

Version	Revision Date:	SDS Number:	Date of last issue: 2023/09/26
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#### **1. PRODUCT AND COMPANY IDENTIFICATION**

Chemical product name	:	Etoricoxib Granulation Formulation
Product code	:	ETORICOXIB GRANULATION
Supplier's company name, a	ddr	ess and phone number
Company name of supplier	:	Organon & Co.
Address	:	30 Hudson Street, 33nd floor Jersey City, New Jersey, U.S.A 07302
Telephone	:	+1-551-430-6000
E-mail address	:	EHSSTEWARD@organon.com
Emergency telephone number	:	+1-215-631-6999

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

Recommended use	:	Pharmaceutical
Restrictions on use	:	Not applicable

#### 2. HAZARDS IDENTIFICATION

GHS classification of chemic Reproductive toxicity	al   :	product Category 2
Specific target organ toxicity - repeated exposure (Oral)	:	Category 2 (Kidney, Liver, Gastrointestinal tract)
Short-term (acute) aquatic hazard	:	Category 3
Long-term (chronic) aquatic hazard	:	Category 2
GHS label elements		
Hazard pictograms	:	
Signal word	:	Warning
Hazard statements	:	H361d Suspected of damaging the unborn child. H373 May cause damage to organs (Kidney, Liver, Gastroin- testinal tract) through prolonged or repeated exposure if swal-



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			l to aquatic life. aquatic life with long lasting effects.
Preca	autionary statements	P202 Do not and understo P260 Do not P273 Avoid re	preathe dust. elease to the environment. rotective gloves/ protective clothing/ eye protec-
		<b>Response:</b> P308 + P313 attention. P391 Collect	IF exposed or concerned: Get medical advice/
		<b>Storage:</b> P405 Store lo	cked up.
		<b>Disposal:</b> P501 Dispose disposal plant	e of contents/ container to an approved waste
Othe	r hazards which do no	ot result in classific	ation
	tant symptoms and ou of the emergency as- d	Contact with on the skin.	with the eyes can lead to mechanical irritation. dust can cause mechanical irritation or drying of losive dust-air mixture during processing, han- means.

#### 3. COMPOSITION/INFORMATION ON INGREDIENTS

Substance / Mixture : Mixture

#### Components

Chemical name	CAS-No.	Concentration (% w/w)	ENCS No.
Cellulose	9004-34-6	>= 40 - < 50	
Etoricoxib	202409-33-4	>= 25 - < 30	

#### 4. FIRST AID MEASURES

General advice	<ol> <li>In the case of accident or if you feel unwell, seek medical ad- vice immediately.</li> </ol>
	When symptoms persist or in all cases of doubt seek medical advice.
If inhaled	: If inhaled, remove to fresh air. Get medical attention.
In case of skin contact	: In case of contact, immediately flush skin with soap and plenty



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If swa Most i and e delaye	se of eye contact Illowed important symptoms ffects, both acute and ed ction of first-aiders	<ul> <li>Get medical at Wash clothing Thoroughly cle</li> <li>If in eyes, rinse Get medical at</li> <li>If swallowed, D Get medical at Rinse mouth th</li> <li>Suspected of c May cause dar exposure if swa Contact with du the skin. Dust contact w</li> <li>First Aid respo and use the re- when the poter</li> </ul>	before reuse. ean shoes before reuse. e well with water. tention if irritation develops and persists. OO NOT induce vomiting. tention. horoughly with water. damaging the unborn child. mage to organs through prolonged or repeated
	GHTING MEASURES		
Unsui media	fic hazards during fire-	concentrations potential dust e	
Hazaı ucts	rdous combustion prod-	: Carbon oxides Metal oxides Oxides of phos Nitrogen oxide Sulphur oxides Chlorine comp	sphorus s (NOx)
ods Speci	fic extinguishing meth- al protective equipment efighters	cumstances ar Use water spra Remove undar so. Evacuate area : In the event of	ing measures that are appropriate to local cir- nd the surrounding environment. ay to cool unopened containers. maged containers from fire area if it is safe to do fire, wear self-contained breathing apparatus. protective equipment.

