

# Ulcer Relief

# International Animal Health Products Pty Ltd

Chemwatch: **4856-66** Version No: **6.1**  Chemwatch Hazard Alert Code: 2

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# SECTION 1 Identification of the substance / mixture and of the company / undertaking

Safety Data Sheet according to Work Health and Safety Regulations (Hazardous Chemicals) 2023 and ADG requirements

#### **Product Identifier**

Product name	Ulcer Relief
Chemical Name	ranitidine hydrochloride
Synonyms	Not Available
Chemical formula	Not Applicable
Other means of identification	Not Available

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

Polovant identified uses	To promote healing of gastric ulcers and reduce the degree of gastric ulceration in foals and in horses in training. Given dry with	
Relevant identified uses	feed, dissolved in water or orally by syringe. Prescription animal remedy only.	

#### Details of the manufacturer or supplier of the safety data sheet

Registered company name	International Animal Health Products Pty Ltd
Address	18 Healey Circuit Huntingwood NSW 2148 Australia
Telephone	+61 2 9672 7944
Fax	+61 2 9672 7988
Website	www.iahp.com.au
Email	info@iahp.com.au

#### Emergency telephone number

Association / Organisation	Australian Poison Information Centre
Emergency telephone numbers	13 11 26 (24 Hours)
Other emergency telephone numbers	New Zealand: National Poisons Centre 0800 764 766 (24 hours)

# **SECTION 2 Hazards identification**

# Classification of the substance or mixture

### HAZARDOUS CHEMICAL. NON-DANGEROUS GOODS. According to the WHS Regulations and the ADG Code.

Poisons Schedule	S4
Classification <sup>[1]</sup>	Acute Toxicity (Oral) Category 4, Skin Corrosion/Irritation Category 2, Sensitisation (Skin) Category 1, Sensitisation (Respiratory) Category 1, Reproductive Toxicity Category 2
Legend:	1. Classified by Chemwatch; 2. Classification drawn from HCIS; 3. Classification drawn from Regulation (EU) No 1272/2008 - Annex VI

#### Label elements

Hazard pictogram(s)	
Signal word	Danger

#### Hazard statement(s)

H302	Harmful if swallowed.
H315	Causes skin irritation.
H317	May cause an allergic skin reaction.
H334	May cause allergy or asthma symptoms or breathing difficulties if inhaled.
H361fd	Suspected of damaging fertility. Suspected of damaging the unborn child.

#### Supplementary statement(s)

Not Applicable

#### Precautionary statement(s) Prevention

P201	Obtain special instructions before use.
P261	Avoid breathing dust/fumes.
P280	Wear protective gloves and protective clothing.
P284	[In case of inadequate ventilation] wear respiratory protection.
P264	Wash all exposed external body areas thoroughly after handling.
P270	Do not eat, drink or smoke when using this product.
P272	Contaminated work clothing should not be allowed out of the workplace.

#### Precautionary statement(s) Response

P304+P340	IF INHALED: Remove person to fresh air and keep comfortable for breathing.
P308+P313	IF exposed or concerned: Get medical advice/ attention.
P342+P311	If experiencing respiratory symptoms: Call a POISON CENTER/doctor/physician/first aider.
P302+P352	IF ON SKIN: Wash with plenty of water.
P333+P313	If skin irritation or rash occurs: Get medical advice/attention.
P362+P364	Take off contaminated clothing and wash it before reuse.
P301+P312	IF SWALLOWED: Call a POISON CENTER/doctor/physician/first aider if you feel unwell.
P330	Rinse mouth.

# Precautionary statement(s) Storage

P405	Store locked up.	
Precautionary statement(s	) Disposal	
P501	Dispose of contents/container to authorised hazardous or special waste collection point in accordance with any local regulation.	

# **SECTION 3 Composition / information on ingredients**

#### Substances

See section below for composition of Mixtures

#### Mixtures

CAS No	%[weight]	Name
66357-59-3	60-100	ranitidine hydrochloride
Legend:	1. Classified by Chemwatch; 2. Classification drawn from HCIS; 3. Classification drawn from Regulation (EU) No 1272/2008 - Annex VI: 4. Classification drawn from C&L: * EU IOELVs available	

# **SECTION 4 First aid measures**

#### Description of first aid measures

Eye Contact	<ul> <li>If this product comes in contact with the eyes:</li> <li>Wash out immediately with fresh running water.</li> <li>Ensure complete irrigation of the eye by keeping eyelids apart and away from eye and moving the eyelids by occasionally lifting the upper and lower lids.</li> <li>Seek medical attention without delay; if pain persists or recurs seek medical attention.</li> <li>Removal of contact lenses after an eye injury should only be undertaken by skilled personnel.</li> </ul>
Skin Contact	<ul> <li>If skin or hair contact occurs:</li> <li>Flush skin and hair with running water (and soap if available).</li> <li>Seek medical attention in event of irritation.</li> </ul>
Inhalation	<ul> <li>If fumes or combustion products are inhaled remove from contaminated area.</li> <li>Lay patient down. Keep warm and rested.</li> <li>Prostheses such as false teeth, which may block airway, should be removed, where possible, prior to initiating first aid procedures.</li> <li>Apply artificial respiration if not breathing, preferably with a demand valve resuscitator, bag-valve mask device, or pocket mask as trained. Perform CPR if necessary.</li> <li>Transport to hospital, or doctor.</li> </ul>
Ingestion	<ul> <li>If swallowed do NOT induce vomiting.</li> <li>If vomiting occurs, lean patient forward or place on left side (head-down position, if possible) to maintain open airway and prevent aspiration.</li> <li>Observe the patient carefully.</li> <li>Never give liquid to a person showing signs of being sleepy or with reduced awareness; i.e. becoming unconscious.</li> <li>Give water to rinse out mouth, then provide liquid slowly and as much as casualty can comfortably drink.</li> <li>Seek medical advice.</li> </ul>

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

Treat symptomatically.

