

# SAFETY DATA SHEET

according to the OSHA Hazard Communication Standard



ORGANON

## Etoricoxib Formulation

Version 8.2      Revision Date: 04/06/2024      SDS Number: 26559-00025      Date of last issue: 09/29/2023  
Date of first issue: 10/29/2014

---

### SECTION 1. IDENTIFICATION

Product name : Etoricoxib Formulation

#### Manufacturer or supplier's details

Company name of supplier : Organon & Co.  
Address : 30 Hudson Street, 33nd floor  
Jersey City, New Jersey, U.S.A 07302  
Telephone : 1-551-430-6000  
Emergency telephone : 1-215-631-6999  
E-mail address : EHSSTEWARD@organon.com

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

Recommended use : Pharmaceutical  
Restrictions on use : Not applicable

---

### 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 : Category 2 (Kidney, Liver, Gastrointestinal tract)  
- repeated exposure (Oral)

#### 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.

---

# SAFETY DATA SHEET

according to the OSHA Hazard Communication Standard



## Etoricoxib Formulation

Version 8.2      Revision Date: 04/06/2024      SDS Number: 26559-00025      Date of last issue: 09/29/2023  
Date of first issue: 10/29/2014

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

Substance / Mixture : Mixture

**Components**

Chemical name	CAS-No.	Concentration (% w/w)
Cellulose	9004-34-6	>= 30 - < 50
Etoricoxib	202409-33-4	>= 20 - < 30
Titanium dioxide	13463-67-7	>= 1 - < 5

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.

# SAFETY DATA SHEET

according to the OSHA Hazard Communication Standard



## Etoricoxib Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 09/29/2023
8.2	04/06/2024	26559-00025	Date of first issue: 10/29/2014

Protection of first-aiders : Dust contact with the eyes can lead to mechanical irritation. 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 (CO<sub>2</sub>)  
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 (NO<sub>x</sub>)  
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

# SAFETY DATA SHEET

according to the OSHA Hazard Communication Standard



## Etoricoxib Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 09/29/2023
8.2	04/06/2024	26559-00025	Date of first issue: 10/29/2014

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.<br>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.<br>Do not swallow.<br>Avoid contact with eyes.<br>Avoid prolonged or repeated contact with skin.<br>Handle in accordance with good industrial hygiene and safety practice, based on the results of the workplace exposure assessment<br>Minimize dust generation and accumulation.<br>Keep container closed when not in use.<br>Keep away from heat and sources of ignition.<br>Take precautionary measures against static discharges.<br>Take care to prevent spills, waste and minimize release to the environment. |
| Conditions for safe storage | : | Keep in properly labeled containers.<br>Store locked up.<br>Store in accordance with the particular national regulations.  |
| Materials to avoid          | : | Do not store with the following product types:<br>Strong oxidizing agents  |

### SECTION 8. EXPOSURE CONTROLS/PERSONAL PROTECTION

#### Ingredients with workplace control parameters

- |                        |   |
|------------------------|---|
| inert or nuisance dust | 50 Million particles per cubic foot<br>Value type (Form of exposure): TWA (total dust)<br>Basis: OSHA Z-3 |
|                        | 15 mg/m <sup>3</sup><br>Value type (Form of exposure): TWA (total dust)<br>Basis: OSHA Z-3                |
|                        | 5 mg/m <sup>3</sup><br>Value type (Form of exposure): TWA (respirable fraction)<br>Basis: OSHA Z-3        |
|                        | 15 Million particles per cubic foot<br>Value type (Form of exposure): TWA (respirable fraction)           |

# SAFETY DATA SHEET

according to the OSHA Hazard Communication Standard



## Etoricoxib Formulation

Version 8.2      Revision Date: 04/06/2024      SDS Number: 26559-00025      Date of last issue: 09/29/2023  
Date of first issue: 10/29/2014

Basis: OSHA Z-3

Dust, nuisance dust and particulates

10 mg/m<sup>3</sup>  
Value type (Form of exposure): PEL (Total dust)  
Basis: CAL PEL

5 mg/m<sup>3</sup>  
Value type (Form of exposure): PEL (respirable dust fraction)  
Basis: CAL PEL

Components	CAS-No.	Value type (Form of exposure)	Control parameters / Permissible concentration	Basis
Cellulose	9004-34-6	TWA	10 mg/m <sup>3</sup>	ACGIH
		TWA (Respirable)	5 mg/m <sup>3</sup>	NIOSH REL
		TWA (total)	10 mg/m <sup>3</sup>	NIOSH REL
		TWA (total dust)	15 mg/m <sup>3</sup>	OSHA Z-1
		TWA (respirable fraction)	5 mg/m <sup>3</sup>	OSHA Z-1
Etoricoxib	202409-33-4	TWA	400 ug/m <sup>3</sup> (OEB 2)	Internal
Titanium dioxide	13463-67-7	TWA (total dust)	15 mg/m <sup>3</sup>	OSHA Z-1

**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** : 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

# SAFETY DATA SHEET

according to the OSHA Hazard Communication Standard



## Etoricoxib Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 09/29/2023
8.2	04/06/2024	26559-00025	Date of first issue: 10/29/2014

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

# SAFETY DATA SHEET

according to the OSHA Hazard Communication Standard



## Etoricoxib Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 09/29/2023
8.2	04/06/2024	26559-00025	Date of first issue: 10/29/2014

---

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 characteristics	:	
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
---------------------	---	--

---

# SAFETY DATA SHEET

according to the OSHA Hazard Communication Standard



## Etoricoxib Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 09/29/2023
8.2	04/06/2024	26559-00025	Date of first issue: 10/29/2014

