Naproxen



SUPPLIER

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SYNONYMS

C14H14O3, CH3OC10H6CH(CH3)CO2H, "(+)-6-methoxy-alpha-methyl-2-naphthaleneacetic acid", "(S)-6-methoxy-alpha-methyl-2-naphthaleneacetic acid", "(-)-2-(methoxy-2-naphthyl)propionic acid", "D-2-(6-methoxy-2-naphthyl)propionic acid", CG-3117, Equiproxen, Floginax, MNPA, Naixan, Naprosine, Naprosyne, Naprux, Naxen, Naxyn, Proxen, RS-3540, Alganil, Aliviomas, Alprofen, Anaprox, Antalgin, Apranax, Artroxen, "Axer Alfa", Denaxpren, Dysmenalgit, Flogogin, Floxalin, Gibinap, Gibixen, Laraflex, Laser, Leniartril, Lundiran, Madaprox, Nafasol, Napren, Naprium, Naprius, Naprogesic, Naprokes, Naprorex, Naproval, Novonaprox, Numidan, Piproxen, Praxenol, Prexan, Primeral, Proxine, Rofanten, Sobronil, Synflex, Ticoflex, "analgesic/ antipyretic/ anti-inflammatory", NSAID, Inza



CANADIAN WHMIS SYMBOLS



EMERGENCY OVERVIEW RISK

Harmful if swallowed.

POTENTIAL HEALTH EFFECTS

ACUTE HEALTH EFFECTS

SWALLOWED

• Accidental ingestion of the material may be harmful; animal experiments indicate that ingestion of less than 150 gram may be fatal or may produce serious damage to the health of the individual.

Side-effects associated with naproxen include gastro-intestinal disturbance (such as bleeding or peptic ulcer), headache, dizziness, nervousness, vomiting, cramps, skin rash, itch, ringing in the ears, oedema, depression, drowsiness, sleeplessness and blurred vision and other eye reactions.

Meningitis and skin effects such as rash, blisters, hives, hair loss, erythema multiforme and Stevens-Johnson syndrome.

Non-steroidal anti-inflammatory drug (NSAID) overdose may produce nausea, vomiting, indigestion and upper abdominal pain.

Other effects may include drowsiness, dizziness, confusion, disorientation, lethargy, "pins and needles", intense headache, blurred vision, ringing in the ears, muscle twitching, convulsions, stupor and coma.

EYE

■ Although the material is not thought to be an irritant (as classified by EC Directives), direct contact with the eye may cause transient discomfort characterised by tearing or conjunctival redness (as with windburn).

Slight abrasive damage may also result.

SKIN

The material is not thought to be a skin irritant (as classified by EC Directives using animal models).

Abrasive damage however, may result from prolonged exposures.

- Skin contact with the material may damage the health of the individual; systemic effects may result following absorption.
- Open cuts, abraded or irritated skin should not be exposed to this material.
- Entry into the blood-stream, through, for example, cuts, abrasions or lesions, may produce systemic injury with harmful effects.
- Examine the skin prior to the use of the material and ensure that any external damage is suitably protected.

INHALED

The material is not thought to produce respiratory irritation (as classified by EC Directives using animal models).

Nevertheless inhalation of dusts, or fumes, especially for prolonged periods, may produce respiratory discomfort and occasionally, distress.

■ Inhalation of dusts, generated by the material during the course of normal handling, may be damaging to the health of the individual.

Persons with impaired respiratory function, airway diseases and conditions such as emphysema or chronic bronchitis, may incur further disability if excessive concentrations of particulate are inhaled.

If prior damage to the circulatory or nervous systems has occurred or if kidney damage has been sustained, proper screenings should be conducted on individuals who may be exposed to further risk if handling and use of the material result in excessive exposures.

CHRONIC HEALTH EFFECTS

• Substance accumulation, in the human body, may occur and may cause some concern following repeated or long-term occupational exposure.

There is some evidence from animal testing that exposure to this material may result in toxic effects to the unborn baby.

Abnormalities of liver-function tests, impairment of renal function, agranulocytosis and thrombocytopenia may be longer term manifestations of Naproxen exposure. Haemolytic and aplastic anaemia, neutropenia and decreases in haemoglobin and haematocrit may also occur.

