

# SAFETY DATA SHEET



## Etoricoxib Formulation



Version 9.0      Revision Date: 2024/04/06      SDS Number: 26548-00025      Date of last issue: 2023/09/29  
Date of first issue: 2014/10/29

---

### 1. PRODUCT AND COMPANY IDENTIFICATION

Chemical product name : Etoricoxib Formulation

#### Supplier's company name, address and phone number

Company name of supplier : Organon & Co.

Address : 30 Hudson Street, 33rd floor  
Jersey City, New Jersey, U.S.A 07302

Telephone : +1-551-430-6000

E-mail address : EHSSTEWARD@organon.com

Emergency telephone number : +1-215-631-6999

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

Recommended use : Pharmaceutical

Restrictions on use : Not applicable

---

### 2. HAZARDS IDENTIFICATION

#### GHS classification of chemical product

Carcinogenicity (Inhalation) : Category 2

Reproductive toxicity : Category 2

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

Short-term (acute) aquatic hazard : Category 3

Long-term (chronic) aquatic hazard : Category 2

#### GHS label elements

Hazard pictograms :



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, Gastroin-

## Etoricoxib Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 2023/09/29
9.0	2024/04/06	26548-00025	Date of first issue: 2014/10/29

testinal tract) through prolonged or repeated exposure if swallowed.

H402 Harmful to aquatic life.

H411 Toxic to aquatic life with long lasting effects.

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.

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.

**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**

Important symptoms and outlines of the emergency assumed

: 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.

### 3. COMPOSITION/INFORMATION ON INGREDIENTS

Substance / Mixture : Mixture

**Components**

Chemical name	CAS-No.	Concentration (% w/w)	ENCS No.
Cellulose	9004-34-6	>= 30 - < 40	
Etoricoxib	202409-33-4	>= 25 - < 30	
Titanium dioxide	13463-67-7	> 0 - < 10	1-558, 5-5225

### 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.

## Etoricoxib Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 2023/09/29
9.0	2024/04/06	26548-00025	Date of first issue: 2014/10/29

---

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.

---

**5. FIREFIGHTING 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> ) 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.

## Etoricoxib Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 2023/09/29
9.0	2024/04/06	26548-00025	Date of first issue: 2014/10/29

---

## 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.

## 7. HANDLING AND STORAGE

### 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.
- Avoidance of contact : Oxidizing agents
- Hygiene measures : If exposure to chemical is likely during typical use, provide eye

# SAFETY DATA SHEET



## Etoricoxib Formulation



Version 9.0      Revision Date: 2024/04/06      SDS Number: 26548-00025      Date of last issue: 2023/09/29  
Date of first issue: 2014/10/29

flushing systems and safety showers close to the working place.  
When using do not eat, drink or smoke.  
Wash contaminated clothing before re-use.

### Storage

- 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
- Packaging material : Unsuitable material: None known.

## 8. EXPOSURE CONTROLS/PERSONAL PROTECTION

### Threshold limit value and permissible exposure limits for each component in the work environment

Components	CAS-No.	Value type (Form of exposure)	Control parameters / Reference concentration / Permissible concentration	Basis
Cellulose	9004-34-6	TWA	10 mg/m <sup>3</sup>	ACGIH
Etoricoxib	202409-33-4	TWA	400 ug/m <sup>3</sup> (OEB 2)	Internal
Titanium dioxide	13463-67-7	OEL-M (Respirable particulate matter)	1.5 mg/m <sup>3</sup> (Titanium)	JP OEL JSOH
	Further information: Group 2B: possibly carcinogenic to humans			
		OEL-M (Total particulate matter)	2 mg/m <sup>3</sup> (Titanium)	JP OEL JSOH
	Further information: Group 2B: possibly carcinogenic to humans			

- 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

# SAFETY DATA SHEET



## Etoricoxib Formulation



Version 9.0	Revision Date: 2024/04/06	SDS Number: 26548-00025	Date of last issue: 2023/09/29 Date of first issue: 2014/10/29
----------------	------------------------------	----------------------------	---

---

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! 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).

