according to Regulation (EC) No. 1907/2006, as amended by Commission Regulation (EU) 2020/878



# **Etoricoxib Formulation**

1.1 **Droduct identifier** 

Version	Revision Date:	SDS Number:	Date of last issue: 29.09.2023
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## 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 th	ne s	ubstance or mixture and uses advised against
	Use of the Sub- stance/Mixture	:	Pharmaceutical
	Recommended restrictions on use	:	Not applicable
1.3	Details of the supplier of the	safe	ety data sheet
	Company	:	Organon & Co. 30 Hudson Street, 33nd floor 07302 Jersey City, New Jersey, U.S.A
	Telephone	:	+1-551-430-6000
	E-mail address of person	:	EHSSTEWARD@organon.com

### **1.4 Emergency telephone number**

responsible for the SDS

+1-215-631-6999

## **SECTION 2: Hazards identification**

#### 2.1 Classification of the substance or mixture

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

Reproductive toxicity, Category 2 Specific target organ toxicity - repeated exposure, Category 2 Long-term (chronic) aquatic hazard, Category 2 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.

#### 2.2 Label elements

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

1

Hazard pictograms



Signal word

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Hazar	rd statements	: H361d H373 H411	Suspected of damaging the unborn child. May cause damage to organs through prolonged or repeated exposure. Toxic to aquatic life with long lasting effects.
Preca	utionary statements	: <b>Preventio</b> P201 P260 P273 P280	n: Obtain special instructions before use. Do not breathe dust. Avoid release to the environment. Wear protective gloves/ protective clothing/ eye protection/ face protection.
		<b>Respons</b> P308 + P3 P391	

### 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

CAS-No.	Classification	Concentration
EC-No.		(% w/w)
Index-No.		· · · ·
Registration number		
202409-33-4	Acute Tox. 4; H302	>= 25 - < 30
	EC-No. Index-No. Registration number	EC-No. Index-No. Registration number

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			Repr. 2; H361d STOT RE 2; H373 (Kidney, Liver, Gas- trointestinal tract) Aquatic Chronic 2; H411 Acute toxicity esti- mate
			Acute oral toxicity: 1,499 mg/kg

For explanation of abbreviations see section 16.

### **SECTION 4: First aid measures**

### 4.1 Description of first aid measures

General advice	<ul> <li>In the case of accident or if you feel unwell, seek medical advice immediately.</li> <li>When symptoms persist or in all cases of doubt seek medical advice.</li> </ul>
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	<ul> <li>In case of contact, immediately flush skin with soap and plenty of water.</li> <li>Remove contaminated clothing and shoes.</li> <li>Get medical attention.</li> <li>Wash clothing before reuse.</li> <li>Thoroughly clean shoes before reuse.</li> </ul>
In case of eye contact	: If in eyes, rinse well with water. Get medical attention if irritation develops and persists.
If swallowed	: If swallowed, DO NOT induce vomiting. Get medical attention. Rinse mouth thoroughly with water.
4.2 Most important symptoms	s 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.
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### 4.3 Indication of any immediate medical attention and special treatment needed

Treatment	: Treat symptomatically and supportively.

## **SECTION 5: Firefighting measures**

5.1 Extinguishing media		
Suitable extinguishing media	:	Water spray Alcohol-resistant foam Carbon dioxide (CO2) Dry chemical
Unsuitable extinguishing media	:	None known.
5.2 Special hazards arising from	the	e 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.

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		Retain and disp	leakage or spillage if safe to do so. bose of contaminated wash water. s should be advised if significant spillages ained.				
6.3 Methods and material for containment and cleaning up							
Methods for cleaning up :		tainer for dispos Avoid dispersal with compresse Dust deposits s es, as these ma leased into the Local or nationa posal of this ma employed in the mine which reg Sections 13 and	of dust in the air (i.e., clearing dust surfaces				

## 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

<ul> <li>Technical measures</li> <li>Static electricity may accumulate and ignite suspended dust causing an explosion. Provide adequate precautions, such as electrical grounding and bonding, or inert atmospheres.</li> <li>Local/Total ventilation</li> <li>Use only with adequate ventilation.</li> <li>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.</li> <li>Hygiene measures</li> <li>If exposure to chemical is likely during typical use, provide eye flushing systems and safety showers close to the working place. When using do not eat, drink or smoke. Wash contaminated clothing before re-use.</li> </ul>		0	
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 as- sessment Minimize dust generation and accumulation. Keep container closed when not in use. Keep away from heat and sources of ignition. Take precautionary measures against static discharges. Take care to prevent spills, waste and minimize release to the environment.Hygiene measures:If exposure to chemical is likely during typical use, provide eye flushing systems and safety showers close to the working place. When using do not eat, drink or smoke. Wash contami-	Technical measures	:	causing an explosion. Provide adequate precautions, such as electrical grounding
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-		:	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. Take precautionary measures against static discharges. Take care to prevent spills, waste and minimize release to the
	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-

