7.3 Specific end use(s)
Specific use(s): No data available

No data available

SECTION 8: Exposure controls/personal protection

8.1 Control parameters

Occupational Exposure Limits

<table>
<thead>
<tr>
<th>Components</th>
<th>CAS-No.</th>
<th>Value type (Form of exposure)</th>
<th>Control parameters</th>
<th>Basis</th>
</tr>
</thead>
<tbody>
<tr>
<td>Cellulose</td>
<td>9004-34-6</td>
<td>OELV - 8 hrs (TWA)</td>
<td>10 mg/m3</td>
<td>IE OEL</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>
</tbody>
</table>

Further information: Where no specific short-term exposure limit is listed, a figure three times the long-term exposure limit value should be used.

8.2 Exposure controls

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**

**Eye protection**
- Wear the following personal protective equipment:
  - Safety goggles
  - Equipment should conform to I.S. EN 166

**Hand protection**
- **Material**: 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!
- **Remarks**: For special applications, we recommend clarifying the resistance to chemicals of the aforementioned protective gloves with the glove manufacturer.
- **Remarks**: Wash hands before breaks and at the end of workday.

**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).

**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 (P)

### SECTION 9: Physical and chemical properties

#### 9.1 Information on basic physical and chemical properties

- **Appearance**: powder
- **Colour**: No data available
- **Odour**: No data available
- **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.
- **Upper explosion limit / Upper**: No data available
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SECTION 10: Stability and reactivity

10.1 Reactivity
Not classified as a reactivity hazard.

10.2 Chemical stability
Stable under normal conditions.

10.3 Possibility of hazardous reactions
Hazardous reactions: May form explosive dust-air mixture during processing, handling or other means. Can react with strong oxidizing agents.

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

10.5 Incompatible materials
Materials to avoid: Oxidizing agents

10.6 Hazardous decomposition products
No hazardous decomposition products are known.

SECTION 11: Toxicological information

11.1 Information on toxicological effects
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: > 2,000 mg/kg
Method: Calculation method

Components:
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

Skin corrosion/irritation
Not classified based on available information.

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

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

Components:
Etoricoxib:
Etoricoxib Granulation Formulation

Species: Rabbit
Result: Mild 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

Germ cell mutagenicity
Not classified based on available information.

Components:

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

Carcinogenicity
Not classified based on available information.
Components:

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

Reproductive toxicity
Suspected of damaging the unborn child.

Components:

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 through prolonged or repeated exposure.

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:

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
LOAEL: 200 mg/kg
Application Route: oral (gavage)
Exposure time: 14 Weeks
Target Organs: Gastrointestinal tract, Kidney

Aspiration toxicity
Not classified based on available information.

Experience with human exposure

Components:

Etoricoxib:
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

12.1 Toxicity

Components:

Etoricoxib:
Toxicity to fish: LC50 (Pimephales promelas (fathead minnow)): > 30 mg/l
Exposure time: 96 h
Method: OECD Test Guideline 203
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Version 3.3  Revision Date: 09/13/2019  SDS Number: 16706-00016  Date of last issue: 24.04.2019
Date of first issue: 29.09.2014

12.2 Persistence and degradability

Components:

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

12.3 Bioaccumulative potential

Components:

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

12.4 Mobility in soil
No data available

12.5 Results of PBT and vPvB assessment
Not relevant
12.6 Other adverse effects
No data available

SECTION 13: Disposal considerations

13.1 Waste treatment methods
- **Product**
  
  Dispose of in accordance with local regulations.
  
  According to the European Waste Catalogue, Waste Codes are not product specific, but application specific.
  
  Waste codes should be assigned by the user, preferably in discussion with the waste disposal authorities.

- **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

14.1 UN number
- **ADN**
  
  : UN 3077

- **ADR**
  
  : UN 3077

- **RID**
  
  : UN 3077

- **IMDG**
  
  : UN 3077

- **IATA**
  
  : UN 3077

14.2 UN proper shipping name

- **ADN**
  
  : ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID, N.O.S.
    
    (Etoricoxib)

- **ADR**
  
  : ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID, N.O.S.
    
    (Etoricoxib)

- **RID**
  
  : ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID, N.O.S.
    