# **SECTION 5 Firefighting measures**

# Extinguishing media

- Water spray or fog.
- ▶ Foam.
- Dry chemical powder.
- BCF (where regulations permit).
- Carbon dioxide.

#### Special hazards arising from the substrate or mixture

Fire Incompatibility	Avoid contamination with oxidising agents i.e. nitrates, oxidising acids, chlorine bleaches, pool chlorine etc. as ignition may result
Advice for firefighters	
Fire Fighting	<ul> <li>Alert Fire Brigade and tell them location and nature of hazard.</li> <li>Wear breathing apparatus plus protective gloves.</li> <li>Prevent, by any means available, spillage from entering drains or water courses.</li> <li>Use water delivered as a fine spray to control fire and cool adjacent area.</li> <li>DO NOT approach containers suspected to be hot.</li> <li>Cool fire exposed containers with water spray from a protected location.</li> <li>If safe to do so, remove containers from path of fire.</li> <li>Equipment should be thoroughly decontaminated after use.</li> </ul>
Fire/Explosion Hazard	<ul> <li>Combustible solid which burns but propagates flame with difficulty; it is estimated that most organic dusts are combustible (circa 70%) - according to the circumstances under which the combustion process occurs, such materials may cause fires and / or dust explosions.</li> <li>Organic powders when finely divided over a range of concentrations regardless of particulate size or shape and suspended in air or some other oxidizing medium may form explosive dust-air mixtures and result in a fire or dust explosion (including secondary explosions).</li> <li>Avoid generating dust, particularly clouds of dust in a confined or unventilated space as dusts may form an explosive mixture with air, and any source of ignition, i.e. flame or spark, will cause fire or explosion. Dust clouds generated by the fine grinding of the solid are a particular hazard; accumulations of fine dust (420 micron or less) may burn rapidly and fiercely if ignited - particles exceeding this limit will generally not form flammable dust clouds; once initiated, however, larger particles up to 1400 microns diameter will contribute to the propagation of an explosive limit (UEL) are applicable to dust clouds but only the LEL is of practical use; - this is because of the inherent difficulty of achieving homogeneous dust clouds at high temperatures (for dusts the LEL is often called the "Minimum Explosible Concentration", MEC).</li> <li>When processed with flammable liquids/vapors/mists,ignitable (hybrid) mixtures may be formed with combustible dusts. Ignitable mixtures will increase the rate of explosion pressure rise and the Minimum Ignition Energy (the minimum amount of energy required to ignite dust clouds - MIE) will be lower than the pure dust in air mixture. The Lower Explosive Limit (LEL) of the vapour/dust mixture will be lower than the individual LELs for the vapors/mists or dusts.</li> </ul>

HAZCHEM	phosgene nitrogen oxides (NOx) sulfur oxides (SOx) other pyrolysis products typical of burning organic material. May emit poisonous fumes. Not Applicable
	carbon dioxide (CO2) hydrogen chloride
	Combustion products include:
	ignition temperature (LIT)); LIT generally falls as the thickness of the layer increases.
	that it is virtually impossible to use flammability data published in the literature for dusts (in contrast to that published for gases and vapours).
	One important effect of the particulate nature of powders is that the surface area and surface structure (and often moisture content) can vary widely from sample to sample, depending of how the powder was manufactured and handled; this means
	and/ or pressure, may result in ignition especially in the absence of an apparent ignition source.
	<ul> <li>All movable parts coming in contact with this material should have a speed of less than 1-meter/sec.</li> <li>A sudden release of statically charged materials from storage or process equipment, particularly at elevated temperatures.</li> </ul>
	<ul> <li>Powder handling equipment such as dust collectors, dryers and mills may require additional protection measures such as explosion venting.</li> </ul>
	<ul> <li>Dry dust can be charged electrostatically by turbulence, pneumatic transport, pouring, in exhaust ducts and during transport.</li> <li>Build-up of electrostatic charge may be prevented by bonding and grounding.</li> </ul>
	<ul> <li>explosive force capable of damaging plant and buildings and injuring people.</li> <li>Usually the initial or primary explosion takes place in a confined space such as plant or machinery, and can be of sufficient force to damage or rupture the plant. If the shock wave from the primary explosion enters the surrounding area, it will disturb any settled dust layers, forming a second dust cloud, and often initiate a much larger secondary explosion. All large scale explosions have resulted from chain reactions of this type.</li> </ul>
	• A dust explosion may release of large quantities of gaseous products; this in turn creates a subsequent pressure rise of

## **SECTION 6 Accidental release measures**

# Personal precautions, protective equipment and emergency procedures

See section 8

# **Environmental precautions**

See section 12

#### Methods and material for containment and cleaning up

Minor Spills	<ul> <li>Clean up waste regularly and abnormal spills immediately.</li> <li>Avoid breathing dust and contact with skin and eyes.</li> <li>Wear protective clothing, gloves, safety glasses and dust respirator.</li> <li>Use dry clean up procedures and avoid generating dust.</li> <li>Vacuum up or sweep up. NOTE: Vacuum cleaner must be fitted with an exhaust micro filter (H-Class HEPA type) (consider explosion-proof machines designed to be grounded during storage and use). H-Class HEPA filtered industrial vacuum cleaners should NOT be used on wet materials or surfaces.</li> <li>Dampen with water to prevent dusting before sweeping.</li> <li>Place in suitable containers for disposal.</li> </ul>
Major Spills	<ul> <li>Moderate hazard.</li> <li>CAUTION: Advise personnel in area.</li> <li>Alert Emergency Services and tell them location and nature of hazard.</li> <li>Control personal contact by wearing protective clothing.</li> <li>Prevent, by any means available, spillage from entering drains or water courses.</li> <li>Recover product wherever possible.</li> <li>IF DRY: Use dry clean up procedures and avoid generating dust. Collect residues and place in sealed plastic bags or other containers for disposal. IF WET: Vacuum/shovel up and place in labelled containers for disposal.</li> <li>ALWAYS: Wash area down with large amounts of water and prevent runoff into drains.</li> <li>If contamination of drains or waterways occurs, advise Emergency Services.</li> </ul>

Personal Protective Equipment advice is contained in Section 8 of the SDS.

