



Metaraminol Phebra 5mg In 10mL Injection In 10ml Vial

Phebra Pty Ltd

Chemwatch Hazard Alert Code: 0

Chemwatch: 82-8936

Issue Date: 29/05/2018

Version No: 3.1.1.1

Print Date: 15/08/2018

Safety Data Sheet according to WHS and ADG requirements

S.GHS.AUS.EN

SECTION 1 IDENTIFICATION OF THE SUBSTANCE / MIXTURE AND OF THE COMPANY / UNDERTAKING

Product Identifier

Product name	Metaraminol Phebra 5mg In 10mL Injection In 10ml Vial
Synonyms	Not Available
Other means of identification	Not Available

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

Relevant identified uses	Prevention and treatment of the acute hypotensive state. Used as is.
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Details of the supplier of the safety data sheet

Registered company name	Phebra
Address	19 Orion Road Lane Cove West NSW 2066 Australia
Telephone	+61 2 9420 9199 1800 720 020
Fax	+61 2 9420 9177
Website	www.phebra.com
Email	info@phebra.com

Emergency telephone number

Association / Organisation	Not Available
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	S4
Classification	Not Applicable

Label elements

Hazard pictogram(s)	Not Applicable
SIGNAL WORD	NOT APPLICABLE

Hazard statement(s)

Not Applicable

Precautionary statement(s) Prevention

Not Applicable

Precautionary statement(s) Response

Not Applicable

Precautionary statement(s) Storage

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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
33402-03-8	0.05	<u>metaraminol tartrate</u>
	<2	Ingredients determined not to be hazardous
7732-18-5	>90	<u>water</u>

SECTION 4 FIRST AID MEASURES

Description of first aid measures

Eye Contact	If this product comes in contact with eyes: ▶ Wash out immediately with water. ▶ If irritation continues, seek medical attention. ▶ Removal of contact lenses after an eye injury should only be undertaken by skilled personnel.
Skin Contact	If skin or hair contact occurs: ▶ Flush skin and hair with running water (and soap if available). ▶ Seek medical attention in event of irritation.
Inhalation	▶ If fumes, aerosols or combustion products are inhaled remove from contaminated area. ▶ Other measures are usually unnecessary.
Ingestion	▶ For advice, contact a Poisons Information Centre or a doctor at once. ▶ Urgent hospital treatment is likely to be needed. ▶ If swallowed do NOT induce vomiting. ▶ If vomiting occurs, lean patient forward or place on left side (head-down position, if possible) to maintain open airway and prevent aspiration. ▶ Observe the patient carefully. ▶ Never give liquid to a person showing signs of being sleepy or with reduced awareness; i.e. becoming unconscious. ▶ Give water to rinse out mouth, then provide liquid slowly and as much as casualty can comfortably drink. ▶ Transport to hospital or doctor without delay.

Indication of any immediate medical attention and special treatment needed

Treat symptomatically.
for metaraminol

Metaraminol is absorbed when taken by mouth.

After metaraminol has been infused for some time, tachyphylaxis may lead to recurrent hypotension; it has been suggested that an infusion of noradrenaline may restore responsiveness. The hypertensive effects of metaraminol may be treated with an alpha-adrenoreceptor blocking agent such as phentolamine mesylate. Martindale

A sympatholytic agent may be given to reduce hypertension. An appropriate antiarrhythmic agent e.g. procainamide hydrochloride, may also be required. With the prolonged action of metaraminol bitartrate, a cumulative effect is possible. If there is excessive vasopressor response (constriction) there may be prolonged elevation of blood pressure therefore, blood or plasma volume expanders should be used when the reason for hypotension or shock is decreased circulating volume.

Mercke, Sharp and Dohme

Treatment of overdose of oral sympathomimetics should be symptomatic and supportive and may include the following:

1. Consider gastric lavage within one hour of ingestion. Induced vomiting may not be advisable because of the potential for seizures and worsening hypertension.
2. Administer activated charcoal slurry.
3. Monitor EKG, ECG, serum electrolytes, blood sugar, blood pressure, urinary output, and renal function. Pharmacological action is required only in severely symptomatic patients.
4. For pulmonary edema (noncardiogenic) - Maintain ventilation and oxygenation with close arterial blood gas monitoring.
5. For seizures or severe agitation - Administer benzodiazepines.
6. For dystonic reactions - Administer benztropine or diphenhydramine.
7. For ventricular tachycardia - Administer lidocaine.
8. For severe hypertension - Nitroprusside, labetalol, or phentolamine may be necessary.
9. For hypotension - Infuse patient with isotonic solution; if condition persists, administer dopamine or norepinephrine.
10. For rhabdomyolysis - Administer sufficient 0.9% saline to maintain urine output of 2 to 3 l/kg/hour. Diuretics may be necessary; urinary alkalization is NOT routinely recommended.
11. For hyperthermia - Manage with external cooling; avoid phenothiazines. [Meditext 2006]

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

Fire Incompatibility	None known.
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Advice for firefighters