#### 6. ACCIDENTAL RELEASE MEASURES

Personal precautions, protec- : Use personal protective equipment.



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gency	quipment and emer- / procedures onmental precautions	tective equipr : Avoid release Prevent furthe Retain and di	andling advice (see section 7) and personal pro- nent recommendations (see section 8). e to the environment. er leakage or spillage if safe to do so. spose of contaminated wash water. ties should be advised if significant spillages ntained.
	Methods and materials for containment and cleaning up		vacuum up spillage and collect in suitable con- oosal. al of dust in the air (i.e., clearing dust surfaces sed air). a should not be allowed to accumulate on surfac- may form an explosive mixture if they are re- e atmosphere in sufficient concentration. anal regulations may apply to releases and dis- naterial, as well as those materials and items the cleanup of releases. You will need to deter- egulations are applicable. and 15 of this SDS provide information regarding or national requirements.

### 7. HANDLING AND STORAGE

Handling	
Technical measures	<ul> <li>Static electricity may accumulate and ignite suspended dust causing an explosion.</li> <li>Provide adequate precautions, such as electrical grounding and bonding, or inert atmospheres.</li> </ul>
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.
Avoidance of contact	: Oxidizing agents
Hygiene measures	: If exposure to chemical is likely during typical use, provide eye flushing systems and safety showers close to the working place.
	When using do not eat, drink or smoke.
	Wash contaminated clothing before re-use.



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Stora	age		
Conc	litions for safe storage	Store locked u	rly labelled containers. p. dance with the particular national regulations.
Mate	rials to avoid		vith the following product types:
Pack	aging material	: Unsuitable ma	aterial: None known.

#### 8. EXPOSURE CONTROLS/PERSONAL PROTECTION

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

Components	CAS-No.	Value type (Form of exposure)	Control parame- ters / Reference concentration / Permissible con- centration	Basis
Cellulose	9004-34-6	TWA	10 mg/m3	ACGIH
Etoricoxib	202409-33-4	TWA	400 ug/m3 (OEB 2)	Internal

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 de- signed in a manner to prevent the escape of dust into the work area (i.e., there is no leakage from the equipment).
Personal protective equipmen	t
Respiratory protection :	sure assessment demonstrates exposures outside the rec- ommended guidelines, use respiratory protection.
Filter type : Hand protection	Particulates type
Material :	Chemical-resistant gloves
Remarks :	Choose gloves to protect hands against chemicals depending on the concentration and quantity of the hazardous sub- stance and specific to place of work. Breakthrough time is not determined for the product. Change gloves often! For special applications, we recommend clarifying the resistance to chemicals of the aforementioned protective gloves with the glove manufacturer. Wash hands before breaks and at the end of workday.
Eye protection :	Wear the following personal protective equipment: Safety goggles
Skin and body protection :	

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			potential. Skin contact must be avoided by using impervious protective clothing (gloves, aprons, boots, etc).
9. PHYS	ICAL AND CHEMICAL P	ROF	PERTIES
Phy	sical state	:	powder
Colo	bur	:	No data available
Odc	bur	:	No data available
Odc	our Threshold	:	No data available
Melt	ting point/freezing point	:	No data available
	ing point, initial boiling It and boiling range	:	No data available
Flar	nmability (solid, gas)	:	May form explosive dust-air mixture during processing, han- dling or other means.
Flar	nmability (liquids)	:	No data available
ι	rer explosion limit and upp Jpper explosion limit / Up- per flammability limit		xplosion limit / flammability limit No data available
	ower explosion limit / ower flammability limit	:	No data available
Flas	sh point	:	No data available
Dec	omposition temperature	:	No data available
pН		:	No data available
Eva	poration rate	:	No data available
Auto	o-ignition temperature	:	No data available
	cosity /iscosity, dynamic	:	No data available
١	/iscosity, kinematic	:	No data available
	ubility(ies) Vater solubility	:	No data available
	ition coefficient: n- nol/water	:	No data available
Vap	our pressure	:	No data available

