

DENTSPLY CALIBRA ESTHETIC RESIN CEMENT - CATALYST PASTE

ChemWatch Material Safety Data Sheet
Issue Date: Thu 29-Jul-2004

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Section 1 - CHEMICAL PRODUCT AND COMPANY IDENTIFICATION

PRODUCT NAME

DENTSPLY CALIBRA ESTHETIC RESIN CEMENT - CATALYST PASTE

SYNONYMS

Part Number 607058 - 607080

PRODUCT USE

Medicine

SUPPLIER

Company: Dentsply (Australia) Pty Ltd

Address:

11-21 Gilby Road
Mount Waverley
VIC, 3149
AUS

Telephone: +61 03 9538 8240

Emergency Tel: 0413 830 239

Fax: 03 9538 8260

Section 2 - HAZARDS IDENTIFICATION

STATEMENT OF HAZARDOUS NATURE

HAZARDOUS SUBSTANCE. NON-DANGEROUS GOODS.

According to the Criteria of NOHSC, and the ADG Code.

POISONS SCHEDULE

None

RISK

Irritating to eyes, respiratory system and skin.
May cause SENSITISATION by skin contact.
Inhalation may produce health damage*.
Cumulative effects may result following exposure*.
Possible respiratory sensitiser*.
Possible cancer-causing agent*.
May be harmful to the foetus/ embryo*.
May possibly affect fertility*.
* (limited evidence)

SAFETY

Keep container in a well ventilated place.

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Section 2 - HAZARDS IDENTIFICATION ...

Avoid exposure - obtain special instructions before use.
Take off immediately all contaminated clothing.
In case of contact with eyes, rinse with plenty of water and contact Doctor or Poisons Information Centre.
If you feel unwell contact Doctor or Poisons Information Centre. (Show the label if possible).

Section 3 - COMPOSITION / INFORMATION ON INGREDIENTS

NAME	CAS RN	%
frits chemical	65997-18-4	>60
bisphenol A glycidylmethacrylate	1565-94-2	<15
triethylene glycol dimethacrylate	109-16-0	<10
2,2-bis[4-(2-methacryloxy)ethoxy]phenyl]propane	24448-20-2	<15
silica, dimethylsiloxane treated	67762-90-7	<5
titanium dioxide	13463-67-7	<5
dibenzoyl peroxide	94-36-0	<2

Section 4 - FIRST AID MEASURES

SWALLOWED

- 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.

EYE

- If this product comes in contact with the eyes:
- Immediately hold eyelids apart and flush the eye continuously with running water.
 - Ensure complete irrigation of the eye by keeping eyelids apart and away from eye and moving the eyelids by occasionally lifting the upper and lower lids.
 - Continue flushing until advised to stop by the Poisons Information Centre or a doctor, or for at least 15 minutes.
 - Transport to hospital or doctor without delay.
 - Removal of contact lenses after an eye injury should only be undertaken by skilled personnel.

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Section 4 - FIRST AID MEASURES ...

SKIN

If skin contact occurs:

- Immediately remove all contaminated clothing, including footwear
- Flush skin and hair with running water (and soap if available).
- Seek medical attention in event of irritation.

INHALED

- If fumes or combustion products are inhaled remove from contaminated area.
- Other measures are usually unnecessary.

NOTES TO PHYSICIAN

Treat symptomatically.

Section 5 - FIRE FIGHTING MEASURES

EXTINGUISHING MEDIA

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

FIRE FIGHTING

- Alert Fire Brigade and tell them location and nature of hazard.
- Wear full body protective clothing with breathing apparatus.
- Consider evacuation (or protect in place).
- Use water delivered as a fine spray to control fire and cool adjacent 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

- Non combustible.
- Not considered a significant fire risk, however containers may burn.

Decomposition may produce toxic fumes of

carbon dioxide (CO₂)

sulfur oxides (SO_x)

metal oxides

other pyrolysis products typical of burning organic material

May emit poisonous fumes.

May emit corrosive fumes.

