according to Regulation (EC) No. 1907/2006



## **Etoricoxib Formulation**

 Version
 Revision Date:
 SDS Number:
 Date of last issue: 02.10.2020

 4.0
 09.04.2021
 26544-00020
 Date of first issue: 29.10.2014

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

1.1 Product identifier

Trade name : Etoricoxib Formulation

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

Use of the Sub- : Pharmaceutical

stance/Mixture

1.3 Details of the supplier of the safety data sheet

Company : Organon & Co.

30 Hudson Street, 33nd floor

07302 Jersey City, New Jersey, U.S.A

Telephone : 551-430-6000

E-mail address of person responsible for the SDS

EHSSTEWARD@organon.com

1.4 Emergency telephone number

215-631-6999

## **SECTION 2: Hazards identification**

## 2.1 Classification of the substance or mixture

Classification (REGULATION (EC) No 1272/2008)

Reproductive toxicity, Category 2

H361d: Suspected of damaging the unborn child.

Specific target organ toxicity - repeated

H373: May cause damage to organs through pro-

exposure, Category 2 longed or repeated exposure.

Long-term (chronic) aquatic hazard, Cat-H411: Toxic to aquatic life with long lasting effects.

egory 2

#### 2.2 Label elements

#### Labelling (REGULATION (EC) No 1272/2008)

Hazard pictograms :



Signal word : Warning

Hazard statements : H361d Suspected of damaging the unborn child.

H373 May cause damage to organs through prolonged or

repeated exposure.

H411 Toxic to aquatic life with long lasting effects.

Precautionary statements : Prevention:

according to Regulation (EC) No. 1907/2006



## **Etoricoxib Formulation**

 Version
 Revision Date:
 SDS Number:
 Date of last issue: 02.10.2020

 4.0
 09.04.2021
 26544-00020
 Date of first issue: 29.10.2014

P201 Obtain special instructions before use.

P260 Do not breathe dust.

P273 Avoid release to the environment.

P280 Wear protective gloves/ protective clothing/ eye protec-

tion/ 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

#### **Additional Labelling**

EUH212 Warning! Hazardous respirable dust may be formed when used. Do not breathe

dust.

#### 2.3 Other hazards

This substance/mixture contains no components considered to be either persistent, bioaccumulative and toxic (PBT), or very persistent and very bioaccumulative (vPvB) at levels of 0.1% or higher.

Ecological information: The substance/mixture does not contain components considered to have endocrine disrupting properties according to REACH Article 57(f) or Commission Delegated regulation (EU) 2017/2100 or Commission Regulation (EU) 2018/605 at levels of 0.1% or higher.

Toxicological information: The substance/mixture does not contain components considered to have endocrine disrupting properties according to REACH Article 57(f) or Commission Delegated regulation (EU) 2017/2100 or Commission Regulation (EU) 2018/605 at levels of 0.1% or higher.

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

#### Components

Chemical name	CAS-No. EC-No. Index-No. Registration number	Classification	Concentration (% w/w)
Etoricoxib	202409-33-4	Acute Tox. 4; H302 Repr. 2; H361d STOT RE 2; H373 (Kidney, Liver, Gastrointestinal tract) Aquatic Chronic 2; H411	>= 25 - < 30

For explanation of abbreviations see section 16.

according to Regulation (EC) No. 1907/2006

## Public → ORGANON

## **Etoricoxib Formulation**

 Version
 Revision Date:
 SDS Number:
 Date of last issue: 02.10.2020

 4.0
 09.04.2021
 26544-00020
 Date of first issue: 29.10.2014

## **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 ad-

vice 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, 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 : None known.

according to Regulation (EC) No. 1907/2006



## **Etoricoxib Formulation**

 Version
 Revision Date:
 SDS Number:
 Date of last issue: 02.10.2020

 4.0
 09.04.2021
 26544-00020
 Date of first issue: 29.10.2014

media

## 5.2 Special hazards arising from the substance or mixture

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 prod: :

ucts

Carbon oxides

Nitrogen oxides (NOx) Sulphur oxides

Chlorine compounds

Metal oxides

Oxides of phosphorus

#### 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 meth-

ods

Use extinguishing measures that are appropriate to local cir-

cumstances 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 (see section 7) and personal pro-

tective equipment recommendations (see section 8).