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Deres		L .		
	ity and / or relative densir elative density	:	No data availa	ble
De	ensity	:	1 g/cm <sup>3</sup>	
Relat	ive vapour density	:	No data availal	ble
Explo	sive properties	:	Not explosive	
Oxidi	zing properties	:	The substance	or mixture is not classified as oxidizing.
Moleo	cular weight	:	No data availal	ble
	ele characteristics article size	:	No data availal	ble
. STABI	LITY AND REACTIVITY	•		
	tivity hical stability bility of hazardous reac-	:	Stable under n May form explo dling or other n	s a reactivity hazard. ormal conditions. sive dust-air mixture during processing, han neans. strong oxidizing agents.
Cond	itions to avoid	:	Heat, flames a Avoid dust form	
	npatible materials rdous decomposition icts	:	Oxidizing agen	
	OLOGICAL INFORMAT	ION		
Inforn expos	nation on likely routes of sure	:	Inhalation Skin contact Ingestion Eye contact	
	e toxicity lassified based on availa	ble i	nformation.	
Prod				
Acute	e oral toxicity	:	Acute toxicity es Method: Calcula	stimate: > 2,000 mg/kg ation method
<u>Com</u>	oonents:			
Cellu	lose:			
Acute	oral toxicity	:	LD50 (Rat): > 5	000 mg/kg
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Acute	inhalation toxicity	:	LC50 (Rat): > 5.8 Exposure time: 4 Test atmosphere:	h
Acute	e dermal toxicity	:	LD50 (Rabbit): > 2	2,000 mg/kg
Etori	coxib:			
Acute	e oral toxicity	:	LD50 (Rat): 1,499	mg/kg
			LD50 (Mouse): 1,	499 mg/kg
	e toxicity (other routes of histration)	:	LD50 (Rat): 238 n Application Route	
			LD50 (Mouse): 59 Application Route	
-	corrosion/irritation lassified based on availa	مام	information	
		ole	information.	
-	ponents:			
Speci Resu		:	Rabbit No skin irritation	
	ous eye damage/eye irri lassified based on availa			
	ponents:	JIE	iniomation.	
	coxib:			
Speci Resu	ies	:	Rabbit Mild eye irritation	
Resp	iratory or skin sensitis	atic	on	
-	sensitisation lassified based on availa	ble	information.	
	iratory sensitisation			
Resp	lassified based on availa	ble	information.	
<b>Resp</b> Not cl		ble	information.	
Resp Not cl <u>Com</u>	lassified based on availa	ble	information.	
Resp Not cl <u>Com</u> Etoric	lassified based on availa ponents: coxib: Type sure routes	ble : :	Information. Local lymph node Skin contact Mouse	assay (LLNA)



ersion 0	Revision Date: 2024/04/06	SDS Number: 16710-00025	Date of last issue: 2023/09/26 Date of first issue: 2014/09/29
Resu	lt	: negative	
	<b>cell mutagenicity</b> lassified based on av	ailable information.	
Com	ponents:		
<b>Cellu</b> Geno	lose: toxicity in vitro	: Test Type: Ba Result: negat	acterial reverse mutation assay (AMES) ive
		Test Type: In Result: negat	vitro mammalian cell gene mutation test ive
Geno	toxicity in vivo	cytogenetic a Species: Mou	ise oute: Ingestion
Etori	coxib:		
Geno	toxicity in vitro	: Test Type: re Result: negat	verse mutation assay ive
			vitro mammalian cell gene mutation test human lymphoblastoid cells ive
			nromosomal aberration Chinese hamster ovary cells ive
		Test Type: Al Result: negat	kaline elution assay ive
Geno	toxicity in vivo	: Test Type: Cl Species: Rat Cell type: Bor Application R Result: negat	oute: Oral
		Test Type: Al Species: Rat Application R Result: negat	

### Carcinogenicity

Not classified based on available information.



