

SAFETY DATA SHEET

Nurofen Zavance caplets



HEALTH • HYGIENE • HOME

1. Identification of the material and supplier

Names

Product name : Nurofen Sodium Ibuprofen 256mg caplets

SDS no. : D0167833 v3.2

Formulation # : 0161573 v4.0

Supplier

: AUSTRALIA
Reckitt Benckiser (Australia) Pty Limited
ABN: 17 003 274 655
680 George Street, Sydney NSW 2000
Tel: +61 (0)2 9857 2000

NEW ZEALAND
Reckitt Benckiser (New Zealand) Limited
2 Fred Thomas Drive, Takapuna,
Auckland, New Zealand 0622
Tel: +64 9 484 1400

Poison Information contact: : Australia - 13 11 26
New Zealand - 0800 764 766 or 0800 POISON

Material uses : Self- medication for pain relief.

Product use : Consumer

Section 2. Hazard(s) identification

This safety data sheet refers to Workplace Health and Safety hazards only. For consumer use, always read the product label and seek advice from your healthcare professional.

Classification of the substance or mixture : ACUTE TOXICITY (oral) - Category 4
SERIOUS EYE DAMAGE/EYE IRRITATION - Category 2A
SPECIFIC TARGET ORGAN TOXICITY - SINGLE EXPOSURE (Respiratory tract irritation) - Category 3

GHS label elements

Hazard pictograms :



Signal word : **WARNING**

Hazard statements : **Harmful if swallowed.**
Causes serious eye irritation.
May cause respiratory irritation.

Precautionary statements

General : Read label before use. Keep out of reach of children. If medical advice is needed, have product container or label at hand.

Prevention : Wear eye or face protection. Use only outdoors or in a well-ventilated area. Avoid breathing dust. Do not eat, drink or smoke when using this product. Wash hands thoroughly after handling.

Section 2. Hazard(s) identification

- Response** : IF INHALED: Remove victim to fresh air and keep at rest in a position comfortable for breathing. Call a POISON CENTER or physician if you feel unwell. IF SWALLOWED: Call a POISON CENTER or physician if you feel unwell. Rinse mouth. IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. If eye irritation persists: Get medical attention.
- Storage** : Store locked up.
- Disposal** : Dispose of contents and container in accordance with all local, regional, national and international regulations.
- Supplemental label elements** : Not applicable.

Other hazards which do not result in classification : None known.

Section 3. Composition and ingredient information

Substance/mixture : Mixture

| Ingredient name | % (w/w) | CAS number |
|--------------------------------------|-----------|------------|
| ibuprofen | ≥30 - ≤60 | 15687-27-1 |
| sucrose | ≥10 - ≤30 | 57-50-1 |
| Cellulose | ≤10 | 9004-34-6 |
| Talc , containing asbestiform fibres | ≤10 | 14807-96-6 |
| magnesium distearate | ≤3 | 557-04-0 |

Other Non-hazardous ingredients to 100%

Occupational exposure limits, if available, are listed in Section 8.

Section 4. First aid measures

Description of necessary first aid measures

- Eye contact** : Immediately flush eyes with plenty of water, occasionally lifting the upper and lower eyelids. Check for and remove any contact lenses. Continue to rinse for at least 10 minutes. Get medical attention.
- Inhalation** : Remove victim to fresh air and keep at rest in a position comfortable for breathing. If it is suspected that fumes are still present, the rescuer should wear an appropriate mask or self-contained breathing apparatus. If not breathing, if breathing is irregular or if respiratory arrest occurs, provide artificial respiration or oxygen by trained personnel. It may be dangerous to the person providing aid to give mouth-to-mouth resuscitation. Get medical attention. If necessary, call a poison center or physician. If unconscious, place in recovery position and get medical attention immediately. Maintain an open airway. Loosen tight clothing such as a collar, tie, belt or waistband.
- Skin contact** : Flush contaminated skin with plenty of water. Remove contaminated clothing and shoes. Get medical attention if symptoms occur. Wash clothing before reuse. Clean shoes thoroughly before reuse.
- Ingestion** : Wash out mouth with water. Remove dentures if any. Remove victim to fresh air and keep at rest in a position comfortable for breathing. If material has been swallowed and the exposed person is conscious, give small quantities of water to drink. Stop if the exposed person feels sick as vomiting may be dangerous. Do not induce vomiting unless directed to do so by medical personnel. If vomiting occurs, the head should be kept low so that vomit does not enter the lungs. Get medical attention. If necessary, call a poison center or physician. Never give anything by mouth to an unconscious person. If unconscious, place in recovery position and get medical attention immediately. Maintain an open airway. Loosen tight clothing such as a collar, tie, belt or waistband.

