

## Cafnea™, Caffeine Citrate Injection, 40mg In 2ml

### Phebra Pty Ltd

Chemwatch: 23-0969

Version No: 6.1

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

Chemwatch Hazard Alert Code: 0

Issue Date: 01/11/2019

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S.GHS.AUS.EN.E

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

### Product Identifier

Product name	Cafnea™, Caffeine Citrate Injection, 40mg In 2ml
Chemical Name	Not Applicable
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

Relevant identified uses	CAFNEA injection is indicated for the short-term treatment of apnoea of prematurity in infants of gestational age 28 to less than 33 weeks.
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### Details of the manufacturer or supplier of the safety data sheet

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

### Emergency telephone number

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

## SECTION 2 Hazards identification

### Classification of the substance or mixture

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

### ChemWatch Hazard Ratings

	Min	Max
Flammability	0	
Toxicity	0	
Body Contact	0	
Reactivity	0	
Chronic	0	

0 = Minimum  
1 = Low  
2 = Moderate  
3 = High  
4 = Extreme

Poisons Schedule	Not Applicable
Classification [1]	Not Applicable

### Label elements

Hazard pictogram(s)	Not Applicable
Signal word	Not Applicable

## Cafnea™, Caffeine Citrate Injection, 40mg In 2ml

**Hazard statement(s)**

Not Applicable

**Precautionary statement(s) Prevention**

Not Applicable

**Precautionary statement(s) Response**

Not Applicable

**Precautionary statement(s) Storage**

Not Applicable

**Precautionary statement(s) Disposal**

Not Applicable

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

See section below for composition of Mixtures

**Mixtures**

CAS No	%[weight]	Name
58-08-2	1	<u>caffeine</u>
77-92-9	0.5	<u>citric acid</u>
6132-04-3	0.83	<u>sodium citrate dihydrate</u>
7732-18-5	>97.5	<u>water</u>
<b>Legend:</b> 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>
<b>Inhalation</b>	<ul style="list-style-type: none"> <li>▶ If fumes, aerosols or combustion products are inhaled remove from contaminated area.</li> <li>▶ Other measures are usually unnecessary.</li> </ul> <p>If you feel unwell contact Doctor or Poisons Information Centre. (Show the label if possible).</p>
<b>Ingestion</b>	<ul style="list-style-type: none"> <li>▶ Immediately give a glass of water.</li> <li>▶ First aid is not generally required. If in doubt, contact a Poisons Information Centre or a doctor.</li> </ul>

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

Treat symptomatically.

**SECTION 5 Firefighting measures****Extinguishing media**

- ▶ There is no restriction on the type of extinguisher which may be used.
- ▶ Use extinguishing media suitable for surrounding area.

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

<b>Fire Incompatibility</b>	None known.
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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 in the event of a fire.</li> <li>▶ Prevent, by any means available, spillage from entering drains or water courses.</li> <li>▶ Use fire fighting procedures suitable for surrounding 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>
<b>Fire/Explosion Hazard</b>	<ul style="list-style-type: none"> <li>▶ The material is not readily combustible under normal conditions.</li> <li>▶ However, it will break down under fire conditions and the organic component may burn.</li> <li>▶ Not considered to be a significant fire risk.</li> <li>▶ Heat may cause expansion or decomposition with violent rupture of containers.</li> <li>▶ Decomposes on heating and may produce toxic fumes of carbon monoxide (CO).</li> <li>▶ May emit acrid smoke.</li> </ul> <p>May emit poisonous fumes.</p>
<b>HAZCHEM</b>	Not Applicable

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**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>▶ Avoid breathing vapours and contact with skin and eyes.</li> <li>▶ Control personal contact with the substance, by using protective equipment.</li> <li>▶ Contain and absorb spill with sand, earth, inert material or vermiculite.</li> <li>▶ Wipe up.</li> <li>▶ Place in a suitable, labelled container for waste disposal.</li> </ul>
<b>Major Spills</b>	<p>Minor hazard.</p> <ul style="list-style-type: none"> <li>▶ Clear area of personnel.</li> <li>▶ Alert Fire Brigade and tell them location and nature of hazard.</li> <li>▶ Control personal contact with the substance, by using protective equipment as required.</li> <li>▶ Prevent spillage from entering drains or water ways.</li> <li>▶ Contain spill with sand, earth or vermiculite.</li> <li>▶ Collect recoverable product into labelled containers for recycling.</li> <li>▶ Absorb remaining product with sand, earth or vermiculite and place in appropriate containers for disposal.</li> </ul>