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<u>Comp</u>	ponents:				
Cellu					
Speci	es cation Route	:	Rat Ingestion		
Expos	sure time	:	72 weeks		
Resul	t	:	negative		
Etorio	coxib:				
Speci		:	Rat, male and fer	nale	
	cation Route sure time	:	oral (gavage) 2 Years		
Resul		:	positive		
Speci	es	:	Mouse, male and	female	
Applic	cation Route	:	oral (gavage)		
Expos Resul	sure time t	:	2 Years negative		
Cellu	oonents: lose: s on fertility	:	Test Type: One-g Species: Rat Application Route Result: negative	eneration reproduction toxicity stuc	ły
Effect ment	s on foetal develop-	:	Test Type: Fertilit Species: Rat Application Route Result: negative	y/early embryonic development	
Etorio	coxib:				
Effect	s on fertility	:	Species: Rat, fem Application Route		reight
			Test Type: Fertilit Species: Rat, ma Application Route Result: negative		
Effect ment	s on foetal develop-	:	Species: Rat Application Route Result: positive	: Oral	



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			Species: Rabbi	
			Application Rou Result: positive	
Repro	ductive toxicity - As-	:	Some evidence	of adverse effects on development, based o
sessm	•		animal experim	
STOT	- single exposure			
Not cl	assified based on avai	lable	information.	
STOT	- repeated exposure	!		
	ause damage to orgar posure if swallowed.	าร (Ki	dney, Liver, Gas	trointestinal tract) through prolonged or repea
-	oonents:			
Etoric	coxib:			
	sure routes	:	Ingestion	
-	t Organs	:		Gastrointestinal tract nage to organs through prolonged or repeate
		•	iviay cause uari	hade to ordans through projonded of repeate
Asses	Sinon		exposure.	
Asses			exposure.	
	ated dose toxicity		exposure.	
Repea			exposure.	
Repea <u>Comp</u> Cellul	ated dose toxicity ponents: lose:			
Repea <u>Comp</u> Cellul Specia	ated dose toxicity ponents: lose: es	:	Rat	
Repea Comp Cellul Specie NOAE	ated dose toxicity ponents: lose: es :L	:	Rat >= 9,000 mg/kg	
Repea Comp Cellul Specia NOAE Applic	ated dose toxicity ponents: lose: es	:	Rat	
Repea Comp Cellul Specia NOAE Applic Expos	ated dose toxicity ponents: lose: es EL sation Route sure time	:	Rat >= 9,000 mg/kg Ingestion	
Repea Comp Cellul Specia NOAE Applic Expose Etoric	ated dose toxicity ponents: lose: es EL sation Route sure time	:	Rat >= 9,000 mg/kg Ingestion 90 Days	
Repea Comp Cellul Specia NOAE Applic Expose Etoric	ated dose toxicity ponents: lose: es EL sation Route sure time coxib: es		Rat >= 9,000 mg/kg Ingestion 90 Days Rat	
Repea Comp Cellul Specia NOAE Applic Expose Etoric Specia LOAE	ated dose toxicity ponents: lose: es EL eation Route sure time coxib: es L		Rat >= 9,000 mg/kg Ingestion 90 Days Rat 30 mg/kg	
Repea Comp Cellul Specia NOAE Applic Expose Etoric Specia LOAE Applic	ated dose toxicity ponents: lose: es EL sation Route sure time coxib: es		Rat >= 9,000 mg/kg Ingestion 90 Days Rat	
Repea Comp Cellul Specie NOAE Applic Expose Etoric Specie LOAE Applic Expose	ated dose toxicity ponents: lose: es EL estion Route sure time coxib: es L es L es		Rat >= 9,000 mg/kg Ingestion 90 Days Rat 30 mg/kg oral (gavage)	3
Repea Comp Cellul Specie NOAE Applic Expos Etoric Specie LOAE Applic Expos Targe	ated dose toxicity <u>ponents:</u> lose: es EL sation Route sure time coxib: es L sation Route sure time t Organs es		Rat >= 9,000 mg/kg Ingestion 90 Days Rat 30 mg/kg oral (gavage) 27 Weeks Gastrointestina Rat	3
