

# SAFETY DATA SHEET



## 1. Identification

**Product name** : Nurofen Zavance Tablets  
**SDS no.** : D0167831  
**Formulation #** : 0161568  
**Supplier** : AUSTRALIA  
RECKITT BENCKISER (AUSTRALIA) PTY LIMITED  
680 George St , Sydney, NSW 2000  
Tel: +61 (02) 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

### Uses

**Product use** : Analgesic  
Consumer use

## 2. Hazard identification

**Classification of the substance or mixture** : SERIOUS EYE DAMAGE/EYE IRRITATION - Category 2A

### GHS label elements

**Hazard pictograms** :



**Signal word** : **WARNING**  
**Hazard statements** : **Causes serious eye irritation.**

### Precautionary statements

**General** : Keep out of reach of children. If medical advice is needed, have product container or label at hand.  
**Prevention** : Wash hands thoroughly after handling.  
**Response** : 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 advice or attention.  
**Storage** : Not applicable.  
**Disposal** : Not applicable.

### 3. Composition/information on ingredients

**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	≤10	14807-96-6
magnesium distearate	≤3	557-04-0

There are no additional ingredients present which, within the current knowledge of the supplier and in the concentrations applicable, are classified and hence require reporting in this section.

The total concentration of ingredients in this product, reported or not in this section, is 100%.

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

### 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 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 adverse health effects persist or are severe. 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. 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 adverse health effects persist or are severe. 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.

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

##### Potential acute health effects

- Eye contact** : Causes serious eye irritation.
- Inhalation** : No known significant effects or critical hazards.
- Skin contact** : No known significant effects or critical hazards.
- Ingestion** : No known significant effects or critical hazards.

##### Over-exposure signs/symptoms

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

## 4. First-aid measures

### 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. It may be dangerous to the person providing aid to give mouth-to-mouth resuscitation.

See toxicological information (Section 11)

## 5. Fire-fighting 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** : No specific data.

**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.

**Hazchem code** : Not applicable

## 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 spilt 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 spilt 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.

## 6. Accidental release measures

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.

## 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. 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. 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. See Section 10 for incompatible materials before handling or use.

## 8. Exposure controls/personal protection

### Control parameters

#### Australia

#### Occupational exposure limits

Ingredient name	Exposure limits
sucrose	<b>Safe Work Australia (Australia, 12/2019).</b> TWA: 10 mg/m <sup>3</sup> 8 hours.
Cellulose	<b>Safe Work Australia (Australia, 12/2019).</b> TWA: 10 mg/m <sup>3</sup> 8 hours. Form: fibres
magnesium distearate	<b>Safe Work Australia (Australia, 12/2019). [Stearates]</b> TWA: 10 mg/m <sup>3</sup> 8 hours.

#### New Zealand

#### Occupational exposure limits

Ingredient name	Exposure limits
sucrose	<b>NZ HSWA 2015 - GRWM 2016 (New Zealand, 11/2020).</b> WES-TWA: 10 mg/m <sup>3</sup> 8 hours. Form: The value for inhalable dust containing no asbestos and less than 1% free silica.
Cellulose	<b>NZ HSWA 2015 - GRWM 2016 (New Zealand, 11/2020).</b> WES-TWA: 10 mg/m <sup>3</sup> 8 hours. Form: The value for inhalable dust containing no asbestos and less than 1% free silica.
magnesium distearate	<b>NZ HSWA 2015 - GRWM 2016 (New Zealand, 11/2020). [Stearates]</b> WES-TWA: 10 mg/m <sup>3</sup> 8 hours. Form: The value for inhalable dust containing no asbestos and less than 1% free silica.

## 8. Exposure controls/personal protection

- Appropriate engineering controls** : Good general ventilation should be sufficient to control worker exposure to airborne contaminants.
- 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.
- 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.

## 9. Physical and chemical properties

The conditions of measurement of all properties are at standard temperature and pressure unless otherwise indicated.

### Appearance

- Physical state** : Solid. [A white, sugar coated, round tablet printed with an identifying logo in red.]
- Colour** : White. [Light]
- Odour** : Not available.
- Odour threshold** : Not available.
- pH** : Not available.
- Melting point/freezing point** : Not available.
- Boiling point, initial boiling point, and boiling range** : Not available.
- Flash point** : Not applicable.
- Evaporation rate** : Not available.
- Flammability** : Not available.
- Lower and upper explosion limit/flammability limit** : Not applicable.

