according to Regulation (EC) No. 1907/2006



## **Etoricoxib Granulation Formulation**

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

1.1 Product identifier

Trade name : Etoricoxib Granulation Formulation

Product code : ETORICOXIB GRANULATION

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) aguatic hazard, Cat-H411: Toxic to aguatic 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.

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Precautionary statements : Prevention:

P201 Obtain special instructions before use.

P260 Do not breathe dust.

P273 Avoid release to the environment.

P280 Wear protective gloves/ protective clothing/ eye 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

### 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.

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#### **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.

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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 Metal oxides

Oxides of phosphorus Nitrogen oxides (NOx) Sulphur oxides

Chlorine compounds

#### 5.3 Advice for firefighters

Special protective equipment :

for firefighters

In the event of fire, wear self-contained breathing apparatus.

Use personal protective equipment.

Specific extinguishing 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



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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

No data available

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

### 8.1 Control parameters

**Occupational Exposure Limits** 

according to Regulation (EC) No. 1907/2006



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Components	CAS-No.	Value type (Form of exposure)	Control parameters	Basis	
Cellulose	9004-34-6	OELV - 8 hrs (TWA)	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				
Etoricoxib	202409-33- 4	TWA	400 ug/m3 (OEB 2)	Internal	

### 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

Filter type : Particulates type (P)

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

### 9.1 Information on basic physical and chemical properties

Physical state : powder

Colour : No data available
Odour : No data available
Odour Threshold : No data available

according to Regulation (EC) No. 1907/2006



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Melting point/freezing point No data available

Initial boiling point and boiling

range

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

dling or other means.

No data available

Flammability (liquids) No data available

Upper explosion limit / Upper

flammability limit

No data available

Lower explosion limit / Lower

flammability limit

No data available

Flash point No data available

Auto-ignition temperature No data available

Decomposition temperature

Decomposition tempera-

No data available

ture

pΗ No data available

Viscosity

No data available Viscosity, dynamic

No data available Viscosity, kinematic

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

Density 1 g/cm<sup>3</sup>

Relative vapour density No data available

Particle characteristics

Particle size No data available

9.2 Other information

**Explosives** Not explosive

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

Evaporation rate No data available

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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

Acute toxicity (other routes of :

administration)

LD50 (Rat): 238 mg/kg

Application Route: Intraperitoneal

LD50 (Mouse): 599 mg/kg

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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)

Exposure routes : Skin contact Species : Mouse

Assessment : Did not cause sensitisation on laboratory animals.

Result : negative

## Germ cell mutagenicity

Not classified based on available information.

## **Components:**

### **Etoricoxib:**

Genotoxicity in vitro : Test Type: reverse mutation assay

Result: negative

Test Type: In vitro mammalian cell gene mutation test

Test system: human lymphoblastoid cells

Result: negative

Test Type: Chromosomal aberration
Test system: Chinese hamster ovary cells

Result: negative

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Test Type: Alkaline elution assay

Result: negative

Genotoxicity in vivo : Test Type: Chromosomal aberration

Species: Rat

Cell type: Bone marrow Application Route: Oral Result: negative

Test Type: Alkaline elution assay

Species: Rat

Application Route: Oral Result: negative

## Carcinogenicity

Not classified based on available information.

#### Components:

#### **Etoricoxib:**

Species : Rat, male and female

Application Route : oral (gavage)
Exposure time : 2 Years
Result : positive

Species : Mouse, male and female

Application Route : oral (gavage)
Exposure time : 2 Years
Result : negative

### Reproductive toxicity

Suspected of damaging the unborn child.

### **Components:**

### **Etoricoxib:**

Effects on fertility : Test Type: Fertility/early embryonic development

Species: Rat, female Application Route: Oral

General Toxicity - Parent: NOAEL: 10 mg/kg body weight

Result: positive

Test Type: Fertility/early embryonic development

Species: Rat, male Application Route: Oral Result: negative

Effects on foetal develop-

ment

Species: Rat

Application Route: Oral

Result: positive

Species: Rabbit

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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

### **Aspiration toxicity**

Not classified based on available information.

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#### 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/l

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

Toxicity to fish (Chronic tox-

icity)

NOEC: 7.93 mg/l

Exposure time: 32 d

Species: Pimephales promelas (fathead minnow)

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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 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.

#### 12.7 Other adverse effects

No data available

### **SECTION 13: Disposal considerations**

#### 13.1 Waste treatment methods

Product Dispose of in accordance with local regulations.

According to the European Waste Catalogue, Waste Codes

according to Regulation (EC) No. 1907/2006



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are not product specific, but application specific.

Waste codes should be assigned by the user, preferably in

discussion with the waste disposal authorities.

Empty containers should be taken to an approved waste han-Contaminated packaging

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)

ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID, **ADR** 

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

ADN

Packing group Ш Classification Code M7 Hazard Identification Number 90 Labels 9

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**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

ΔDR

Environmentally hazardous : yes

RID

Environmentally hazardous : yes

**IMDG** 

Marine pollutant : yes

IATA (Passenger)

Environmentally hazardous : yes

IATA (Cargo)

Environmentally hazardous : yes

14.6 Special precautions for user

The transport classification(s) provided herein are for informational purposes only, and solely based upon the properties of the unpackaged material as it is described within this Safety Data Sheet. Transportation classifications may vary by mode of transportation, package sizes, and variations in regional or country regulations.

14.7 Maritime transport in bulk according to IMO instruments

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Not applicable for product as supplied. Remarks

## **SECTION 15: Regulatory information**

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

REACH - Restrictions on the manufacture, placing on : Not applicable

the market and use of certain dangerous substances,

preparations and articles (Annex XVII)

REACH - Candidate List of Substances of Very High Not applicable

Concern for Authorisation (Article 59).

REACH - List of substances subject to authorisation Not applicable

(Annex XIV)

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

plete the ozone layer Not applicable

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

tants (recast) Regulation (EC) No 649/2012 of the European Parlia-Not applicable

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

Not applicable

lines.

**Full text of H-Statements** 

H302 Harmful if swallowed.

H361d Suspected of damaging the unborn child.

May cause damage to organs through prolonged or repeated H373

according to Regulation (EC) No. 1907/2006



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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**

compile the Safety Data Sheet

Sources of key data used to : Internal technical data, data from raw material SDSs, OECD eChem Portal search results and European Chemicals Agen-

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

### Classification of the mixture:

#### Classification procedure:

Repr. 2 H361d Calculation method STOT RE 2 H373 Calculation method

according to Regulation (EC) No. 1907/2006



## **Etoricoxib Granulation Formulation**

 Version
 Revision Date:
 SDS Number:
 Date of last issue: 16.10.2020

 3.6
 09.04.2021
 16706-00019
 Date of first issue: 29.09.2014

Aquatic Chronic 2 H411 Calculation method

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IE / EN