# **SECTION 7 Handling and storage**

#### Precautions for safe handling

DO NOT

- - 4

distant.

	when handling, DO NOT eat, drink of smoke.
	Keep containers securely sealed when not in use.
	Avoid physical damage to containers.
	Always wash hands with soap and water after handling.
	Work clothes should be laundered separately. Launder contaminated clothing before re-use.
	Use good occupational work practice.
	<ul> <li>Observe manufacturer's storage and handling recommendations contained within this SDS.</li> </ul>
	Atmosphere should be regularly checked against established exposure standards to ensure safe working conditions are maintained.
	<ul> <li>Organic powders when finely divided over a range of concentrations regardless of particulate size or shape and suspended in air or some other oxidizing medium may form explosive dust-air mixtures and result in a fire or dust explosion (including secondary explosions)</li> </ul>
	<ul> <li>Minimise airborne dust and eliminate all ignition sources. Keep away from heat, hot surfaces, sparks, and flame.</li> <li>Establish good housekeeping practices</li> </ul>
	Establishing your industrice printing induced.     Example dust accumulations on a regular basis by vacuuming or gentle sweeping to avoid creating dust clouds.
	<ul> <li>Nenive dust accumulations on a regular basis by vacuuming or gente sweeping to avoid creating dust clouds.</li> <li>Use continuous suction at points of dust generation to capture and minimise the accumulation of dusts. Particular attention should be given to overhead and hidden horizontal surfaces to minimise the probability of a "secondary" explosion. According to NFPA Standard 654, dust layers 1/32 in.(0.8 mm) thick can be sufficient to warrant immediate cleaning of the area.</li> <li>Do not use air bases for cleaning</li> </ul>
	<ul> <li>Minimise dry sweeping to avoid generation of dust clouds. Vacuum dust-accumulating surfaces and remove to a chemical disposal area. Vacuums with explosion-proof meters should be used.</li> </ul>
	<ul> <li>Control sources of static electricity. Dusts or their packages may accumulate static charges, and static discharge can be a source of ignition</li> </ul>
	<ul> <li>Solids handling systems must be designed in accordance with applicable standards (e.g. NFPA including 654 and 77) and other national guidance</li> </ul>
	Lo not empty directly into flammable solvents or in the presence of flammable vanors
	<ul> <li>Do not empty decay into naminable solvents of in the presence of naminable vapors.</li> <li>The presence the predictions and an environment must be grounded with electrical bending and grounding evidence.</li> </ul>
	Plastic bags and plastics cannot be grounded, and antistatic bags do not completely protect against development of static
	charges.
	the presence of an appropriate ignition source.
	<ul> <li>Do NOT cut drill arind or weld such containers.</li> </ul>
	<ul> <li>In addition ensure such activity is not performed near full, partially empty or empty containers without appropriate workplace safety authorisation or permit.</li> </ul>
	<ul> <li>Store in original containers.</li> </ul>
	<ul> <li>Keep containers securely sealed.</li> </ul>
	<ul> <li>Store in a cool, dry area protected from environmental extremes.</li> </ul>
	<ul> <li>Store away from incompatible materials and foodstuff containers.</li> </ul>
	Protect containers against physical damage and check regularly for leaks.
Other information	Observe manufacturer's storage and handling recommendations contained within this SDS.
	For major quantities:
	Consider storage in bunded areas - ensure storage areas are isolated from sources of community water (including
	stormwater, ground water, lakes and streams}.
	<ul> <li>Ensure that accidental discharge to air or water is the subject of a contingency disaster management plan; this may require consultation with local authorities.</li> </ul>

# Conditions for safe storage, including any incompatibilities

Suitable container	<ul> <li>190g plastic jar.</li> <li>Check that containers are clearly labelled and free from leaks</li> <li>Packaging as recommended by manufacturer.</li> </ul>
Storage incompatibility	Avoid reaction with oxidising agents

# **SECTION 8 Exposure controls / personal protection**

#### **Control parameters**

Occupational Exposure Limits (OEL)						
INGREDIENT DATA						
Not Available						
Emergency Limits						
Ingredient	TEEL-1	TEEL-2		TEEL-3		
Ulcer Relief	Not Available	Not Available		Not Available		
Ingredient	Original IDLH		Revised IDLH			
ranitidine hydrochloride	Not Available		Not Available			

Occupational Exposure Banding

#### Ulcer Relief

Ingredient	Occupational Exposure Band Rating	Occupational Exposure Band Limit	
ranitidine hydrochloride	$E \leq 0.01 \text{ mg/m}^3$		
Notes:	Occupational exposure banding is a process of assigning chemicals into specific categories or bands based on a chemical's potency and the adverse health outcomes associated with exposure. The output of this process is an occupational exposure band (OEB), which corresponds to a range of exposure concentrations that are expected to protect worker health.		