---

### 9. PHYSICAL AND CHEMICAL PROPERTIES

Physical state	:	powder
Colour	:	coloured
Odour	:	odourless
Odour Threshold	:	No data available
Melting point/freezing point	:	No data available
Boiling point, initial boiling point and boiling range	:	No data available
Flammability (solid, gas)	:	May form explosive dust-air mixture during processing, handling or other means.
Flammability (liquids)	:	No data available
Lower explosion limit and upper explosion limit / flammability limit	:	
Upper explosion limit / Upper flammability limit	:	No data available
Lower explosion limit / Lower flammability limit	:	No data available
Flash point	:	No data available
Decomposition temperature	:	No data available
pH	:	No data available
Evaporation rate	:	No data available

# SAFETY DATA SHEET



## Etoricoxib Formulation



Version	Revision Date:	SDS Number:	Date of last issue: 2023/09/29
9.0	2024/04/06	26548-00025	Date of first issue: 2014/10/29

---

Auto-ignition temperature : No data available

Viscosity  
Viscosity, kinematic : No data available

Solubility(ies)  
Water solubility : No data available

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

Vapour pressure : No data available

Density and / or relative density  
Relative density : No data available

Relative vapour density : 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

---

### 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.

---

### 11. TOXICOLOGICAL INFORMATION

Information on likely routes of exposure : Inhalation  
Skin contact  
Ingestion  
Eye contact

## Etoricoxib Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 2023/09/29
9.0	2024/04/06	26548-00025	Date of first issue: 2014/10/29

---

**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



## Etoricoxib Formulation

Version 9.0      Revision Date: 2024/04/06      SDS Number: 26548-00025      Date of last issue: 2023/09/29  
Date of first issue: 2014/10/29

---

|||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

**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

## Etoricoxib Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 2023/09/29
9.0	2024/04/06	26548-00025	Date of first issue: 2014/10/29

---

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

## Etoricoxib Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 2023/09/29
9.0	2024/04/06	26548-00025	Date of first issue: 2014/10/29

---

**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
--	---

## Etoricoxib Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 2023/09/29
9.0	2024/04/06	26548-00025	Date of first issue: 2014/10/29

---

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	:	>= 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
---------	---	-----

## Etoricoxib Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 2023/09/29
9.0	2024/04/06	26548-00025	Date of first issue: 2014/10/29

---

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

**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 yr

**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
-----------	---

**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
------------------	--

# SAFETY DATA SHEET



## Etoricoxib Formulation



Version 9.0      Revision Date: 2024/04/06      SDS Number: 26548-00025      Date of last issue: 2023/09/29  
Date of first issue: 2014/10/29

---

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:**

# SAFETY DATA SHEET



## Etoricoxib Formulation



Version 9.0      Revision Date: 2024/04/06      SDS Number: 26548-00025      Date of last issue: 2023/09/29  
Date of first issue: 2014/10/29

---

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

#### Hazardous to the ozone layer

Not applicable

#### Other adverse effects

No data available

---

## 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.

---

## 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) : 956

# SAFETY DATA SHEET



## Etoricoxib Formulation



Version	Revision Date:	SDS Number:	Date of last issue: 2023/09/29
9.0	2024/04/06	26548-00025	Date of first issue: 2014/10/29

---

aircraft)  
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

Refer to section 15 for specific national regulation.

### 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.

ERG Code : 171

---

## 15. REGULATORY INFORMATION

### Related Regulations

#### Fire Service Law

Not applicable to dangerous materials / designated flammables.

#### Chemical Substance Control Law

Not applicable for Specified Chemical Substance, Monitoring Chemical Substance and Priority Assessment Chemical Substance.

#### Industrial Safety and Health Law

#### Harmful Substances Prohibited from Manufacture

Not applicable

#### Harmful Substances Required Permission for Manufacture

Not applicable

#### Substances Prevented From Impairment of Health

Not applicable



## Etoricoxib Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 2023/09/29
9.0	2024/04/06	26548-00025	Date of first issue: 2014/10/29

---

**Circular concerning Information on Chemicals having Mutagenicity - Annex 2: Information on Existing Chemicals having Mutagenicity**

Not applicable

**Circular concerning Information on Chemicals having Mutagenicity - Annex 1: Information on Notified Substances having Mutagenicity**