FIRE INCOMPATIBILITY

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Section 5 - FIRE FIGHTING MEASURES ...

HAZCHEM

None

Personal Protective Equipment

Glasses:
Full face- shield.

Gloves:
PVC chemical resistant type.

Respirator:
Type -P2 Filter of sufficient capacity

Section 6 - ACCIDENTAL RELEASE MEASURES

EMERGENCY PROCEDURES

MINOR SPILLS

- Clean up all spills immediately.
- Avoid breathing vapours/ aerosols/ or dusts and avoid contact with skin and eyes.
- Control personal contact by using protective equipment.
- Contain and absorb spill with sand, earth, inert material or vermiculite.
- Place in a suitable labelled container for waste disposal.

MAJOR SPILLS

- Clear area of personnel and move upwind.
- Alert Fire Brigade and tell them location and nature of hazard.
- Wear breathing apparatus plus protective gloves.
- Prevent, by any means available, spillage from entering drains or water course.
- Stop leak if safe to do so.
- Contain spill with sand, earth or vermiculite.
- Collect recoverable product into labelled containers for recycling.
- Neutralise/decontaminate residue.
- Collect solid residues and seal in labelled drums for disposal.
- Wash area and prevent runoff into drains.
- After clean up operations, decontaminate and launder all protective clothing and equipment before storing and re-using.
- If contamination of drains or waterways occurs, advise emergency services.

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

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Section 7 - HANDLING AND STORAGE

PROCEDURE FOR 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 storing and handling recommendations.

SUITABLE CONTAINER

- Polyethylene or polypropylene container.
- Packing as recommended by manufacturer
- Check all containers are clearly labelled and free from leaks.

STORAGE INCOMPATIBILITY

amines

STORAGE REQUIREMENTS

- 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 storing and handling recommendations.

Section 8 - EXPOSURE CONTROLS / PERSONAL PROTECTION

EXPOSURE CONTROLS

None assigned. Refer to individual constituents.

EXPOSURE STANDARDS FOR MIXTURE

"Worst Case" computer-aided prediction of spray/ mist or fume/ dust components and concentration:

Composite Exposure Standard for Mixture (TWA) :0.0526 mg/m³.

Operations which produce a spray/mist or fume/dust, introduce particulates to the breathing zone.

If the breathing zone concentration of ANY of the components listed below is exceeded, "Worst Case" considerations deem the individual to be overexposed.

Component Breathing Zone ppm Breathing Zone mg/m³ Mixture Conc (%)

Component	Breathing Zone (mg/m ³)	Mixture Conc (%)
frits chemical	0.0499	95.0

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bisphenol A glycidylmethacrylate	0.0005	1.0
2,2-bis[4-(2-methacryloxy)ethoxy]p	0.0005	1.0
titanium dioxide	0.0005	1.0
dibenzoyl peroxide	0.0005	1.0
silica, dimethylsiloxane treated	0.0005	1.0

INGREDIENT DATA

FRITS CHEMICAL:

TLV TWA: 2.5 mg/m³ A4;BEI [ACGIH]

PEL TWA: 1 mg/m³ [OSHA Z1]

antimony and compounds as Sb

TLV TWA: 0.5 mg/m³

ES TWA: 0.5 mg/m³

IDLH Level: 50 mg/m³ (as Sb)

The wide-ranging effects of antimony compounds have made it difficult to recommend an exposure standard which characterises the toxicology of these substances. One criteria, reflecting the irritant properties of antimony pentachloride, produced a calculated value of 5.0 mg/m³ (as antimony), which on the basis of experience was felt to be too high but did act as an "out-rider".

