

Calcitonin Salmon Injection USP,400USP Units/2ml (200 USP Units/ml)

Cipla Ltd

Chemwatch: 5648-09

Version No: 3.1

Safety Data Sheet according to OSHA HazCom Standard (2012) requirements

Chemwatch Hazard Alert Code: 2

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L.GHS.U.SA.EN

SECTION 1 Identification

Product Identifier

Product name: Calcitonin Salmon Injection USP,400USP Units/2ml (200 USP Units/ml)

Chemical Name: Not Applicable

Synonyms: Not Available

Chemical formula: Not Applicable

Other means of identification: Not Available

Recommended use of the chemical and restrictions on use

Relevant identified uses: Human Pharmaceutical Use according to manufacturer's directions.

Name, address, and telephone number of the chemical manufacturer, importer, or other responsible party

| | |
|-------------------------|--|
| Registered company name | Cipla Ltd |
| Address | Peninsula Business Park, Ganpatrao Kadam Marg, Lower Parel, Maharashtra 400013 India |
| Telephone | 022 2576 1928 |
| Fax | Not Available |
| Website | Not Available |
| Email | Not Available |

Emergency phone number

| | | |
|-------------------------------------|-----------------|-------------------------------------|
| Association / Organisation | Cipla Ltd | CHEMWATCH EMERGENCY RESPONSE (24/7) |
| Emergency telephone number(s) | +918000403230 | +1 855-237-5573 |
| Other emergency telephone number(s) | +61 3 9573 3188 | +61 3 9573 3188 |

Once connected and if the message is not in your preferred language then please dial 01

Una vez conectado y si el mensaje no está en su idioma preferido, por favor marque 02

SECTION 2 Hazard(s) identification

Classification of the substance or mixture

NFPA 704 diamond



Note: The hazard category numbers found in GHS classification in section 2 of this SDSs are NOT to be used to fill in the NFPA 704 diamond. Blue = Health Red = Fire Yellow = Reactivity White = Special (Oxidizer or water reactive substances)

| | |
|----------------|---------------|
| Classification | Non hazardous |
|----------------|---------------|

Label elements

Hazard pictogram(s)

Not Applicable

Signal word: Not Applicable

Hazard statement(s)

Not Applicable

Hazard(s) not otherwise classified

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 |
|------------|-----------|-----------------------------------|
| 7647-14-5 | <1 | <u>sodium chloride</u> |
| 108-95-2 | <1 | <u>phenol</u> |
| 64-19-7 | <1 | <u>acetic acid glacial</u> |
| 6131-90-4 | <1 | <u>sodium acetate, trihydrate</u> |
| 47931-85-1 | <1 | <u>calcitonin</u> |
| 7732-18-5 | balance | <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 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.

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.

Most important symptoms and effects, both acute and delayed

See Section 11

Indication of any immediate medical attention and special treatment needed

Treat symptomatically.

SECTION 5 Fire-fighting 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.
- carbon dioxide.

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

None known.

Special protective equipment and precautions for fire-fighters**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)

hydrogen chloride

phosgene

other pyrolysis products typical of burning organic material.

May emit poisonous fumes.

May emit corrosive fumes.

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

Moderate hazard.

- 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 (see Section 13 for specific agent).
- 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 SDS.

SECTION 7 Handling and storage

Precautions for safe handling

Safe handling

- **DO NOT allow clothing wet with material to stay in contact with skin**
- Avoid all personal contact, including inhalation.
- Wear protective clothing when risk of exposure occurs.
- Use in a well-ventilated area.
- Prevent concentration in hollows and sumps.
- **DO NOT enter confined spaces until atmosphere has been checked.**
- **DO NOT allow material to contact humans, exposed food or food utensils.**
- 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.
- Work clothes should be laundered separately. Launder contaminated clothing before re-use.
- Use good occupational work practice.
- Observe manufacturer's storage and handling recommendations contained within this SDS.
- Atmosphere should be regularly checked against established exposure standards to ensure safe working conditions are maintained.

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.

Conditions for safe storage, including any incompatibilities

Suitable container

Vial.

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

Storage incompatibility

None known



X — Must not be stored together

O — May be stored together with specific preventions

+ — May be stored together

Note: Depending on other risk factors, compatibility assessment based on the table above may not be relevant to storage situations, particularly where large volumes of dangerous goods are stored and handled. Reference should be made to the Safety Data Sheets for each substance or article and risks assessed accordingly.

