



## Dithiazide™, Hydrochlorothiazide, 25mg, Tablet

### Phebra Pty Ltd

Chemwatch Hazard Alert Code: 2

Chemwatch: 23-3289

Version No: 5.1

Safety Data Sheet according to WHS Regulations (Hazardous Chemicals) Amendment 2020 and ADG requirements

Issue Date: 10/12/2021

Print Date: 30/06/2022

S.GHS.AUS.EN.E

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

### Product Identifier

<b>Product name</b>	Dithiazide™, Hydrochlorothiazide, 25mg, Tablet
<b>Chemical Name</b>	Not Applicable
<b>Synonyms</b>	Not Available
<b>Chemical formula</b>	Not Applicable
<b>Other means of identification</b>	Not Available

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

<b>Relevant identified uses</b>	Dithiazide is a thiazide diuretic which is indicated for the treatment of hypertension either used alone or in combination with other antihypertensive drugs. Dithiazide is also approved for the treatment of oedema associated with congestive heart failure, hepatic cirrhosis, nephrotic syndrome, acute glomerulonephritis, chronic renal failure, premenstrual tension and drug induced oedema.
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### Details of the supplier of the safety data sheet

<b>Registered company name</b>	Phebra
<b>Address</b>	17-19 Orion Road Lane Cove West NSW 2066 Australia
<b>Telephone</b>	+61 2 9420 9199 1800 720 020
<b>Fax</b>	+61 2 9420 9177
<b>Website</b>	<a href="http://www.phebra.com">www.phebra.com</a>
<b>Email</b>	msds@phebra.com

### Emergency telephone number

<b>Association / Organisation</b>	Phebra
<b>Emergency telephone numbers</b>	+61 401 264 004
<b>Other emergency telephone numbers</b>	N/A

## SECTION 2 Hazards identification

### Classification of the substance or mixture

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


#### ChemWatch Hazard Ratings

	Min	Max	
Flammability	1	1	
Toxicity	1	1	0 = Minimum
Body Contact	1	1	1 = Low
Reactivity	1	1	2 = Moderate
Chronic	2	2	3 = High
			4 = Extreme

<b>Poisons Schedule</b>	S4
<b>Classification [1]</b>	Skin Corrosion/Irritation Category 2, Serious Eye Damage/Eye Irritation Category 2A, Germ Cell Mutagenicity Category 2, Carcinogenicity Category 2, Specific Target Organ Toxicity - Repeated Exposure Category 2
<b>Legend:</b>	1. Classified by Chemwatch; 2. Classification drawn from HCIS; 3. Classification drawn from Regulation (EU) No 1272/2008 - Annex VI

### Label elements

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Hazard pictogram(s)	
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Signal word	<b>Warning</b>
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**Hazard statement(s)**

H315	Causes skin irritation.
H319	Causes serious eye irritation.
H341	Suspected of causing genetic defects.
H351	Suspected of causing cancer.
H373	May cause damage to organs through prolonged or repeated exposure.

**Precautionary statement(s) Prevention**

P201	Obtain special instructions before use.
P260	Do not breathe dust/fume.
P280	Wear protective gloves, protective clothing, eye protection and face protection.
P264	Wash all exposed external body areas thoroughly after handling.

**Precautionary statement(s) Response**

P308+P313	IF exposed or concerned: Get medical advice/ attention.
P305+P351+P338	IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.
P314	Get medical advice/attention if you feel unwell.
P337+P313	If eye irritation persists: Get medical advice/attention.
P302+P352	IF ON SKIN: Wash with plenty of water.
P332+P313	If skin irritation occurs: Get medical advice/attention.
P362+P364	Take off contaminated clothing and wash it before reuse.

**Precautionary statement(s) Storage**

P405	Store locked up.
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**Precautionary statement(s) Disposal**

P501	Dispose of contents/container to authorised hazardous or special waste collection point in accordance with any local regulation.
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Not Applicable

**SECTION 3 Composition / information on ingredients**

**Substances**

See section below for composition of Mixtures

**Mixtures**

CAS No	%[weight]	Name
63-42-3	>60	<u>alpha-lactose</u>
58-93-5	23.15	<u>hydrochlorothiazide</u>
7757-93-9	<10	<u>calcium phosphate, dibasic</u>
9005-25-8	<10	<u>starch</u>
557-04-0	<1	<u>magnesium stearate</u>
2783-94-0	<0.1	<u>C.I. Food Yellow 3</u>