The present value reflects this thinking.

fluorides, as F (A.Wt: 19.00)

ES TWA: 2.5 mg/m³

TLV TWA: 2.5 mg/m³

OES TWA: 2.5 mg/m³

IDLH Level: 500 mg/m³

Based on a study in which the threshold for minimum increase in bone density due to fluoride exposure was 3.38 mg/m³ (as fluoride), the present TLV-TWA has been adopted to prevent irritant effects and disabling bone changes. There is also support for the proposition that occupational exposure below the TLV will have no adverse effect on pregnant women or off-spring. IARC has classified fluorides in drinking water as Group 3 carcinogens; i.e. Not classifiable as to its carcinogenicity to humans. Equivocal evidence of carcinogenic activity (osteosarcoma) has been found in male rats administered sodium fluoride in drinking water. (0-175 ppm) Evidence was not found in female rats or in male or female mice.

ES TWA: 0.15 mg/m³

ES* TWA: 0.15 mg/m³ (fumes)

TLV TWA: 0.05 mg/m³, A3

NIOSH REL-TWA: 0.1 mg Pb/m³ for inorganic lead

IDLH Level: 100 mg/m³ (as Pb)

CAUTION: This substance has been classified by the ACGIH as A3

Animal Carcinogen (at relatively high doses).

The lead concentration in air is to be maintained so that the lead concentration in workers' blood remains below 0.060 mg/100 g of whole blood. The recommended TLV-TWA has been derived following a review of reports of adverse effects on reproduction, blood-pressure and other end-points of toxicity. A particular focus was an assessment of pre-natal blood lead (PbB) levels and post-natal cognitive levels. The fact that lead is a cumulative toxicant which can produce subtle, persistent and apparently permanent effects in the off-spring of lead exposed women is of particular concern. A current view holds that the identification of the PbB levels, that are protective during a working lifetime, is a necessary prerequisite in the recommendation of the TLV because PbB values, rather than workplace air lead concentrations, are more clearly related to

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Section 8 - EXPOSURE CONTROLS / PERSONAL PROTECTION ...

adverse health effects.

(see Biological Exposure Index - BEI - in "Advice to Doctor".)

ES TWA: 1 mg/m³

OES TWA: 5 mg/m³

IDLH Level: 500 mg/m³

A number of studies have shown that susceptibility to the effects of manganese at or about 1 - 5 mg/m³ (TWA) can lead to clinical manifestations of manganism or more commonly to the development of indicators of sub-clinical manganism (e.g. hand tremor, exaggerated reflexes, short-term memory deficits, poor psychomotor performance). Controlling long-term exposure to the recommended ES TWA level or below should provide protection for those individuals susceptible to neurological effects of prolonged exposure.

nickel, insoluble compounds, as Ni (A. Wt. 58.69)

TLV TWA: 0.2 mg/m³ A1 (insoluble compounds, inhalable particulate fraction)

WARNING: Classified by the ACGIH as A1 - CONFIRMED HUMAN CARCINOGEN

ES TWA: 1 mg/m³ SENSITISER (for nickel metal) (Substance Requiring Review)

MEL TWA: 0.5 mg/m³

NOTE: Detector tubes for nickel, measuring in excess of 0.25 mg/m³ (as Ni) are commercially available.

Use control measures / protective gear to avoid personal contact. Animal inhalation studies with insoluble nickel dusts (other than nickel sulfide) at concentrations of 1 to 3 mg/m³ show no difference in respiratory cancer between exposed and control animals.

These studies do not provide evidence that there is no excess risk of lung and nasal cancer - in view of limited exposure data and the absence of guidance for a TLV based on epidemiological studies of nickel induced respiratory tract cancer, it has been necessary to incorporate the results of animal studies that have demonstrated the production of pulmonary pathology. These studies have shown consistent pulmonary damage following inhalation of 0.1 to 1 mg/m³ insoluble inorganic nickel compounds. Individuals who may be hypersusceptible or otherwise unusually responsive to industrial chemicals may not be adequately protected against adverse health effects from nickel or its compounds at concentrations below the recommended or proposed TLV.