SECTION 8 Exposure controls / personal protection

Control parameters

Occupational Exposure Limits (OEL)

INGREDIENT DATA

| Source | Ingredient | Material name | TWA | STEL | Peak | Notes |
|--|---------------------|---------------|-------------------------------|-------------------------------|---|------------------|
| US OSHA Permissible Exposure Limits (PELs) Table Z-1 | phenol | Phenol | 5 ppm / 19 mg/m ³ | Not Available | Not Available | Skin designation |
| US NIOSH Recommended Exposure Limits (RELs) | phenol | Phenol | 5 ppm / 19 mg/m ³ | Not Available | 15.6 (15-minute) ppm / 60 (15-minute) mg/m ³ | [skin] |
| US OSHA Permissible Exposure Limits (PELs) Table Z-1 | acetic acid glacial | Acetic acid | 10 ppm / 25 mg/m ³ | Not Available | Not Available | Not Available |
| US NIOSH Recommended Exposure Limits (RELs) | acetic acid glacial | Acetic acid | 10 ppm / 25 mg/m ³ | 37 mg/m ³ / 15 ppm | Not Available | Not Available |

Occupational Exposure Banding

| Ingredient | Occupational Exposure Band Rating | Occupational Exposure Band Limit |
|----------------------------|---|----------------------------------|
| sodium chloride | E | ≤ 0.01 mg/m ³ |
| sodium acetate, trihydrate | E | ≤ 0.01 mg/m ³ |
| Notes: | <i>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.</i> | |

MATERIAL DATA

Exposure controls

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.

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. Air contaminants generated in the workplace possess varying "escape" velocities which, in turn, determine the "capture velocities" of fresh circulating air required to effectively remove the contaminant.

Type of Contaminant:

solvent, vapours, degreasing etc., evaporating from tank (in still air).

aerosols, fumes from pouring operations, intermittent container filling, low speed conveyer transfers, welding, spray drift, plating acid fumes, pickling (released at low velocity into zone of active generation)

direct spray, spray painting in shallow booths, drum filling, conveyer loading, crusher dusts, gas discharge (active generation into zone of rapid air motion)

grinding, abrasive blasting, tumbling, high speed wheel generated dusts (released at high initial velocity into zone of very high rapid air motion).

Air Speed:

0.25-0.5 m/s (50-100 f/min.)

0.5-1 m/s (100-200 f/min.)

1-2.5 m/s (200-500 f/min.)

2.5-10 m/s (500-2000 f/min.)

Within each range the appropriate value depends on:

Lower end of the range

1: Room air currents minimal or favourable to capture

2: Contaminants of low toxicity or of nuisance value only.

3: Intermittent, low production.

4: Large hood or large air mass in motion

Upper end of the range

1: Disturbing room air currents

2: Contaminants of high toxicity

3: High production, heavy use

4: Small hood-local control only

Simple theory shows that air velocity falls rapidly with distance away from the opening of a simple extraction pipe. Velocity generally decreases with the square of distance from the extraction point (in simple cases). Therefore the air speed at the extraction point should be adjusted, accordingly, after reference to distance from the contaminating source. The air velocity at the extraction fan, for example, should be a minimum of 1-2 m/s (200-400 f/min) for extraction of solvents generated in a tank 2 meters distant from the extraction point. Other mechanical considerations, producing performance deficits within the extraction apparatus, make it essential that theoretical air velocities are multiplied by factors of 10 or more when extraction systems are installed or used.

Individual protection measures, such as personal protective equipment



Eye and face protection

– Safety glasses with side shields.

– Chemical goggles. [AS/NZS 1337.1, EN166 or national equivalent]

– 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].

Skin protection

See Hand protection below

Hands/feet protection

– Wear chemical protective gloves, e.g. PVC.

– Wear safety footwear or safety gumboots, e.g. Rubber

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. Important factors in the selection of gloves include:

- frequency and duration of contact,
- chemical resistance of glove material,
- glove thickness and
- dexterity

Select gloves tested to a relevant standard (e.g. Europe EN 374, US F739, AS/NZS 2161.1 or national equivalent).

