

Calcium Gluconate Injection

Safety Data Sheet according to WHS and ADG requirements

Phebra Pty Ltd

Chemwatch: 23-2281
Version No: 6.1.1.1

Chemwatch Hazard Alert Code: 0

Issue Date: 27/06/2017

Print Date: **02/03/2018** S.GHS.AUS.EN

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

Product Identifier

Product name	Calcium Gluconate Injection	
Synonyms	Not Available	
Other means of identification	Not Available	

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

Relevant identified uses	Used primarily for the prevention and treatment of calcium deficiency.
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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

Poisons Schedule	Not Applicable
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

Not Applicable

Precautionary statement(s) Disposal

Not Applicable

SECTION 3 COMPOSITION / INFORMATION ON INGREDIENTS

Substances

See section below for composition of Mixtures

Chemwatch: 23-2281 Page 2 of 8 Version No: 6.1.1.1

Calcium Gluconate Injection

Issue Date: 27/06/2017 Print Date: 02/03/2018

Mixtures

CAS No	%[weight]	Name
299-28-5	9.53	Calcium Gluconate
5793-88-4	0.3	Calcium D-Saccharate tetrahydrate
7732-18-5	>90	water

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	 Immediately give a glass of water. First aid is not generally required. If in doubt, contact a Poisons Information Centre or a doctor.

Indication of any immediate medical attention and special treatment needed

Treat symptomatically.

SECTION 5 FIREFIGHTING MEASURES

Extinguishing media

The product contains a substantial proportion of water, therefore there are no restrictions on the type of extinguishing media which may be used. Choice of extinguishing media should take into account surrounding areas.

Though the material is non-combustible, evaporation of water from the mixture, caused by the heat of nearby fire, may produce floating layers of combustible substances. In such an event consider:

- Foam.
- dry chemical powder.
- rearbon dioxide.

Special hazards arising from the substrate or mixture

Fire Incompatibility	None known.		
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. Equipment should be thoroughly decontaminated after use. 		
Fire/Explosion Hazard	 The material is not readily combustible under normal conditions. However, it will break down under fire conditions and the organic component may burn. Not considered to be a significant fire risk. Heat may cause expansion or decomposition with violent rupture of containers. Decomposes on heating and may produce toxic fumes of carbon monoxide (CO). May emit acrid smoke. Decomposes on heating and produces toxic fumes of: carbon dioxide (CO2) other pyrolysis products typical of burning organic material. 		
HAZCHEM	ZCHEM 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.

Chemwatch: 23-2281 Page 3 of 8 Issue Date: 27/06/2017
Version No: 6.1.1.1 Print Date: 02/03/2018

Calcium Gluconate Injection

	 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.
- When handling DO NOT eat, drink or smoke.
 - Always wash hands with soap and water after handling.
 - Avoid physical damage to containers.
 - Use good occupational work practice.
 - ▶ Observe manufacturer's storage and handling recommendations contained within this SDS.

Other information

- Store in original containers.
- Keep containers securely sealed.Store in a cool, dry, well-ventilated area.
- er information
 - 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.

Conditions for safe storage, including any incompatibilities

Suitable container

- $\qquad \qquad \blacktriangleright \ \ \mbox{Polyethylene or polypropylene container}.$
- Packing as recommended by manufacturer.
- ► Check all containers are clearly labelled and free from leaks.
- ▶ Glass container is suitable for laboratory quantities

glass vial

Storage incompatibility

 $\label{eq:contamination} \mbox{Avoid contamination of water, foodstuffs, feed or seed.} \\ \mbox{None known}$

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
Calcium Gluconate Injection	Not Available	Not Available	Not Available	Not Available
Ingredient	Original IDLH		Revised IDLH	
Calcium Gluconate	Not Available		Not Available	
Calcium D-Saccharate tetrahydrate	Not Available		Not Available	
water	Not Available		Not Available	

Exposure 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.