**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**

<b>Eye Contact</b>	<p>If this product comes in contact with eyes:</p> <ul style="list-style-type: none"> <li>▶ Wash out immediately with water.</li> <li>▶ If irritation continues, seek medical attention.</li> <li>▶ Removal of contact lenses after an eye injury should only be undertaken by skilled personnel.</li> </ul>
<b>Skin Contact</b>	<p>If skin or hair contact occurs:</p> <ul style="list-style-type: none"> <li>▶ Flush skin and hair with running water (and soap if available).</li> <li>▶ Seek medical attention in event of irritation.</li> </ul>

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<b>Inhalation</b>	<ul style="list-style-type: none"> <li>▶ If dust is inhaled, remove from contaminated area.</li> <li>▶ Encourage patient to blow nose to ensure clear passage of breathing.</li> <li>▶ If irritation or discomfort persists seek medical attention.</li> </ul>
<b>Ingestion</b>	<ul style="list-style-type: none"> <li>▶ <b>If swallowed do NOT induce vomiting.</b></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

In massive overdose treatment should be symptomatic and directed at fluid and electrolyte replacement. In case of recent ingestion gastric lavage should be carried out.  
MARTINDALE: The Extra Pharmacopoeia, 29th Edition.  
Treat symptomatically.

In cases of recent sulfonamide overdose the stomach should be emptied by aspiration and lavage. If kidney function is adequate, a saline purgative, such as sodium sulfate, 30 g in 250 ml water, may be given to promote peristalsis and elimination of sulfonamide in the urine may be assisted by giving alkalies, such as sodium bicarbonate and increasing fluid intake. Severe crystalluria may require ureteric catheterisation and irrigation with warm 2.5% sodium bicarbonate solution. Treatment should be continued until it can be assumed that the sulfonamide has been eliminated. The majority of sulfonamides are metabolised to acetylated derivatives which retain the toxicity of the parent compound and thus may indicate more active removal when adverse effects are very severe. Active measures may include forced diuresis, peritoneal dialysis and charcoal haemoperfusion.

[Martindale: The Extra Pharmacopoeia, 28th Ed.]

## SECTION 5 Firefighting measures

### Extinguishing media

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

### Special hazards arising from the substrate or mixture

<b>Fire Incompatibility</b>	▶ Avoid contamination with oxidising agents i.e. nitrates, oxidising acids, chlorine bleaches, pool chlorine etc. as ignition may result
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### Advice for firefighters

<b>Fire Fighting</b>	<ul style="list-style-type: none"> <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>▶ <b>DO NOT</b> 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> <p>Slight hazard when exposed to heat, flame and oxidisers.</p>
<b>Fire/Explosion Hazard</b>	<ul style="list-style-type: none"> <li>▶ Combustible.</li> <li>▶ Slight fire hazard when exposed to heat or flame.</li> <li>▶ Heating may cause expansion or decomposition leading to violent rupture of containers.</li> <li>▶ On combustion, may emit toxic fumes of carbon monoxide (CO).</li> <li>▶ May emit acrid smoke.</li> <li>▶ Mists containing combustible materials may be explosive.</li> </ul> <p>Combustion products include: carbon dioxide (CO<sub>2</sub>) hydrogen chloride phosgene nitrogen oxides (NO<sub>x</sub>) sulfur oxides (SO<sub>x</sub>) other pyrolysis products typical of burning organic material. May emit corrosive fumes.</p>
<b>HAZCHEM</b>	Not Applicable

## 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

<b>Minor Spills</b>	<ul style="list-style-type: none"> <li>▶ Clean up all spills immediately.</li> <li>▶ Secure load if safe to do so.</li> <li>▶ Bundle/collect recoverable product.</li> <li>▶ Collect remaining material in containers with covers for disposal.</li> </ul>
<b>Major Spills</b>	<ul style="list-style-type: none"> <li>▶ Minor hazard.</li> <li>▶ Clear area of personnel.</li> <li>▶ Alert Fire Brigade and tell them location and nature of hazard.</li> <li>▶ Wear physical protective gloves e.g. Leather.</li> <li>▶ Contain spill/secure load if safe to do so.</li> </ul>

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- ▶ Bundle/collect recoverable product and label for recycling.
- ▶ Collect remaining product and place in appropriate containers for disposal.
- ▶ Clean up/sweep up area.