Repea Comp Cellul Specie NOAE Applic Expos Etoric Specie LOAE Applic Expos Targe	ated dose toxicity ponents: lose: es EL sation Route sure time coxib: es L sation Route sure time t Organs es EL		Rat >= 9,000 mg/kg Ingestion 90 Days Rat 30 mg/kg oral (gavage) 27 Weeks Gastrointestina Rat 30 mg/kg	3
Repea Comp Cellul Specie NOAE Applic Expos Etoric Specie LOAE Applic Expos Targe	ated dose toxicity ponents: lose: es EL sation Route sure time t Organs es EL sation Route sure time t Organs		Rat >= 9,000 mg/kg Ingestion 90 Days Rat 30 mg/kg oral (gavage) 27 Weeks Gastrointestina Rat 30 mg/kg oral (gavage)	3
Repea Comp Cellul Specia NOAE Applic Expos Etoric Specia LOAE Applic Expos Targe Specia NOAE Applic Expos	ated dose toxicity ponents: lose: es EL estion Route sure time coxib: es L estion Route sure time t Organs es EL eation Route sure time t Organs		Rat >= 9,000 mg/kg Ingestion 90 Days Rat 30 mg/kg oral (gavage) 27 Weeks Gastrointestina Rat 30 mg/kg oral (gavage) 53 Weeks	3
Repea Comp Cellul Specia NOAE Applic Expos Etoric Specia LOAE Applic Expos Targe	ated dose toxicity ponents: lose: es EL cation Route sure time t Organs es EL cation Route sure time t Organs es EL cation Route sure time t Organs		Rat >= 9,000 mg/kg Ingestion 90 Days Rat 30 mg/kg oral (gavage) 27 Weeks Gastrointestina Rat 30 mg/kg oral (gavage) 53 Weeks Liver	3
Repea Comp Cellul Specia NOAE Applic Expos Etoric Specia LOAE Applic Expos Targe Specia NOAE Applic Expos Targe	ated dose toxicity ponents: lose: es EL cation Route sure time t Organs es EL cation Route sure time t Organs es EL cation Route sure time t Organs es EL cation Route sure time t Organs		Rat >= 9,000 mg/kg Ingestion 90 Days Rat 30 mg/kg oral (gavage) 27 Weeks Gastrointestina Rat 30 mg/kg oral (gavage) 53 Weeks Liver Dog	3
Repea Comp Cellul Specia NOAE Applic Expos Etoric Specia LOAE Applic Expos Targe Specia NOAE Applic Expos Targe	ated dose toxicity ponents: lose: es EL cation Route sure time t Organs es EL cation Route sure time t Organs es EL cation Route sure time t Organs es EL cation Route sure time t Organs		Rat >= 9,000 mg/kg Ingestion 90 Days Rat 30 mg/kg oral (gavage) 27 Weeks Gastrointestina Rat 30 mg/kg oral (gavage) 53 Weeks Liver Dog 50 mg/kg	3
Repea Comp Cellul Specie NOAE Applic Expos Etoric Specie LOAE Applic Expos Targe Specie NOAE Applic Expos Targe	ated dose toxicity ponents: lose: es EL cation Route sure time t Organs es EL cation Route sure time t Organs es EL cation Route sure time t Organs es EL cation Route sure time t Organs		Rat >= 9,000 mg/kg Ingestion 90 Days Rat 30 mg/kg oral (gavage) 27 Weeks Gastrointestina Rat 30 mg/kg oral (gavage) 53 Weeks Liver Dog	3



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Expo		: Dog : 200 mg : oral (ga : 14 We : Gastro	avage)
-	ration toxicity lassified based on ava	ailable informa	tion.
Expe	rience with human e	xposure	
Com	ponents:		
Etori	coxib:		
Inges	stion	tensior heartb	oms: upper respiratory tract infection, Headache, hyper- n, Diarrhoea, urinary tract infection, flu-like symptoms, urn, Nausea, bronchitis, Dizziness, asthenia, Rash, ain, Cough, Abdominal pain, pharyngitis, Oedema
12. ECOL	OGICAL INFORMAT	ON	
Ecote	oxicity		
<u>Com</u>	ponents:		
Cellu	llose:		