Not applicable

**Substances Subject to be Notified Names**

Article 57-2 (Enforcement Order Table 9)

Chemical name	Concentration (%)	Remarks
Titanium(IV) oxide	>0 - <10	-

**Substances Subject to be Indicated Names**

Article 57 (Enforcement Order Article 18)

Chemical name	Remarks
Titanium(IV) oxide	-

**Carcinogenic Substances (Article 577-2 of the Occupational Health and Safety Regulations)**

Not applicable

**Ordinance on Prevention of Hazards Due to Specified Chemical Substances**

Not applicable

**Ordinance on Prevention of Lead Poisoning**

Not applicable

**Ordinance on Prevention of Tetraalkyl Lead Poisoning**

Not applicable

**Ordinance on Prevention of Organic Solvent Poisoning**

Not applicable

**Enforcement Order of the Industrial Safety and Health Law - Attached table 1 (Dangerous Substances)**

Not applicable

**Poisonous and Deleterious Substances Control Law**

Not applicable

**Act on Confirmation, etc. of Release Amounts of Specific Chemical Substances in the Environment and Promotion of Improvements to the Management Thereof**

Not applicable

**High Pressure Gas Safety Act**

Not applicable

**Explosive Control Law**

Not applicable

**Vessel Safety Law**

Miscellaneous dangerous substances and articles (Article 2 and 3 of rules on shipping and storage of dangerous goods and its Attached Table 1)

## Etoricoxib Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 2023/09/29
9.0	2024/04/06	26548-00025	Date of first issue: 2014/10/29

---

**Aviation Law**

Miscellaneous dangerous substances and articles (Article 194 of The Enforcement Rules of Aviation Law and its Attached Table 1)

**Marine Pollution and Sea Disaster Prevention etc Law**

Bulk transportation : Not classified as noxious liquid substance

Pack transportation : Classified as marine pollutant

**Narcotics and Psychotropics Control Act**

Narcotic or Psychotropic Raw Material (Export / Import Permission)

Not applicable

Specific Narcotic or Psychotropic Raw Material (Export / Import permission)

Not applicable

**Waste Disposal and Public Cleansing Law**

Industrial waste

**The components of this product are reported in the following inventories:**

AICS : not determined

DSL : not determined

IECSC : not determined

**16. OTHER INFORMATION**

In this SDS, if the concentration of substances subject to notification under the Industrial Safety and Health Law is indicated as a range, it includes cases where it is a trade secret.

**Further information**

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

Items where changes have been made to the previous version are highlighted in the body of this document by two vertical lines.

Date format : yyyy/mm/dd

**Full text of other abbreviations**

ACGIH : USA. ACGIH Threshold Limit Values (TLV)

JP OEL JSOH : Japan. The Japan Society for Occupational Health. Recommendation of Occupational Exposure Limits

ACGIH / TWA : 8-hour, time-weighted average

JP OEL JSOH / OEL-M : Occupational Exposure Limit-Mean

AIIC - Australian Inventory of Industrial Chemicals; ANTT - National Agency for Transport by Land of Brazil; ASTM - American Society for the Testing of Materials; bw - Body weight; CMR - Carcinogen, Mutagen or Reproductive Toxicant; DIN - Standard of the German Institute for Standardisation; DSL - Domestic Substances List (Canada); ECx - Concentration associated with

# SAFETY DATA SHEET



## Etoricoxib Formulation



Version	Revision Date:	SDS Number:	Date of last issue: 2023/09/29
9.0	2024/04/06	26548-00025	Date of first issue: 2014/10/29

---

x% response; 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; 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; n.o.s. - Not Otherwise Specified; Nch - Chilean Norm; NO(A)EC - No Observed (Adverse) Effect Concentration; NO(A)EL - No Observed (Adverse) Effect Level; NOELR - No Observable Effect Loading Rate; NOM - Official Mexican Norm; 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; REACH - Regulation (EC) No 1907/2006 of the European Parliament and of the Council concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals; SADT - Self-Accelerating Decomposition Temperature; SDS - Safety Data Sheet; TCSI - Taiwan Chemical Substance Inventory; TDG - Transportation of Dangerous Goods; 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; WHMIS - Workplace Hazardous Materials Information System

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.

JP / EN