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

### SECTION 7 Handling and storage

#### Precautions for safe handling

<b>Safe handling</b>	No special handling procedures required.
<b>Other information</b>	▶ Store away from incompatible materials.

#### Conditions for safe storage, including any incompatibilities

<b>Suitable container</b>	<ul style="list-style-type: none"> <li>▶ Polyethylene or polypropylene container.</li> <li>▶ Packing as recommended by manufacturer.</li> <li>▶ Check all containers are clearly labelled and free from leaks.</li> </ul> Plastic container
<b>Storage incompatibility</b>	▶ Avoid reaction with oxidising agents

### SECTION 8 Exposure controls / personal protection

#### Control parameters

##### Occupational Exposure Limits (OEL)

##### INGREDIENT DATA

Source	Ingredient	Material name	TWA	STEL	Peak	Notes
Australia Exposure Standards	starch	Starch	10 mg/m <sup>3</sup>	Not Available	Not Available	(a) This value is for inhalable dust containing no asbestos and < 1% crystalline silica.
Australia Exposure Standards	magnesium stearate	Stearates	10 mg/m <sup>3</sup>	Not Available	Not Available	(a) This value is for inhalable dust containing no asbestos and < 1% crystalline silica.

##### Emergency Limits

Ingredient	TEEL-1	TEEL-2	TEEL-3
starch	30 mg/m <sup>3</sup>	330 mg/m <sup>3</sup>	2,000 mg/m <sup>3</sup>


Ingredient	Original IDLH	Revised IDLH
alpha-lactose	Not Available	Not Available
hydrochlorothiazide	Not Available	Not Available
calcium phosphate, dibasic	Not Available	Not Available
starch	Not Available	Not Available
magnesium stearate	Not Available	Not Available
C.I. Food Yellow 3	Not Available	Not Available

##### Occupational Exposure Banding

Ingredient	Occupational Exposure Band Rating	Occupational Exposure Band Limit
hydrochlorothiazide	E	≤ 0.01 mg/m <sup>3</sup>
calcium phosphate, dibasic	E	≤ 0.01 mg/m <sup>3</sup>
C.I. Food Yellow 3	E	≤ 0.01 mg/m <sup>3</sup>

**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

<b>Appropriate engineering controls</b>	<p>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.</p>
<b>Personal protection</b>	
<b>Eye and face protection</b>	<p>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:</p> <ul style="list-style-type: none"> <li>▶ Chemical goggles.</li> <li>▶ Face shield. Full face shield may be required for supplementary but never for primary protection of eyes.</li> </ul>

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	<ul style="list-style-type: none"> <li>▶ 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.</li> </ul>
<b>Skin protection</b>	See Hand protection below
<b>Hands/feet protection</b>	Wear general protective gloves, eg. light weight rubber gloves. No special equipment required due to the physical form of the product.
<b>Body protection</b>	See Other protection below
<b>Other protection</b>	No special equipment needed when handling small quantities. <b>OTHERWISE:</b> <ul style="list-style-type: none"> <li>▶ Overalls.</li> <li>▶ Barrier cream.</li> <li>▶ Eyewash unit.</li> </ul>

**Respiratory protection**

Particulate. (AS/NZS 1716 & 1715, EN 143:2000 & 149:001, ANSI Z88 or national equivalent)

Where the concentration of gas/particulates in the breathing zone, approaches or exceeds the "Exposure Standard" (or ES), respiratory protection is required.

Degree of protection varies with both face-piece and Class of filter; the nature of protection varies with Type of filter.

Required Minimum Protection Factor	Half-Face Respirator	Full-Face Respirator	Powered Air Respirator
up to 10 x ES	-AUS P2	-	-PAPR-AUS / Class 1 P2
up to 50 x ES	-	-AUS / Class 1 P2	-
up to 100 x ES	-	-2 P2	-PAPR-2 P2 ^

^ - Full-face

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(SO<sub>2</sub>), G = Agricultural chemicals, K = Ammonia(NH<sub>3</sub>), Hg = Mercury, NO = Oxides of nitrogen, MB = Methyl bromide, AX = Low boiling point organic compounds(below 65 degC)