ES TWA: 5 mg/m³; STEL: 10 mg/m³

TLV TWA: 5 mg/m³; STEL: 10 mg/m³

OES TWA: 5 mg/m³; STEL: 10 mg/m³

IDLH Level: 50 mg/m³

OSHA concluded that the recommended TLV-TWA and STEL would protect workers from any significant risk of pulmonary effects. NIOSH conclude that a separate limit should be considered for zirconium tetrachloride (because of the irritancy of hydrogen chloride derived from hydrolysis). This was based on a 60-day inhalation study at 6 mg/m³ zirconium tetrachloride which found an increase in mortality of rats and guinea pigs due to respiratory infection and reductions of borderline statistical significance in circulating hemoglobin and erythrocyte counts in dogs.

For each of the following

BISPHENOL A GLYCIDYLMETHACRYLATE:

2,2-BIS[4-(2-METHACRYLOXY)ETHOXY]PHENYL]PROPANE:

CEL TWA: 1 mg/m³ [compare WEEL-TWA* for multifunctional acrylates (MFAs)]

Exposure to MFAs has been reported to cause contact dermatitis in humans and serious eye injury in laboratory animals. Exposure to some MFA-resin containing aerosols has also been reported to cause dermatitis. As no assessment of the possible effects of long-term exposure to aerosols was found, a conservative Workplace Environmental Exposure Level (WEEL) was suggested by the American

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Section 8 - EXPOSURE CONTROLS / PERSONAL PROTECTION ...

Industrial Hygiene Association (AIHA).

TRIETHYLENE GLYCOL DIMETHACRYLATE:
No exposure limits set by NOHSC or ACGIH

SILICA, DIMETHYLSILOXANE TREATED:
TLV TWA: 10 mg/m³ (Value for particulate matter containing no asbestos and <1% crystalline silica, Inhalable fraction) [ACGIH]
TLV TWA: 3 mg/m³ (Value for particulate matter containing no asbestos and <1% crystalline silica, Respirable fraction) [ACGIH]
Dusts not otherwise classified, as inspirable dust;
ES TWA: 10 mg/m³

TITANIUM DIOXIDE:
TLV TWA: 10 mg/m³ A4 [ACGIH]
PEL Total particulate: 15)mg/m³ [OSHA Z1]
TLV TWA: 10 mg/m³ A4
NOTE: This substance has been classified by the ACGIH as A4 NOT classifiable as causing Cancer in humans
ES TWA: 10 mg/m³
(total dust containing no asbestos and < 1% crystalline silica)
OES TWA: 10 mg/m³ total inhalable dust
OES TWA: 4 mg/m³ respirable dust
IDLH Level: 5000 mg/m³
Animal studies at 10 mg/m³ show no significant fibrosis, possibly reversible tissue reaction and the architecture of lung air spaces remains intact.

DIBENZOYL PEROXIDE:
TLV TWA: 5 mg/m³ A4 [ACGIH]
PEL TWA: 5 mg/m³ [OSHA Z1]
TLV TWA: 5 mg/m³ A4
NOTE: This substance has been classified by the ACGIH as A4 NOT classifiable as causing Cancer in humans
ES TWA: 5 mg/m³
OES TWA: 5 mg/m³
MAK value: 5 mg/m³
- measured as the inhalable fraction of the aerosol
MAK Category I Peak Limitation: For local irritants Allows excursions of twice the MAK value for 5 minutes at a time, 8 times per shift.
MAK values, and categories and groups are those recommended within the Federal Republic of Germany
IDLH Level: 1500 mg/m³

The recommendation for the TLV-TWA is based on the absence of subjective symptoms of irritation of the nose and throat in humans exposed to 5.25 mg/m³. Whether this is sufficiently low to prevent cumulative effects in man is not known.

PERSONAL PROTECTION

EYE

- Chemical goggles.
- Full face shield.

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Section 8 - EXPOSURE CONTROLS / PERSONAL PROTECTION ...

· Contact lenses pose a special hazard; soft lenses may absorb irritants and all lenses concentrate them.

HANDS/FEET

Wear protective gloves, eg. PVC.

NOTE: The material may produce skin sensitisation in predisposed individuals. Care must be taken, when removing gloves and other protective equipment, to avoid all possible skin contact.