---

### 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.



# SAFETY DATA SHEET

according to the OSHA Hazard Communication Standard



## Etoricoxib Formulation

Version 8.2      Revision Date: 04/06/2024      SDS Number: 26559-00025      Date of last issue: 09/29/2023  
Date of first issue: 10/29/2014

---

### 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.  
Result : negative

#### **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:**

# SAFETY DATA SHEET

according to the OSHA Hazard Communication Standard



## Etoricoxib Formulation

Version 8.2      Revision Date: 04/06/2024      SDS Number: 26559-00025      Date of last issue: 09/29/2023  
Date of first issue: 10/29/2014

---

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

#### **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)

# SAFETY DATA SHEET

according to the OSHA Hazard Communication Standard



## Etoricoxib Formulation

Version 8.2      Revision Date: 04/06/2024      SDS Number: 26559-00025      Date of last issue: 09/29/2023  
Date of first issue: 10/29/2014

---

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

# SAFETY DATA SHEET

according to the OSHA Hazard Communication Standard



## Etoricoxib Formulation

Version 8.2      Revision Date: 04/06/2024      SDS Number: 26559-00025      Date of last issue: 09/29/2023  
Date of first issue: 10/29/2014

---

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 :  $\geq 9,000$  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

# SAFETY DATA SHEET

according to the OSHA Hazard Communication Standard



## Etoricoxib Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 09/29/2023
8.2	04/06/2024	26559-00025	Date of first issue: 10/29/2014

---

Target Organs : Liver

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

Species : Rat

NOAEL : 10 mg/m<sup>3</sup>

Application Route : inhalation (dust/mist/fume)

Exposure time : 2 y

### Aspiration toxicity

Not classified based on available information.

### Experience with human exposure

#### Components:

#### **Etoricoxib:**

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

---

## 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

# SAFETY DATA SHEET

according to the OSHA Hazard Communication Standard



## Etoricoxib Formulation

Version 8.2      Revision Date: 04/06/2024      SDS Number: 26559-00025      Date of last issue: 09/29/2023  
Date of first issue: 10/29/2014

---

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

# SAFETY DATA SHEET

according to the OSHA Hazard Communication Standard



## Etoricoxib Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 09/29/2023
8.2	04/06/2024	26559-00025	Date of first issue: 10/29/2014

### 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.  
Do not dispose of waste into sewer.

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

Environmentally hazardous : yes

#### 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)

# SAFETY DATA SHEET

according to the OSHA Hazard Communication Standard



## Etoricoxib Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 09/29/2023
8.2	04/06/2024	26559-00025	Date of first issue: 10/29/2014

---

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.

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

<b>SARA 313</b>	:	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



# SAFETY DATA SHEET

according to the OSHA Hazard Communication Standard



## Etoricoxib Formulation

Version 8.2      Revision Date: 04/06/2024      SDS Number: 26559-00025      Date of last issue: 09/29/2023  
Date of first issue: 10/29/2014

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](http://www.P65Warnings.ca.gov).

### California Permissible Exposure Limits for Chemical Contaminants

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

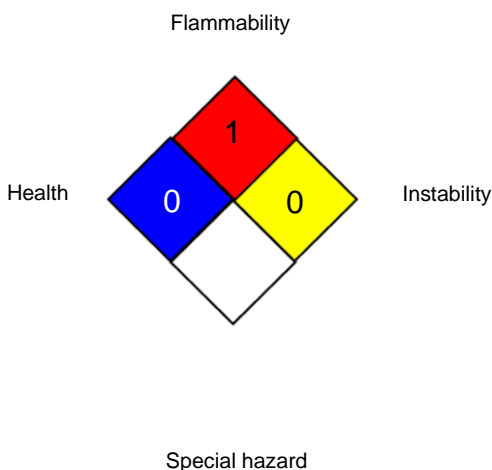
### The ingredients of this product are reported in the following inventories:

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

## SECTION 16. OTHER INFORMATION

### Further information

#### NFPA 704:



#### 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)  
CAL PEL : California permissible exposure limits for chemical contaminants (Title 8, Article 107)  
NIOSH REL : USA. NIOSH Recommended Exposure Limits  
OSHA Z-1 : USA. Occupational Exposure Limits (OSHA) - Table Z-1 Limits for Air Contaminants

# SAFETY DATA SHEET

according to the OSHA Hazard Communication Standard



ORGANON

## Etoricoxib Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 09/29/2023
8.2	04/06/2024	26559-00025	Date of first issue: 10/29/2014

OSHA Z-3 : USA. Occupational Exposure Limits (OSHA) - Table Z-3 Mineral Dusts  
ACGIH / TWA : 8-hour, time-weighted average  
CAL PEL / PEL : Permissible exposure limit  
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  
OSHA Z-3 / 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; KECI - 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; RCRA - Resource Conservation and Recovery Act; REACH - Regulation (EC) No 1907/2006 of the European Parliament and of the Council concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals; RQ - Reportable Quantity; SADT - Self-Accelerating Decomposition Temperature; SARA - Superfund Amendments and Reauthorization Act; SDS - Safety Data Sheet; TCSI - Taiwan Chemical Substance Inventory; TECL - Thailand Existing Chemicals Inventory; TSCA - Toxic Substances Control Act (United States); UN - United Nations; UNRTDG - United Nations Recommendations on the Transport of Dangerous Goods; vPvB - Very Persistent and Very Bioaccumulative

Sources of key data used to compile the Material Safety Data Sheet : Internal technical data, data from raw material SDSs, OECD eChem Portal search results and European Chemicals Agency, <http://echa.europa.eu/>

Revision Date : 04/06/2024

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

# SAFETY DATA SHEET

according to the OSHA Hazard Communication Standard



## Etoricoxib Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 09/29/2023
8.2	04/06/2024	26559-00025	Date of first issue: 10/29/2014

---

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.

US / Z8