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>	<ul style="list-style-type: none"> <li>▶ Limit all unnecessary personal contact.</li> <li>▶ Wear protective clothing when risk of exposure occurs.</li> <li>▶ Use in a well-ventilated area.</li> <li>▶ Avoid contact with incompatible materials.</li> <li>▶ When handling, <b>DO NOT eat, drink or smoke.</b></li> <li>▶ Keep containers securely sealed when not in use.</li> <li>▶ Avoid physical damage to containers.</li> <li>▶ Always wash hands with soap and water after handling.</li> </ul>
<b>Other information</b>	<ul style="list-style-type: none"> <li>▶ Store in original containers.</li> <li>▶ Keep containers securely sealed.</li> <li>▶ Store in a cool, dry, well-ventilated area.</li> <li>▶ Store away from incompatible materials and foodstuff containers.</li> <li>▶ Protect containers against physical damage and check regularly for leaks.</li> <li>▶ Observe manufacturer's storage and handling recommendations contained within this SDS.</li> </ul>

**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>
<b>Storage incompatibility</b>	None known

**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
sodium citrate dihydrate	9.3 mg/m <sup>3</sup>	100 mg/m <sup>3</sup>	610 mg/m <sup>3</sup>

Ingredient	Original IDLH	Revised IDLH
caffeine	Not Available	Not Available
citric acid	Not Available	Not Available
sodium citrate dihydrate	Not Available	Not Available
water	Not Available	Not Available

**Occupational Exposure Banding**


Ingredient	Occupational Exposure Band Rating	Occupational Exposure Band Limit
caffeine	E	≤ 0.01 mg/m <sup>3</sup>
citric acid	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.

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## Exposure controls

<b>Appropriate engineering controls</b>	<p>Engineering controls are used to remove a hazard or place a barrier between the worker and the hazard. Well-designed engineering controls can be highly effective in protecting workers and will typically be independent of worker interactions to provide this high level of protection.</p> <p>The basic types of engineering controls are:</p> <p>Process controls which involve changing the way a job activity or process is done to reduce the risk.</p> <p>Enclosure and/or isolation of emission source which keeps a selected hazard "physically" away from the worker and ventilation that strategically "adds" and "removes" air in the work environment. Ventilation can remove or dilute an air contaminant if designed properly. The design of a ventilation system must match the particular process and chemical or contaminant in use.</p> <p>Employers may need to use multiple types of controls to prevent employee overexposure.</p> <p>Local exhaust ventilation usually required.</p>
<b>Personal protection</b>	
<b>Eye and face protection</b>	<ul style="list-style-type: none"> <li>▶ Safety glasses with side shields</li> <li>▶ Chemical goggles.</li> <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. In the 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], [AS/NZS 1336 or national equivalent]</li> </ul>
<b>Skin protection</b>	See Hand protection below
<b>Hands/feet protection</b>	<ul style="list-style-type: none"> <li>▶ Wear chemical protective gloves, e.g. PVC.</li> <li>▶ Wear safety footwear or safety gumboots, e.g. Rubber</li> </ul>
<b>Body protection</b>	See Other protection below
<b>Other protection</b>	<ul style="list-style-type: none"> <li>▶ Overalls.</li> <li>▶ P.V.C apron.</li> <li>▶ Barrier cream.</li> <li>▶ Skin cleansing cream.</li> <li>▶ Eye wash unit.</li> </ul>

## Recommended material(s)

## GLOVE SELECTION INDEX

Glove selection is based on a modified presentation of the:

"Forsberg Clothing Performance Index".

The effect(s) of the following substance(s) are taken into account in the **computer-generated** selection:

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Material	CPI
BUTYL	A
NEOPRENE	A
VITON	A
NATURAL RUBBER	C
PVA	C

\* CPI - Chemwatch Performance Index

A: Best Selection

B: Satisfactory; may degrade after 4 hours continuous immersion

C: Poor to Dangerous Choice for other than short term immersion

**NOTE:** As a series of factors will influence the actual performance of the glove, a final selection must be based on detailed observation. -

\* Where the glove is to be used on a short term, casual or infrequent basis, factors such as "feel" or convenience (e.g. disposability), may dictate a choice of gloves which might otherwise be unsuitable following long-term or frequent use. A qualified practitioner should be consulted.

## Respiratory protection

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

Selection of the Class and Type of respirator will depend upon the level of breathing zone contaminant and the chemical nature of the contaminant. Protection Factors (defined as the ratio of contaminant outside and inside the mask) may also be important.