#### **Exposure controls**

	Enclosed local exhaust ventilation is required at points of dust, fume or vapour generation. HEPA terminated local exhaust ventilation should be considered at point of generation of dust, fumes or vapours. Barrier protection or laminar flow cabinets should be considered for laboratory scale handling. A fume hood or vented balance enclosure is recommended for weighing/ transferring quantities exceeding 500 mg. When handling quantities up to 500 gram in either a standard laboratory with general dilution ventilation (e.g. 6-12 air changes per hour) is preferred. Quantities up to 1 kilogram may require a designated laboratory using fume hood, biological safety cabinet, or approved vented enclosures. Quantities exceeding 1 kilogram should be handled in a designated laboratory or containment laboratory using appropriate barrier/ containment technology. Manufacturing and pilot plant operations require barrier/ containment and direct coupling technologies. Barrier/ containment technology and direct coupling (totally enclosed processes that create a barrier between the equipment and the room) typically use double or split butterfly valves and hybrid unidirectional airflow/ local exhaust ventilation solutions (e.g. powder containment booths). Glove bags, isolator glove box systems are optional. HEPA filtration of exhaust from dry product handling areas is required. Fume-hoods and other open-face containment devices are acceptable when face velocities of at least 1 m/s (200 feet/minute) are achieved. Partitions, barriers, and other partial containment technologies are required to prevent migration of the material to uncontrolled areas. For non-routine emergencies maximum local and general exhaust are necessary. Air contaminants generated in the workplace possess varying "escape" velocities which, in turn, determine the "capture velocities" of fresh circulating air required to effectively remove the contaminant.				
	Type of Contaminant:		Air Speed:		
	solvent, vapours, etc. evaporating from tank (in still air)		0.25-0.5 m/s (50- 100 f/min.)		
	aerosols, fumes from pouring operations, intermittent conta (released at low velocity into zone of active generation)	0.5-1 m/s (100-200 f/min.)			
Appropriate engineering	direct spray, drum filling, conveyer loading, crusher dusts, a of rapid air motion)	1-2.5 m/s (200-500 f/min.)			
controls	Within each range the appropriate value depends on:				
	Lower end of the range	Upper end of the range			
	1: Room air currents minimal or favourable to capture	1: Disturbing room air currents			
	2: Contaminants of low toxicity or of nuisance value only.	ow toxicity or of nuisance value only. 2: Contaminants of high toxicity			
	3: Intermittent, low production.	3: Intermittent, low production. 3: High production, heavy use			
	4: Large hood or large air mass in motion	10tion 4: Small hood-local control only			
	Simple theory shows that air velocity falls rapidly with distance away from the opening of a simple extraction pipe. Velocity generally decreases with the square of distance from the extraction point (in simple cases). Therefore the air speed at the extraction point should be adjusted, accordingly, after reference to distance from the contaminating source. The air velocity at the extraction fan, for example, should be a minimum of 1-2.5 m/s (200-500 f/min.) for extraction of gases discharged 2 meters distant from the extraction point. Other mechanical considerations, producing performance deficits within the extraction apparatus, make it essential that theoretical air velocities are multiplied by factors of 10 or more when extraction systems are installed or used. The need for respiratory protection should also be assessed where incidental or accidental exposure is anticipated: Dependent on levels of contamination, PAPR, full face air purifying devices with P2 or P3 filters or air supplied respirators should be evaluated. The following protective devices are recommended where exposures exceed the recommended exposure control guidelines by factors of: 10, high efficiency particulate (HEPA) filters or cartridges 10-25; loose-fitting (Tyvek or helmet type) HEPA powered-air purifying respirator. 25-50; a full face-piece negative pressure respirator with HEPA filters 50-100; tight-fitting, full face-piece HEPA PAPR 100-1000; a hood-shroud HEPA PAPR or full face-piece supplied air respirator operated in pressure demand or other positive pressure mode.				
Individual protection measures, such as personal protective equipment					

When handling very small quantities of the material eye protection may not be required.

- For laboratory, larger scale or bulk handling or where regular exposure in an occupational setting occurs:
  - Chemical goggles. [AS/NZS 1337.1, EN166 or national equivalent]
  - Face shield. Full face shield may be required for supplementary but never for primary protection of eyes.
  - Contact lenses may pose a special hazard; soft contact lenses may absorb and concentrate irritants. A written policy
    document, describing the wearing of lenses or restrictions on use, should be created for each workplace or task. This should
    include a review of lens absorption and adsorption for the class of chemicals in use and an account of injury experience.
    Medical and first-aid personnel should be trained in their removal and suitable equipment should be readily available. In the

Eye and face protection

	event of chemical exposure, begin eye irrigation immediately and remove contact lens as soon as practicable. Lens should be removed at the first signs of eye redness or irritation - lens should be removed in a clean environment only after workers have washed hands thoroughly. [CDC NIOSH Current Intelligence Bulletin 59].
Skin protection	See Hand protection below
Skin protection	See Hand protection below The selection of suitable gloves does not only depend on the material, but also on further marks of quality which vary from manufacturer to manufacturer. Where the chemical is a preparation of several substances, the resistance of the glove material can not be calculated in advance and has therefore to be checked prior to the application. The exact break through time for substances has to be obtained from the manufacturer of the protective gloves and has to be observed when making a final choice. Personal hygiene is a key element of effective hand care. Gloves must only be worn on clean hands. After using gloves, hands should be washed and dried thoroughly. Application of a non-perfumed moisturiser is recommended. Suitability and duratility of glove by be is dependent on usage. Important factors in the selection of gloves include: - frequency and duration of contact, - chemical resistance of glove material, - glove thickness and - dexterity Select gloves tested to a relevant standard (e.g. Europe EN 374, US F739, AS/NZS 2161.1 or national equivalent), - When only begi of frequently repeated contact may occur, glove with a protection class of 5 or higher (breakthrough time greater than 240 minutes according to EN 374, AS/NZS 2161.10.1 or national equivalent), - When only brief contact is expected, a glove with a protection class of 3 or higher (breakthrough time greater than 240 minutes according to EN 374, AS/NZS 2161.10.1 or national equivalent), - Some glove polymer types are less affected by movement and this should be taken into account when considering gloves for long-term usage Contaminated gloves should be replaced. As defined in AS/M EN 573-95 for any application, gloves are rated as: - Excellent when breakthrough time < 20 min - Fair when break
Body protection	See Other protection below
Other protection	<ul> <li>For quantities up to 500 grams a laboratory coat may be suitable.</li> <li>For quantities up to 1 kilogram a disposable laboratory coat or coverall of low permeability is recommended. Coveralls should be buttoned at collar and cuffs.</li> <li>For quantities over 1 kilogram and manufacturing operations, wear disposable coverall of low permeability and disposable shoe covers.</li> <li>For manufacturing operations, air-supplied full body suits may be required for the provision of advanced respiratory protection.</li> <li>Eye wash unit.</li> <li>Ensure there is ready access to an emergency shower.</li> <li>For Emergencies: Vinyl suit</li> </ul>