**SECTION 9 Physical and chemical properties****Information on basic physical and chemical properties**

<b>Appearance</b>	Round, light, orange, flat face, bevelled edge tablets.		
<b>Physical state</b>	Manufactured	<b>Relative density (Water = 1)</b>	Not Available
<b>Odour</b>	Not Available	<b>Partition coefficient n-octanol / water</b>	Not Available
<b>Odour threshold</b>	Not Available	<b>Auto-ignition temperature (°C)</b>	Not Available
<b>pH (as supplied)</b>	Not Applicable	<b>Decomposition temperature (°C)</b>	Not Available
<b>Melting point / freezing point (°C)</b>	Not Available	<b>Viscosity (cSt)</b>	Not Applicable
<b>Initial boiling point and boiling range (°C)</b>	Not Applicable	<b>Molecular weight (g/mol)</b>	Not Available
<b>Flash point (°C)</b>	Not Available	<b>Taste</b>	Not Available
<b>Evaporation rate</b>	Not Applicable	<b>Explosive properties</b>	Not Available
<b>Flammability</b>	Not Available	<b>Oxidising properties</b>	Not Available
<b>Upper Explosive Limit (%)</b>	Not Available	<b>Surface Tension (dyn/cm or mN/m)</b>	Not Applicable
<b>Lower Explosive Limit (%)</b>	Not Available	<b>Volatile Component (%vol)</b>	Not Applicable
<b>Vapour pressure (kPa)</b>	Not Applicable	<b>Gas group</b>	Not Available
<b>Solubility in water</b>	Not Available	<b>pH as a solution (Not Available%)</b>	Not Available
<b>Vapour density (Air = 1)</b>	Not Applicable	<b>VOC g/L</b>	Not Available

**SECTION 10 Stability and reactivity**

<b>Reactivity</b>	See section 7
<b>Chemical stability</b>	Product is considered stable and hazardous polymerisation will not occur.
<b>Possibility of hazardous reactions</b>	See section 7
<b>Conditions to avoid</b>	See section 7
<b>Incompatible materials</b>	See section 7
<b>Hazardous decomposition products</b>	See section 5

**SECTION 11 Toxicological information****Information on toxicological effects**

<b>Inhaled</b>	Not normally a hazard due to non-volatile nature of product
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	Considered an unlikely route of entry in commercial/industrial environments
<b>Ingestion</b>	Accidental ingestion of the material may be damaging to the health of the individual. Thiazides in general dilate the blood vessels. Large doses may produce gastrointestinal disturbances with nausea, vomiting and hypermobility; producing severe imbalance in patients salt levels. Potassium deficiency may cause confusion, dizziness and muscle weakness. Low blood pressure on standing, depressed function of the cardiovascular, respiratory and central nervous system may also occur; lethargy may turn into coma within hours. Hypersensitivity reactions have also been recorded. Giving treatment doses of thiazide may lead to low blood potassium, low chloride, alkalosis or acidosis, low chloride, acidosis or alkalosis, high calcium, low sodium, low magnesium, low phosphate, high urate (rarely with gout), azotemia, high blood cholesterol, reversible hyperthyroidism and a reduced serum protein-bound iodine. Impaired glucose tolerance, high blood sugar, sugar in the urine and precipitation or worsening of diabetes mellitus may occur. Gastrointestinal symptoms may include dry mouth, an unpleasant or bitter taste, salivary gland obstruction, diarrhoea, bloating, abdominal pain, constipation, poor appetite, and weight loss. Starch is generally of low toxicity. An abnormal craving for starch (amylophagia) during pregnancy has been recognized in certain areas. Sulfonamides and their derivatives can cause extensive kidney damage, and destroy red blood cells. Overdose may cause an accumulation of acid in the blood or a diminished blood sugar level with confusion and coma resulting.
<b>Skin Contact</b>	Open cuts, abraded or irritated skin should not be exposed to this material Entry into the blood-stream, through, for example, cuts, abrasions or lesions, may produce systemic injury with harmful effects. Examine the skin prior to the use of the material and ensure that any external damage is suitably protected. Not normally a hazard due to physical form of product.
<b>Eye</b>	There is some evidence to suggest that this material can cause eye irritation and damage in some persons. Eye drops with sulfonamides can cause local irritation, sensations of burning and stinging, blurred vision and loss of depth perception. The conjunctiva and cornea may become inflamed, and the cornea and lens may become clouded.
<b>Chronic</b>	Repeated or long-term occupational exposure is likely to produce cumulative health effects involving organs or biochemical systems. Strong evidence exists that this substance may cause irreversible mutations (though not lethal) even following a single exposure. There is some evidence from animal testing that exposure to this material may result in reduced fertility. Based on experience with animal studies, there is a possibility that exposure to the material may result in toxic effects to the development of the foetus, at levels which do not cause significant toxic effects to the mother. Some workers may develop chronic occupational dermatitis (generally mild) through the handling of starch products. When starch is used as a lubricant in surgical gloves, small amounts, released into the patient during the course of surgery, have resulted in granulomas and peritonitis. Prolonged oral treatment with sulfonamides has caused nausea, vomiting, diarrhoea, abdominal pain, loss of appetite, inflammation of the mouth cavity, impaired folic acid absorption, exacerbation of porphyria, acidosis, liver damage with impaired blood clotting, jaundice and inflammation of the pancreas. Effects on the kidney include blood and crystals in the urine, painful and frequent urination or lack of urine with nitrogen retention.

