

# **Etoricoxib Granulation Formulation**



 Version
 Revision Date:
 SDS Number:
 Date of last issue: 23.03.2020

 5.5
 16.10.2020
 16692-00018
 Date of first issue: 29.09.2014

#### **SECTION 1. PRODUCT AND COMPANY IDENTIFICATION**

Product name : Etoricoxib Granulation Formulation

Product code : ETORICOXIB GRANULATION

Manufacturer or supplier's details

Company : Organon & Co.

Address : Rua Treze de Maio, 1161

Campinas, São Paulo, Brazil B-2220

Telephone : 551-430-6000

Emergency telephone : 215-631-6999

E-mail address : EHSSTEWARD@organon.com

Recommended use of the chemical and restrictions on use

Recommended use : Pharmaceutical

# **SECTION 2. HAZARDS IDENTIFICATION**

GHS Classification in accordance with ABNT NBR 14725 Standard

Reproductive toxicity : Category 2

repeated exposure (Oral)

Specific target organ toxicity - : Category 2 (Kidney, Liver, Gastrointestinal tract)

Short-term (acute) aquatic

hazard

Category 3

Long-term (chronic) aquatic

hazard

Category 2

GHS label elements in accordance with ABNT NBR 14725 Standard

Hazard pictograms





Signal Word : Warning

Hazard Statements : H361d Suspected of damaging the unborn child.

H373 May cause damage to organs (Kidney, Liver,

Gastrointestinal tract) through prolonged or repeated exposure

if swallowed.

H402 Harmful to aquatic life.

H411 Toxic to aquatic life with long lasting effects.



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Precautionary Statements : Prevention:

P201 Obtain special instructions before use.

P260 Do not breathe dust.

P273 Avoid release to the environment.

P280 Wear protective gloves/ protective clothing/ eye protec-

tion/ face protection.

Response:

P308 + P313 IF exposed or concerned: Get medical advice/

attention

P391 Collect spillage.

### Other hazards which do not result in classification

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**

Substance / Mixture : Mixture

### Components

Chemical name	CAS-No.	Classification	Concentration (% w/w)
Cellulose	9004-34-6		>= 30 -< 50
Etoricoxib	202409-33-4	Acute toxicity (Oral), Category 4 Reproductive toxicity, Category 2 Specific target organ toxicity - repeated exposure (Oral) (Kid- ney, Liver, Gastroin- testinal tract), Catego- ry 2 Short-term (acute) aquatic hazard, Category 3 Long-term (chronic) aquatic hazard, Category 2	>= 25 -< 30

### **SECTION 4. 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.

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.







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Remove contaminated clothing and shoes.

Get medical attention. Wash clothing before reuse.

Thoroughly clean shoes before reuse.

If in eyes, rinse well with water. In case of eye contact

Get medical attention if irritation develops and persists.

If swallowed If swallowed, DO NOT induce vomiting.

Get medical attention.

Rinse mouth thoroughly with water. Suspected of damaging the unborn child.

Most important symptoms

and effects, both acute and delayed

Protection of first-aiders

May cause damage to organs through prolonged or repeated

exposure if swallowed.

Contact with dust can cause mechanical irritation or drying of

the skin.

Dust contact with the eyes can lead to mechanical irritation. 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).

Treat symptomatically and supportively. Notes to physician

#### **SECTION 5. FIRE-FIGHTING MEASURES**

Suitable extinguishing media Water spray

> Alcohol-resistant foam Carbon dioxide (CO2)

Dry chemical

Unsuitable extinguishing

media

None known.

Specific hazards during fire

fighting

Avoid generating dust; fine dust dispersed in air in sufficient concentrations, and in the presence of an ignition source is a

potential dust explosion hazard.

Exposure to combustion products may be a hazard to health.

Hazardous combustion prod-

ucts

Carbon oxides

Metal oxides

Oxides of phosphorus Nitrogen oxides (NOx)

Sulfur oxides

Chlorine compounds

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.

Special protective equipment :

for fire-fighters

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

Use personal protective equipment.

### **SECTION 6. ACCIDENTAL RELEASE MEASURES**

Personal precautions, protec: : tive equipment and emer-

gency procedures

Use personal protective equipment.