Section 4. First aid measures

Most important symptoms/effects, acute and delayed

Potential acute health effects

- Eye contact** : Causes serious eye irritation.
- Inhalation** : May cause respiratory irritation.
- Skin contact** : No known significant effects or critical hazards.
- Ingestion** : Harmful if swallowed.

Over-exposure signs/symptoms

- Eye contact** : Adverse symptoms may include the following:
pain or irritation
watering
redness
- Inhalation** : Adverse symptoms may include the following:
respiratory tract irritation
coughing
- Skin contact** : No specific data.
- Ingestion** : No specific data.

Indication of immediate medical attention and special treatment needed, if necessary

- Notes to physician** : Treat symptomatically. Contact poison treatment specialist immediately if large quantities have been ingested or inhaled.
- Specific treatments** : No specific treatment.
- Protection of first-aiders** : No action shall be taken involving any personal risk or without suitable training. If it is suspected that fumes are still present, the rescuer should wear an appropriate mask or self-contained breathing apparatus. It may be dangerous to the person providing aid to give mouth-to-mouth resuscitation.

See toxicological information (Section 11)

Section 5. Firefighting measures

Extinguishing media

- Suitable extinguishing media** : Use an extinguishing agent suitable for the surrounding fire.
- Unsuitable extinguishing media** : None known.

Specific hazards arising from the chemical : No specific fire or explosion hazard.

- Hazardous thermal decomposition products** : Decomposition products may include the following materials:
carbon dioxide
carbon monoxide
metal oxide/oxides

Special protective actions for fire-fighters : Promptly isolate the scene by removing all persons from the vicinity of the incident if there is a fire. No action shall be taken involving any personal risk or without suitable training.

Special protective equipment for fire-fighters : Fire-fighters should wear appropriate protective equipment and self-contained breathing apparatus (SCBA) with a full face-piece operated in positive pressure mode.

Section 6. Accidental release measures

Personal precautions, protective equipment and emergency procedures

- For non-emergency personnel** : No action shall be taken involving any personal risk or without suitable training. Evacuate surrounding areas. Keep unnecessary and unprotected personnel from entering. Do not touch or walk through spilled material. Provide adequate ventilation. Wear appropriate respirator when ventilation is inadequate. Put on appropriate personal protective equipment.
- For emergency responders** : If specialised clothing is required to deal with the spillage, take note of any information in Section 8 on suitable and unsuitable materials. See also the information in "For non-emergency personnel".

- Environmental precautions** : Avoid dispersal of spilled material and runoff and contact with soil, waterways, drains and sewers. Inform the relevant authorities if the product has caused environmental pollution (sewers, waterways, soil or air).

Methods and material for containment and cleaning up

- Small spill** : Move containers from spill area. Avoid dust generation. Using a vacuum with HEPA filter will reduce dust dispersal. Place spilled material in a designated, labeled waste container. Dispose of via a licensed waste disposal contractor.
- Large spill** : Move containers from spill area. Approach the release from upwind. Prevent entry into sewers, water courses, basements or confined areas. Avoid dust generation. Do not dry sweep. Vacuum dust with equipment fitted with a HEPA filter and place in a closed, labeled waste container. Dispose of via a licensed waste disposal contractor. Note: see Section 1 for emergency contact information and Section 13 for waste disposal.