· When prolonged or frequently repeated contact may occur, a glove with a protection class of 5 or higher (breakthrough time greater than 240 minutes according to EN 374, AS/NZS 2161.10.1 or national equivalent) is recommended.

· When only brief contact is expected, a glove with a protection class of 3 or higher (breakthrough time greater than 60 minutes according to EN 374, AS/NZS 2161.10.1 or national equivalent) is recommended.

· Some glove polymer types are less affected by movement and this should be taken into account when considering gloves for long-term use.

· Contaminated gloves should be replaced.

As defined in ASTM F-739-96 in any application, gloves are rated as:

- Excellent when breakthrough time > 480 min
- Good when breakthrough time > 20 min
- Fair when breakthrough time < 20 min
- Poor when glove material degrades

For general applications, gloves with a thickness typically greater than 0.35 mm, are recommended.

It should be emphasised that glove thickness is not necessarily a good predictor of glove resistance to a specific chemical, as the permeation efficiency of the glove will be dependent on the exact composition of the glove material. Therefore, glove selection should also be based on consideration of the task requirements and knowledge of breakthrough times.

Glove thickness may also vary depending on the glove manufacturer, the glove type and the glove model. Therefore, the manufacturers technical data should always be taken into account to ensure selection of the most appropriate glove for the task.

Note: Depending on the activity being conducted, gloves of varying thickness may be required for specific tasks. For example:

- Thinner gloves (down to 0.1 mm or less) may be required where a high degree of manual dexterity is needed. However, these gloves are only likely to give short duration protection and would normally be just for single use applications, then disposed of.
- Thicker gloves (up to 3 mm or more) may be required where there is a mechanical (as well as a chemical) risk i.e. where there is abrasion or puncture potential

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.

Body protection

See Other protection below

Other protection

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

SECTION 9 Physical and chemical properties

Information on basic physical and chemical properties

Appearance: Clear liquid; mixes with water.

| | | | |
|---|----------------|--|----------------|
| Physical state | Liquid | Relative density (Water = 1) | Not Available |
| Odour | Not Available | Partition coefficient n-octanol / water | Not Available |
| Odour threshold | Not Available | Auto-ignition temperature (°C) | Not Applicable |
| pH (as supplied) | Not Applicable | Decomposition temperature (°C) | 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 |
| Solubility in water | Miscible | pH as a solution (1%) | 3.9-4.5 |
| Vapour density (Air = 1) | Not Available | VOC g/L | Not Available |
| Heat of Combustion (kJ/g) | Not Available | Ignition Distance (cm) | Not Available |
| Flame Height (cm) | Not Available | Flame Duration (s) | Not Available |
| Enclosed Space Ignition Time Equivalent (s/m3) | Not Available | Enclosed Space Ignition Deflagration Density (g/m3) | 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

Continued...

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. The material may still be damaging to the health of the individual, following ingestion, especially where pre-existing organ (e.g 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.

Skin Contact

Skin contact is not thought to have harmful health effects (as classified under EC Directives); the material may still produce health damage following entry through wounds, lesions or abrasions.

Limited evidence exists, or practical experience predicts, that the material either produces inflammation of the skin in a substantial number of individuals following direct contact, and/or produces significant inflammation when applied to the healthy intact skin of animals, for up to four hours, such inflammation being present twenty-four hours or more after the end of the exposure period. Skin irritation may also be present after prolonged or repeated exposure; this may result in a form of contact dermatitis (nonallergic). The dermatitis is often characterised by skin redness (erythema) and swelling (oedema) which may progress to blistering (vesiculation), scaling and thickening of the epidermis. At the microscopic level there may be intercellular oedema of the spongy layer of the skin (spongiosis) and intracellular oedema of the epidermis.

Open cuts, abraded or irritated skin should not be exposed to this material

Entry into the blood-stream through, for example, cuts, abrasions, puncture wounds 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

Limited evidence suggests that repeated or long-term occupational exposure may produce cumulative health effects involving organs or biochemical systems.