Follow safe handling advice (see section 7) and personal protective equipment recommendations (see section 8).



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Avoid release to the environment. **Environmental precautions** 

> Prevent further leakage or spillage if safe to do so. Retain and dispose of contaminated wash water.

Local authorities should be advised if significant spillages

cannot be contained.

Methods and materials for containment and 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.

#### **SECTION 7. HANDLING AND STORAGE**

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 Advice on safe handling Use only with adequate ventilation.

Do not swallow.

Do not breathe dust.

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

When using do not eat, drink or smoke. Wash contaminated clothing before re-use.

Conditions for safe storage Keep in properly labeled containers.

Store locked up.

Store in accordance with the particular national regulations.

Materials to avoid Do not store with the following product types:

Strong oxidizing agents



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#### SECTION 8. EXPOSURE CONTROLS/PERSONAL PROTECTION

### Ingredients with workplace control parameters

Components	CAS-No.	Value type (Form of exposure)	Control parameters / Permissible concentration	Basis
Cellulose	9004-34-6	TWA	10 mg/m <sup>3</sup>	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 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

Respiratory protection : If adequate local exhaust ventilation is not available or

exposure assessment demonstrates exposures outside the

recommended 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 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 : 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).

### **SECTION 9. PHYSICAL AND CHEMICAL PROPERTIES**

Appearance : powder

Color : No data available

Odor : No data available

Odor Threshold : No data available

pH : No data available



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Melting point/freezing point : No data available

Initial boiling point and boiling

range

: No data available

Flash point : No data available

Evaporation rate : 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

Vapor pressure : No data available

Relative vapor density : No data available

Relative density : No data available

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

Solubility(ies)

Water solubility : No data available

Partition coefficient: n-

octanol/water

: No data available

Autoignition temperature : No data available

Decomposition temperature : No data available

Viscosity

Viscosity, dynamic : No data available

Viscosity, kinematic : No data available

Explosive properties : Not explosive

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

Molecular weight : No data available

Particle size : No data available

#### **SECTION 10. STABILITY AND REACTIVITY**

Reactivity : Not classified as a reactivity hazard.



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Chemical stability

Stable under normal conditions.

Possibility of hazardous reactions

May form explosive dust-air mixture during processing,

handling or other means.

Can react with strong oxidizing agents.

Conditions to avoid : Heat, flames and sparks.

Avoid dust formation.

Incompatible materials

: Oxidizing agents

Hazardous decomposition

No hazardous decomposition products are known.

products

#### **SECTION 11. TOXICOLOGICAL INFORMATION**

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: > 5.000 mg/kg

Method: Calculation method

#### **Components:**

Cellulose:

Acute oral toxicity : LD50 (Rat): > 5.000 mg/kg

Acute inhalation toxicity : LC50 (Rat): > 5,8 mg/l

Exposure time: 4 h

Test atmosphere: dust/mist

Acute dermal toxicity : LD50 (Rabbit): > 2.000 mg/kg

**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



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Result : No skin irritation

### Serious eye damage/eye irritation

Not classified based on available information.

### **Components:**

**Etoricoxib:** 

Species : Rabbit

Result : Mild eye irritation

# Respiratory or skin sensitization

#### Skin sensitization

Not classified based on available information.

# Respiratory sensitization

Not classified based on available information.

#### Components:

#### **Etoricoxib:**

Test Type : Local lymph node assay (LLNA)

Routes of exposure : Skin contact Species : Mouse

Assessment : Did not cause sensitization on laboratory animals.

Result : negative

# Germ cell mutagenicity

Not classified based on available information.

### **Components:**

#### Cellulose:

Genotoxicity in vitro : Test Type: Bacterial reverse mutation assay (AMES)

Result: negative

Test Type: In vitro mammalian cell gene mutation test

Result: negative

Genotoxicity in vivo : Test Type: Mammalian erythrocyte micronucleus test (in vivo

cytogenetic assay) Species: Mouse

**Application Route: Ingestion** 

Result: negative

**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



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

Result: negative

Test Type: Alkaline elution assay

Result: negative

Genotoxicity in vivo : Test Type: Chromosomal aberration

Species: Rat

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

Test Type: Alkaline elution assay

Species: Rat

Application Route: Oral Result: negative

### Carcinogenicity

Not classified based on available information.