    (Etoricoxib)

- **IMDG**
  
  : ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID, N.O.S.
    
    (Etoricoxib)

- **IATA**
  
  : Environmentally hazardous substance, solid, n.o.s.
    
    (Etoricoxib)

14.3 Transport hazard class(es)

- **ADN**
  
  : 9

- **ADR**
  
  : 9

- **RID**
  
  : 9

- **IMDG**
  
  : 9
14.4 Packing group

**ADN**
- Packing group: III
- Classification Code: M7
- Hazard Identification Number: 90
- Labels: 9

**ADR**
- Packing group: III
- Classification Code: M7
- Hazard Identification Number: 90
- Labels: 9
- Tunnel restriction code: (-)

**RID**
- Packing group: III
- Classification Code: M7
- Hazard Identification Number: 90
- Labels: 9

**IMDG**
- Packing group: III
- Labels: 9
- EmS Code: F-A, S-F

**IATA (Cargo)**
- Packing instruction (cargo aircraft): 956
- Packing instruction (LQ): Y956
- Packing group: III
- Labels: Miscellaneous

**IATA (Passenger)**
- Packing instruction (passenger aircraft): 956
- Packing instruction (LQ): Y956
- Packing group: III
- Labels: Miscellaneous

14.5 Environmental hazards

**ADN**
- Environmentally hazardous: yes

**ADR**
- Environmentally hazardous: yes

**RID**
- Environmentally hazardous: yes

**IMDG**
- Marine pollutant: yes

**IATA (Passenger)**
- Environmentally hazardous: yes

**IATA (Cargo)**
Environmentally hazardous: yes

14.6 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.

14.7 Transport in bulk according to Annex II of Marpol and the IBC Code
Remarks: Not applicable for product as supplied.

SECTION 15: Regulatory information

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

REACH - Candidate List of Substances of Very High Concern for Authorisation (Article 59): Not applicable
REACH - List of substances subject to authorisation (Annex XIV): Not applicable
Regulation (EC) No 1005/2009 on substances that deplete the ozone layer: Not applicable
Regulation (EC) No 850/2004 on persistent organic pollutants: Not applicable
Regulation (EC) No 649/2012 of the European Parliament and the Council concerning the export and import of dangerous chemicals: Not applicable
REACH - Restrictions on the manufacture, placing on the market and use of certain dangerous substances, preparations and articles (Annex XVII): Not applicable

<table>
<thead>
<tr>
<th>Quantity 1</th>
<th>Quantity 2</th>
</tr>
</thead>
<tbody>
<tr>
<td>200 t</td>
<td>500 t</td>
</tr>
</tbody>
</table>

Other regulations:
Take note of Directive 92/85/EEC regarding maternity protection or stricter national regulations, where applicable.
Take note of Directive 94/33/EC on the protection of young people at work or stricter national regulations, where applicable.

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

15.2 Chemical safety assessment
A Chemical Safety Assessment has not been carried out.

SECTION 16: Other information

Other information: Items where changes have been made to the previous version
SAFETY DATA SHEET
according to Regulation (EC) No. 1907/2006

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Version 3.3 Revision Date: 09/13/2019 SDS Number: 16706-00016 Date of last issue: 24.04.2019 Date of first issue: 29.09.2014

are highlighted in the body of this document by two vertical lines.

Full text of H-Statements
H302 : Harmful if swallowed.
H361d : Suspected of damaging the unborn child.
H373 : May cause damage to organs through prolonged or repeated exposure if swallowed.
H411 : Toxic to aquatic life with long lasting effects.

Full text of other abbreviations
Acute Tox. : Acute toxicity
Aquatic Chronic : Long-term (chronic) aquatic hazard
Repr. : Reproductive toxicity
STOT RE : Specific target organ toxicity - repeated exposure
IE OEL : Ireland. List of Chemical Agents and Occupational Exposure Limit Values - Schedule 1
IE OEL / OELV - 8 hrs (TWA) : Occupational exposure limit value (8-hour reference period)

Further information
SAFETY DATA SHEET
according to Regulation (EC) No. 1907/2006

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

Classification of the mixture:
- Repr. 2: H361d
- STOT RE 2: H373
- Aquatic Chronic 2: H411

Classification procedure:
- Calculation method

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.

IE / EN