## 6.2 Environmental precautions

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.

#### 6.3 Methods and material for containment and cleaning up

Methods for cleaning up : Sweep up or vacuum up spillage and collect in suitable con-

tainer 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

according to Regulation (EC) No. 1907/2006

## Public → ORGANON

## **Etoricoxib Formulation**

 Version
 Revision Date:
 SDS Number:
 Date of last issue: 02.10.2020

 4.0
 09.04.2021
 26544-00020
 Date of first issue: 29.10.2014

employed in the cleanup of releases. You will need to deter-

mine 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. Use only with adequate ventilation.

Local/Total 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 as-

sessment

Minimize dust generation and accumulation. Keep container closed when not in use. Keep away from heat and sources of ignition.

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 contami-

nated 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

## **SECTION 8: Exposure controls/personal protection**

## 8.1 Control parameters

#### **Occupational Exposure Limits**

Components	CAS-No.	Value type (Form	Control parameters	Basis	

according to Regulation (EC) No. 1907/2006



## **Etoricoxib Formulation**

 Version
 Revision Date:
 SDS Number:
 Date of last issue: 02.10.2020

 4.0
 09.04.2021
 26544-00020
 Date of first issue: 29.10.2014

		of exposure)					
Cellulose	9004-34-6	OELV - 8 hrs (TWA)	10 mg/m3	IE OEL			
	Further inform	Further information: Where no specific short-term exposure limit is listed, a					
	figure three til	figure three times the long-term exposure limit value should be used					
Etoricoxib	202409-33- 4	TWA	400 ug/m3 (OEB 2)	Internal			
Titanium dioxide	13463-67-7	OELV - 8 hrs (TWA) (Respira- ble dust)	4 mg/m3	IE OEL			
	Further inform	Further information: Where no specific short-term exposure limit is listed, a					
	figure three til	figure three times the long-term exposure limit value should be used					
		OELV - 8 hrs (TWA) (inhalable dust)	10 mg/m3	IE OEL			
	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! 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.

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 expo-

sure assessment demonstrates exposures outside the rec-

ommended guidelines, use respiratory protection.

Equipment should conform to I.S. EN 143

according to Regulation (EC) No. 1907/2006



## **Etoricoxib Formulation**

SDS Number: Date of last issue: 02.10.2020 Version **Revision Date:** 4.0 09.04.2021 26544-00020 Date of first issue: 29.10.2014

Particulates type (P) Filter type

## **SECTION 9: Physical and chemical properties**

## 9.1 Information on basic physical and chemical properties

Physical state powder Colour coloured Odour odourless

Odour Threshold No data available

Melting point/freezing point No data available

Initial boiling point and boiling

range

No data available

Flammability (solid, gas) May form explosive dust-air mixture during processing, han-

dling or other means.

No data available Flammability (liquids)

Upper explosion limit / Upper

flammability limit

No data available

Lower explosion limit / Lower

flammability limit

No data available

Flash point No data available

No data available Auto-ignition temperature

Decomposition temperature

Decomposition tempera-

ture

No data available

pΗ 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

Relative density No data available

Relative vapour density No data available

Particle characteristics

No data available Particle size

9.2 Other information

**Explosives** Not explosive

according to Regulation (EC) No. 1907/2006

## ♣ ORGANON

## **Etoricoxib Formulation**

 Version
 Revision Date:
 SDS Number:
 Date of last issue: 02.10.2020

 4.0
 09.04.2021
 26544-00020
 Date of first issue: 29.10.2014

Oxidizing properties : The substance or mixture is not classified as oxidizing.