<b>Dithiazide™, Hydrochlorothiazide, 25mg, Tablet</b>	<b>TOXICITY</b>	<b>IRRITATION</b>
	Not Available	Not Available
<b>alpha-lactose</b>	<b>TOXICITY</b>	<b>IRRITATION</b>
	Oral (Rat) LD50; >10000 mg/kg <sup>[2]</sup>	Not Available
<b>hydrochlorothiazide</b>	<b>TOXICITY</b>	<b>IRRITATION</b>
	Oral (Mouse) LD50; 1175 mg/kg <sup>[2]</sup>	Not Available
<b>calcium phosphate, dibasic</b>	<b>TOXICITY</b>	<b>IRRITATION</b>
	Dermal (rabbit) LD50: >7940 mg/kg <sup>[2]</sup>	Eye (rabbit): 8 on a scale of 110
	Inhalation(Rat) LC50; >2.6 mg/l4h <sup>[1]</sup>	Eye: no adverse effect observed (not irritating) <sup>[1]</sup>
	Oral (Rat) LD50; >10000 mg/kg <sup>[2]</sup>	Skin (rabbit): 0 on a scale of 8 Skin: no adverse effect observed (not irritating) <sup>[1]</sup>
<b>starch</b>	<b>TOXICITY</b>	<b>IRRITATION</b>
	Not Available	Skin (human): 0.3 mg/3d-I mild
<b>magnesium stearate</b>	<b>TOXICITY</b>	<b>IRRITATION</b>
	Oral (Rat) LD50; >10000 mg/kg <sup>[2]</sup>	Not Available
<b>C.I. Food Yellow 3</b>	<b>TOXICITY</b>	<b>IRRITATION</b>
	dermal (rat) LD50: >2000 mg/kg <sup>[1]</sup>	Eye: no adverse effect observed (not irritating) <sup>[1]</sup>
	Oral (Rat) LD50; >2000 mg/kg <sup>[1]</sup>	Skin: no adverse effect observed (not irritating) <sup>[1]</sup>

**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

<b>ALPHA-LACTOSE</b>	Equivocal tumorigenic agent by RTECS criteria.
<b>HYDROCHLOROTHIAZIDE</b>	Oral (woman) LDLo: 2.5 mg/kg/5d - I <b>WARNING:</b> This substance has been classified by the IARC as Group 2B: Possibly Carcinogenic to Humans. <b>NOTE:</b> Substance has been shown to be mutagenic in at least one assay, or belongs to a family of chemicals producing damage or change to cellular DNA.
<b>CALCIUM PHOSPHATE, DIBASIC</b>	For calcium: Toxicity from calcium is not common, because the gastrointestinal tract normally limits the amount of calcium absorbed. Therefore, short-term intake of large amounts of calcium does not generally produce any ill effects aside from constipation and an increased risk of kidney stones. However, more severe toxicity can occur when excess calcium is ingested over long periods, or when calcium is combined with increased amounts of vitamin D, which increases calcium absorption. Calcium toxicity is also found sometimes after excessive administration of calcium via a vein. Toxicity shows as abnormal deposition of calcium in tissues and by elevated blood calcium levels. However, high blood calcium is often due to other causes, such as abnormally high amounts of parathyroid hormone (PTH). Usually, under these circumstances, bone density is lost,