Long term exposure to high dust concentrations may cause changes in lung function i.e. pneumoconiosis; caused by particles less than 0.5 micron penetrating and remaining in the lung. Prime symptom is breathlessness; lung shadows show on X-ray.

Prolonged use of non-steroidal analgesics damages the lining of the gastrointestinal tract, causing ulcers and bleeding. There may be diarrhoea or constipation, perforations causing serious infection, and blood in the vomit or stools. Kidney damage can result in blood or pus in the urine, changes in urine chemistry, change in the frequency of urination, insufficiency of kidney function, destruction of the kidney lining and kidney inflammation. Occasionally, the liver may be affected, causing inflammation (hepatitis) and jaundice. There may be changes in blood cell distribution, and disturbance in platelet function. Sensitivity to light may occur. Anaphylactic-like syndrome is characterised by rash with redness, spots and blisters, itching, and fainting. The eyes, ears and urinary tract can all be affected. Asthma and anaemia may be exacerbated. These drugs can cause circulatory defects in the foetus and newborn. Once the kidney has been damaged, there is an increased likelihood that cancers could develop there.

Exposure to the material for prolonged periods may cause physical defects in the developing embryo (teratogenesis).

Section 3 - COMPOSITION / INFORMATION ON INGREDIENTS						
NAME	CAS RN	%				
Naproxen	22204-53-1	>98				

Section 4 - FIRST AID MEASURES

SWALLOWED

- IF SWALLOWED, REFER FOR MEDICAL ATTENTION, WHERE POSSIBLE, WITHOUT DELAY.
- For advice, contact a Poisons Information Centre or a doctor.
- Urgent hospital treatment is likely to be needed.
- In the mean time, qualified first-aid personnel should treat the patient following observation and employing supportive measures as indicated by the patient's condition.

EYE

- If this product comes in contact with the eyes
- Wash out immediately with fresh running water.
- Ensure complete irrigation of the eye by keeping eyelids apart and away from eye and moving the eyelids by occasionally lifting the upper and lower lids.
- Seek medical attention without delay; if pain persists or recurs seek medical attention.
- Removal of contact lenses after an eye injury should only be undertaken by skilled personnel.

SKIN

If skin contact occurs

- Immediately remove all contaminated clothing, including footwear.
- Flush skin and hair with running water (and soap if available).
- Seek medical attention in event of irritation.

INHALED

- If fumes or combustion products are inhaled remove from contaminated area.
- Lay patient down. Keep warm and rested.
- Prostheses such as false teeth, which may block airway, should be removed, where possible, prior to initiating first aid procedures.
- Apply artificial respiration if not breathing, preferably with a demand valve resuscitator, bag-valve mask device, or pocket mask as trained. Perform CPR if necessary.

NOTES TO PHYSICIAN

Treat symptomatically.

- for non-steroidal anti-inflammatories (NSAIDs)
- Symptoms following acute NSAIDs overdoses are usually limited to lethargy, drowsiness, nausea, vomiting, and epigastric pain, which are generally reversible with supportive care. Gastrointestinal bleeding can occur. Hypertension, acute renal failure, respiratory depression, and coma may occur, but are rare. Anaphylactoid reactions have been reported with therapeutic ingestion of NSAIDs, and may occur following an overdose.
- Patients should be managed by symptomatic and supportive care following a NSAIDs overdose.
- There are no specific antidotes.
- Emesis and/or activated charcoal (60 to 100 grams in adults, 1 to 2 g/kg in children), and/or osmotic cathartic may be indicated in patients seen within 4 hours of ingestion with symptoms or following a large overdose (5 to 10 times the usual dose).

Section 5 - FIRE FIGHTING MEASURES						
Vapor Pressure (mmHG)	Negligible					
Upper Explosive Limit (%)	Not available.					
Specific Gravity (water=1)	Not available.					
Lower Explosive Limit (%)	Not available.					

EXTINGUISHING MEDIA

- Foam.
- Dry chemical powder.
- BCF (where regulations permit).
- Carbon dioxide.

FIRE FIGHTING

- Alert Fire Brigade and tell them location and nature of hazard.
- Wear full body protective clothing with breathing apparatus.

- Prevent, by any means available, spillage from entering drains or water course.
- Use fire fighting procedures suitable for surrounding area.