#### **Respiratory protection**

Type -P Filter of sufficient capacity. (AS/NZS 1716 & 1715, EN 143:2000 & 149:2001, ANSI Z88 or national equivalent)

up to 10 x ES	P1 Air-line*	-	PAPR-P1 -
up to 50 x ES	Air-line**	P2	PAPR-P2
up to 100 x ES	-	P3	-
		Air-line*	-
100+ x ES	-	Air-line**	PAPR-P3

\* - Negative pressure demand \*\* - Continuous flow

A(All classes) = Organic vapours, B AUS or B1 = Acid gasses, B2 = Acid gas or hydrogen cyanide(HCN), B3 = Acid gas or hydrogen cyanide(HCN), E = Sulfur dioxide(SO2), G = Agricultural chemicals, K = Ammonia(NH3), Hg = Mercury, NO = Oxides of nitrogen, MB = Methyl bromide, AX = Low boiling point organic compounds(below 65 degC)

· Respirators may be necessary when engineering and administrative controls do not adequately prevent exposures.

• The decision to use respiratory protection should be based on professional judgment that takes into account toxicity information, exposure measurement data, and frequency and likelihood of the worker's exposure - ensure users are not subject to high thermal loads which may result in heat stress or distress due to personal protective equipment (powered, positive flow, full face apparatus may be an option).

· Published occupational exposure limits, where they exist, will assist in determining the adequacy of the selected respiratory protection. These may be government mandated or vendor recommended.

· Certified respirators will be useful for protecting workers from inhalation of particulates when properly selected and fit tested as part of a complete respiratory protection program.

· Where protection from nuisance levels of dusts are desired, use type N95 (US) or type P1 (EN143) dust masks. Use respirators and components tested and approved under appropriate government standards such as NIOSH (US) or CEN (EU)

· Use approved positive flow mask if significant quantities of dust becomes airborne.

· Try to avoid creating dust conditions.

# **SECTION 9** Physical and chemical properties

#### Information on basic physical and chemical properties

Appearance	white to pale yellow crystalline powder; mixes with water.			
Physical state	Divided Solid	Relative density (Water = 1)	Not Available	
Odour	Not Available	Partition coefficient n- octanol / water	Not Available	
Odour threshold	Not Available	Auto-ignition temperature (°C)	Not Available	
pH (as supplied)	Not Available	Decomposition temperature (°C)	Not Available	
Melting point / freezing point (°C)	Not Available	Viscosity (cSt)	Not Applicable	
Initial boiling point and boiling range (°C)	Not Applicable	Molecular weight (g/mol)	Not Applicable	
Flash point (°C)	Not Available	Taste	Not Available	
Evaporation rate	Not Applicable	Explosive properties	Not Available	
Flammability	Not Available	Oxidising properties	Not Available	
Upper Explosive Limit (%)	Not Available	Surface Tension (dyn/cm or mN/m)	Not Applicable	
Lower Explosive Limit (%)	Not Available	Volatile Component (%vol)	Negligible	
Vapour pressure (kPa)	Negligible	Gas group	Not Available	
Solubility in water	Miscible	pH as a solution (1%)	4.5-6.0	
Vapour density (Air = 1)	Not Applicable	VOC g/L	Not Available	
Heat of Combustion (kJ/g)	Not Available	Ignition Distance (cm)	Not Available	
Flame Height (cm)	Not Available	Flame Duration (s)	Not Available	
Enclosed Space Ignition Time Equivalent (s/m3)	Not Available	Enclosed Space Ignition Deflagration Density (g/m3)	Not Available	

#### **SECTION 10 Stability and reactivity**

Reactivity	See section 7
Chemical stability	<ul> <li>Unstable in the presence of incompatible materials.</li> <li>Product is considered stable.</li> <li>Hazardous polymerisation will not occur.</li> </ul>

Possibility of hazardous reactions	See section 7
Conditions to avoid	See section 7
Incompatible materials	See section 7
Hazardous decomposition products	See section 5

#### **SECTION 11 Toxicological information**

#### Information on toxicological effects

	······································	
Chronic	Long-term exposure to the product is not thought to produce ch using animal models); nevertheless exposure by all routes sho Long term exposure to high dust concentrations may cause ch less than 0.5 micron penetrating and remaining in the lung.	nronic effects adverse to the health (as classified by EC Directives uld be minimised as a matter of course. anges in lung function i.e. pneumoconiosis, caused by particles
Eye	Although the material is not thought to be an irritant (as classifi transient discomfort characterised by tearing or conjunctival re-	ed by EC Directives), direct contact with the eye may cause dness (as with windburn). Slight abrasive damage may also result.
Skin Contact	The material is not thought to produce adverse health effects o using animal models). Nevertheless, good hygiene practice rec be used in an occupational setting. Open cuts, abraded or irritated skin should not be exposed to t	or skin irritation following contact (as classified by EC Directives quires that exposure be kept to a minimum and that suitable gloves his material
Ingestion	Accidental ingestion of the material may be damaging to the he H2-receptor antagonist antihistamines, such as Ranitidine (Zar redness, skin death and inflammation.	ealth of the individual. ntac), can change the heart rate, cause a rash, blisters and
Inhaled	<ul> <li>Inhalation of dusts, generated by the material during the course individual.</li> <li>Persons with impaired respiratory function, airway diseases an further disability if excessive concentrations of particulate are in If prior damage to the circulatory or nervous systems has occur should be conducted on individuals who may be exposed to ful exposures.</li> <li>H2-receptor antagonist antihistamines, such as Ranitidine (Zar redness, skin death and inflammation.</li> </ul>	e of normal handling, may be damaging to the health of the d conditions such as emphysema or chronic bronchitis, may incur nhaled. rred or if kidney damage has been sustained, proper screenings rther risk if handling and use of the material result in excessive ntac), can change the heart rate, cause a rash, blisters and