Fire Fighting	▶ Alert Fire Brigade and tell them location and nature of hazard. ▶ Wear breathing apparatus plus protective gloves in the event of a fire. ▶ Prevent, by any means available, spillage from entering drains or water courses. ▶ Use fire fighting procedures suitable for surrounding area. ▶ DO NOT approach containers suspected to be hot. ▶ Cool fire exposed containers with water spray from a protected location. ▶ If safe to do so, remove containers from path of fire.
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	Equipment should be thoroughly decontaminated after use.
Fire/Explosion Hazard	- Non combustible. - Not considered a significant fire risk, however containers may burn.
HAZCHEM	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

Minor Spills	- Clean up all spills immediately. - Avoid breathing vapours and contact with skin and eyes. - Control personal contact with the substance, by using protective equipment. - Contain and absorb spill with sand, earth, inert material or vermiculite. - Wipe up. - Place in a suitable, labelled container for waste disposal.
Major Spills	Minor hazard. - Clear area of personnel. - Alert Fire Brigade and tell them location and nature of hazard. - Control personal contact with the substance, by using protective equipment as required. - Prevent spillage from entering drains or water ways. - Contain spill with sand, earth or vermiculite. - Collect recoverable product into labelled containers for recycling. - Absorb remaining product with sand, earth or vermiculite and place in appropriate containers for disposal.

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

SECTION 7 HANDLING AND STORAGE

Precautions for safe handling

Safe handling	- Limit all unnecessary personal contact. - Wear protective clothing when risk of exposure occurs. - Use in a well-ventilated area. - Avoid contact with incompatible materials. - When handling, DO NOT eat, drink or smoke. - Keep containers securely sealed when not in use. - Avoid physical damage to containers. - Always wash hands with soap and water after handling.
Other information	- Store in original containers. - Keep containers securely sealed. - Store in a cool, dry, well-ventilated area. - Store away from incompatible materials and foodstuff containers. - Protect containers against physical damage and check regularly for leaks. - Observe manufacturer's storage and handling recommendations contained within this SDS. Keep cool. Store below 25 deg.C

Conditions for safe storage, including any incompatibilities

Suitable container	- Polyethylene or polypropylene container. - Packing as recommended by manufacturer. - Check all containers are clearly labelled and free from leaks.
Storage incompatibility	None known

SECTION 8 EXPOSURE CONTROLS / PERSONAL PROTECTION

Control parameters

OCCUPATIONAL EXPOSURE LIMITS (OEL)

INGREDIENT DATA

Not Available

EMERGENCY LIMITS

Ingredient	Material name	TEEL-1	TEEL-2	TEEL-3
Metaraminol Phebra 5mg In 10mL Injection In 10ml Vial	Not Available	Not Available	Not Available	Not Available

Ingredient	Original IDLH	Revised IDLH
metaraminol tartrate	Not Available	Not Available
water	Not Available	Not Available

Exposure controls

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Appropriate engineering controls	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. The basic types of engineering controls are: Process controls which involve changing the way a job activity or process is done to reduce the risk. 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. Employers may need to use multiple types of controls to prevent employee overexposure. General exhaust is adequate under normal operating conditions.
Personal protection	
Eye and face protection	▶ Safety glasses with side shields ▶ Chemical goggles. ▶ 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]
Skin protection	See Hand protection below
Hands/feet protection	Wear general protective gloves, eg. light weight rubber gloves. 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 durability of glove type is dependent on usage.
Body protection	See Other protection below
Other protection	No special equipment needed when handling small quantities. OTHERWISE: ▶ Overalls. ▶ Barrier cream. ▶ Eyewash unit.

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	C
NATURAL RUBBER	C
NATURAL+NEOPRENE	C
NEOPRENE	C
NITRILE	C
PVA	C
VITON	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(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)

SECTION 9 PHYSICAL AND CHEMICAL PROPERTIES

Information on basic physical and chemical properties

Appearance	Clear colourless liquid; mixes with water.		
Physical state	Liquid	Relative density (Water = 1)	1.0076
Odour	Not Available	Partition coefficient n-octanol / water	Not Available
Odour threshold	Not Available	Auto-ignition temperature (°C)	Not Available

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pH (as supplied)	3.2-4.5	Decomposition temperature	Not Available
Melting point / freezing point (°C)	Not Available	Viscosity (cSt)	Not Available
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 (g/L)	Miscible	pH as a solution (1%)	Not Available
Vapour density (Air = 1)	Not Available	VOC g/L	Not Available

SECTION 10 STABILITY AND REACTIVITY

Reactivity	See section 7
Chemical stability	Product is considered stable and hazardous polymerisation will not occur.
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.
Ingestion	Metaraminol overdose may result in hypertension accompanied by headache, nausea, vomiting, diaphoresis (sweating), constricting sensation in the chest, cerebral haemorrhage, cardiac arrhythmias, cardiac arrest, myocardial infarction, or convulsions. Fatally poisoned rats and mice showed clonic convulsions, dyspnea, and loss of righting before death. Surviving animals exhibited tachypnea, mild excitement with subsequent lethargy and frequent piloerection. In clinical use acute pulmonary oedema, arrhythmias, cerebral haemorrhage or cardiac arrest has been reported when the hypertensive response is too rapidly induced. Due to its vasoconstricting effects, exposure by individuals with diabetes, cardiac or thyroid disease or hypertension should be avoided.
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.
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	Animal testing shows that metaraminol may cause vomiting, salivation, decreased weight, increased urine output, and increase in white cell count. No studies have been performed regarding potential to cause cancer, mutations or effects on fertility. It is not known whether metaraminol can harm the foetus or reproductive ability or whether it is secreted in human milk.

