

SAFETY DATA SHEET

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



ORGANON

Etoricoxib Granulation Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 26.09.2023
4.2	06.04.2024	16706-00026	Date of first issue: 29.09.2014

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-stance/Mixture : Pharmaceutical
Recommended restrictions on use : Not applicable

1.3 Details of the supplier of the safety data sheet

Company : Organon & Co.
30 Hudson Street, 33rd floor
07302 Jersey City, New Jersey, U.S.A
Telephone : +1-551-430-6000
E-mail address of person responsible for the SDS : EHSSTEWARD@organon.com

1.4 Emergency telephone number

+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	H361d: Suspected of damaging the unborn child.
Specific target organ toxicity - repeated exposure, Category 2	H373: May cause damage to organs through prolonged or repeated exposure.
Long-term (chronic) aquatic hazard, Category 2	H411: Toxic to aquatic life with long lasting effects.

2.2 Label elements

Labelling (REGULATION (EC) No 1272/2008)

Hazard pictograms :



SAFETY DATA SHEET

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



Etoricoxib Granulation Formulation

Version 4.2 Revision Date: 06.04.2024 SDS Number: 16706-00026 Date of last issue: 26.09.2023
Date of first issue: 29.09.2014

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: P201 Obtain special instructions before use. P260 Do not breathe dust. P273 Avoid release to the environment. P280 Wear protective gloves/ protective clothing/ eye protection/ face protection. Response: P308 + P313 IF exposed or concerned: Get medical advice/ attention. P391 Collect spillage.

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, Gas-	>= 25 - < 30

SAFETY DATA SHEET

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



Etoricoxib Granulation Formulation

Version 4.2 Revision Date: 06.04.2024 SDS Number: 16706-00026 Date of last issue: 26.09.2023
Date of first issue: 29.09.2014

		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 : In the case of accident or if you feel unwell, seek medical advice immediately.
When symptoms persist or in all cases of doubt seek medical advice.
- 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 : 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

SAFETY DATA SHEET

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



Etoricoxib Granulation Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 26.09.2023
4.2	06.04.2024	16706-00026	Date of first issue: 29.09.2014

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 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 products : Carbon oxides
Metal oxides
Oxides of phosphorus
Nitrogen oxides (NO_x)
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 methods : Use extinguishing measures that are appropriate to local circumstances and the surrounding environment.
Use water spray to cool unopened containers.
Remove undamaged containers from fire area if it is safe to do so.
Evacuate area.

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 protective 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.

SAFETY DATA SHEET

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



Etoricoxib Granulation Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 26.09.2023
4.2	06.04.2024	16706-00026	Date of first issue: 29.09.2014

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 container for disposal.
Avoid dispersal of dust in the air (i.e., clearing dust surfaces with compressed air).
Dust deposits should not be allowed to accumulate on surfaces, as these may form an explosive mixture if they are released into the atmosphere in sufficient concentration.
Local or national regulations may apply to releases and disposal of this material, as well as those materials and items employed in the cleanup of releases. You will need to determine which regulations are applicable.
Sections 13 and 15 of this SDS provide information regarding certain local or national requirements.

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.

Local/Total ventilation : Use only with adequate ventilation.

Advice on safe handling : Do not breathe dust.
Do not swallow.
Avoid contact with eyes.
Avoid prolonged or repeated contact with skin.
Handle in accordance with good industrial hygiene and safety practice, based on the results of the workplace exposure assessment
Minimize dust generation and accumulation.
Keep container closed when not in use.
Keep away from heat and sources of ignition.
Take precautionary measures against static discharges.
Take care to prevent spills, waste and minimize release to the environment.

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.

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.

SAFETY DATA SHEET

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



Etoricoxib Granulation Formulation

Version 4.2 Revision Date: 06.04.2024 SDS Number: 16706-00026 Date of last issue: 26.09.2023
Date of first issue: 29.09.2014

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

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/m ³	IE OEL
Etoricoxib	202409-33-4	TWA	400 ug/m ³ (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/face 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 sub-

SAFETY DATA SHEET

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



Etoricoxib Granulation Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 26.09.2023
4.2	06.04.2024	16706-00026	Date of first issue: 29.09.2014

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.

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 exposure assessment demonstrates exposures outside the recommended 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

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, handling or other means.

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 : No data available

SAFETY DATA SHEET

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



ORGANON

Etoricoxib Granulation Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 26.09.2023
4.2	06.04.2024	16706-00026	Date of first issue: 29.09.2014

pH : No data available

Viscosity

Viscosity, dynamic : No data available

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

Density : 1 g/cm³

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

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, handling or other means.
Can react with strong oxidizing agents.

10.4 Conditions to avoid

Conditions to avoid : Heat, flames and sparks.
Avoid dust formation.