### 7.2 Conditions for safe storage, including any incompatibilities

Requirements for storage	:	Keep in properly labelled containers. Store locked up. Store in
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according to Regulation (EC) No. 1907/2006, as amended by Commission Regulation (EU) 2020/878



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areas	and containers	aco	cordance with	the particular national regulations.
Advic	e on common storage		not store with ong oxidizing	the following product types: agents
-	fic end use(s) fic use(s)	: No	data available	9

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

### 8.1 Control parameters

### Occupational Exposure Limits

dusts non-specific

4 mg/m3 Value type (Form of exposure): OELV - 8 hrs (TWA) (Respirable dust) Basis: IE OEL

10 mg/m3 Value type (Form of exposure): OELV - 8 hrs (TWA) (inhalable dust) Basis: IE OEL

Components	CAS-No.	Value type (Form of exposure)	Control parameters	Basis
Cellulose	9004-34-6	OELV - 8 hrs (TWA)	10 mg/m3	IE OEL
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
		OELV - 8 hrs (TWA) (inhalable dust)	10 mg/m3	IE OEL

### 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/face protection

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

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Hand	protection		
Ma	aterial	: Chemical-res	stant gloves
Re	emarks	on the concer stance and sp determined for applications, chemicals of t	is to protect hands against chemicals depending intration and quantity of the hazardous sub- becific to place of work. Breakthrough time is not in the product. Change gloves often! For special we recommend clarifying the resistance to the aforementioned protective gloves with the cturer. Wash hands before breaks and at the av
Skin a	and body protection	: Select appropresistance da potential. Skin contact r	riate protective clothing based on chemical ta and an assessment of the local exposure nust be avoided by using impervious protective es, aprons, boots, etc).
Respi	iratory protection	: If adequate lo sure assessm ommended g	cal exhaust ventilation is not available or expo- lent demonstrates exposures outside the rec- uidelines, use respiratory protection. ould conform to I.S. EN 143
Fil	ter type	: Particulates ty	

## **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.
Flammability (solid, gas) Flammability (liquids)	:	dling or other means.
	-	dling or other means. No data available

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	Flash p	point	:	No data available	9
	Auto-ig	nition temperature	:	No data available	e
	Decom	position temperature	:	No data available	9
	pН		:	No data available	9
	Viscos Visc	ity cosity, kinematic	:	No data available	e
	Solubil Wat	ity(ies) ter solubility	:	No data available	e
	Partitio octano	n coefficient: n- I/water	:	No data available	9
	Vapou	r pressure	:	No data available	e
	Relativ	e density	:	No data available	e
	Relativ	e vapour density	:	No data available	e
		e characteristics ticle size	:	No data available	e
		nformation			
	Explos	ives	:	Not explosive	
	Oxidizi	ng properties		The substance o	r mixture is not classified as oxidizing.
	Evapoi	ration rate	:	No data available	e
	Molecu	ılar weight	:	No data available	e

## **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	<ul> <li>May form explosive dust-air mixture during processing, han- dling or other means.</li> <li>Can react with strong oxidizing agents.</li> </ul>
10.4 Conditions to avoid	

Conditions to avoid : Heat, flames and sparks.

according to Regulation (EC) No. 1907/2006, as amended by Commission Regulation (EU) 2020/878



# **Etoricoxib Formulation**

ersion 2	Revision Date: 06.04.2024	SDS Number: 26544-00027	Date of last issue: 29.09.2023 Date of first issue: 29.10.2014
		Avoid dust fo	rmation.
.5 Incom	npatible materials		
Materi	als to avoid	: Oxidizing age	ents
.6 Hazar	dous decomposition	products	
No ha	zardous decomposition	products are know	n.
ECTION	11: Toxicological in	formation	
.1 Inform	nation on hazard class	ses as defined in I	Regulation (EC) No 1272/2008
Inform expos	ation on likely routes of ure	: Inhalation Skin contact Ingestion Eye contact	
	toxicity assified based on availa	ble information.	
<u>Produ</u>	<u>ict:</u>		
Acute	oral toxicity		estimate: > 2,000 mg/kg ulation method
<u>Comp</u>	onents:		
Etoric	oxib:		
Acute	oral toxicity	: LD50 (Rat): 1	,499 mg/kg
		LD50 (Mouse)	): 1,499 mg/kg
	toxicity (other routes of istration)		38 mg/kg oute: Intraperitoneal
		LD50 (Mouse) Application Ro	): 599 mg/kg bute: Intraperitoneal
	corrosion/irritation assified based on availa	ble information.	
<u>Comp</u>	oonents:		
Etoric	oxib:		
Specie	es t	: Rabbit : No skin irritati	

Not classified based on available information.

