

SAFETY DATA SHEET

according to Regulation (EC) No. 1907/2006

 Version: 3.0
 Revision Date 15.10.2012

Print Date 16.10.2012

ONSIOR 20 MG/ML INJ

SECTION 1: IDENTIFICATION OF THE SUBSTANCE/MIXTURE AND OF THE COMPANY/UNDERTAKING

1.1 Product identifiers

Substance No. : 000070002496
 NAH Substance Code : A-20053 B
 Trade name : ROBENACOXIB LIVI 400MG/20ML
 : ONSIOR 20 MG/ML INJ
 Product name : ROBENACOXIB 2.0 % IJL
 : CGS 34975 2.0 % IJL
 Type of preparation : Solution for injection

1.2 Relevant identified uses of the substance or mixture and uses advised against

Use : Veterinary medicinal product

1.3 Details of the supplier of the safety data sheet

Company : Novartis Animal Health Inc.
 : Schwarzwaldallee 215
 : CH - 4058 Basel
 : Switzerland

 Telephone : +41616971111
 Contact person : Phone (office hours) +41 61 697 30 65
 E-mail address : msds.nah@novartis.com

1.4 Emergency telephone number

Emergency telephone number : **Phone (24 h) +41 61 696 33 33**

Emergency information : concerning transport see emergency phone number in the shipping documents
 : concerning storage see emergency phone number of local Novartis organization

SECTION 2: HAZARDS IDENTIFICATION

2.1 Classification of the substance or mixture

Classification according to Regulation (EC) No 1272/2008.

Classification according to EU Directives 67/548/EEC or 1999/45/EC

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2.2 Label elements

Labelling according to Regulation (EC) No. 1907/2006

Labelling according to EC Directives 67/548/EEC or 1999/45/EC

Symbol(s) : --- classification not required
 : The product is not subject of Directive 1999/45 EEC.

SECTION 3: COMPOSITION/INFORMATION ON INGREDIENTS

Hazardous components

Identification	CAS-No.	Classification 67/548/EEC	Classification REGULATION (EC) No 1272/2008		Concentration (% w/w)
Robenacoxib	220991-32-2	Xn, N R63 R51/53			1.90
Ethanol	64-17-5	F R11	Flam. Liq. 2	H225	>= 10.00 - 12.00 <=

For the full text of the R-phrases mentioned in this Section, see Section 16.
 For the full text of the H-Statements mentioned in this Section, see Section 16.

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ONSIOR 20 MG/ML INJ**SECTION 4: FIRST AID MEASURES****4.1 Description of first aid measures**

- General advice : When symptoms persist or in all cases of doubt seek medical advice.
- Inhalation : Move to fresh air.
- Skin contact : Wash off with soap and plenty of water.
- Eye contact : Rinse immediately with plenty of water for at least 15 minutes.
- Ingestion : Clean mouth with water and drink afterwards plenty of water. Next administer a large quantity of medicinal charcoal in plenty of water. ATTENTION : Never give anything by mouth to an unconscious person.

4.2 Most important symptoms/effects, acute and delayed

- Poisoning Symptoms : No information available.

4.3 Indication of any immediate medical attention and special treatment needed

- Antidote : No specific antidote is known! Apply symptomatic therapy.

SECTION 5: FIREFIGHTING MEASURES**5.1 Extinguishing media**

- Suitable extinguishing media : Dry powder, foam, carbon dioxide (CO₂) or water spray (do not use water jet).

5.2 Special hazards arising from the substance or mixture

- Hazardous decomposition products : yes

5.3 Advice for firefighters

- Special protective equipment for firefighters : In the event of fire, wear self-contained breathing apparatus.
- Further information : Collect contaminated fire extinguishing water separately. This must not be discharged into drains.

SECTION 6: ACCIDENTAL RELEASE MEASURES**6.1 Personal precautions, protective equipment and emergency procedures****6.2 Environmental precautions****6.3 Methods and materials for containment and cleaning up**

- Methods for cleaning up : Refer to protective measures listed in sections 7 and 8.
Soak up with inert absorbent material (e.g. sand, silica gel, acid binder, universal binder, sawdust).
Pick up and transfer to properly labelled containers.
Dispose of in an incinerator approved for chemicals.
Treat contaminated surfaces with water.
Spilled product cannot be used further and must be disposed of.
If safe disposal is not possible, contact the manufacturer, the dealer or the local representative.
- Additional advice : No hazards to be specially mentioned.

SECTION 7: HANDLING AND STORAGE**7.1 Precautions for safe handling**

- Safe handling advice : Handle in accordance with good industrial hygiene and safety practice.
Avoid contact with skin, eyes and clothing.

Storage

- Place of storage : Store in a refrigerator.

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- Advice on common storage : Keep away from food, drink and animal feedingstuffs.
- Novartis storage class : 20.1
- Storage temperature: : min. 2 °C - max. 8 °C
- Other data : Store the product in closed original containers.
Protect from light.