Appropriate engineering

controls

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







Version No: **6.1.1.1**

Calcium Gluconate Injection

Issue Date: **27/06/2017**Print Date: **02/03/2018**

 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 Eye and face protection 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 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. Hands/feet protection 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 moisturizer is recommended. Suitability and durability of glove type is dependent on usage. See Other protection below **Body protection** No special equipment needed when handling small quantities. OTHERWISE: Overalls. Other protection ▶ Barrier cream. Eyewash unit. Thermal hazards Not Available

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:

Calcium Gluconate Injection

Material	СРІ
BUTYL	С
NATURAL RUBBER	С
NEOPRENE	С
PVA	С
VITON	С

^{*} 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

Cartridge respirators should never be used for emergency ingress or in areas of unknown vapour concentrations or oxygen content. The wearer must be warned to leave the contaminated area immediately on detecting any odours through the respirator. The odour may indicate that the mask is not functioning properly, that the vapour concentration is too high, or that the mask is not properly fitted. Because of these limitations, only restricted use of cartridge respirators is considered appropriate.

SECTION 9 PHYSICAL AND CHEMICAL PROPERTIES

Information on basic physical and chemical properties

Appearance	Clear, colourless liquid; mixes with water. It is a 10mL or 50mL aqueous solution in a 10mL or 50mL clear glass vial with a crimped rubber stopper and plastic lid.		
Physical state	Liquid	Relative density (Water = 1)	1.048
Odour	Not Available	Partition coefficient n-octanol / water	Not Available
Odour threshold	Not Available	Auto-ignition temperature (°C)	Not Applicable
pH (as supplied)	7.0-8.0	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 Applicable	Taste	Not Available
Evaporation rate	Not Available	Explosive properties	Not Available
Flammability	Not Applicable	Oxidising properties	Not Available
Upper Explosive Limit (%)	Not Applicable	Surface Tension (dyn/cm or mN/m)	Not Available
Lower Explosive Limit (%)	Not Applicable	Volatile Component (%vol)	Not Available
Vapour pressure (kPa)	Not Available	Gas group	Not Available

Chemwatch: 23-2281 Page 5 of 8

Version No: 6.1.1.1

Calcium Gluconate Injection

Issue Date: **27/06/2017**Print Date: **02/03/2018**

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	 Unstable in the presence of incompatible materials. Product is considered stable. 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. Not normally a hazard due to non-volatile nature of product		
Ingestion	The material has NOT 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. Irritation and skin reactions are possible with sensitive skin		
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	Long-term exposure to the product is not thought to produce chronic effects adverse to the health (as classified by EC Directives using animal models); nevertheless exposure by all routes should be minimised as a matter of course.		
Calcium Gluconate Injection	TOXICITY	IRRITATION	
Galcium Gideonate Injection	Not Available	Not Available	
Calcium Gluconate	TOXICITY	IRRITATION	
Calcium Gluconate	Not Available	Not Available	
Calcium D-Saccharate	TOXICITY	IRRITATION	
tetrahydrate	Not Available	Not Available	
	TOXICITY	IRRITATION	
water	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

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, 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.

CALCIUM GLUCONATE for gluconic acid and its salts:

Gluconic acid and its mineral salts freely dissociate to the gluconate anion and the respective cations. Glucono-delta-lactone (GDL), the 1,5-inner ester of gluconic acid, is formed from the free acid by the removal of water. On the basis of these spontaneous chemical rearrangements, glucono-delta-lactone, gluconic acid and its sodium, calcium and potassium salts can be considered as a category, with all members sharing the same representative moiety, the gluconate anion.

Acute toxicity: Gluconic acid and its derivatives are naturally occurring substances. In mammalian organisms both D-gluconic acid and its 1,5-lactone are important intermediates in the carbohydrate metabolism. Gluconate is a metabolite of glucose oxidation. The daily production of gluconate from endogenous sources is about 450 mg/kg for a 60 kg person. A significant portion (60-85%) of parenterally administered gluconate is excreted unchanged in the urine.