When any large container (including road and rail tankers) is involved in a fire, consider evacuation by 800 metres in all directions.

GENERAL FIRE HAZARDS/HAZARDOUS COMBUSTIBLE PRODUCTS

- Combustible solid which burns but propagates flame with difficulty; it is estimated that most organic dusts are combustible (circa 70%) according to the circumstances under which the combustion process occurs, such materials may cause fires and / or dust explosions.
- Avoid generating dust, particularly clouds of dust in a confined or unventilated space as dusts may form an explosive mixture with air, and any source of ignition, i.e. flame or spark, will cause fire or explosion. Dust clouds generated by the fine grinding of the solid are a particular hazard; accumulations of fine dust (420 micron or less) may burn rapidly and fiercely if ignited particles exceeding this limit will generally not form flammable dust clouds.; once initiated, however, larger particles up to 1400 microns diameter will contribute to the propagation of an explosion.
- In the same way as gases and vapors, dusts in the form of a cloud are only ignitable over a range of concentrations; in principle, the concepts of lower explosive limit (LEL) and upper explosive limit (UEL).are applicable to dust clouds but only the LEL is of practical use; this is because of the inherent difficulty of achieving homogeneous dust clouds at high temperatures (for dusts the LEL is often called the "Minimum Explosible Concentration", MEC)
- A dust explosion may release of large quantities of gaseous products; this in turn creates a subsequent pressure rise of explosive force capable of damaging plant and buildings and injuring people.

Combustion products include carbon monoxide (CO), carbon dioxide (CO2), other pyrolysis products typical of burning organic material. May emit poisonous fumes.

FIRE INCOMPATIBILITY

Avoid contamination with oxidizing agents i.e. nitrates, oxidizing acids, chlorine bleaches, pool chlorine etc. as ignition may result

Section 6 - ACCIDENTAL RELEASE MEASURES

MINOR SPILLS

- Clean up waste regularly and abnormal spills immediately.
- Avoid breathing dust and contact with skin and eyes.
- Wear protective clothing, gloves, safety glasses and dust respirator.
- Use dry clean up procedures and avoid generating dust.

MAJOR SPILLS

- Clear area of personnel and move upwind.
- Alert Fire Brigade and tell them location and nature of hazard.
- Wear full body protective clothing with breathing apparatus.
- Prevent, by any means available, spillage from entering drains or water course.

Section 7 - HANDLING AND STORAGE

PROCEDURE FOR HANDLING

- Avoid all personal contact, including inhalation.
- Wear protective clothing when risk of exposure occurs.
- Use in a well-ventilated area.
- Prevent concentration in hollows and sumps.

Empty containers may contain residual dust which has the potential to accumulate following settling. Such dusts may explode in the presence of an appropriate ignition source.

- Do NOT cut, drill, grind or weld such containers.
- In addition ensure such activity is not performed near full, partially empty or empty containers without appropriate workplace safety authorization or permit.

RECOMMENDED STORAGE METHODS

- Packaging as recommended by manufacturer.
- Check that containers are clearly labelled.
- Tamper-proof containers.
- Polyethylene or polypropylene containers.
- Glass container is suitable for laboratory quantities

For low viscosity materials

- Drums and jerricans must be of the non-removable head type.
- Where a can is to be used as an inner package, the can must have a screwed enclosure.

STORAGE REQUIREMENTS

- Store in original containers.
- Keep containers securely sealed.
- Store in a cool, dry, well-ventilated area.

- Store away from incompatible materials and foodstuff containers.Store at room temperature.

