SAFETY DATA SHEET

Conforms to SWA Preparation of Safety Data Sheets for Hazardous Chemicals - Code of Practice Feb 2016

HEALTH · HYGIENE · HOME

Section 1 - Identification of the Material and Supplier

Product Name:

Nurofen 200mg Tablets and Caplets

Product Type: **Nurofen 200mg tablets and caplets (12's, 24's, 48's, 96's)**

SDS No.: D0094623 v3.3

Product Use: Consumer

Supplier Details:

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

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

Poisons Information Centre: **Australia: Phone 13 11 26**
New Zealand: 0800 764 766 or 0800 POISON

Section 2 - Hazards 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

Statement of Hazardous Nature

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

SUSMP Classification: section 15
ADG Classification: section 14
UN Number: section 14

HAZARD PICTOGRAM:

GHS Signal word: WARNING

HAZARD STATEMENT: Harmful if swallowed.
Causes serious eye irritation.
May cause respiratory irritation

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.

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.

Section 3 - Composition/Information on Ingredients

Ingredients	CAS No	Conc,%
Ibuprofen	15687-27-1	30 – 60% (200mg per dose)
Other Non-hazardous ingredients to 100%		

Section 4 - 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.

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

Section 5 - Fire Fighting Measures

Extinguishing Media:

Suitable Extinguishing Media: Use an extinguishing agent suitable for the surrounding fire.

Unsuitable Extinguishing Media: None known.

Fire and Explosion Hazards: No specific fire or explosion hazard.

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

Advice 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.

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 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, labelled 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, labelled waste container. Dispose of via a licensed waste disposal contractor. Note: see Section 1 for emergency contact information and Section 13 for waste disposal.

Reference to Other Sections: **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 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:-
60°C – Not permitted
50°C – Not more than 3 week
40°C – Not more than 8 weeks
The excursions are not cumulative.
The product should not be stored below 10°C

Section 8 - Exposure Controls and Personal Protection

Control parameters
Australia: Occupational exposure limits: None
New Zealand: Occupational exposure limits: No exposure standard allocated.
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
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: 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

Physical Description & colour: Solid tablet or caplet. White
Odour: None
pH: Not Available

Freezing/Melting Point: Not Available
Boiling Point: Not Available
Flash Point: Not Available
Flammability (solid, gas): Not Available
Vapour Pressure: Not Available
Vapour Density: Not Available
Relative Density: Not Available
Solubility: Not Available
Partition coefficient: n-octanol/water: Not Available
Viscosity: Not Available
Explosive Properties: Not Available
Oxidising Properties: 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

Acute Toxicity:

Product/Ingredient Name	Result	Species	Dose	Exposure
Ibuprofen	LD50 oral	Rat	636 mg/kg	

Acute toxicity Estimates:

Route	ATE value
Oral	1120.9 mg/kg

Irritation/Corrosion: Not available

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

Carcinogenicity: Not available

Reproductive Toxicity: Not available

Teratogenicity: Not available

Specific Target Organ Toxicity (single exposure):

Product/Ingredient 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

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 and also chronic effects from short and long term exposure:
Short Term Exposure: Not available
Long Term Exposure: 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 12 - Ecological Information

Ecotoxicity:

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:

Bioaccumulative Potential:

Product/Ingredient Name	$LogP_{ow}$	BCF	Potential
Ibuprofen	3.87	-	low

Mobility in Soil: 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 nonrecyclable 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 spilt material and runoff and contact with soil, waterways, drains and sewers.

Section 14 - Transport Information

	ADG	IMDG	IATA
UN Number	**Not regulated**	**Not regulated**	**Not regulated**
UN Proper Shipping Name			
Transport Hazard Class			
Packing Group			
Environmental Hazards			
Hazchem code			

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

Poisons schedule (SUSMP): Schedule 2
Australian Inventory (AICS): Not applicable
New Zealand Inventory (NZIoC): All components are listed or exempted
Regulatory Status
Australia: AUST R 127287(caplets), 127272 (tablets), 127273 (tablets). GSL packsize ≤ 24; Pharmacy Only packsize >24
New Zealand: Medsafe TT50-1377/10b (caplet), TT50-1377/2a (Tablet pharmacy only), TT50-1377/2b (Tablet GSL). NZ GSL packsize <25 (tabs/caps), Pharmacy >25 (tabs/caps)
Approved Handler Requirement: Not required
Tracking Requirement: Not required

Section 16 - Other Information

This SDS contains only safety-related information. For other data see product literature.

Acronyms:

ADG Code	Australian Code for the Transport of Dangerous Goods by Road and Rail (7th edition)
AICS	Australian Inventory of Chemical Substances
SWA	Safe Work Australia, formerly ASCC and NOHSC
CAS number	Chemical Abstracts Service Registry Number
Hazchem Code	Emergency action code of numbers and letters that provide information to emergency services especially firefighters
IARC	International Agency for Research on Cancer
NOS	Not otherwise specified
NTP	National Toxicology Program (USA)
R-Phrase	Risk Phrase
SUSMP	Standard for the Uniform Scheduling of Medicines & Poisons
UN Number	United Nations Number

Creation Date: **27th December 2016**
This version: **3.3**
Revision Comments: AU GHS SDS

Please read all labels carefully before using product.

This SDS is prepared in accord with the SWA document "Preparation of Safety Data Sheets for Hazardous Chemicals - Code of Practice" (Feb 2016)