See Section 1 for emergency contact information.

See Section 8 for information on appropriate personal protective equipment.

See Section 13 for additional waste treatment information.

Section 7. Handling and storage

Precautions for safe handling

- Protective measures** : Put on appropriate personal protective equipment (see Section 8). Do not ingest. Avoid contact with eyes, skin and clothing. Use only with adequate ventilation. Wear appropriate respirator when ventilation is inadequate. Keep in the original container or an approved alternative made from a compatible material, kept tightly closed when not in use. Empty containers retain product residue and can be hazardous. Do not reuse container.

- Advice on general occupational hygiene** : Eating, drinking and smoking should be prohibited in areas where this material is handled, stored and processed. Workers should wash hands and face before eating, drinking and smoking. Remove contaminated clothing and protective equipment before entering eating areas. See also Section 8 for additional information on hygiene measures.

- Conditions for safe storage, including any incompatibilities** : Do not store above the following temperature: 25°C (77°F). Store in accordance with local regulations. Store in original container protected from direct sunlight in a dry, cool and well-ventilated area, away from incompatible materials (see Section 10) and food and drink. Store locked up. Keep container tightly closed and sealed until ready for use. Containers that have been opened must be carefully resealed and kept upright to prevent leakage. Do not store in unlabelled containers. Use appropriate containment to avoid environmental contamination.

Long term average storage temperature should not exceed 25°C .

The following requirements are in place for shipping and distribution (they may be different to those on the pack which provide guidance for long term storage by the consumer):

Protect from direct sunlight

The following excursions are permitted:

Section 7. Handling and storage

60°C – Not permitted
 50°C – Not more than 3 weeks
 40°C – Not more than 8 weeks
 The excursions are not cumulative
 There are no low temperature control requirements

Do not store above the following temperature : 25 °C

Section 8. Exposure controls and personal protection

Control parameters

Australia

Occupational exposure limits

| Ingredient name | Exposure limits |
|--------------------------------------|--|
| sucrose | Safe Work Australia (Australia, 1/2014). TWA: 10 mg/m ³ 8 hours. |
| Cellulose | Safe Work Australia (Australia, 1/2014). TWA: 10 mg/m ³ 8 hours. Form: fibres |
| Talc , containing asbestiform fibres | Safe Work Australia (Australia, 1/2014). TWA: 2.5 mg/m ³ 8 hours. |
| magnesium distearate | Safe Work Australia (Australia, 1/2014). TWA: 10 mg/m ³ 8 hours. |

New Zealand

| Ingredient name | Exposure limits |
|--------------------------------------|--|
| sucrose | NZ OSH (New Zealand, 2/2013). WES-TWA: 10 mg/m ³ 8 hours. Form: The value for inhalable dust containing no asbestos and less than 1% free silica. |
| Cellulose | NZ OSH (New Zealand, 2/2013). WES-TWA: 10 mg/m ³ 8 hours. Form: The value for inhalable dust containing no asbestos and less than 1% free silica. |
| Talc , containing asbestiform fibres | NZ OSH (New Zealand, 2/2013). WES-TWA: 6 mg/m ³ 8 hours. Form: Inhalable dust WES-TWA: 2 mg/m ³ 8 hours. Form: Respirable dust |
| magnesium distearate | NZ OSH (New Zealand, 2/2013). WES-TWA: 10 mg/m ³ 8 hours. Form: The value for inhalable dust containing no asbestos and less than 1% free silica. |

Appropriate engineering controls : Use only with adequate ventilation. If user operations generate dust, fumes, gas, vapour or mist, use process enclosures, local exhaust ventilation or other engineering controls to keep worker exposure to airborne contaminants below any recommended or statutory limits.