OTHER

- Overalls.
- P.V.C. apron.
- Barrier cream.
- Skin cleansing cream.
- Eye wash unit.

RESPIRATOR

Protection Factor	Half-Face Respirator	Full-Face Respirator	Powered Air Respirator
10 x ES	P2 Air-line*	-	-
50 x ES	Air-line**	P2 Air-line*	PAPR-P2
100 x ES	-	Air-line**	PAPR-P3

* - Negative pressure demand ** - Continuous flow

The local concentration of material, quantity and conditions of use determine the type of personal protective equipment required. For further information consult site specific CHEMWATCH data (if available), or your Occupational Health and Safety Advisor.

ENGINEERING CONTROLS

Local exhaust ventilation usually required. If risk of overexposure exists, wear approved respirator. Correct fit is essential to obtain adequate protection. Supplied-air type respirator may be required in special circumstances. Correct fit is essential to ensure adequate protection. An approved self contained breathing apparatus (SCBA) may be required in some situations. Provide adequate ventilation in warehouse or closed storage area.

Section 9 - PHYSICAL AND CHEMICAL PROPERTIES

APPEARANCE

Creamy off white paste with sweet acrylic ester odour; does not mix

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Section 9 - PHYSICAL AND CHEMICAL PROPERTIES ...

PHYSICAL PROPERTIES

Does not mix with water.
Sinks in water.

Molecular Weight: Not Applicable
Melting Range (°C): Not Available
Solubility in water (g/L): Immiscible
pH (1% solution): Not Available
Volatile Component (%vol): Not Available
Relative Vapour Density (air=1): Not Applicable
Lower Explosive Limit (%): Not Applicable
Autoignition Temp (°C): Not Available
State: Free-flowing Paste

Boiling Range (°C): Not Applicable
Specific Gravity (water=1): 1.8 approx.
pH (as supplied):
Vapour Pressure (kPa): Not Applicable
Evaporation Rate: Not Applicable
Flash Point (°C): Not Applicable
Upper Explosive Limit (%): Not Applicable
Decomposition Temp (°C): Not Available

Section 10 - CHEMICAL STABILITY AND REACTIVITY INFORMATION

CONDITIONS CONTRIBUTING TO INSTABILITY

- Presence of incompatible materials.
- Product is considered stable.
- Hazardous polymerisation will not occur.

Section 11 - TOXICOLOGICAL INFORMATION

POTENTIAL HEALTH EFFECTS

ACUTE HEALTH EFFECTS

SWALLOWED

(No Oral LD50, any animal species) 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. The material may still be damaging to the health of the individual, following ingestion, especially where pre-existing organ (eg. liver, kidney) damage is evident. Present definitions of harmful or toxic substances are generally based on doses producing mortality rather than those producing morbidity (disease, ill-health). Gastrointestinal tract discomfort may produce nausea and vomiting. In an occupational setting however, ingestion of insignificant quantities is not thought to be cause for concern.

EYE

There is some evidence to suggest that this material can cause eye irritation and damage in some persons.

SKIN

There is some evidence to suggest that this material can cause inflammation of the skin on contact in some persons.

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Section 11 - TOXICOLOGICAL INFORMATION ...

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.

INHALED

Not normally a hazard due to physical form of product.

Not normally a hazard due to non-volatile nature of product

The material is not thought to produce respiratory irritation (as classified by EC Directives using animal models). Nevertheless inhalation of the material, especially for prolonged periods, may produce respiratory discomfort and occasionally, distress.

CHRONIC HEALTH EFFECTS

Substance accumulation, in the human body, may occur and may cause some concern following repeated or long-term occupational exposure.

There is some evidence that inhaling this product is more likely to cause a sensitisation reaction in some persons compared to the general population.

Skin contact with the material is more likely to cause a sensitisation reaction in some persons compared to the general population.

There is some evidence that human exposure to the material may result in developmental toxicity. This evidence is based on animal studies where effects have been observed in the absence of marked maternal toxicity, or at around the same dose levels as other toxic effects but which are not secondary non-specific consequences of the other toxic effects.