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# **Etoricoxib Formulation**

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Comp	oonents:		
Etorio	coxib:		
Speci	es	: Rabbit	
Resul	t	: Mild eye irrit	ation
Respi	iratory or skin sensi	tisation	
Skins	sensitisation		
Not cl	assified based on ava	ailable information.	

### **Respiratory sensitisation**

Not classified based on available information.

### **Components:**

#### Etoricoxib:

Test Type :	Local lymph node assay (LLNA)
Exposure routes :	Skin contact
Species :	Mouse
Assessment :	Did not cause sensitisation on laboratory animals.
Result :	negative

## Germ cell mutagenicity

Not classified based on available information.

#### **Components:**

Etoricoxib:			
Genotoxicity in vitro :	Test Type: reverse mutation assay Result: negative		
	Test Type: In vitro mammalian cell gene mutation test Test system: human lymphoblastoid cells Result: negative		
	Test Type: Chromosomal aberration Test system: Chinese hamster ovary cells Result: negative		
	Test Type: Alkaline elution assay Result: negative		
Genotoxicity in vivo :	Test Type: Chromosomal aberration Species: Rat Cell type: Bone marrow Application Route: Oral Result: negative		
	Test Type: Alkaline elution assay Species: Rat Application Route: Oral Result: negative		

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## Carcinogenicity

Not classified based on available information.

### **Components:**

	-	
Fto	ricc	oxib:
<b>_</b>		<b>MIN</b> .

Species Application Route Exposure time Result	:	Rat, male and female oral (gavage) 2 Years positive
Species Application Route Exposure time Result		Mouse, male and female oral (gavage) 2 Years 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 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.

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Com	ponents:		
Etori	coxib:		
Targe	sure routes et Organs ssment		, Gastrointestinal tract amage to organs through prolonged or repeated
Repe	eated dose toxicity		
Com	ponents:		
Etori	coxib:		
Expo		: Rat : 30 mg/kg : oral (gavage) : 27 Weeks : Gastrointestii	nal tract, Kidney
Expo		: Rat : 30 mg/kg : oral (gavage) : 53 Weeks : Liver	
Expo		: Dog : 50 mg/kg : oral (gavage) : 53 Weeks : Liver	
Expo		: Dog : 200 mg/kg : oral (gavage) : 14 Weeks : Gastrointestin	nal tract, Kidney

### 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 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.

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Expe	rience with human e	xposure	
Com	ponents:		
Etori	coxib:		
Inges	stion	tension, Diarr heartburn, Na	pper respiratory tract infection, Headache, hyper- hoea, urinary tract infection, flu-like symptoms, husea, bronchitis, Dizziness, asthenia, Rash, bugh, Abdominal pain, pharyngitis, Oedema
SECTION	N 12: Ecological inf	ormation	
12.1 Toxi	city		
Com	ponents:		
Etori	coxib:		
Toxic	sity to fish	Exposure tim	hales promelas (fathead minnow)): > 30 mg/l e: 96 h D Test Guideline 203

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) Method: OECD Test Guideline 210
Toxicity to daphnia and other aquatic invertebrates (Chronic toxicity)	:	NOEC: 0.75 mg/l Exposure time: 21 d Species: Daphnia magna (Water flea) Method: OECD Test Guideline 211

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12.2	Persis	tence and degradabi	lity		
9	Compo	onents:			
	<b>Etorico</b> Biodeg	<b>oxib:</b> radability	:	Result: not rapidly Biodegradation: ( Exposure time: 28	0.2 %
12.3	Bioaco	cumulative potential			
<u>(</u>	Compo	onents:			
I	<b>Etorico</b> Partitio octanol	n coefficient: n-	:	log Pow: 2.3	
		<b>ty in soil</b> a available			
12.5	Result	s of PBT and vPvB a	sse	ssment	
-	<b>Produc</b> Assess		:	to be either persis	ixture contains no components considered stent, bioaccumulative and toxic (PBT), or id very bioaccumulative (vPvB) at levels of
12.6	Endoc	rine disrupting prope	ertie	S	
-	<b>Produc</b> Assess		:	ered to have endo REACH Article 57	ixture does not contain components consid- ocrine disrupting properties according to '(f) or Commission Delegated regulation or Commission Regulation (EU) 2018/605 at higher.
	•••••	<b>adverse effects</b> a available			
SEC	TION	13: Disposal consid	dera	ations	
13.1	Waste	treatment methods			
	Produc		:	According to the I are not product sp Waste codes sho	ordance with local regulations. European Waste Catalogue, Waste Codes becific, but application specific. uld be assigned by the user, preferably in