Evaporation rate : No data available

Molecular weight : No data available

## **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, han-

dling 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 hazard classes as defined in Regulation (EC) No 1272/2008

Information on likely routes of : Inhalation

exposure 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

according to Regulation (EC) No. 1907/2006

# ORGANON

## **Etoricoxib Formulation**

Version SDS Number: Date of last issue: 02.10.2020 Revision Date: 4.0 09.04.2021 26544-00020 Date of first issue: 29.10.2014

Acute toxicity (other routes of : LD50 (Rat): 238 mg/kg

administration) 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:**

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)

: Skin contact Exposure routes

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

according to Regulation (EC) No. 1907/2006



## **Etoricoxib Formulation**

 Version
 Revision Date:
 SDS Number:
 Date of last issue: 02.10.2020

 4.0
 09.04.2021
 26544-00020
 Date of first issue: 29.10.2014

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

according to Regulation (EC) No. 1907/2006



## **Etoricoxib Formulation**

Version Revision Date: SDS Number: Date of last issue: 02.10.2020 4.0 09.04.2021 26544-00020 Date of first issue: 29.10.2014

Effects on foetal develop-

ment

Species: Rat

**Application Route: Oral** 

Result: positive

Species: Rabbit Application Route: Oral

Result: positive

Reproductive toxicity - As-

sessment

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

according to Regulation (EC) No. 1907/2006

## ♣ ORGANON

## **Etoricoxib Formulation**

 Version
 Revision Date:
 SDS Number:
 Date of last issue: 02.10.2020

 4.0
 09.04.2021
 26544-00020
 Date of first issue: 29.10.2014

#### **Aspiration toxicity**

Not classified based on available information.

#### 11.2 Information on other hazards

#### **Endocrine disrupting properties**

### **Product:**

Assessment : The substance/mixture does not contain components consid-

ered to have endocrine disrupting properties according to REACH Article 57(f) or Commission Delegated regulation (EU) 2017/2100 or Commission Regulation (EU) 2018/605 at

levels of 0.1% or higher.

## **Experience with human exposure**

#### **Components:**

#### **Etoricoxib:**

Ingestion : Symptoms: upper respiratory tract infection, Headache, hyper-

tension, 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

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/

Exposure time: 72 h

Method: OECD Test Guideline 201

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

according to Regulation (EC) No. 1907/2006

## ♣ Public ORGANON

## **Etoricoxib Formulation**

Version Revision Date: SDS Number: Date of last issue: 02.10.2020 4.0 09.04.2021 26544-00020 Date of first issue: 29.10.2014

Toxicity to fish (Chronic tox-

city)

NOEC: 7.93 mg/l

Exposure time: 32 d

Species: Pimephales promelas (fathead minnow)

Method: OECD Test Guideline 210

Toxicity to daphnia and other : aquatic invertebrates (Chron-

ic toxicity)

NOEC: 0.75 mg/l Exposure time: 21 d

Species: Daphnia magna (Water flea) Method: OECD Test Guideline 211

## 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

#### **Product:**

Assessment

: This substance/mixture contains no components considered to be either persistent, bioaccumulative and toxic (PBT), or very persistent and very bioaccumulative (vPvB) at levels of

0.1% or higher.

#### 12.6 Endocrine disrupting properties

## **Product:**

Assessment

: The substance/mixture does not contain components considered to have endocrine disrupting properties according to REACH Article 57(f) or Commission Delegated regulation (EU) 2017/2100 or Commission Regulation (EU) 2018/605 at

levels of 0.1% or higher.

## 12.7 Other adverse effects

No data available

according to Regulation (EC) No. 1907/2006



## **Etoricoxib Formulation**

 Version
 Revision Date:
 SDS Number:
 Date of last issue: 02.10.2020

 4.0
 09.04.2021
 26544-00020
 Date of first issue: 29.10.2014

## **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 han-

dling site for recycling or disposal.

If not otherwise specified: Dispose of as unused product.