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.

| | | |
|--|--|--|
| Calcitonin Salmon Injection USP,400USP Units/2ml (200 USP Units/ml) | TOXICITY | IRRITATION |
| | Not Available | Not Available |
| sodium chloride | TOXICITY | IRRITATION |
| | Dermal (rabbit) LD50: >10000 mg/kg ^[1] | Eye (Rodent - rabbit): 100mg/24H - Moderate |
| | Inhalation (Rat) LC50: >10.5 mg/l4h ^[1] | Eye (Rodent - rabbit): 10mg - Moderate |
| | Oral (Rat) LD50: 3000 mg/kg ^[2] | Eye: adverse effect observed (irritating) ^[1] |
| | | Skin (Rodent - rabbit): 500mg/24H - Mild |
| | Skin: no adverse effect observed (not irritating) ^[1] | |
| phenol | TOXICITY | IRRITATION |
| | Dermal (rabbit) LD50: 850 mg/kg ^[2] | Eye (Rodent - rabbit): 5mg - Severe |
| | Inhalation (Mouse) LC50: 0.177 mg/L4h ^[2] | Eye (Rodent - rabbit): 5mg/30S - Mild |
| | Oral (Rat) LD50: 317 mg/kg ^[2] | Eye: adverse effect observed (irritating) ^[1] |
| | | Skin (Mammal - pig): 400uL/30S - Severe |
| | | Skin (Rodent - rabbit): 100mg - Mild |
| | | Skin (Rodent - rabbit): 535mg - Severe |
| | Skin: adverse effect observed (corrosive) ^[1] | |
| acetic acid glacial | TOXICITY | IRRITATION |
| | Dermal (rabbit) LD50: 1060 mg/kg ^[2] | Eye (Rodent - rabbit): 0.1mL |
| | Inhalation (Mouse) LC50: 1.405 mg/L4h ^[2] | Eye (Rodent - rabbit): 5mg/30S - Mild |
| | Oral (Rat) LD50: 3310 mg/kg ^[2] | Eye: adverse effect observed (irritating) ^[1] |
| | | Skin (Human): 50mg/24H - Mild |
| | | Skin (Rodent - rabbit): 50mg/24H - Mild |
| | | Skin (Rodent - rabbit): 525mg - Severe |
| | Skin: adverse effect observed (corrosive) ^[1] | |
| | Skin: adverse effect observed (irritating) ^[1] | |
| sodium acetate, trihydrate | TOXICITY | IRRITATION |
| | Oral (Rat) LD50: 3530 mg/kg ^[2] | Not Available |
| calcitonin | TOXICITY | IRRITATION |
| | Oral (Rat) LD50: >72.8 mg/kg ^[2] | Not Available |
| water | TOXICITY | IRRITATION |
| | Oral (Rat) LD50: >90000 mg/kg ^[2] | 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

SODIUM CHLORIDE

The material may produce moderate eye irritation leading to inflammation. Repeated or prolonged exposure to irritants may produce conjunctivitis.

The material may cause skin irritation after prolonged or repeated exposure and may produce a contact dermatitis (nonallergic). This form of dermatitis is often characterised by skin redness (erythema) and swelling epidermis. Histologically there may be intercellular oedema of the spongy layer (spongiosis) and intracellular oedema of the epidermis.

PHENOL

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.

ACETIC ACID GLACIAL

for acid mists, aerosols, vapours

Data from assays for genotoxic activity in vitro suggest that eukaryotic cells are susceptible to genetic damage when the pH falls to about 6.5. Cells from the respiratory tract have not been examined in this respect. Mucous secretion may protect the cells of the airways from direct exposure to inhaled acidic mists, just as mucous plays an important role in protecting the gastric epithelium from its auto-secreted hydrochloric acid. In considering whether pH itself induces genotoxic events in vivo in the respiratory system, comparison should be made with the human stomach, in which gastric juice may be at pH 1-2 under fasting or nocturnal conditions, and with the human urinary bladder, in which the pH of urine can range from <5 to > 7 and normally averages 6.2. Furthermore, exposures to low pH in vivo differ from exposures in vitro in that, in vivo, only a portion of the cell surface is subjected to the adverse conditions, so that perturbation of intracellular homeostasis may be maintained more readily than in vitro.

NOAELs following repeated exposure to acetic acid and its salts range from 210 mg/kg bw/day (2-4 month acetic acid drinking water study; systemic toxicity) to 3600 mg/kg bw/day (acetic acid, sodium salt, 4 week dietary study; no effects reported). Signs of irritation/corrosion at the site of contact as well as systemic toxicity have been reported. Prolonged inhalation exposure to acetic acid results in muscle imbalance, increase in blood cholinesterase activity, decreases in albumins and decreased growth at concentrations greater than 0.01 mg/m³/day.