CALCIUM D-SACCHARATE TETRAHYDRATE

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.

Page 6 of 8 Calcium Gluconate Injection

Issue Date: **27/06/2017**Print Date: **02/03/2018**

CALCIUM GLUCONATE &
CALCIUM D-SACCHARATE
TETRAHYDRATE & WATER

No significant acute toxicological data identified in literature search.

Acute Toxicity	0	Carcinogenicity	0
Skin Irritation/Corrosion	0	Reproductivity	0
Serious Eye Damage/Irritation	0	STOT - Single Exposure	0
Respiratory or Skin sensitisation	0	STOT - Repeated Exposure	0
Mutagenicity	0	Aspiration Hazard	0

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

Calcium Gluconate Injection	ENDPOINT	TEST DURATION (HR)	SPECIES	VALUE SOURCE
	Not Available	Not Available	Not Available	Not Not Available Available
	ENDPOINT	TEST DURATION (HR)	SPECIES	VALUE SOURCE
Calcium Gluconate	Not Available	Not Available	Not Available	Not Not Available Available
Calcium D-Saccharate tetrahydrate	ENDPOINT	TEST DURATION (HR)	SPECIES	VALUE SOURCE
	Not Available	Not Available	Not Available	Not Not Available Available
water	ENDPOINT	TEST DURATION (HR)	SPECIES	VALUE SOURCE
	Not Available	Not Available	Not Available	Not Not Available 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
Calcium D-Saccharate tetrahydrate	LOW	LOW
water	LOW	LOW

Bioaccumulative potential

Ingredient	Bioaccumulation
Calcium D-Saccharate tetrahydrate	LOW (LogKOW = -2.5073)
water	LOW (LogKOW = -1.38)

Mobility in soil

Ingredient	Mobility
Calcium D-Saccharate tetrahydrate	LOW (KOC = 10)
water	LOW (KOC = 14.3)

SECTION 13 DISPOSAL CONSIDERATIONS

Waste treatment methods

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.

Continued...

Product / Packaging disposal

Chemwatch: 23-2281 Page 7 of 8 Issue Date: 27/06/2017 Version No: 6.1.1.1

Calcium Gluconate Injection

Print Date: 02/03/2018

- ▶ 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.

SECTION 14 TRANSPORT INFORMATION

Labels Required

Marine Pollutant	NO
HAZCHEM	Not Applicable

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

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

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

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

CALCIUM GLUCONATE(299-28-5) IS FOUND ON THE FOLLOWING REGULATORY LISTS

Australia Inventory of Chemical Substances (AICS)

CALCIUM D-SACCHARATE TETRAHYDRATE(5793-88-4) IS FOUND ON THE FOLLOWING REGULATORY LISTS

Australia Inventory of Chemical Substances (AICS)

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

Australia Inventory of Chemical Substances (AICS)

National Inventory	Status
Australia - AICS	Υ
Canada - DSL	Υ
Canada - NDSL	N (Calcium Gluconate; water; Calcium D-Saccharate tetrahydrate)
China - IECSC	Υ
Europe - EINEC / ELINCS / NLP	Υ
Japan - ENCS	N (Calcium D-Saccharate tetrahydrate)
Korea - KECI	N (Calcium D-Saccharate tetrahydrate)
New Zealand - NZIoC	Y
Philippines - PICCS	N (Calcium D-Saccharate tetrahydrate)
USA - TSCA	Υ
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

Other information

Ingredients with multiple cas numbers

•	
Name	CAS No
Calcium Gluconate	299-28-5, 18016-24-5, 66905-23-5
Calcium D-Saccharate tetrahydrate	5793-88-4, 5793-89-5

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

Issue Date: 27/06/2017 Chemwatch: 23-2281 Page 8 of 8 Version No: 6.1.1.1 Print Date: 02/03/2018

Calcium Gluconate Injection

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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