Required minimum protection factor	Maximum gas/vapour concentration present in air p.p.m. (by volume)	Half-face Respirator	Full-Face Respirator
up to 10	1000	-AUS / Class1 P2	-
up to 50	1000	-	-AUS / Class 1 P2
up to 50	5000	Airline *	-
up to 100	5000	-	-2 P2
up to 100	10000	-	-3 P2
100+			Airline**

\* - Continuous Flow \*\* - Continuous-flow or positive pressure demand

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>	Clear colourless solution; mixes with water.		
<b>Physical state</b>	Liquid	<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>	4.2-5.2	<b>Decomposition temperature (°C)</b>	Not Available
<b>Melting point / freezing point (°C)</b>	Not Available	<b>Viscosity (cSt)</b>	Not Available

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Initial boiling point and boiling range (°C)	Not Available	Molecular weight (g/mol)	Not Applicable
Flash point (°C)	Not Available	Taste	Not Available
Evaporation rate	Not Available	Explosive properties	Not Available
Flammability	Not Available	Oxidising properties	Not Available
Upper Explosive Limit (%)	Not Available	Surface Tension (dyn/cm or mN/m)	Not Available
Lower Explosive Limit (%)	Not Available	Volatile Component (%vol)	Not Available
Vapour pressure (kPa)	Not Available	Gas group	Not Available
Solubility in water	Miscible	pH as a solution (Not Available%)	Not Available
Vapour density (Air = 1)	Not Available	VOC g/L	Not Available

## SECTION 10 Stability and reactivity

Reactivity	See section 7
Chemical stability	<ul style="list-style-type: none"> <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

Inhaled	The material is not thought to produce adverse health effects or irritation of the respiratory tract (as classified by EC Directives using animal models). Nevertheless, good hygiene practice requires that exposure be kept to a minimum and that suitable control measures be used in an occupational setting. Not normally a hazard due to non-volatile nature of product
Ingestion	The material has <b>NOT</b> been classified by EC Directives or other classification systems as "harmful by ingestion". This is because of the lack of corroborating animal or human evidence.
Skin Contact	The material is not thought to produce adverse health effects or skin irritation following contact (as classified by EC Directives using animal models). Nevertheless, good hygiene practice requires that exposure be kept to a minimum and that suitable gloves be used in an occupational setting. 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.
Eye	Although the liquid is not thought to be an irritant (as classified by EC Directives), direct contact with the eye may produce transient discomfort characterised by tearing or conjunctival redness (as with windburn).
Chronic	Substance accumulation, in the human body, may occur and may cause some concern following repeated or long-term occupational exposure.

Cafnea™, Caffeine Citrate Injection, 40mg In 2ml	<b>TOXICITY</b>	<b>IRRITATION</b>
	Not Available	Not Available
caffeine	<b>TOXICITY</b>	<b>IRRITATION</b>
	dermal (rat) LD50: >2000 mg/kg <sup>[1]</sup>	Not Available
	Inhalation(Rat) LC50; ~4.94 mg/l4h <sup>[1]</sup>	
	Oral (Mouse) LD50; 127 mg/kg <sup>[2]</sup>	
citric acid	<b>TOXICITY</b>	<b>IRRITATION</b>
	dermal (rat) LD50: >2000 mg/kg <sup>[1]</sup>	Eye (rabbit): 0.75 mg/24h-SEVERE
	Oral (Rat) LD50; 3000 mg/kg <sup>[2]</sup>	Skin (rabbit): 500 mg/24h - mild
sodium citrate dihydrate	<b>TOXICITY</b>	<b>IRRITATION</b>
	dermal (rat) LD50: >2000 mg/kg <sup>[1]</sup>	Not Available
	Oral (Mouse) LD50; 5000-6000 mg/kg <sup>[2]</sup>	
water	<b>TOXICITY</b>	<b>IRRITATION</b>
	Oral (Rat) LD50; >90000 mg/kg <sup>[2]</sup>	Not Available
<b>Legend:</b>	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	

