

# SAFETY DATA SHEET

according to Regulation (EC) No. 1907/2006

Version: 3.0

Revision Date 28.03.2012

Print Date 29.03.2012

## ATOPICA CAT Solution

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

#### 1.1 Product identifiers

Substance No. : 000070003169  
 NAH Substance Code : A-12211 A  
 Trade name : ATOPLUS 100 MG/ML SOL  
                   : ATOPICA CAT Solution  
                   : NEORAL 100 MG/ML SOL  
                   : ATOPICA 100 MG/ML SOL  
 Type of preparation : Solution vet. use  
 Active ingredient : CGA 116231 B; Ciclosporin A

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

Use : Veterinary Product / Treatment of atopic dermatitis

#### 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 not required The product is not subject of the Regulation (EC) No. 1272/2008.	
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##### Classification according to EU Directives 67/548/EEC or 1999/45/EC

classification not required The product is not subject of Directive 1999/45 EEC.	
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#### 2.2 Label elements

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

Hazard pictograms : not required  
   The product is not subject of the Regulation (EC) No. 1272/2008.

##### 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.

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### SECTION 3: COMPOSITION/INFORMATION ON INGREDIENTS

#### Substances/Mixtures

#### Hazardous components

Identification	CAS-No.	Classification 67/548/EEC	Classification REGULATION (EC) No 1272/2008	Concentration (% w/w)
Cyclosporin	59865-13-3	Xn R40	Acute Tox. 4 Carc.Cat.2 Aquatic Acute 3 Aquatic Chronic 3	10.70
Ethanol	64-17-5	F R11	Flam. Liq. 2	< 10.00

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.

### 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 (show the label where possible).
- Inhalation : Move to fresh air.
- Skin contact : Wash off immediately with soap and plenty of water while removing all contaminated clothes and shoes.
- Eye contact : Rinse immediately with plenty of water and seek medical advice.
- Ingestion : If swallowed, seek medical advice immediately and show this container or label.

#### 4.2 Most important symptoms/effects, acute and delayed

- Poisoning Symptoms : Kidney injury may occur.  
Gastrointestinal disturbance

#### 4.3 Indication of any immediate medical attention and special treatment needed

- Antidote : Apply symptomatic therapy.

### SECTION 5: FIREFIGHTING MEASURES

#### 5.1 Extinguishing media

- Suitable extinguishing media : Dry powder, foam, carbon dioxide (CO<sub>2</sub>) or water spray (do not use water jet).

#### 5.2 Special hazards arising from the substance or mixture

- Hazardous decomposition products : No information available.

#### 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

- Personal precautions : Refer to protective measures listed in sections 7 and 8.

#### 6.2 Environmental precautions

- Environmental precautions : Remove all sources of ignition.

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### 6.3 Methods and materials for containment and cleaning up

- Methods for cleaning up :
- Soak up with inert absorbent material (e.g. sand, silica gel, acid binder, universal binder, sawdust).
  - Pick up and transfer to properly labelled containers.
  - Treat contaminated surfaces with water.
  - Put washing water in containers too, to avoid any contamination of surface and ground water, water supplies and drains. Hose down the area for a prolonged period. Heavily contaminated soil layers have to be dug out.
  - 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.

## SECTION 7: HANDLING AND STORAGE

### 7.1 Precautions for safe handling

- Safe handling advice :
- Avoid exposure - obtain special instructions before use.
  - Do not breathe vapours or spray mist.
  - Handle in accordance with good industrial hygiene and safety practice.
  - Wash hands after handling.
- :
- In addition to the measures taken usually in the chemical works like splashproof filling and measuring equipment (including vapour stripping) further personal protection measures may have to be implemented to avoid possible contact with the product.

#### Storage

- Advice on common storage :
- Keep away from food, drink and animal feedingstuffs.

- Novartis storage class :
- 20.1

**||** Storage temperature: : min. 20 °C - max. 30 °C

- Other data :
- Store the product in closed original containers.
  - Protect from light.