SECTION 8: EXPOSURE CONTROLS/PERSONAL PROTECTION

8.1 Control parameters

8.2 Exposure controls

Personal protective equipment

Open handling

- Respiratory protection : No personal respiratory protective equipment normally required.
- Hand protection : Impervious gloves
- Eye protection : Safety glasses
- Skin and body protection : protective suit
impervious clothing
- Hygiene measures : Shower or bathe at the end of working.
Change clothing.
Thoroughly clean contaminated equipment with soap or soda solution.
Thoroughly clean protective gear.

SECTION 9: PHYSICAL AND CHEMICAL PROPERTIES

9.1 Information on basic physical and chemical properties

- Physical state : liquid
- Form : clear solution
- Colour : colourless - slightly coloured
- Density : 1.06 g/ml
- pH : 7.4 - 8.4
- Flash point : Remarks: no data available
- : Remarks: Solution contains >40% water.
- Solubility(ies) : Water soluble
- Flammability : Solution contains >40% water.

SECTION 10: STABILITY AND REACTIVITY

10.1 Reactivity

10.2 Chemical stability

- Chemical Stability : Stable under normal conditions.

10.3 Possibility of hazardous reactions

10.4 Conditions to avoid

10.5 Incompatible materials

10.6 Hazardous decomposition products

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ONSIOR 20 MG/ML INJ**SECTION 11: TOXICOLOGICAL INFORMATION****11.1 Information on toxicological effects**

- Acute oral toxicity : LD50 > 2,000 mg/kg
Species: Rat
Remarks: Derived from the active ingredient(s)
- Skin irritation : No skin irritation
Species: rabbit
Remarks: Derived from the active ingredient(s)
- Sensitisation : not sensitizing
Species: guinea pig
Remarks: Derived from the active ingredient(s)
- Mutagenicity (in vitro) : negative
Remarks: Derived from the active ingredient(s)
- Mutagenicity (in vivo) : negative
Remarks: Derived from the active ingredient(s)
- Mutagenicity : Did not show mutagenic effects in animal experiments.

SECTION 12: ECOLOGICAL INFORMATION**12.1 Toxicity**

- Toxicity to daphnia : EC50 > 100 mg/l
Species: Daphnia
Exposure time: 48 h
Remarks: Derived from the active ingredient(s)
- Toxicity to algae : EBC50 > 100 mg/l
Species: Selenastrum capricornutum (green algae)
Exposure time: 72 h
Remarks: Derived from the active ingredient(s)
- ERC50 > 100 mg/l
Species: Selenastrum capricornutum (green algae)
Exposure time: 72 h
Remarks: Derived from the active ingredient(s)
- Toxicity to microorganisms : EC50 > 100 mg/l
Species: act.sewage sludge
Exposure time: 3 h
Remarks: Derived from the active ingredient(s)

12.2 Persistence and degradability

- Biodegradability : Not readily biodegradable.
Remarks: Derived from the active ingredient(s)

SECTION 13: DISPOSAL CONSIDERATIONS**13.1 Waste treatment methods**

- Product : Refer to protective measures listed in sections 7 and 8. Collect product and dispose of in an incinerator approved for chemicals. Spilled product cannot be used further and must be disposed of. If safe disposal is not possible, contact the manufacturer, the dealer or the local representative.
- Contaminated packaging : Dispose of empty containers in an incinerator approved for chemicals.

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SECTION 14: TRANSPORT INFORMATION

Transport Condition	:	COOL: refrigerated transport at 2-8°C Do not freeze.
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Land transport (ADR/RID)

UN number	:	FREE
Class	:	Not classified as dangerous good

Sea transport (IMDG)

UN number	:	FREE
Class	:	Not classified as dangerous good

Air transport (ICAO/IATA)

UN number	:	FREE
Class	:	Not classified as dangerous good

Postal delivery - Switzerland	:	1 allowed
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SECTION 15: REGULATORY INFORMATION

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

National legislation

Weight limit (Switzerland - StFV)	:	200,000 kg
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Swiss Fire Prevention Code	:	F3 L
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15.2 Chemical Safety Assessment

SECTION 16: OTHER INFORMATION

Full text of R-phrases referred to under sections 2 and 3	
Full text of H-Statements referred to under sections 2 and 3.	
R63	: Possible risk of harm to the unborn child.
R51/53	: Toxic to aquatic organisms, may cause long-term adverse effects in the aquatic environment.
R11	: Highly flammable.
H225	: Highly flammable liquid and vapour.

Changes since the last version are highlighted in the margin. This version replaces all previous versions.

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 given is designed only as a guidance for safe handling, use, processing, storage, transportation, disposal and release and is not to be considered a warranty or quality specification. The information relates only to the specific material designated and may not be valid for such material used in combination with any other materials or in any process, unless specified in the text.