Metaraminol Phebra 5mg In 10mL Injection In 10ml Vial	TOXICITY	IRRITATION
	Not Available	Not Available
metaraminol tartrate	TOXICITY	IRRITATION
	Oral (rat) LD50: 240 mg/kg ^[2]	Not Available
water	TOXICITY	IRRITATION
	Not Available	Not Available

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

METARAMINOL TARTRATE	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. The material may cause severe 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. Repeated exposures may produce severe ulceration. ADI: 0.01 mg/day * function/structure of salivary glands recorded. * Merckle, Sharp and Dohme
WATER	No significant acute toxicological data identified in literature search.

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Acute Toxicity	⊘	Carcinogenicity	⊘
Skin Irritation/Corrosion	⊘	Reproductivity	⊘
Serious Eye Damage/Irritation	⊘	STOT - Single Exposure	⊘
Respiratory or Skin sensitisation	⊘	STOT - Repeated Exposure	⊘
Mutagenicity	⊘	Aspiration Hazard	⊘

Legend: ✗ – Data available but does not fill the criteria for classification

✔ – Data available to make classification

⊘ – Data Not Available to make classification

SECTION 12 ECOLOGICAL INFORMATION

Toxicity

Metaraminol Phebra 5mg In 10mL Injection In 10ml Vial	ENDPOINT	TEST DURATION (HR)	SPECIES	VALUE	SOURCE
	Not Available	Not Available	Not Available	Not Available	Not Available
metaraminol tartrate	ENDPOINT	TEST DURATION (HR)	SPECIES	VALUE	SOURCE
	Not Available	Not Available	Not Available	Not Available	Not Available
water	ENDPOINT	TEST DURATION (HR)	SPECIES	VALUE	SOURCE
	Not Available	Not Available	Not Available	Not Available	Not Available

Legend: Extracted from 1. IUCLID Toxicity Data 2. Europe ECHA Registered Substances - Ecotoxicological Information - Aquatic Toxicity 3. EPIWIN Suite V3.12 (QSAR) - Aquatic Toxicity Data (Estimated) 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

Persistence and degradability

Ingredient	Persistence: Water/Soil	Persistence: Air
water	LOW	LOW

Bioaccumulative potential

Ingredient	Bioaccumulation
water	LOW (LogKOW = -1.38)

Mobility in soil

Ingredient	Mobility
water	LOW (KOC = 14.3)

SECTION 13 DISPOSAL CONSIDERATIONS

Waste treatment methods

Product / Packaging disposal	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. A Hierarchy of Controls seems to be common - the user should investigate: ▶ Reduction ▶ Reuse ▶ Recycling ▶ Disposal (if all else fails) 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. ▶ DO NOT allow wash water from cleaning or process equipment to enter drains. ▶ It may be necessary to collect all wash water for treatment before disposal. ▶ In all cases disposal to sewer may be subject to local laws and regulations and these should be considered first. ▶ Where in doubt contact the responsible authority. ▶ Recycle wherever possible. ▶ 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. ▶ 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). ▶ Decontaminate empty containers. Observe all label safeguards until containers are cleaned and destroyed.
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SECTION 14 TRANSPORT INFORMATION

Labels Required

Marine Pollutant	NO
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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

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

Not Applicable

SECTION 15 REGULATORY INFORMATION

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

METARAMINOL TARTRATE(33402-03-8) IS FOUND ON THE FOLLOWING REGULATORY LISTS

Australia Inventory of Chemical Substances (AICS)

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

WATER(7732-18-5) IS FOUND ON THE FOLLOWING REGULATORY LISTS

Australia Inventory of Chemical Substances (AICS)

National Inventory Status

National Inventory	Status
Australia - AICS	Y
Canada - DSL	N (metaraminol tartrate)
Canada - NDSL	N (metaraminol tartrate; water)
China - IECSC	N (metaraminol tartrate)
Europe - EINEC / ELINCS / NLP	Y
Japan - ENCS	N (metaraminol tartrate)
Korea - KECI	N (metaraminol tartrate)
New Zealand - NZIoC	N (metaraminol tartrate)
Philippines - PICCS	N (metaraminol tartrate)
USA - TSCA	N (metaraminol tartrate)
Legend:	Y = All ingredients are on the inventory N = Not determined or one or more ingredients are not on the inventory and are not exempt from listing(see specific ingredients in brackets)

SECTION 16 OTHER INFORMATION

Revision Date	29/05/2018
Initial Date	17/07/2017

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
 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

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