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## **SECTION 14: Transport information**

14.1 UN number or ID number		
ADN	:	UN 3077
ADR	:	UN 3077
RID	:	UN 3077
IMDG	:	UN 3077
ΙΑΤΑ	:	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)
ΙΑΤΑ	:	Environmentally hazardous substance, solid, n.o.s. (Etoricoxib)
14.3 Transport hazard class(es)		
		Class Subsidiary risks
ADN	:	9
ADR	:	9
RID	:	9
IMDG	:	9
ΙΑΤΑ	:	9
14.4 Packing group		
ADN Packing group Classification Code Hazard Identification Number Labels ADR Packing group Classification Code Hazard Identification Number		III M7 90 9 9

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# **Etoricoxib Formulation**

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Labe Tunn	ls el restriction code	: 9 : (-)	
Class	ing group sification Code ırd Identification Number Is	: III : M7 : 90 : 9	
Labe	ing group	: III : 9 : F-A, S-F	
Pack aircra Pack Pack	ing instruction (LQ) ing group	: 956 : Y956 : III	
Pack ger a Pack	( <b>Passenger</b> ) ing instruction (passen- ircraft) ing instruction (LQ) ing group	: Miscellar : 956 : Y956 : III : Miscellar	
14.5 Envi	ronmental hazards		
<b>ADN</b> Envir	onmentally hazardous	: yes	
<b>ADR</b> Envir	onmentally hazardous	: yes	
<b>RID</b> Envir	onmentally hazardous	: yes	
<b>IMDO</b> Marir	<b>3</b> ne pollutant	: yes	
	(Passenger) onmentally hazardous	: yes	
	( <b>Cargo)</b> onmentally 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

Remarks

: Not applicable for product as supplied.

according to Regulation (EC) No. 1907/2006, as amended by Commission Regulation (EU) 2020/878



of

# **Etoricoxib Formulation**

Version	Revision Date:	SDS Number:	Date of last issue: 29.09.2023
5.2	06.04.2024	26544-00027	Date of first issue: 29.10.2014

## **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, mixtures and articles (Annex XVII)	
REACH - Candidate List of Substances of Very High : Not applicable Concern for Authorisation (Article 59).	
Regulation (EC) No 1005/2009 on substances that de- : Not applicable	
plete the ozone layer	
Regulation (EU) 2019/1021 on persistent organic pollu- : Not applicable tants (recast)	
Regulation (EU) No 649/2012 of the European Parlia- : Not applicable ment and the Council concerning the export and import	
of dangerous chemicals	
REACH - List of substances subject to authorisation : Not applicable (Annex XIV)	
Seveso III: Directive 2012/18/EU of the European Parliament and of the Council major-accident hazards involving dangerous substances.	on the control
niajor-accident nazaros involving dangerous substances. Quantity 1	Quantity 2

		Quantity I	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**

H373

Other information	:	Items where changes have been made to the previous version are highlighted in the body of this document by two vertical lines.
Full text of H-Statements		
H302	:	Harmful if swallowed.
H361d		Suspected of damaging the unborn child.

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H411		:	exposure if swall Toxic to aquatic l	owed. ife with long lasting effects.
Full text of other abbreviations				
	ΓRE	:	Reproductive tox Specific target or Ireland. List of Cl	nic) aquatic hazard icity gan toxicity - repeated exposure hemical Agents and Carcinogens with Occu- e Limit Values - Code of Practice, Schedule 1
IE OE	EL / OELV - 8 hrs (TWA	A) :	Occupational exp	oosure limit value (8-hour reference period)

ADN - European Agreement concerning the International Carriage of Dangerous Goods by Inland Waterways; ADR - 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; TECI -Thailand Existing Chemicals 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 Agency, http://echa.europa.eu/

### **Classification of the mixture:**

**Classification procedure:** 

according to Regulation (EC) No. 1907/2006, as amended by Commission Regulation (EU) 2020/878



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Version 5.2	Revision Date: 06.04.2024	SDS Number: 26544-00027	Date of last issue: 29.09.2023 Date of first issue: 29.10.2014
Repr.	2	H361d	Calculation method
STOT	RE 2	H373	Calculation method
Aquat	tic Chronic 2	H411	Calculation method

The information provided in this Safety Data Sheet is correct to the best of our knowledge, information and belief at the date of its publication. The information is designed only as a guidance for safe handling, use, processing, storage, transportation, disposal and release and shall not be considered a warranty or quality specification of any type. The information provided relates only to the specific material identified at the top of this SDS and may not be valid when the SDS material is used in combination with any other materials or in any process, unless specified in the text. Material users should review the information and recommendations in the specific context of their intended manner of handling, use, processing and storage, including an assessment of the appropriateness of the SDS material in the user's end product, if applicable.

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