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	and the resulting high blood calcium can cause kidney stones and abdominal pain. Some cancers can also cause high blood calcium, either by secreting abnormal proteins that act like PTH or by invading and killing bone cells causing them to release calcium.
<b>STARCH</b>	The material may cause skin irritation after prolonged or repeated exposure and may produce on contact skin redness, swelling, the production of vesicles, scaling and thickening of the skin.
<b>MAGNESIUM STEARATE</b>	Fatty acid salts of low acute toxicity. Their potential to irritate the skin and eyes is dependent on chain length.
<b>C.I. FOOD YELLOW 3</b>	<p>There has been public concern that food colourings may cause ADHD-like behavior in children. These concerns have led the FDA and other food safety authorities to regularly review the scientific literature, and led the UK FSA to commission a study by researchers at Southampton University of the effect of a mixture of six food dyes (Tartrazine, Allura Red AC, Ponceau 4R, Quinoline Yellow WS, Sunset Yellow and Carmoisine (dubbed the "Southampton 6")) and sodium benzoate (a preservative) on children in the general population, who consumed them in beverages; the study published in 2007. The study found "a possible link between the consumption of these artificial colours and a sodium benzoate preservative and increased hyperactivity" in the children; the advisory committee to the FSA that evaluated the study also determined that because of study limitations, the results could not be extrapolated to the general population, and further testing was recommended".</p> <p>The European regulatory community, with a stronger emphasis on the precautionary principle, required labelling and temporarily reduced the acceptable daily intake (ADI) for the food colourings; the UK FSA called for voluntary withdrawal of the colourings by food manufacturers. However, in 2009 the EFSA re-evaluated the data at hand and determined that "the available scientific evidence does not substantiate a link between the colour additives and behavioural effects".</p> <p>There is no evidence to support broad claims that food colouring causes food intolerance and ADHD-like behaviour in children. It is possible that certain food colouring may act as a trigger in those who are genetically predisposed, but the evidence is weak.</p> <p>Acceptable daily intake as food additive = 2.5 mg/kg FAO/WHO 1982</p>
<b>Dithiazide™, Hydrochlorothiazide, 25mg, Tablet &amp; HYDROCHLOROTHIAZIDE</b>	<p>The following information refers to contact allergens as a group and may not be specific to this product.</p> <p>Contact allergies quickly manifest themselves as contact eczema, more rarely as urticaria or Quincke's oedema. The pathogenesis of contact eczema involves a cell-mediated (T lymphocytes) immune reaction of the delayed type. Other allergic skin reactions, e.g. contact urticaria, involve antibody-mediated immune reactions. The significance of the contact allergen is not simply determined by its sensitisation potential: the distribution of the substance and the opportunities for contact with it are equally important. A weakly sensitising substance which is widely distributed can be a more important allergen than one with stronger sensitising potential with which few individuals come into contact. From a clinical point of view, substances are noteworthy if they produce an allergic test reaction in more than 1% of the persons tested.</p> <p>Allergic reactions involving the respiratory tract are usually due to interactions between IgE antibodies and allergens and occur rapidly. Allergic potential of the allergen and period of exposure often determine the severity of symptoms. Some people may be genetically more prone than others, and exposure to other irritants may aggravate symptoms. Allergy causing activity is due to interactions with proteins.</p> <p>Attention should be paid to atopic diathesis, characterised by increased susceptibility to nasal inflammation, asthma and eczema.</p> <p>Exogenous allergic alveolitis is induced essentially by allergen specific immune-complexes of the IgG type; cell-mediated reactions (T lymphocytes) may be involved. Such allergy is of the delayed type with onset up to four hours following exposure.</p>
<b>CALCIUM PHOSPHATE, DIBASIC &amp; MAGNESIUM STEARATE &amp; C.I. FOOD YELLOW 3</b>	<p>Asthma-like symptoms may continue for months or even years after exposure to the material ends. This may be due to a non-allergic condition known as reactive airways dysfunction syndrome (RADS) which can occur after exposure to high levels of highly irritating compound. Main criteria for diagnosing RADS include the absence of previous airways disease in a non-atopic individual, with sudden onset of persistent asthma-like symptoms within minutes to hours of a documented exposure to the irritant. Other criteria for diagnosis of RADS include a reversible airflow pattern on lung function tests, moderate to severe bronchial hyperreactivity on methacholine challenge testing, and the lack of minimal lymphocytic inflammation, without eosinophilia. RADS (or asthma) following an irritating inhalation is an infrequent disorder with rates related to the concentration of and duration of exposure to the irritating substance. On the other hand, industrial bronchitis is a disorder that occurs as a result of exposure due to high concentrations of irritating substance (often particles) and is completely reversible after exposure ceases. The disorder is characterized by difficulty breathing, cough and mucus production.</p>