### Components:

### Cellulose:

Species : Rat
Application Route : Ingestion
Exposure time : 72 weeks
Result : negative

#### **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:

#### Cellulose:

Effects on fertility : Test Type: One-generation reproduction toxicity study

Species: Rat

Application Route: Ingestion

Result: negative

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

Species: Rat

Application Route: Ingestion



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Result: negative

**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 fetal development : 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 (Kidney, Liver, Gastrointestinal tract) through prolonged or repeated exposure if swallowed.

#### **Components:**

#### **Etoricoxib:**

Routes of exposure : Ingestion

Target Organs : Kidney, Liver, Gastrointestinal tract

Assessment : May cause damage to organs through prolonged or repeated

exposure.

### Repeated dose toxicity

# Components:

#### Cellulose:

Species : Rat

NOAEL : >= 9.000 mg/kg
Application Route : Ingestion
Exposure time : 90 Days

**Etoricoxib:** 

Species : Rat LOAEL : 30 mg/kg



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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.

### **Experience with human exposure**

### Components:

**Etoricoxib:** 

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

tension, Diarrhea, urinary tract infection, flu-like symptoms, heartburn, Nausea, bronchitis, Dizziness, asthenia, Rash, Back pain, Cough, Abdominal pain, pharyngitis, Edema

#### **SECTION 12. ECOLOGICAL INFORMATION**

### **Ecotoxicity**

# **Components:**

Cellulose:

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



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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-

ic toxicity)

NOEC (Daphnia magna (Water flea)): 0,75 mg/l

Exposure time: 21 d

Method: OECD Test Guideline 211

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

# Persistence and degradability

### **Components:**

Cellulose:

Biodegradability : Result: Readily biodegradable.

**Etoricoxib:** 

Biodegradability : Result: not rapidly degradable

Biodegradation: 0,2 % Exposure time: 28 d

### **Bioaccumulative potential**

### **Components:**

**Etoricoxib:** 

Partition coefficient: n-

octanol/water

log Pow: 2,3

Mobility in soil
No data available

Other adverse effects

No data available



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#### **SECTION 13. DISPOSAL CONSIDERATIONS**

Disposal methods

Waste from residues Dispose of in accordance with local regulations.

Empty containers should be taken to an approved waste Contaminated packaging

handling site for recycling or disposal.

If not otherwise specified: Dispose of as unused product.

#### **SECTION 14. TRANSPORT INFORMATION**

#### International Regulations

**UNRTDG** 

**UN** number **UN 3077** 

ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID, Proper shipping name

N.O.S.

(Etoricoxib)

Class 9 Ш Packing group Labels 9

**IATA-DGR** 

UN/ID No. UN 3077

Proper shipping name Environmentally hazardous substance, solid, n.o.s.

(Etoricoxib)

9 Class Ш Packing group

Miscellaneous Labels

Packing instruction (cargo 956

aircraft)

Packing instruction (passen-

ger aircraft)

956

Environmentally hazardous yes

**IMDG-Code** 

UN 3077 **UN** number

ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID, Proper shipping name

N.O.S.

(Etoricoxib)

Class 9 Packing group Ш Labels 9 EmS Code F-A, S-F yes Marine pollutant

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

Not applicable for product as supplied.

# **Domestic regulation**

**ANTT** 

**UN** number UN 3077

Proper shipping name ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID,

> N.O.S. (Etoricoxib)

Class 9



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Packing group Ш Labels 9 Hazard Identification Number 90

#### 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.

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

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

National List of Carcinogenic Agents for Humans -: Not applicable

(LINACH)

Brazil. List of chemicals controlled by the Federal

Police

: Not applicable

### International Regulations

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

**AICS** not determined

DSL not determined

**IECSC** not determined

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

#### **Further information**

**Data Sheet** 

Sources of key data used to compile the Material Safety

eChem Portal search results and European Chemicals Agency, http://echa.europa.eu/

Internal technical data, data from raw material SDSs, OECD

#### Full text of other abbreviations

**ACGIH** USA. ACGIH Threshold Limit Values (TLV)

ACGIH / TWA 8-hour, time-weighted average

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 con-



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centration; 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; 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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