## SECTION 8: EXPOSURE CONTROLS/PERSONAL PROTECTION

### 8.1 Control parameters

Components with workplace control parameters			
Identification	CAS-No.	Notes	Exposure limit(s)
Cyclosporin	59865-13-3	Novartis Internal Exposure Limit (NPIEL) Highly hazardous substance	0.0175 mg/m <sup>3</sup>
Ethanol	64-17-5	A health risk of teratogenic effects can be excluded, if there is compliance with the TLV.	Max. exposure level at working place (MAK SUVA (TLV)): 500 ppm    960 mg/m <sup>3</sup>
			Short time exposure limit (STEL SUVA): 1,000 ppm    1,960 mg/m <sup>3</sup>

### 8.2 Exposure controls

- Protective measures :
- In working with or around this product precautionary measures should be taken according to workplace health risk assessments and local policies.
  - The use of technical measures should always have priority over the use of personal protective equipment.
- Open handling
- Hand protection :
- Protective gloves complying with EN 374.
- Eye protection :
- Safety glasses (EN166)
- Hygiene measures :
- Wash hands and face before breaks and immediately after handling the product.
  - Shower or bathe at the end of working.
  - Change clothing.
  - Thoroughly clean contaminated equipment with soap or soda solution.
  - Thoroughly clean protective gear.

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### SECTION 9: PHYSICAL AND CHEMICAL PROPERTIES

#### 9.1 Information on basic physical and chemical properties

Physical state	:	liquid
Form	:	clear solution
Colour	:	yellowish - yellow brown
Density	:	0.995 g/ml at 20 °C
Flash point	:	24 °C Test type: Abel-Pensky c.c. at 975 mbar
Solubility(ies)	:	miscible Water

### SECTION 10: STABILITY AND REACTIVITY

#### 10.1 Reactivity

Reactivity : no data available

#### 10.2 Chemical stability

Chemical Stability : Stable under normal conditions.

#### 10.3 Possibility of hazardous reactions

Hazardous reactions : No dangerous reaction known under conditions of normal use.

#### 10.4 Conditions to avoid

Conditions to avoid : Heat, flames and sparks.  
: Keep away from heat and sources of ignition.

#### 10.5 Incompatible materials

Materials to avoid : no data available

#### 10.6 Hazardous decomposition products

Hazardous decomposition products : no data available

### 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	:	Classification: No skin irritation Remarks: Derived from the active ingredient(s)
Mutagenicity (in vitro)	:	not mutagenic Remarks: Derived from the active ingredient(s)

### SECTION 12: ECOLOGICAL INFORMATION

#### 12.1 Toxicity

Toxicity to fish	:	LC50 > 100 mg/l Species: Oncorhynchus mykiss (rainbow trout) Remarks: Derived from the active ingredient(s)
Toxicity to daphnia	:	EC50 > 100 mg/l Species: Daphnia Remarks: Derived from the active ingredient(s)
Toxicity to algae	:	IC50 > 100 mg/l Species: Scenedesmus subspicatus (green algae) Remarks: Derived from the active ingredient(s)

#### 12.2 Persistence and degradability

Biodegradability : readily biodegradable  
Remarks: Derived from the active ingredient(s)

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### SECTION 13: DISPOSAL CONSIDERATIONS

#### 13.1 Waste treatment methods

- Product : Refer to protective measures listed in sections 7 and 8. 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. Check possibilities of recycling large empty containers, drums and barrels. Damaged Containers: Place original containers in specially marked larger ones.

### SECTION 14: TRANSPORT INFORMATION

**Transport Condition** : **SPECIAL: Transport + intermediate storage 15 - 30°C**

#### Land transport (ADR/RID)

- UN number : 1293  
 Class : 3  
 Packaging group : III  
 Labelling No. : 3  
 Hazard identification No : 30  
 CEFIC No. : 30GF1-III  
 Proper shipping name : Tinctures, medicinal

#### Sea transport (IMDG)

- UN number : 1293  
 Class : 3  
 Packaging group : III  
 Labelling No. : 3  
 Marine pollutant : no  
 Proper shipping name : Tinctures, medicinal

#### Air transport (ICAO/IATA)

- UN number : 1293  
 Class : 3  
 Packaging group : III  
 Labelling No. : 3  
 Proper shipping name : Tinctures, medicinal

### SECTION 15: REGULATORY INFORMATION

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

##### National legislation

Weight limit (Switzerland - StFV) : 20,000 kg

#### 15.2 Chemical Safety Assessment

: not necessary

### SECTION 16: OTHER INFORMATION

Text of R-phrases mentioned in Section 3	
R40	: Limited evidence of a carcinogenic effect.
R11	: Highly flammable.
H302	: Harmful if swallowed.
H351	: Suspected of causing cancer.
H402	: Harmful to aquatic life.
H412	: Harmful to aquatic life with long lasting effects.
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.