<b>Acute Toxicity</b>	✗	<b>Carcinogenicity</b>	✓
<b>Skin Irritation/Corrosion</b>	✓	<b>Reproductivity</b>	✗
<b>Serious Eye Damage/Irritation</b>	✓	<b>STOT - Single Exposure</b>	✗
<b>Respiratory or Skin sensitisation</b>	✗	<b>STOT - Repeated Exposure</b>	✓
<b>Mutagenicity</b>	✓	<b>Aspiration Hazard</b>	✗

**Legend:** ✗ – Data either not available or does not fill the criteria for classification  
 ✓ – Data available to make classification

## SECTION 12 Ecological information

## Toxicity

Dithiazide™, Hydrochlorothiazide, 25mg, Tablet	Endpoint	Test Duration (hr)	Species	Value	Source
	Not Available	Not Available	Not Available	Not Available	Not Available
alpha-lactose	Endpoint	Test Duration (hr)	Species	Value	Source
	Not Available	Not Available	Not Available	Not Available	Not Available
hydrochlorothiazide	Endpoint	Test Duration (hr)	Species	Value	Source
	NOEC(ECx)	53h	Fish	0.012mg/L	4
calcium phosphate, dibasic	Endpoint	Test Duration (hr)	Species	Value	Source
	EC50(ECx)	48h	Crustacea	>2.9mg/l	2
	EC50	72h	Algae or other aquatic plants	>4.4mg/l	2
	EC50	48h	Crustacea	>2.9mg/l	2
	LC50	96h	Fish	>13.5mg/l	2
starch	Endpoint	Test Duration (hr)	Species	Value	Source
	Not Available	Not Available	Not Available	Not Available	Not Available

Continued...

## Dithiazide™, Hydrochlorothiazide, 25mg, Tablet

magnesium stearate	Endpoint	Test Duration (hr)	Species	Value	Source
	Not Available	Not Available	Not Available	Not Available	Not Available

C.I. Food Yellow 3	Endpoint	Test Duration (hr)	Species	Value	Source
	EC50	72h	Algae or other aquatic plants	113.2mg/l	2
	NOEC(ECx)	72h	Algae or other aquatic plants	15.729mg/l	2
	EC50	48h	Crustacea	>100mg/l	2
	EC50	96h	Algae or other aquatic plants	44524mg/l	2
	LC50	96h	Fish	>100mg/l	2

**Legend:** *Extracted from 1. IUCLID Toxicity Data 2. Europe ECHA Registered Substances - Ecotoxicological Information - Aquatic Toxicity 4. US EPA, Ecotox database - Aquatic Toxicity Data 5. ECETOC Aquatic Hazard Assessment Data 6. NITE (Japan) - Bioconcentration Data 7. METI (Japan) - Bioconcentration Data 8. Vendor Data*

Toxic to soil organisms.

For Sulfonamides:

Environmental Fate: Sulfonamides are the oldest and most widely used sulfa-related antibiotics which are used to treat bacterial, and some fungal, infections. These substances are used to in humans, and animals, as well as in aquaculture. Partitioning and reactivity of the different species of these substances are pH dependent, which plays an important role in their behavior in the environment and extraction techniques.

Atmospheric Fate: Natural sunlight may enhance the toxicity of the sulfonamides, likely because of the contribution of UVA light.

Terrestrial Fate: The sulfonamides dissipate more rapidly from the silt loam soil compared to sandy soil. Low concentrations of these substances are not expected to negatively impact soil microbes. Sulfonamides are only partially sorptive in soil and are non-persistent, and leachable. They are not classified as readily biodegradable .

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

#### Persistence and degradability

Ingredient	Persistence: Water/Soil	Persistence: Air
alpha-lactose	LOW	LOW
hydrochlorothiazide	HIGH	HIGH

#### Bioaccumulative potential

Ingredient	Bioaccumulation
alpha-lactose	LOW (LogKOW = -5.1249)
hydrochlorothiazide	LOW (LogKOW = -0.07)

#### Mobility in soil

Ingredient	Mobility
alpha-lactose	LOW (KOC = 10)
hydrochlorothiazide	LOW (KOC = 79.59)