Bisphenol A may have effects similar to female sex hormones and when administered to pregnant women, may damage the foetus. It may also damage male reproductive organs and sperm.

Sensitisation may give severe responses to very low levels of exposure, i.e. hypersensitivity. Sensitised persons should not be allowed to work in situations where exposure may occur.

Dentsply Calibra Esthetic Resin Cement - Catalyst Paste

Not available. Refer to individual constituents.
unless otherwise specified data extracted from RTECS - Register of Toxic Effects of Chemical Substances

FRITS CHEMICAL:

No significant acute toxicological data identified in literature search.

BISPHENOL A GLYCIDYLMETHACRYLATE:

Not available. Refer to individual constituents.

TRIETHYLENE GLYCOL DIMETHACRYLATE:

IRRITATION	TOXICITY
Nil reported	Oral (rat) LD50: 10837 mg/kg
	Oral (mouse) LD50: 10750 mg/kg

2,2-BIS[4-(2-METHACRYLOXY)ETHOXY]PHENYL]PROPANE:

No significant acute toxicological data identified in literature search.

Based on the available oncogenicity data and without a better understanding of the carcinogenic mechanism the Health and Environmental Review Division (HERD), Office of Toxic Substances (OTS), of the US EPA previously concluded that all chemicals that contain the acrylate or methacrylate moiety (CH₂=CHCOO or

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Section 11 - TOXICOLOGICAL INFORMATION ...

CH₂=C(CH₃)COO) should be considered to be a carcinogenic hazard unless shown otherwise by adequate testing.
This position has now been revised and acrylates and methacrylates are no longer de facto carcinogens.

SILICA, DIMETHYLSILOXANE TREATED:

TOXICITY

Oral (rat) LD50: >5000 mg/kg

IRRITATION

Skin: 0/8 non-irritating

Eyes: 0.7/110 @ 24hr Draize

non-irritating

[Cabot]

TITANIUM DIOXIDE:

TOXICITY

Nil reported

IRRITATION

Skin (human): 0.3 mg/3d-I mild

DIBENZOYL PEROXIDE:

IRRITATION

Eye (rabbit): 500 mg/24h - mild

TOXICITY

Oral (rat) LD50: 7710 mg/kg

Inhalation (human) TCLo: 12 mg/m³

The substance is classified by IARC as Group 3:

NOT classifiable as to its carcinogenicity to humans.

Evidence of carcinogenicity may be inadequate or limited in animal testing.

Skin effects (MAK): very weak

(@ 50%)

Section 12 - ECOLOGICAL INFORMATION

Transport and distribution of nickel particulates between different environmental compartments, is strongly influenced by particle size. Fine particulate matter has a longer residence time in the environment and is carried a long distance from its source; larger particles are deposited near the emission source. Atmospheric residence time for nickel particulates is estimated to be 5.4-7.9 days. Water solubility and bioavailability is affected by soil pH; decrease in pH generally mobilises nickel, thus acid rain can mobilise nickel from the soil and increase nickel concentrations in ground water. Nickel bioaccumulates in the food chain but is not bioconcentrated.

Drinking Water Standards:

Nickel 50 ug/l (UK max.)

20 ug/l (WHO guideline)

Soil Guidelines:

Dutch Criteria: 35 mg/kg (target)

210 mg/kg (intervention)

DO NOT discharge into sewer or waterways.

Section 13 - DISPOSAL CONSIDERATIONS

Consult State Land Waste Management Authority for disposal.

Puncture containers to prevent re-use and bury at an authorised landfill.

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Section 14 - TRANSPORTATION INFORMATION

Shipping Name:
None
Dangerous Goods Class: None
UN/NA Number: None
ADR Number:
Packing Group: None
Labels Required:
Additional Shipping Information:
International Transport Regulations:
IMO: None

HAZCHEM

None

Section 15 - REGULATORY INFORMATION

POISONS SCHEDULE

None

Section 16 - OTHER INFORMATION

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