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<b>CAFFEINE</b>	<p>Oral (woman) TDLo: 96 mg/kg/1d-I Tumorigenic - Carcinogenic by RTECS criteria.</p> <p>Goitrogenic: Goitrogens are substances that suppress the function of the thyroid gland by interfering with iodine uptake, which can, as a result, cause an enlargement of the thyroid (a goitre). Goitrogens include: - Vitexin, a flavonoid, which inhibits thyroid peroxidase, contributing to goitre - Thiocyanate and perchlorate, which decrease iodide uptake by competitive inhibition and consequently increase release of TSH from the pituitary gland - Lithium, which inhibits thyroid hormone release - Certain foods, such as soy and millet (containing vitexins) and vegetables in the genus Brassica (which includes broccoli, Brussels sprouts, cabbage, cauliflower and horseradish). - Caffeine (found in coffee, tea, cola and chocolate), which acts on thyroid function as a suppressant.</p> <p>Methylxanthine overdose may result in hyperventilation, respiratory alkalosis, and respiratory arrest.</p> <p>Methylated xanthines (methylxanthines), which include caffeine, aminophylline, IBMX, paraxanthine, pentoxifylline, theobromine, and theophylline, affect not only the airways but stimulate heart rate, force of contraction, and cardiac arrhythmias at high concentrations. In high doses, they can lead to convulsions that are resistant to anticonvulsants. Methylxanthines induce acid and pepsin secretions in the gastrointestinal tract. Methylxanthines are metabolized by cytochrome P450 in the liver.</p> <p>Headaches, tension and nervousness are characteristics of excessive caffeine consumption. Over long periods agitation, psychosis, heartburn and hyperventilation can occur.</p> <p>Derivatives of xanthine (known collectively as xanthines) are a group of alkaloids commonly used for their effects as mild stimulants and as bronchodilators, notably in the treatment of asthma or influenza symptoms. In contrast to other, more potent stimulants like sympathomimetic amines, xanthines mainly act to oppose the actions of adenosine, and increase alertness in the central nervous system.</p> <p>In vitro pharmacological studies, xanthines act :</p> <ul style="list-style-type: none"> <li>▶ as competitive nonselective phosphodiesterase inhibitors which raise intracellular cyclic adenosine monophosphate (cAMP) - cAMP is a second messenger, used for intracellular signal transduction, such as transferring into cells the effects of hormones like glucagon and adrenaline, which cannot pass through the plasma membrane. It is also involved in the activation of protein kinases</li> <li>▶ to activate protein kinase A (PKA) - PKA targeting is largely known to control cell growth in many cancer types in vitro and in vivo; remarkably, targeting PKA by either site-selective cAMP analogs or antisense approaches has clearly shown antitumor activity in cancer patients</li> <li>▶ to inhibit TNF-alpha (using anti-inflammatory drugs to inhibit cytokines, in particular TNF-alpha, has been successful in several clinical trials for treating rheumatoid arthritis) and</li> <li>▶ to inhibit leukotriene synthesis</li> <li>▶ to reduce inflammation and innate immunity and are nonselective adenosine receptor antagonists which inhibit sleepiness-inducing adenosine.</li> </ul> <p>Different analogues show varying potency at the numerous subtypes, and a wide range of synthetic xanthines (some nonmethylated) have been developed searching for compounds with greater selectivity for phosphodiesterase enzyme or adenosine receptor subtypes.</p> <p>People with the rare genetic disorders, specifically xanthinuria and Lesch-Nyhan syndrome, lack sufficient xanthine oxidase and cannot convert xanthine to uric acid.</p> <p>Neuroactive agents may produce tachyphylaxis whereby a high-intensity prolonged stimulus or often-repeated stimulus may bring about a diminished response (also known as desensitization)</p> <p>The substance is classified by IARC as Group 3: <b>NOT</b> classifiable as to its carcinogenicity to humans. Evidence of carcinogenicity may be inadequate or limited in animal testing.</p>
<b>CITRIC ACID</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> <p>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.</p>
<b>WATER</b>	No significant acute toxicological data identified in literature search.
<b>CITRIC ACID &amp; SODIUM CITRATE DIHYDRATE</b>	For citric acid (and its inorganic citrate salts) Based on extensive animal testing data and on human experience, citric acid has low acute toxicity. Citric acid is not suspected of causing cancer, birth defects or reproductive toxicity. Further, it does not cause mutations. Also, the sensitizing potential is considered low. In contrast, irritation, particularly of the eyes but also the airways and the skin, is the main hazard presented by citric acid.

<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

Cafnea™, Caffeine Citrate Injection, 40mg In 2ml	Endpoint	Test Duration (hr)	Species	Value	Source
	Not Available	Not Available	Not Available	Not Available	Not Available
caffeine	Endpoint	Test Duration (hr)	Species	Value	Source
	NOEC(ECx)	24h	Fish	0.003mg/l	4
	EC50	72h	Algae or other aquatic plants	>100mg/l	2

Continued...