### SECTION 13 Disposal considerations

#### Waste treatment methods

<b>Product / Packaging disposal</b>	<ul style="list-style-type: none"> <li>▶ Containers may still present a chemical hazard/ danger when empty.</li> <li>▶ Return to supplier for reuse/ recycling if possible.</li> </ul> <p>Otherwise:</p> <ul style="list-style-type: none"> <li>▶ If container can not be cleaned sufficiently well to ensure that residuals do not remain or if the container cannot be used to store the same product, then puncture containers, to prevent re-use, and bury at an authorised landfill.</li> <li>▶ Where possible retain label warnings and SDS and observe all notices pertaining to the product.</li> <li>▶ <b>DO NOT allow wash water from cleaning or process equipment to enter drains.</b></li> <li>▶ It may be necessary to collect all wash water for treatment before disposal.</li> <li>▶ In all cases disposal to sewer 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 or consult manufacturer for recycling options.</li> <li>▶ Consult State Land Waste Authority for disposal.</li> <li>▶ Bury or incinerate residue at an approved site.</li> <li>▶ Recycle containers if possible, or dispose of in an authorised landfill.</li> </ul>
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### SECTION 14 Transport information

#### Labels Required

<b>Marine Pollutant</b>	NO
<b>HAZCHEM</b>	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

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

Not Applicable

Continued...



**Transport in bulk in accordance with MARPOL Annex V and the IMSBC Code**

Product name	Group
alpha-lactose	Not Available
hydrochlorothiazide	Not Available
calcium phosphate, dibasic	Not Available
starch	Not Available
magnesium stearate	Not Available
C.I. Food Yellow 3	Not Available

**Transport in bulk in accordance with the ICG Code**

Product name	Ship Type
alpha-lactose	Not Available
hydrochlorothiazide	Not Available
calcium phosphate, dibasic	Not Available
starch	Not Available
magnesium stearate	Not Available
C.I. Food Yellow 3	Not Available

**SECTION 15 Regulatory information****Safety, health and environmental regulations / legislation specific for the substance or mixture****alpha-lactose is found on the following regulatory lists**

Australian Inventory of Industrial Chemicals (AIIC)

**hydrochlorothiazide is found on the following regulatory lists**

Australia Chemicals with non-industrial uses removed from the Australian Inventory of Chemical Substances (old Inventory)

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

FEI Equine Prohibited Substances List - Controlled Medication

FEI Equine Prohibited Substances List (EPSL)

International Agency for Research on Cancer (IARC) - Agents Classified by the IARC Monographs

International Agency for Research on Cancer (IARC) - Agents Classified by the IARC Monographs - Group 2B: Possibly carcinogenic to humans

**calcium phosphate, dibasic is found on the following regulatory lists**

Australian Inventory of Industrial Chemicals (AIIC)

**starch is found on the following regulatory lists**

Australian Inventory of Industrial Chemicals (AIIC)

**magnesium stearate is found on the following regulatory lists**

Australian Inventory of Industrial Chemicals (AIIC)

International WHO List of Proposed Occupational Exposure Limit (OEL) Values for Manufactured Nanomaterials (MNMS)

**C.I. Food Yellow 3 is found on the following regulatory lists**

Australian Inventory of Industrial Chemicals (AIIC)

International Agency for Research on Cancer (IARC) - Agents Classified by the IARC Monographs

**National Inventory Status**

National Inventory	Status
Australia - AIIC / Australia Non-Industrial Use	Yes
Canada - DSL	Yes
Canada - NDSL	No (alpha-lactose; hydrochlorothiazide; calcium phosphate, dibasic; magnesium stearate; C.I. Food Yellow 3)
China - IECSC	No (hydrochlorothiazide)
Europe - EINEC / ELINCS / NLP	Yes
Japan - ENCS	Yes
Korea - KECI	No (hydrochlorothiazide)
New Zealand - NZIoC	Yes
Philippines - PICCS	Yes
USA - TSCA	Yes
Taiwan - TCSI	Yes
Mexico - INSQ	No (hydrochlorothiazide; C.I. Food Yellow 3)
Vietnam - NCI	Yes
Russia - FBEPH	Yes
<b>Legend:</b>	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**

## Dithiazide™, Hydrochlorothiazide, 25mg, Tablet

<b>Revision Date</b>	10/12/2021
<b>Initial Date</b>	19/03/2010

**SDS Version Summary**

Version	Date of Update	Sections Updated
4.1	01/11/2019	One-off system update. NOTE: This may or may not change the GHS classification
5.1	10/12/2021	Classification change due to full database hazard calculation/update.

**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  
 AIIIC: 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

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