## 9. Physical and chemical properties

Vapour pressure	: Not available.
Relative vapour density	: Not applicable.
Relative density	: Not available.
Solubility(ies)	:

Media	Result
cold water	Soluble
hot water	Soluble

Partition coefficient: n-octanol/water	: Not applicable.
Auto-ignition temperature	: Not applicable.
Decomposition temperature	: Not available.
Viscosity	: Not applicable.
<u>Particle characteristics</u>	
Median particle size	: Not available.

## 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.

## 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	Skin - Mild irritant	Human	-	72 hours 300 ug l	-

#### Conclusion/Summary

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

**Eyes** Calculation method Causes serious eye irritation.

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

#### Sensitisation

Not available.

## 11. Toxicological information

### Conclusion/Summary

#### **Skin**

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

#### **Respiratory**

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

### Germ Cell 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.

### 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	-	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**

: No known significant effects or critical hazards.

#### **Skin contact**

: No known significant effects or critical hazards.

#### **Ingestion**

: No known significant effects or critical hazards.

### Symptoms related to the physical, chemical and toxicological characteristics

#### **Eye contact**

: Adverse symptoms may include the following:  
pain or irritation  
watering  
redness

#### **Inhalation**

: No specific data.

#### **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.

## 11. Toxicological information

**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.

**Germ Cell 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.

**Developmental effects** : No known significant effects or critical hazards.

### Numerical measures of toxicity

#### Acute toxicity estimates

Not available.

## 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 IC50 77.19 mg/l Fresh water	Algae - Chlorella vulgaris - Exponential growth phase	72 hours
	Acute IC50 77.69 mg/l Fresh water	Algae - Chlorella vulgaris - Exponential growth phase	96 hours
	Acute LC50 >100 mg/l Fresh water	Fish - Oryzias latipes - Larvae	96 hours
	Chronic NOEC 35 mg/l Fresh water	Algae - Chlorella vulgaris - Exponential growth phase	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 <sub>ow</sub>	BCF	Potential
ibuprofen	3.87	-	low
sucrose	-3.7	-	low

### Mobility in soil

**Soil/water partition coefficient (K<sub>oc</sub>)** : Not available.

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



## 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

	ADG	ADR/RID	IMDG	IATA
UN number	Not regulated.	Not regulated.	Not regulated.	Not regulated.
UN proper shipping name	-	-	-	-
Transport hazard class(es)	-	-	-	-
Packing group	-	-	-	-
Environmental hazards	No.	No.	No.	No.

**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.

**Transport in bulk according to IMO instruments** : Not available.

## 15. Regulatory information

### Standard for the Uniform Scheduling of Medicines and Poisons

Schedule 2 PHARMACY MEDICINE

### Australian Inventory of Industrial Chemicals (AIIC)

All components are listed or exempted.

### New Zealand Inventory of Chemicals (NZIoC)

All components are listed or exempted.

### HSNO Group Standard

Medicinal Product

### HSNO Approval Number

HSR100425

### Approved Handler Requirement

No.

### Tracking Requirement

No.

## 16. Other information

**Key to abbreviations** : ADG = Australian Dangerous Goods  
 ADR = The European Agreement concerning the International Carriage of Dangerous Goods by Road  
 RID = The Regulations concerning the International Carriage of Dangerous Goods by Rail  
 IATA = International Air Transport Association  
 IMDG = International Maritime Dangerous Goods  
 GHS = Globally Harmonized System of Classification and Labelling of Chemicals  
 IBC = Intermediate Bulk Container  
 SUSMP = Standard Uniform Schedule of Medicine and Poisons  
 UN = United Nations  
 SWA = Safe Work Australia  
 HSNO = Hazardous Substances and New Organisms Act 1996

**Date of issue / Date of revision** : 03/09/2023

**Version** : 1  
 (Version for updated GHS Revision 7 PSDS Template)

### Procedure used to derive the classification

Classification	Justification
SERIOUS EYE DAMAGE/EYE IRRITATION - Category 2A	Calculation method

**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.