## Cafnea™, Caffeine Citrate Injection, 40mg In 2ml

	EC50	48h	Crustacea	177.8mg/l	4
	LC50	96h	Fish	~87mg/l	2
citric acid	<b>Endpoint</b>	<b>Test Duration (hr)</b>	<b>Species</b>	<b>Value</b>	<b>Source</b>
	EC50(ECx)	48h	Crustacea	>50mg/l	2
	EC50	72h	Algae or other aquatic plants	990mg/l	2
	EC50	48h	Crustacea	>50mg/l	2
	LC50	96h	Fish	>100mg/l	2
sodium citrate dihydrate	<b>Endpoint</b>	<b>Test Duration (hr)</b>	<b>Species</b>	<b>Value</b>	<b>Source</b>
	EC50(ECx)	48h	Crustacea	>50mg/l	2
	EC50	48h	Crustacea	>50mg/l	2
	EC50	96h	Algae or other aquatic plants	>18000-32000mg/l	1
water	<b>Endpoint</b>	<b>Test Duration (hr)</b>	<b>Species</b>	<b>Value</b>	<b>Source</b>
	Not Available	Not Available	Not Available	Not Available	Not Available
<b>Legend:</b>	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				

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

#### Persistence and degradability

Ingredient	Persistence: Water/Soil	Persistence: Air
caffeine	HIGH	HIGH
citric acid	LOW	LOW
water	LOW	LOW

#### Bioaccumulative potential

Ingredient	Bioaccumulation
caffeine	LOW (LogKOW = -0.07)
citric acid	LOW (LogKOW = -1.64)

#### Mobility in soil

Ingredient	Mobility
caffeine	LOW (KOC = 10)
citric acid	LOW (KOC = 10)

### SECTION 13 Disposal considerations

#### Waste treatment methods

<b>Product / Packaging disposal</b>	<p>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.</p> <p>A Hierarchy of Controls seems to be common - the user should investigate:</p> <ul style="list-style-type: none"> <li>▶ Reduction</li> <li>▶ Reuse</li> <li>▶ Recycling</li> <li>▶ Disposal (if all else fails)</li> </ul> <p>This material may be recycled if unused, or if it has not been contaminated so as to make it unsuitable for its intended use. If it has been contaminated, it may be possible to reclaim the product by filtration, distillation or some other means. 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.</p> <ul style="list-style-type: none"> <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.</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>
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### SECTION 14 Transport information

#### Labels Required

<b>Marine Pollutant</b>	NO
<b>HAZCHEM</b>	Not Applicable

Continued...

## Cafnea™, Caffeine Citrate Injection, 40mg In 2ml

**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

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

Product name	Group
caffeine	Not Available
citric acid	Not Available
sodium citrate dihydrate	Not Available
water	Not Available

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

Product name	Ship Type
caffeine	Not Available
citric acid	Not Available
sodium citrate dihydrate	Not Available
water	Not Available

## SECTION 15 Regulatory information

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

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

Australia Hazardous Chemical Information System (HCIS) - Hazardous Chemicals  
 Australia Standard for the Uniform Scheduling of Medicines and Poisons (SUSMP) - Schedule 4  
 Australia Standard for the Uniform Scheduling of Medicines and Poisons (SUSMP) - Schedule 6  
 Australian Inventory of Industrial Chemicals (AIIC)

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

**citric acid is found on the following regulatory lists**

Australia Hazardous Chemical Information System (HCIS) - Hazardous Chemicals

Australian Inventory of Industrial Chemicals (AIIC)

**sodium citrate dihydrate is found on the following regulatory lists**

Australian Inventory of Industrial Chemicals (AIIC)

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

Australian Inventory of Industrial Chemicals (AIIC)

**National Inventory Status**

National Inventory	Status
Australia - AIIC / Australia Non-Industrial Use	Yes
Canada - DSL	Yes
Canada - NDSL	No (caffeine; citric acid; water)
China - IECSC	Yes
Europe - EINEC / ELINCS / NLP	Yes
Japan - ENCS	Yes
Korea - KECI	Yes
New Zealand - NZIoC	Yes
Philippines - PICCS	Yes
USA - TSCA	Yes
Taiwan - TCSI	Yes
Mexico - INSQ	Yes
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**

Revision Date	01/11/2019
Initial Date	01/11/2009

SDS Version Summary

Continued...



**Cafnea™, Caffeine Citrate Injection, 40mg In 2ml**

Version	Date of Update	Sections Updated
4.1	23/04/2010	Physical Properties, Name
6.1	01/11/2019	One-off system update. NOTE: This may or may not change the GHS classification

**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  
 AIC: 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  
 KECl: 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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