SAFETY DATA SHEET

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



ORGANON

Etoricoxib Granulation Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 26.09.2023
4.2	06.04.2024	16706-00026	Date of first issue: 29.09.2014

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 exposure : Inhalation
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
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

SAFETY DATA SHEET

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



Etoricoxib Granulation Formulation

Version 4.2 Revision Date: 06.04.2024 SDS Number: 16706-00026 Date of last issue: 26.09.2023
Date of first issue: 29.09.2014

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

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.

SAFETY DATA SHEET

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



ORGANON

Etoricoxib Granulation Formulation

Version 4.2 Revision Date: 06.04.2024 SDS Number: 16706-00026 Date of last issue: 26.09.2023
Date of first issue: 29.09.2014

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 development : Species: Rat
Application Route: Oral
Result: positive

Species: Rabbit
Application Route: Oral
Result: positive

Reproductive toxicity - Assessment : Some evidence of adverse effects on development, based on animal experiments.

STOT - single exposure

Not classified based on available information.

STOT - repeated exposure

May cause damage to organs 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

SAFETY DATA SHEET

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



Etoricoxib Granulation Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 26.09.2023
4.2	06.04.2024	16706-00026	Date of first issue: 29.09.2014

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.

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.
------------	---	---

Experience with human exposure

Components:

Etoricoxib:

Ingestion	:	Symptoms: upper respiratory tract infection, Headache, hypertension, Diarrhoea, urinary tract infection, flu-like symptoms,
-----------	---	---

SAFETY DATA SHEET

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



Etoricoxib Granulation Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 26.09.2023
4.2	06.04.2024	16706-00026	Date of first issue: 29.09.2014

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 toxicity) | : | 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 |

12.2 Persistence and degradability

Components:

Etoricoxib:

- | | | |
|------------------|---|--|
| Biodegradability | : | Result: not rapidly degradable
Biodegradation: 0.2 %
Exposure time: 28 d |
|------------------|---|--|

SAFETY DATA SHEET

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



Etoricoxib Granulation Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 26.09.2023
4.2	06.04.2024	16706-00026	Date of first issue: 29.09.2014

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

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.
Do not dispose of waste into sewer.

Contaminated packaging : Empty containers should be taken to an approved waste handling site for recycling or disposal.
If not otherwise specified: Dispose of as unused product.

SECTION 14: Transport information

14.1 UN number or ID number

ADN : UN 3077
ADR : UN 3077
RID : UN 3077

SAFETY DATA SHEET

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



Etoricoxib Granulation Formulation

Version 4.2 Revision Date: 06.04.2024 SDS Number: 16706-00026 Date of last issue: 26.09.2023
Date of first issue: 29.09.2014

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)

	Class	Subsidiary risks
ADN	: 9	
ADR	: 9	
RID	: 9	
IMDG	: 9	
IATA	: 9	

14.4 Packing group

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

SAFETY DATA SHEET

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



Etoricoxib Granulation Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 26.09.2023
4.2	06.04.2024	16706-00026	Date of first issue: 29.09.2014

Packing group : III
Labels : 9
EmS Code : F-A, S-F

IATA (Cargo)

Packing instruction (cargo aircraft) : 956
Packing instruction (LQ) : Y956
Packing group : III
Labels : Miscellaneous

IATA (Passenger)

Packing instruction (passenger aircraft) : 956
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

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

REACH - Restrictions on the manufacture, placing on the market and use of certain dangerous substances, mixtures and articles (Annex XVII) : Not applicable
REACH - Candidate List of Substances of Very High Concern for Authorisation (Article 59). : Not applicable

SAFETY DATA SHEET

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



Etoricoxib Granulation Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 26.09.2023
4.2	06.04.2024	16706-00026	Date of first issue: 29.09.2014

Regulation (EC) No 1005/2009 on substances that deplete the ozone layer : Not applicable
Regulation (EU) 2019/1021 on persistent organic pollutants (recast) : Not applicable
Regulation (EU) No 649/2012 of the European Parliament and the Council concerning the export and import of dangerous chemicals : Not applicable
REACH - List of substances subject to authorisation (Annex XIV) : Not applicable
Seveso III: Directive 2012/18/EU of the European Parliament and of the Council on the control of major-accident hazards involving dangerous substances.

E2	ENVIRONMENTAL HAZARDS	Quantity 1 200 t	Quantity 2 500 t
----	-----------------------	---------------------	---------------------

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 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 Carcinogens with Occupational Exposure Limit Values - Code of Practice, Schedule 1

SAFETY DATA SHEET

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



ORGANON

Etoricoxib Granulation Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 26.09.2023
4.2	06.04.2024	16706-00026	Date of first issue: 29.09.2014

and 2

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 - Agreement concerning the International Carriage of Dangerous Goods by Road; AIIIC - 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

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

Classification of the mixture:

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

Classification procedure:

Calculation method
Calculation method
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 mate-

SAFETY DATA SHEET

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



Etoricoxib Granulation Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 26.09.2023
4.2	06.04.2024	16706-00026	Date of first issue: 29.09.2014

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