Environmental exposure controls : Emissions from ventilation or work process equipment should be checked to ensure they comply with the requirements of environmental protection legislation. In some cases, fume scrubbers, filters or engineering modifications to the process equipment will be necessary to reduce emissions to acceptable levels.

Individual protection measures

Hygiene measures : Wash hands, forearms and face thoroughly after handling chemical products, before eating, smoking and using the lavatory and at the end of the working period. Appropriate techniques should be used to remove potentially contaminated clothing. Wash contaminated clothing before reusing. Ensure that eyewash stations and safety showers are close to the workstation location.

Section 8. Exposure controls and personal protection

- Eye/face protection** : Safety eyewear complying with an approved standard should be used when a risk assessment indicates this is necessary to avoid exposure to liquid splashes, mists, gases or dusts. If contact is possible, the following protection should be worn, unless the assessment indicates a higher degree of protection: chemical splash goggles.
- Skin protection**
- Hand protection** : Chemical-resistant, impervious gloves complying with an approved standard should be worn at all times when handling chemical products if a risk assessment indicates this is necessary. Considering the parameters specified by the glove manufacturer, check during use that the gloves are still retaining their protective properties. It should be noted that the time to breakthrough for any glove material may be different for different glove manufacturers. In the case of mixtures, consisting of several substances, the protection time of the gloves cannot be accurately estimated.
- Body protection** : Personal protective equipment for the body should be selected based on the task being performed and the risks involved and should be approved by a specialist before handling this product.
- Other skin protection** : Appropriate footwear and any additional skin protection measures should be selected based on the task being performed and the risks involved and should be approved by a specialist before handling this product.
- Respiratory protection** : Based on the hazard and potential for exposure, select a respirator that meets the appropriate standard or certification. Respirators must be used according to a respiratory protection program to ensure proper fitting, training, and other important aspects of use.

Section 9. Physical and chemical properties

Appearance

- Physical state** : Solid. [caplet]
- Colour** : White.
- Odour** : no odor
- Odour threshold** : Not available.
- pH** : Not available.
- Melting point** : Not available.
- Boiling point** : Not available.
- Flash point** : Not available.
- Evaporation rate** : Not available.
- Flammability (solid, gas)** : Not available.
- Lower and upper explosive (flammable) limits** : Not available.
- Vapour pressure** : Not available.
- Vapour density** : Not available.
- Relative density** : Not available.
- Solubility** : Partially soluble in the following materials: cold water and hot water.
- Solubility in water** : Not available.
- Partition coefficient: n-octanol/water** : Not available.
- Auto-ignition temperature** : Not available.
- Decomposition temperature** : Not available.
- Viscosity** : Not available.
- Flow time (ISO 2431)** : Not available.

Section 10. Stability and reactivity

- Reactivity** : No specific test data related to reactivity available for this product or its ingredients.
- Chemical stability** : The product is stable.
- Possibility of hazardous reactions** : Under normal conditions of storage and use, hazardous reactions will not occur.
- Conditions to avoid** : No specific data.
- Incompatible materials** : No specific data.
- Hazardous decomposition products** : Under normal conditions of storage and use, hazardous decomposition products should not be produced.

Section 11. Toxicological information

Information on toxicological effects

Acute toxicity

| Product/ingredient name | Result | Species | Dose | Exposure |
|-------------------------|-----------|---------|--------------|----------|
| ibuprofen | LD50 Oral | Rat | 636 mg/kg | - |
| sucrose | LD50 Oral | Rat | 29700 mg/kg | - |
| Cellulose | LD50 Oral | Rat | >5 g/kg | - |
| magnesium distearate | LD50 Oral | Rat | >10000 mg/kg | - |

Conclusion/Summary : Based on available data, the classification criteria are not met.