#### **SECTION 14: Transport information**

## 14.1 UN number or ID 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

 IATA
 : 9

## 14.4 Packing group

according to Regulation (EC) No. 1907/2006



## **Etoricoxib Formulation**

 Version
 Revision Date:
 SDS Number:
 Date of last issue: 02.10.2020

 4.0
 09.04.2021
 26544-00020
 Date of first issue: 29.10.2014

**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 : 956

aircraft)

Packing instruction (LQ) : Y956
Packing group : III

Labels : Miscellaneous

IATA (Passenger)

Packing instruction (passen- : 956

ger aircraft)

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

according to Regulation (EC) No. 1907/2006

## ♣ ORGANON

## **Etoricoxib Formulation**

Version Revision Date: SDS Number: Date of last issue: 02.10.2020 4.0 09.04.2021 26544-00020 Date of first issue: 29.10.2014

#### 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 Maritime transport in bulk according to IMO instruments

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

Not applicable

Not applicable

Not applicable

Not applicable

Not applicable

Not applicable

REACH - Restrictions on the manufacture, placing on

the market and use of certain dangerous substances,

preparations and articles (Annex XVII)

REACH - Candidate List of Substances of Very High

Concern for Authorisation (Article 59).

REACH - List of substances subject to authorisation :

(Annex XIV)

Regulation (EC) No 1005/2009 on substances that de-

plete the ozone layer

Regulation (EU) 2019/1021 on persistent organic pollu-

tants (recast)

Regulation (EC) No 649/2012 of the European Parlia-

ment and the Council concerning the export and import

of dangerous chemicals

Seveso III: Directive 2012/18/EU of the European Parliament and of the Council on the control of

major-accident hazards involving dangerous substances.

Quantity 1 Quantity 2

E2 ENVIRONMENTAL 200 t 500 t

**HAZARDS** 

## 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

are highlighted in the body of this document by two vertical

according to Regulation (EC) No. 1907/2006



## **Etoricoxib Formulation**

 Version
 Revision Date:
 SDS Number:
 Date of last issue: 02.10.2020

 4.0
 09.04.2021
 26544-00020
 Date of first issue: 29.10.2014

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)

ADN - European Agreement concerning the International Carriage of Dangerous Goods by Inland Waterways; ADR - European Agreement concerning the International Carriage of Dangerous Goods by Road; AIIC - Australian Inventory of Industrial Chemicals; ASTM - American Society for the Testing of Materials; bw - Body weight; CLP - Classification Labelling Packaging Regulation; Regulation (EC) No 1272/2008; CMR - Carcinogen, Mutagen or Reproductive Toxicant; DIN -Standard of the German Institute for Standardisation; DSL - Domestic Substances List (Canada); ECHA - European Chemicals Agency; EC-Number - European Community number; ECx - Concentration associated with 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; 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; NO(A)EC - No Observed (Adverse) Effect Concentration; NO(A)EL - No Observed (Adverse) Effect Level; NOELR - No Observable Effect Loading Rate; 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; RID - Regulations concerning the International Carriage of Dangerous Goods by Rail; SADT - Self-Accelerating Decomposition Temperature; SDS - Safety Data Sheet; SVHC - Substance of Very High Concern; TCSI - Taiwan Chemical Substance Inventory; TRGS -Technical Rule for Hazardous Substances; TSCA - Toxic Substances Control Act (United States); UN - United Nations; vPvB - Very Persistent and Very Bioaccumulative

#### **Further information**

Sources of key data used to : compile the Safety Data

Internal technical data, data from raw material SDSs, OECD eChem Portal search results and European Chemicals Agen-

according to Regulation (EC) No. 1907/2006



## **Etoricoxib Formulation**

 Version
 Revision Date:
 SDS Number:
 Date of last issue: 02.10.2020

 4.0
 09.04.2021
 26544-00020
 Date of first issue: 29.10.2014

Sheet cy, http://echa.europa.eu/

Classification of the mixture: Classification procedure:

Repr. 2 H361d Calculation method STOT RE 2 H373 Calculation method Aquatic Chronic 2 H411 Calculation method

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

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