Ulcer Relief	TOXICITY	IRRITATION
	Not Available	Not Available
	ΤΟΧΙΟΙΤΥ	IRRITATION
ranitidine hydrochloride	Oral (Rabbit) LD50; 2500 mg/kg <sup>[2]</sup>	Eye (rabbit): minimal OECD 405 Kay and Calandra score=3 IRE Assay: negative Not likely to be a sever irritant
Legend:	1. Value obtained from Europe ECHA Registered Substances - Acute toxicity 2. Value obtained from manufacturer's SDS. Unless otherwise specified data extracted from RTECS - Register of Toxic Effect of chemical Substances	

RANITIDINE Coma, pulse change, sweating, dyspnea, dermatitis after systemic, headache, hallucinations, convulsions, excitement, change in HYDROCHLORIDE cardiac rate, somnolence, cyanosis recorded Respiratory or skin sensitization Respiratory sensitization May cause sensitization by inhalation. May cause allergy or asthma symptoms or breathing difficulties if inhaled. Occupational exposure Result: Positive Species: Human Skin sensitization May cause sensitization by skin contact. May cause an allergic skin reaction. Sensitization Occupational exposure- Result: Positive:Species: Human Optimisation Test: Result: Weak sensitiser: Species: Guinea pig Germ cell mutagenicity Based on available data, the classification criteria are not met. No data available to indicate product or any components present at greater than 0.1% are mutagenic or genotoxic. Mutagenicity Ames Assay, GLP assay - Result: Negative Chromosomal Aberration Assay In Vitro, human lymphocytes, Ranitidine bismuth citrate tested: Result: Positive Chromosomal Aberration Assay In Vivo; germ cells, Maximum dose = 1000 mg/kg: Result: Negative - Species: Mouse GreenScreen Assay: Result: Negative Micronucleus Test: Result: Negative - Species: Rat Mouse Lymphoma Cell (L5178Y) Mutation Assay, GLP assay: Result: Negative SOS/umu Assay: Result: Negative Unscheduled DNA Synthesis in vivo, Maximum dose = 200 mg/kg: Result: Negative -Species: Rat; Organ: Stomach Yeast Mutation Assay: Result: Negative Carcinogenicity Based on available data, the classification criteria are not met. This product is not considered to be a carcinogen by IARC, ACGIH, NTP, or OSHA. 2 year bioassay, Maximum dose = 2000 mg/kg/day: Result: Negative - Species: Mouse 2 year bioassay, Maximum dose = 2000 mg/kg/day Result .: negative - Species: rat Reproductive toxicity Based on available data, the classification criteria are not met. Reproductivity Embryo-foetal development - Oral: Result: Foetal NOAEL = 100 mg/kg/day (maximum dose); Maternal NOAEL = 25 mg/kg/day (decreased weight gain at 50 and 100 mg/kg/day) Species: Rat Embryo-foetal development - Oral: Result: NOAEL = 100 mg/kg/day (maximum dose) - Species: Rabbit Fertility: Result: NOAEL / fertility = 100 mg/kg/day (male) and 200 mg/kg/day (female) (maximum doses) - Species: Rat Specific target organ toxicity - single exposure: Due to lack of data the classification is not possible. Specific target organ toxicity - repeated exposure Chronic effects Prolonged inhalation may be harmful Side effects H2 blockers are uncommon, usually minor and include diarrhea, constipation, fatigue, drowsiness, headache confusion, rash and muscle aches. Reversible confusional states may occur, for example, in elderly patients. Other adverse effects may include allergic reactions, arthralgia and myalgia, blood disorders including agranulocytosis or granulocytopenia and thrombocytopenia, headache, interstitial nephritis, hepatotoxicity and pancreatitis.

In addition, gynecomastia occurred in 0.1% to .5% of men treated for nonhypersecretory conditions with cimetidine for 1 month or longer and in about 2% of men treated for pathologic hypersecretory conditions; in even fewer men, cimetidine may also cause loss of libido, and impotence, all of which are reversible upon discontinuation

A 31-study review found that overall risk of pneumonia is about 1 in 4 higher among H2 antagonist users

The H2 receptor blockers are metabolized in the liver by the cytochrome P450 system. Among the four agents, cimetidine is distinctive in its potent inhibition of the P450 system (CYP 1A2, 2C9 and 2D6), which can result in significant drug interactions. All four H2 receptor blockers have been implicated in rare cases of clinically apparent, acute liver injury. The most cases have been linked to ranitidine and cimetidine, but these two agents are also the most commonly used.

Famotidine has negligible effect on the CYP system, and appears to have no significant interactions.

The effects derived from the inhibition of acetylcholinesterase by H2-antagonists may affect intestinal motility. Ranitidine had the most potent stimulating effect on contraction, the pattern of which was similar to physostigmine and was blocked by atropine and morphine.

For G-protein inhibitors:/ antagonists/ modulators.

G protein-coupled receptors (GPCRs) are essential cell membrane signaling molecules and represent the most important class of drug targets. Some signaling pathways downstream of a GPCR may be responsible for drug adverse effects, while others mediate therapeutic efficacy. Biased ligands preferentially activate only a subset of all GPCR signaling pathways. They hold great potential to become next-generation GPCR drugs with less side effects due to their potential to exclusively activate desired signaling pathways.

GPCR ligands include odorants, tastants, and neurotransmitters, and vary in size and properties. Dramatic chemical diversity may occur even among ligands of the same receptor. Chemical variability of antagonists significantly correlates with the binding site hydrophobicity and anti-correlates with the number of hydrogen bond donors in the binding site. The number of disulfide bridges in the extracellular region of a receptor anti-correlates with the range of molecular weights of its antagonists, highlighting the role of the entrance pathway in determining the size selectivity for GPCR antagonists.

The number of protein targets included in the cross-pharmacology profile of the different GPCRs changes significantly upon varying the ligand similarity and binding affinity criteria. However, with the exception of muscarinic receptors, aminergic GPCRs distinguish themselves from the rest of the members in the family by their remarkably high levels of pharmacological similarity among them.