Toxicity to fish	:	LC50 (Oryzias latipes (Japanese medaka)): > 100 mg/l Exposure time: 48 h Remarks: Based on data from similar materials
Etoricoxib:		
Toxicity to fish	:	LC50 (Pimephales promelas (fathead minnow)): > 30 mg/l Exposure time: 96 h Method: OECD Test Guideline 203
Toxicity to daphnia and other aquatic invertebrates	:	EC50 (Daphnia magna (Water flea)): > 30 mg/l Exposure time: 48 h Method: OECD Test Guideline 202
Toxicity to algae/aquatic plants	:	EC50 (Pseudokirchneriella subcapitata (green algae)): > 10 mg/l Exposure time: 72 h Method: OECD Test Guideline 201
Toxicity to fish (Chronic tox- icity)	:	NOEC (Pimephales promelas (fathead minnow)): 7.93 mg/l Exposure time: 32 d Method: OECD Test Guideline 210
Toxicity to daphnia and other aquatic invertebrates (Chron-	:	NOEC (Daphnia magna (Water flea)): 0.75 mg/l Exposure time: 21 d

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ic toxi	icity)		Method: OECI	D Test Guideline 211
Toxic	ity to microorganisms	:	Method: OECI NOEC: 1,000 i Exposure time Test Type: Res	: 3 ĥ spiration inhibition D Test Guideline 209 mg/l
Persi	stence and degradabi	ility		
<u>Com</u>	ponents:			
Cellu	lose:			
Biode	egradability	:	Result: Readily	y biodegradable.
Etorie	coxib:			
Biode	gradability	:	Result: not rap Biodegradation Exposure time	
Bioad	ccumulative potential			
Com	ponents:			
Etorie	coxib:			
	ion coefficient: n- ol/water	:	log Pow: 2.3	
	<b>lity in soil</b> ata available			
	rdous to the ozone lay pplicable	yer		
	r adverse effects ata available			
DISPC	SAL CONSIDERATIO	NS		
Dispo	osal methods			
Waste	e from residues	:		accordance with local regulations.
Conta	aminated packaging	:	Empty contain dling site for re	e of waste into sewer. ers should be taken to an approved waste har ecycling or disposal. e specified: Dispose of as upused product

If not otherwise specified: Dispose of as unused product.



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#### 14. TRANSPORT INFORMATION

#### International Regulations

UNRTDG		
UN number	:	UN 3077
Proper shipping name	:	ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID, N.O.S. (Etoricoxib)
Class	:	9
Packing group	:	III
Labels	:	9
Environmentally hazardous	:	yes
IATA-DGR		
UN/ID No.	:	UN 3077
Proper shipping name	:	Environmentally hazardous substance, solid, n.o.s. (Etoricoxib)
Class	:	9
Packing group	:	III
Labels	:	Miscellaneous
Packing instruction (cargo aircraft)	:	956
Packing instruction (passen- ger aircraft)	:	956
Environmentally hazardous	:	yes
IMDG-Code		
UN number	:	UN 3077
Proper shipping name	:	ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID, N.O.S. (Etoricoxib)
Class		9
Packing group	:	
Labels	:	9
EmS Code	÷	F-A, S-F
Marine pollutant	÷	yes
	-	,

#### Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code

Not applicable for product as supplied.

#### **National Regulations**

Refer to section 15 for specific national regulation.

#### Special precautions for user

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

**ERG Code** : 171



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#### **15. REGULATORY INFORMATION**

#### **Related Regulations**

#### **Fire Service Law**

Not applicable to dangerous materials / designated flammables.