Irritation/Corrosion

| Product/ingredient name | Result | Species | Score | Exposure | Observation |
|--------------------------------------|----------------------|---------|-------|--------------------------------------|-------------|
| Talc , containing asbestiform fibres | Skin - Mild irritant | Human | - | 72 hours 300 Micrograms Intermittent | - |

Conclusion/Summary

Skin : Based on available data, the classification criteria are not met.

Eyes : Based on available data, the classification criteria are not met.

Respiratory : Based on available data, the classification criteria are not met.

Sensitisation

Not available.

Conclusion/Summary

Skin : Based on available data, the classification criteria are not met.

Respiratory : Based on available data, the classification criteria are not met.

Mutagenicity

Not available.

Conclusion/Summary

: Based on available data, the classification criteria are not met.

Carcinogenicity

Not available.

Conclusion/Summary

: Based on available data, the classification criteria are not met.

Reproductive toxicity

Not available.

Conclusion/Summary

: Based on available data, the classification criteria are not met.

Teratogenicity

Not available.

Section 11. Toxicological information

Conclusion/Summary : Based on available data, the classification criteria are not met.

Specific target organ toxicity (single exposure)

| Name | Category | Route of exposure | Target organs |
|-----------|------------|-------------------|------------------------------|
| ibuprofen | Category 3 | Not applicable. | Respiratory tract irritation |

Specific target organ toxicity (repeated exposure)

Not available.

Aspiration hazard

Not available.

Information on likely routes of exposure : Not available.

Potential acute health effects

- Eye contact** : Causes serious eye irritation.
Inhalation : May cause respiratory irritation.
Skin contact : No known significant effects or critical hazards.
Ingestion : Harmful if swallowed.

Symptoms related to the physical, chemical and toxicological characteristics

- Eye contact** : Adverse symptoms may include the following:
 pain or irritation
 watering
 redness
- Inhalation** : Adverse symptoms may include the following:
 respiratory tract irritation
 coughing
- Skin contact** : No specific data.
Ingestion : No specific data.

Delayed and immediate effects as well as chronic effects from short and long-term exposure

Short term exposure

- Potential immediate effects** : Not available.
Potential delayed effects : Not available.

Long term exposure

- Potential immediate effects** : Not available.
Potential delayed effects : Not available.

Potential chronic health effects

Not available.

- Conclusion/Summary** : Based on available data, the classification criteria are not met.
General : No known significant effects or critical hazards.
Carcinogenicity : No known significant effects or critical hazards.
Mutagenicity : No known significant effects or critical hazards.
Teratogenicity : No known significant effects or critical hazards.
Developmental effects : No known significant effects or critical hazards.
Fertility effects : No known significant effects or critical hazards.

Section 11. Toxicological information

Numerical measures of toxicity

Acute toxicity estimates

| Route | ATE value |
|-------|--------------|
| Oral | 1183.5 mg/kg |

Section 12. Ecological information

Toxicity

| Product/ingredient name | Result | Species | Exposure |
|-------------------------|------------------------------------|---|----------|
| ibuprofen | Acute EC50 72.6 mg/l Fresh water | Crustaceans - Moina macrocopa | 48 hours |
| | Acute EC50 34.1 mg/l Fresh water | Daphnia - Daphnia magna - Neonate | 48 hours |
| | Acute LC50 >100 mg/l Fresh water | Fish - Oryzias latipes - Larvae | 96 hours |
| | Chronic NOEC 10 µg/l Fresh water | Algae - Pseudokirchneriella subcapitata | 72 hours |
| | Chronic NOEC 1.23 mg/l Fresh water | Daphnia - Daphnia magna - Neonate | 21 days |
| | Chronic NOEC 0.1 µg/l Fresh water | Fish - Oryzias latipes - Embryo | 132 days |

Persistence and degradability

Not available.

Bioaccumulative potential

| Product/ingredient name | LogP _{ow} | BCF | Potential |
|-------------------------|--------------------|-----|-----------|
| ibuprofen | 3.87 | - | low |
| sucrose | -3.7 | - | low |

Mobility in soil

Soil/water partition coefficient (K_{oc}) : Not available.