GPCRs are classified under the GRAFS system (Metabotropic Glutamate, Rhodopsin, Adhesion, Frizzled/taste2/Smoothened and Secretin), with therapies having been developed for about 30 GPCRs from the glutamate, rhodopsin and secretin families. GPCR signaling requires significant conformational changes within the trans-membrane TM domain, triggered by agonist binding, and is often coupled to interactions from the extracellular domains or loops. It is becoming clear that many binding sites and mechanisms exist for positive and negative allosteric regulation, and for biased signaling pathways, likely in greater numbers than seen in most other protein systems.

When GPCRs are exposed to a neutral agonist, such as morphine on mu-opioid receptor, an occupied receptor can generate several signal waves (non-biased agonist). In GPCR signaling, the ability of a molecule to selectively activate one pathway without affecting another pathway is called biased agonism. Biased signaling occurs at different signaling proteins, including G proteins, GRKs, beta-arrestins, and even at levels of the allosteric binding site. Since GPCR activation-induced two distinct signal waves, G protein-dependent signaling followed by beta-arrestin-dependent signaling opens a new promising therapeutic future in the world of GPCRs. This is true since discovering such molecules dramatically lowers the adverse effects by turning off unwanted signals. For example, the analgesic effect of morphine (neutral agonist) through the activation of u-receptors is accompanied by several side effects, including constipation, respiratory depression, tolerance, nausea, and sedation Despite the long history and obvious desirability of developing drugs targeting GPCRs, there are several problems associated with their development. For example, the muscarinic M1 receptor is a well-validated target for agonists that could alleviate cognitive decline during neurodegeneration .

Muscarinic acetylcholine receptors (MRs, or mAChRs), which are more sensitive to muscarine than to nicotine, are a group of class A GPCRs comprising five distinct subtypes, named as muscarinic M1, M2, M3, M4, and M5 receptors (M1R-M5R) M1R, M3R, and M5R are coupled to the Gq/11 family of G proteins, whereas M2R and M4R are coupled to the Gi/o family of G proteins.

However, the orthosteric binding site of M1 is virtually identical to those of the related receptors M2,M3, M4, and M5 as they all bind the native ligand acetylcholine, and activation of M2 and M3 in particular gives rise to dose-limiting side effects (gastrointestinal [GI] disturbances, cardiovascular effects).

Atropine and other anticholinergic agents exert their bronchodilator effects through the blockade of MRs in the airways. As a tertiary ammonium derivative, atropine is a nonselective antagonist with similar affinity for all of the MR subtypes The half-life of atropine for M3R residence is 3.5 hours. Although extensively used in the past, atropine is rarely used at the present time because it is well absorbed into the systemic circulation and penetrates the blood–brain barrier, leading to multiple systemic side effects, including tachycardia.

Several long-acting muscarinic antagonists (LAMAs) are under investigation or are available for the treatment of obstructive airway diseases. LAMAs are considered to be safe drugs at recommended dosages. However, because MRs are expressed not only in the lungs, but also in the heart and the digestive and urinary tracts, the blockade of different MR subtypes in these organs by LAMA treatment can cause diverse, unwanted physiologic effects. For example, these agents can initially block prejunctional M2R on cholinergic airway nerves that normally reduce the release of the bronchoconstricting neurotransmitter acetylcholine, thus resulting in cough and paradoxical bronchoconstriction. Side effects including cardiovascular morbidity and mortality of inhaled LAMA agents in asthma need to be further studied and defined.

Another potential source of side effects when targeting other receptors could arise due to signaling through multiple different pathways

There are multiple signaling pathways for GPCRs, and it is sometimes possible to bias the signaling of a given GPCR through either a specific G protein or through beta arrestin which could reduce the side effects of some drugs

Targeting G protein alpha-subunits has the potential for pleiotropic effects and could result in multiple side effects.

Particular targets of concern include ion channels such as the G protein-activated inward rectifier K+ channel (GIRK) and the Ntype voltage-gated calcium channels. Gbeta-gamma activates GIRK channels in neurons and in atria, leading to a

hyperpolarization-induced decrease in action potential firing. Therefore, when considering the use of Gbeta-gamma inhibitors in cardiac or immune therapy, interfering with the regulation of action potentials would have highly undesirable side effects, such as arrhythmias. However, empirical data using prototypical Gbeta-gamma blockers indicate that these pathways are unaffected by Gbeta-gamma inhibitors, and animals treated with gallein show no signs of arrhythmias or alterations in heart rate.

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Skin Irritation/Corrosion	Reproc	luctivity 💙
Serious Eye Damage/Irritation	K STOT - Single E	kposure X
Respiratory or Skin sensitisation	STOT - Repeated E	kposure 🗙
Mutagenicity 🗙	K Aspiration	Hazard X

Legend: X – Data either not available or does not fill the criteria for classification V – Data available to make classification

# **SECTION 12 Ecological information**

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Ulcer Relief	Endpoint	Test Duration (hr)	Species	Value	Source
	Not Available	Not Available	Not Available	Not Available	Not Available
ranitidine hydrochloride	Endpoint	Test Duration (hr)	Species	Value	Source
	Not Available	Not Available	Not Available	Not Available	Not Available
Legend:	Extracted from 4. US EPA, E Bioconcentra	n 1. IUCLID Toxicity Data 2. Europe ECHA cotox database - Aquatic Toxicity Data 5. E0 tion Data 7. METI (Japan) - Bioconcentratio	Registered Substances - Ecotoxicolog CETOC Aquatic Hazard Assessment D n Data 8. Vendor Data	ical Information - Aqu Data 6. NITE (Japan)	latic Toxicity -

#### DO NOT discharge into sewer or waterways.

# Persistence and degradability

Ingredient	Persistence: Water/Soil	Persistence: Air
	No Data available for all ingredients	No Data available for all ingredients