Section 8 - EXPOSURE CONTROLS / PERSONAL PROTECTION

EXPOSURE CONTROLS

Source	Material	TWA ppm	TWA mg/m³	STEL ppm	STEL mg/m³	Peak ppm	Peak mg/m³	TWA F/CC	Notes
Canada - Ontario Occupational Exposure Limits	Naproxen (Particles (Insoluble or Poorly Soluble) Not Otherwise)		10 (I)						
Canada - British Columbia Occupational Exposure Limits	Naproxen (Particles (Insoluble or Poorly Soluble) Not Otherwise Classified (PNOC))		10 (N)						
Canada - Ontario Occupational Exposure Limits	Naproxen (Specified (PNOS) / Particules (insolubles ou peu solubles) non précisées par ailleurs)		3 (R)						
US - Tennessee Occupational Exposure Limits - Limits For Air Contaminants	Naproxen (Particulates not otherwise regulated Respirable fraction)		5						
US - California Permissible Exposure Limits for Chemical Contaminants	Naproxen (Particulates not otherwise regulated Respirable fraction)		5						(n)
US - Oregon Permissible Exposure Limits (Z-1)	Naproxen (Particulates not otherwise regulated (PNOR) (f) Total Dust)	-	10						Bold print identifies substances for which the Oregon Permissible Exposure Limits (PELs) are different than the federal Limits. PNOR means "particles not otherwise regulated."
US - Michigan Exposure Limits for Air Contaminants	Naproxen (Particulates not otherwise regulated, Respirable dust)		5						

US - Oregon Permissible Exposure Limits (Z-1)	Naproxen (Particulates not otherwise regulated (PNOR) (f) Respirable Fraction)	5
	,	

US - Wyoming Toxic and Hazardous Substances Table Z1 Limits for Air Contaminants

5

Bold print identifies substances for which the Oregon Permissible Exposure Limits (PELs) are different than the federal Limits. PNOR means "particles not otherwise regulated."

PERSONAL PROTECTION



RESPIRATOR

• Particulate. (AS/NZS 1716 & 1715, EN 1432000 & 1492001, ANSI Z88 or national equivalent)

EYE

For laboratory, larger scale or bulk handling or where regular exposure in an occupational setting occurs

- Chemical goggles
- Face shield. Full face shield may be required for supplementary but never for primary protection of eyes
- Contact lenses may pose a special hazard; soft contact lenses may absorb and concentrate irritants. A written policy document, describing the wearing of lens or restrictions on use, should be created for each workplace or task. This should include a review of lens absorption and adsorption for the class of chemicals in use and an account of injury experience. Medical and first-aid personnel should be trained in their removal and suitable equipment should be readily available. In the event of chemical exposure, begin eye irrigation immediately and remove contact lens as soon as practicable. Lens should be removed at the first signs of eye redness or irritation lens should be removed in a clean environment only after workers have washed hands thoroughly. [CDC NIOSH Current Intelligence Bulletin 59], [AS/NZS 1336 or national equivalent]

HANDS/FEET

Suitability and durability of glove type is dependent on usage. Important factors in the selection of gloves include

- frequency and duration of contact,
- chemical resistance of glove material,
- glove thickness and
- dexterity
- Rubber gloves (nitrile or low-protein, powder-free latex). Employees allergic to latex gloves should use nitrile gloves in preference.
- Double gloving should be considered.
- PVC gloves.
- Protective shoe covers. [AS/NZS 2210]
- OTHER
- For quantities up to 500 grams a laboratory coat may be suitable.
- For quantities up to 1 kilogram a disposable laboratory coat or coverall of low permeability is recommended. Coveralls should be buttoned at collar and cuffs.
- For quantities over 1 kilogram and manufacturing operations, wear disposable coverall of low permeability and disposable shoe covers.
- For manufacturing operations, air-supplied full body suits may be required for the provision of advanced respiratory protection.

ENGINEERING CONTROLS

Enclosed local exhaust ventilation is required at points of dust, fume or vapor generation.

HEPA terminated local exhaust ventilation should be considered at point of generation of dust, fumes or vapors.

Barrier protection or laminar flow cabinets should be considered for laboratory scale handling.

When handling quantities up to 500 gram in either a standard laboratory with general dilution ventilation (e.g.

Section 9 - PHYSICAL AND CHEMICAL PROPERTIES

PHYSICAL PROPERTIES

Solid. Does not mix with water.			
State	Divided solid	Molecular Weight	230.26
Melting Range (°F)	315- 316	Viscosity	Not Applicable
Boiling Range (°F)	Not available.	Solubility in water (g/L)	Immiscible
Flash Point (°F)	Not available	pH (1% solution)	Not applicable
Decomposition Temp (°F)	Not Available	pH (as supplied)	Not applicable
Autoignition Temp (°F)	Not available.	Vapor Pressure (mmHG)	Negligible
Upper Explosive Limit (%)	Not available.	Specific Gravity (water=1)	Not available.
Lower Explosive Limit (%)	Not available.	Relative Vapor Density (air=1)	Not applicable
Volatile Component (%vol)	Negligible	Evaporation Rate	Not applicable

APPEARANCE

Odorless crystalline powder; does not mix well with water. Soluble in alcohol (125), chloroform (115), ether (140), methanol (120).