Other adverse effects : No known significant effects or critical hazards.

Section 13. Disposal considerations

Disposal methods : The generation of waste should be avoided or minimised wherever possible. Disposal of this product, solutions and any by-products should at all times comply with the requirements of environmental protection and waste disposal legislation and any regional local authority requirements. Dispose of surplus and non-recyclable products via a licensed waste disposal contractor. Waste should not be disposed of untreated to the sewer unless fully compliant with the requirements of all authorities with jurisdiction. Waste packaging should be recycled. Incineration or landfill should only be considered when recycling is not feasible. This material and its container must be disposed of in a safe way. Care should be taken when handling emptied containers that have not been cleaned or rinsed out. Empty containers or liners may retain some product residues. Avoid dispersal of spill material and runoff and contact with soil, waterways, drains and sewers.

14. Transport information

| Regulation | UN number | Proper shipping name | Classes | PG* | Label | Additional information |
|------------|----------------|----------------------|---------|-----|-------|------------------------|
| ADG | Not regulated. | - | - | - | | - |
| IMDG | Not regulated. | - | - | - | | - |
| IATA | Not regulated. | - | - | - | | - |

PG* : Packing group

Special precautions for user : **Transport within user's premises:** always transport in closed containers that are upright and secure. Ensure that persons transporting the product know what to do in the event of an accident or spillage.

Section 15. Regulatory information

Standard Uniform Schedule of Medicine and Poisons

AUSTRALIA

Not scheduled (pack size < 25, i.e. 2,4,6,8,10,20,24)

Schedule 2 (pack size > 25, i.e. 40,48,72,80,96)

Scheduled substance(s): Ibuprofen

Model Work Health and Safety Regulations - Scheduled Substances

Ibuprofen

Australia Therapeutic Goods Administration (TGA) : AUST R 156294

NEW ZEALAND

GSL (pack size < 25)

Pharmacy only (pack size > 25)

New Zealand Ministry of Health (MoH) Approval No. : TT50-1377/15

Approved Handler Requirement : No.

Tracking Requirement : No.

Section 16. Any other relevant information

Key to abbreviations :

- ADG = Australian Dangerous Goods
- ATE = Acute Toxicity Estimate
- BCF = Bioconcentration Factor
- GHS = Globally Harmonized System of Classification and Labelling of Chemicals
- IATA = International Air Transport Association
- IBC = Intermediate Bulk Container
- IMDG = International Maritime Dangerous Goods
- LogPow = logarithm of the octanol/water partition coefficient
- MARPOL = International Convention for the Prevention of Pollution From Ships, 1973 as modified by the Protocol of 1978. ("Marpol" = marine pollution)
- NOHSC = National Occupational Health and Safety Commission
- SUSMP = Standard Uniform Schedule of Medicine and Poisons
- UN = United Nations

Section 16. Any other relevant information

| Classification | Justification |
|---|--|
| ACUTE TOXICITY (oral) - Category 4 SERIOUS EYE DAMAGE/EYE IRRITATION - Category 2A SPECIFIC TARGET ORGAN TOXICITY - SINGLE EXPOSURE (Respiratory tract irritation) - Category 3 | Calculation method Calculation method Calculation method |

Date of issue / Date of revision : 05/12/2016

Revision comments : AUS GHS SDS

Version : 3.2

Procedure used to derive the classification

References : Not available.

Indicates information that has changed from previously issued version.

Notice to reader

To the best of our knowledge, the information contained herein is accurate. However, neither the above-named supplier, nor any of its subsidiaries, assumes any liability whatsoever for the accuracy or completeness of the information contained herein.

Final determination of suitability of any material is the sole responsibility of the user. All materials may present unknown hazards and should be used with caution. Although certain hazards are described herein, we cannot guarantee that these are the only hazards that exist.

Please read all labels carefully before using product.