#### **Chemical Substance Control Law**

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

#### Industrial Safety and Health Law

#### Harmful Substances Prohibited from Manufacture

Not applicable

#### Harmful Substances Required Permission for Manufacture

Not applicable

#### Substances Prevented From Impairment of Health

Not applicable

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

Not applicable

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

Not applicable

#### Substances Subject to be Notified Names

Not applicable

#### Substances Subject to be Indicated Names

Not applicable

#### Substances Subject to be Indicated Names

Not applicable

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

Not applicable

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

Not applicable

Ordinance on Prevention of Lead Poisoning

Not applicable

#### Ordinance on Prevention of Tetraalkyl Lead Poisoning Not applicable

Ordinance on Prevention of Organic Solvent Poisoning Not applicable



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

Not applicable

# Poisonous and Deleterious Substances Control Law

Not applicable

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

Not applicable

#### High Pressure Gas Safety Act

Not applicable

**Explosive Control Law** 

Not applicable

#### Vessel Safety Law

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

#### **Aviation Law**

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

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

Bulk transportation	:	Not classified as noxious liquid substance
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Pack transportation : Classified as marine pollutant

#### Narcotics and Psychotropics Control Act

Narcotic or Psychotropic Raw Material (Export / Import Permission) Not applicable Specific Narcotic or Psychotropic Raw Material (Export / Import permission) Not applicable

#### Waste Disposal and Public Cleansing Law

Industrial waste

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

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

#### **16. OTHER INFORMATION**

#### Further information

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

ACGIH / TWA



### Etoricoxib Granulation Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 2023/09/26
9.0	2024/04/06	16710-00025	Date of first issue: 2014/09/29

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

: 8-hour, time-weighted average

Date format	:	yyyy/mm/dd
Full text of other abbreviation		
ACGIH	:	USA. ACGIH Threshold Limit Values (TLV)

AIIC - Australian Inventory of Industrial Chemicals; ANTT - National Agency for Transport by Land of Brazil; ASTM - American Society for the Testing of Materials; bw - Body weight; CMR -Carcinogen, Mutagen or Reproductive Toxicant; DIN - Standard of the German Institute for Standardisation; DSL - Domestic Substances List (Canada); ECx - Concentration associated with x% response; ELx - Loading rate associated with x% response; EmS - Emergency Schedule; ENCS - Existing and New Chemical Substances (Japan); ErCx - Concentration associated with x% growth rate response; ERG - Emergency Response Guide; GHS - Globally Harmonized System; GLP - Good Laboratory Practice; IARC - International Agency for Research on Cancer; IATA - International Air Transport Association; IBC - International Code for the Construction and Equipment of Ships carrying Dangerous Chemicals in Bulk; IC50 - Half maximal inhibitory concentration; ICAO - International Civil Aviation Organization; IECSC - Inventory of Existing Chemical Substances in China; IMDG - International Maritime Dangerous Goods; IMO - International Maritime Organization; ISHL - Industrial Safety and Health Law (Japan); ISO - International Organisation for Standardization; KECI - Korea Existing Chemicals Inventory; LC50 - Lethal Concentration to 50 % of a test population; LD50 - Lethal Dose to 50% of a test population (Median Lethal Dose); MARPOL - International Convention for the Prevention of Pollution from Ships; n.o.s. - Not Otherwise Specified; Nch - Chilean Norm; NO(A)EC - No Observed (Adverse) Effect Concentration; NO(A)EL - No Observed (Adverse) Effect Level; NOELR - No Observable Effect Loading Rate; NOM - Official Mexican Norm; NTP - National Toxicology Program; NZIoC - New Zealand Inventory of Chemicals; OECD - Organization for Economic Co-operation and Development; OPPTS - Office of Chemical Safety and Pollution Prevention; PBT - Persistent, Bioaccumulative and Toxic substance; PICCS - Philippines Inventory of Chemicals and Chemical Substances; (Q)SAR - (Quantitative) Structure Activity Relationship; REACH - Regulation (EC) No 1907/2006 of the European Parliament and of the Council concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals; SADT - Self-Accelerating Decomposition Temperature; SDS - Safety Data Sheet; TCSI - Taiwan Chemical Substance Inventory; TDG - Transportation of Dangerous Goods; TECI - Thailand Existing Chemicals Inventory; TSCA - Toxic Substances Control Act (United States); UN - United Nations; UNRTDG - United Nations Recommendations on the Transport of Dangerous Goods; vPvB - Very Persistent and Very Bioaccumulative; WHMIS - Workplace Hazardous Materials Information System

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

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