Section 10 - CHEMICAL STABILITY

CONDITIONS CONTRIBUTING TO INSTABILITY

- Presence of incompatible materials.
- Product is considered stable.
- Hazardous polymerization will not occur.

STORAGE INCOMPATIBILITY

• Avoid oxidizing agents, acids, acid chlorides, acid anhydrides, chloroformates. Avoid exposure to light and air.

For incompatible materials - refer to Section 7 - Handling and Storage.

Section 11 - TOXICOLOGICAL INFORMATION

Naproxen

TOXICITY AND IRRITATION

Exposure to the material for prolonged periods may cause physical defects in the developing embryo (teratogenesis).

CARCINOGEN

Naproxen US - Maine Chemicals of High Concern List

Carcinogen

Section 12 - ECOLOGICAL INFORMATION

This material and its container must be disposed of as hazardous waste.

Ecotoxicity

Ingredient					Pe Wa	rsisteno ater/Soi	ce: I		Persiste	nce: Air		Bioaco	cumulati	ion	Mob	ility	
Naproxen					HIC	GH			No Data	Availat	ole	LOW			MED)	
GESAMP/EHS COMPOSITE LIST - GESAMP Hazard Profiles																	
Name / EHS Cas No / RTECS	TRN	A1a	A1b	A1	A2	B1	B2	C1	C2	C3	D1	D2	D3	E1	E2	E3	

Poly(2+)cyclic aromati cs / CAS:222 04- 53- 1 /	224 6	574	4	4	NR	(4)	NI	(1)	(1)	(2)	(1)	(1)	СМ	S	3

Legend: EHS=EHS Number (EHS=GESAMP Working Group on the Evaluation of the Hazards of Harmful Substances Carried by Ships) NRT=Net Register Tonnage, A1a=Bioaccumulation log Pow, A1b=Bioaccumulation BCF, A1=Bioaccumulation, A2=Biodegradation, B1=Acuteaquatic toxicity LC/ECIC50 (mg/l), B2=Chronic aquatic toxicity NOEC (mg/l), C1=Acute mammalian oral toxicity LD50 (mg/kg), C2=Acutemammalian dermal toxicity LD50 (mg/kg), C3=Acute mammalian inhalation toxicity LC50 (mg/kg), D1=Skin irritation & corrosion, D2=Eye irritation& corrosion, D3=Long-term health effects, E1=Tainting, E2=Physical effects on wildlife & benthic habitats, E3=Interference with coastal amenities, For column A2: R=Readily biodegradable, NR=Not readily biodegradable. For column D3: C=Carcinogen, M=Mutagenic, R=Reprotoxic, S=Sensitizing, A=Aspiration hazard, T=Target organ systemic toxicity, L=Lunginjury, N=Neurotoxic, I=Immunotoxic. For column E1: NT=Not tainting (tested), T=Tainting test positive. For column E2: Fp=Persistent floater, F=Floater, S=Sinking substances. The numerical scales start from 0 (no hazard), while higher numbers reflect increasing hazard. (GESAMP/EHS Composite List of Hazard Profiles - Hazard evaluation of substances transported by ships)

Section 13 - DISPOSAL CONSIDERATIONS

Disposal Instructions

All waste must be handled in accordance with local, state and federal regulations.

- Containers may still present a chemical hazard/ danger when empty.
- Return to supplier for reuse/ recycling if possible.

Otherwise:

No

 If container can not be cleaned sufficiently well to ensure that residuals do not remain or if the container cannot be used to store the same product, then puncture containers, to prevent re-use, and bury at an authorized landfill.

• Where possible retain label warnings and MSDS and observe all notices pertaining to the product.

Legislation addressing waste disposal requirements may differ by country, state and/ or territory. Each user must refer to laws operating in their area. In some areas, certain wastes must be tracked.