# **Bioaccumulative potential**

Ingredient	Bioaccumulation
	No Data available for all ingredients
Mahility in anil	

mobility in Son	
Ingredient	Mobility
	No Data available for all ingredients

#### **SECTION 13 Disposal considerations**

Waste treatment methods	
Product / Packaging disposal	<ul> <li>Legislation addressing waste disposal requirements may differ by country, state and/ or territory. Each user must refer to laws operating in their area. In some areas, certain wastes must be tracked.</li> <li>A Hierarchy of Controls seems to be common - the user should investigate: <ul> <li>Reduction</li> <li>Reuse</li> <li>Recycling</li> <li>Disposal (if all else fails)</li> </ul> </li> <li>This material may be recycled if unused, or if it has not been contaminated so as to make it unsuitable for its intended use. Shelf life considerations should also be applied in making decisions of this type. Note that properties of a material may change in use, and recycling or reuse may not always be appropriate. In most instances the supplier of the material should be consulted.</li> <li>DO NOT allow wash water from cleaning or process equipment to enter drains.</li> <li>It may be necessary to collect all wash water for treatment before disposal.</li> <li>In all cases disposal to sever may be subject to local laws and regulations and these should be considered first.</li> <li>Where in doubt contact the responsible authority.</li> <li>Recycle wherever possible.</li> <li>Consult manufacturer for recycling options or consult local or regional waste management authority for disposal if no suitable treatment or disposal facility can be identified.</li> <li>Dispose of by: burial in a land-fill specifically licensed to accept chemical and / or pharmaceutical wastes or Incineration in a licensed apparatus (after admixture with suitable combustible material)</li> <li>Decontaminate empty containers. Observe all label safeguards until containers are cleaned and destroyed.</li> </ul>

#### Labels Required

Marine Pollutant	NO
HAZCHEM	Not Applicable

#### Land transport (ADG): NOT REGULATED FOR TRANSPORT OF DANGEROUS GOODS

# Air transport (ICAO-IATA / DGR): NOT REGULATED FOR TRANSPORT OF DANGEROUS GOODS

#### Sea transport (IMDG-Code / GGVSee): NOT REGULATED FOR TRANSPORT OF DANGEROUS GOODS

#### 14.7.1. Transport in bulk according to Annex II of MARPOL and the IBC code

Not Applicable

#### 14.7.2. Transport in bulk in accordance with MARPOL Annex V and the IMSBC Code

Product name	Group
ranitidine hydrochloride	Not Available

#### 14.7.3. Transport in bulk in accordance with the IGC Code

Product name	Ship Type
ranitidine hydrochloride	Not Available

#### **SECTION 15 Regulatory information**

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

ranitidine hydrochloride is found on the following regulatory lists

Australia Standard for the Uniform Scheduling of Medicines and Poisons (SUSMP) - Schedule 2 Australia Standard for the Uniform Scheduling of Medicines and Poisons (SUSMP) - Schedule 4

#### **Additional Regulatory Information**

Not Applicable

# National Inventory Status

National Inventory	Status
Australia - AIIC / Australia Non-Industrial Use	No (ranitidine hydrochloride)
Canada - DSL	No (ranitidine hydrochloride)
Canada - NDSL	No (ranitidine hydrochloride)
China - IECSC	No (ranitidine hydrochloride)
Europe - EINEC / ELINCS / NLP	Yes
Japan - ENCS	No (ranitidine hydrochloride)
Korea - KECI	No (ranitidine hydrochloride)
New Zealand - NZIoC	Yes
Philippines - PICCS	No (ranitidine hydrochloride)
USA - TSCA	No (ranitidine hydrochloride)
Taiwan - TCSI	Yes
Mexico - INSQ	Yes
Vietnam - NCI	Yes
Russia - FBEPH	No (ranitidine hydrochloride)
Legend:	Yes = All CAS declared ingredients are on the inventory No = One or more of the CAS listed ingredients are not on the inventory. These ingredients may be exempt or will require registration.

#### **SECTION 16 Other information**

Revision Date	10/12/2021
Initial Date	20/05/2013

#### Other information

Classification of the preparation and its individual components has drawn on official and authoritative sources as well as independent review by the Chemwatch Classification committee using available literature references.

The SDS is a Hazard Communication tool and should be used to assist in the Risk Assessment. Many factors determine whether the reported Hazards are Risks in the workplace or other settings. Risks may be determined by reference to Exposures Scenarios. Scale of use, frequency of use and current or available engineering controls must be considered.

#### **Definitions and abbreviations**

- PC TWA: Permissible Concentration-Time Weighted Average
- PC STEL: Permissible Concentration-Short Term Exposure Limit
- IARC: International Agency for Research on Cancer
- ACGIH: American Conference of Governmental Industrial Hygienists
- STEL: Short Term Exposure Limit
- TEEL: Temporary Emergency Exposure Limit。
- IDLH: Immediately Dangerous to Life or Health Concentrations
- ES: Exposure Standard
- OSF: Odour Safety Factor
- NOAEL: No Observed Adverse Effect Level
- LOAEL: Lowest Observed Adverse Effect Level
- TLV: Threshold Limit Value
- LOD: Limit Of Detection
- OTV: Odour Threshold Value
- BCF: BioConcentration Factors
- BEI: Biological Exposure Index
- DNEL: Derived No-Effect Level
- PNEC: Predicted no-effect concentration
- AIIC: Australian Inventory of Industrial Chemicals
- DSL: Domestic Substances List
- NDSL: Non-Domestic Substances List
- IECSC: Inventory of Existing Chemical Substance in China
- EINECS: European INventory of Existing Commercial chemical Substances
- ELINCS: European List of Notified Chemical Substances
- NLP: No-Longer Polymers
- ENCS: Existing and New Chemical Substances Inventory
- KECI: Korea Existing Chemicals Inventory
- NZIoC: New Zealand Inventory of Chemicals
- PICCS: Philippine Inventory of Chemicals and Chemical Substances
- TSCA: Toxic Substances Control Act
- TCSI: Taiwan Chemical Substance Inventory
- INSQ: Inventario Nacional de Sustancias Químicas
- NCI: National Chemical Inventory
- FBEPH: Russian Register of Potentially Hazardous Chemical and Biological Substances