- A Hierarchy of Controls seems to be common the user should investigate:
- Reduction
- Reuse
- Recycling
- Disposal (if all else fails)

This material may be recycled if unused, or if it has not been contaminated so as to make it unsuitable for its intended use. Shelf life considerations should also be applied in making decisions of this type. Note that properties of a material may change in use, and recycling or reuse may not always be appropriate. In most instances the supplier of the material should be consulted.

- DO NOT allow wash water from cleaning or process equipment to enter drains.
- It may be necessary to collect all wash water for treatment before disposal.
- In all cases disposal to sewer may be subject to local laws and regulations and these should be considered first.
- Where in doubt contact the responsible authority.
- Recycle wherever possible.
- Consult manufacturer for recycling options or consult local or regional waste management authority for disposal if no suitable treatment or disposal facility can be identified.
- Dispose of by: burial in a land-fill specifically licenced to accept chemical and / or pharmaceutical wastes or Incineration in a licenced apparatus (after admixture with suitable combustible material)
- Decontaminate empty containers. Observe all label safeguards until containers are cleaned and destroyed.

Section 14 - TRANSPORTATION INFORMATION

DOT:			
Symbols:	None	Hazard class or Division:	6.1
Identification Numbers:	UN3249	PG:	III
Label Codes:	6.1	Special provisions:	T1, TP33
Packaging: Exceptions:	153	Packaging: Non-bulk:	213
Packaging: Exceptions:	153	Quantity limitations: Passenger aircraft/rail:	5 kg

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Quantity Limitations: Cargo aircraft only:	5 kg	Vessel stowage: Location:	С					
Vessel stowage: Other:	40							
Hazardous materials descriptions Medicine, solid, toxic, n.o.s. Air Transport IATA:	and proper shipping names:							
ICAO/IATA Class:	6.1	ICAO/IATA Subrisk:	None					
UN/ID Number:	3249	Packing Group:	III					
Special provisions:	A3							
Cargo Only								
Packing Instructions:	677	Maximum Qty/Pack:	200 kg					
Passenger and Cargo		Passenger and Cargo						
Packing Instructions:	670	Maximum Qty/Pack:	100 kg					
Passenger and Cargo Limited Quantity		Passenger and Cargo Limited Quantity						
Packing Instructions:	Y645	Maximum Qty/Pack:	5 kg					
Shipping name:MEDICINE, SOLII Maritime Transport IMDG:	Shipping name:MEDICINE, SOLID, TOXIC, N.O.S.(contains Naproxen) Maritime Transport IMDG:							
IMDG Class:	6.1	IMDG Subrisk:	None					
UN Number:	3249	Packing Group:	III					
EMS Number:	F-A,S-A	Special provisions:	221 223					
Limited Quantities:	5 ka							

Shipping name: MEDICINE, SOLID, TOXIC, N.O.S. (contains Naproxen)

Section 15 - REGULATORY INFORMATION

Naproxen (CAS: 22204-53-1) is found on the following regulatory lists;

"Canada Domestic Substances List (DSL)","Canada Substances In Products Regulated Under the Food and Drugs Act (F&DA) That Were In Commerce In Canada Between January 1, 1984 and December 31, 1986 (English)"

Section 16 - OTHER INFORMATION

LIMITED EVIDENCE

- Inhalation and/or skin contact may produce health damage*.
- Cumulative effects may result following exposure*.
- May be harmful to the foetus/embryo*.
- * (limited evidence).

Denmark Advisory list for selfclassification of dangerous substances

Substance	CAS	Suggested codes
Naproxen	22204- 53- 1	Xn; R22

Classification of the preparation and its individual components has drawn on official and authoritative sources as well as independent review by the Chemwatch Classification committee using available literature references. A list of reference resources used to assist the committee may be found at:

www.chemwatch.net/references.

■ The (M)SDS is a Hazard Communication tool and should be used to assist in the Risk Assessment. Many factors determine whether the reported Hazards are Risks in the workplace or other settings.

■ For detailed advice on Personal Protective Equipment, refer to the following U.S. Regulations and Standards: OSHA Standards - 29 CFR:

1910.132 - Personal Protective Equipment - General requirements

1910.133 - Eye and face protection

1910.134 - Respiratory Protection

1910.136 - Occupational foot protection

1910.138 - Hand Protection

Eye and face protection - ANSI Z87.1 Foot protection - ANSI Z41 Respirators must be NIOSH approved.

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