Groups of 20 mice/sex were given 0.025% sodium acetate in drinking water (about 60 mg/kg bw/day) for 1 week before breeding, during a 9-day breeding period and (females only) throughout pregnancy, lactation and until the offspring were weaned at 3 weeks of age. No effects on fertility were observed. The male offspring were given the same solution until they were 5-7 weeks old and were then examined in a 24-hour activity test. Examination of the litters revealed no overt deformities and normal pup weights at day 1 and day 21. The activity of offspring of the treated group was lower than that of controls during the first 12 hours but was similar during the second 12 hours. It is unknown if the decreased activity observed in the sodium acetate treated group to was a result of exposure in utero and/or post-weaning, since the pups were exposed during both time periods. Acetic acid had no effects on implantation or on maternal or fetal survival in rats, mice or rabbits dosed via gavage during gestation days 6-19 at doses up to 1600 mg/kg/day. The number of abnormalities seen in either soft or skeletal tissues of the test groups did not differ from the number occurring in the controls. Sodium acetate had no effect on pregnant mice or offspring when mice were administered 1000 mg/kg bw, by gavage on days 8-12 of gestation.

SODIUM ACETATE, TRIHYDRATE

Data for anhydrous form

CALCITONIN

Paraesthesia recorded. Equivocal tumourigen by RTECS criteria. Calcitonin (salmon) RTECS NO: EV800000

To date, two different classes of drugs blocking CGRP have been developed: small molecule CGRP receptor antagonists (gepants), and monoclonal antibodies, targeting either CGRP or the CGRP receptor. Several trials have been conducted to test the efficacy and safety of these drugs. In general, a superior efficacy compared to placebo has been shown, especially with regards to the antibodies. In addition, the efficacy is in line with other currently used prophylactic treatments. The drugs have also been well tolerated, except for some of the gepants, which induced a transient increase in transaminases.

The first generation of gepants was abandoned because of liver toxicity, a problem not seen in the second generation of gepants. Gepants are small molecules, unlike their large injectable preventive cousins the monoclonal antibodies. The gepants are antagonists of the CGRP receptor, meaning they block the ability of CGRP to bind to the CGRP docking station, where CGRP starts up or prolongs migraine attacks. Gepants unlike the triptan class usually used to treat a migraine, do not cause constriction of blood vessels, and therefore, could be used in people who have vascular disease, heart disease, or stroke. Similar to monoclonal antibodies, there have not been any studies to determine gepant safety in pregnancy.

Although outcome data are early, a signal for worsening migraines with frequent use (sometimes called medication overuse headache or rebound) has not been seen with gepants, and this is one of the reasons this class of medications is being studied for both acute and preventive treatment of migraine. Studies have suggested that when people with migraine frequently took a gepant acutely for their migraine attacks, they actually had fewer migraines over time.

There are drug interaction cautions for the gepants, ubrogepant and rimegepant. They are processed through a similar liver processing pathway (CYP3A4) as a number of medications, and therefore, use of these medications could either increase or decrease the effectiveness of medications using the same pathway. CGRP and its receptor are abundantly present in both the vasculature, and in the peripheral and central nervous system, and are involved in several physiological processes. Therefore, blocking CGRP may pose a risk in subjects with comorbidities such as cardiovascular diseases. In addition, long-term effects are still unknown. Evidence from animal studies suggests that blocking CGRP may induce constipation, affect the homeostatic functions of the pituitary hormones or attenuate wound healing. However, these effects have so far not been reported in human studies. CGRP and its receptor are abundantly present in both the vasculature, and in the peripheral and central nervous system, and are involved in several physiological processes. Therefore, blocking CGRP may pose a risk in subjects with comorbidities such as cardiovascular diseases. In addition, long-term effects are still unknown. Evidence from animal studies suggests that blocking CGRP may induce constipation, affect the homeostatic functions of the pituitary hormones or attenuate wound healing. However, these effects have so far not been reported in human studies.

Prophylactic therapy with CGRPs may have unknown fertility consequences for women of child bearing age. This is of particular concern, as females (16.6%) are more genetically predisposed to migraine than are males (7.5%)

SODIUM CHLORIDE & PHENOL & ACETIC ACID GLACIAL & SODIUM ACETATE, TRIHYDRATE

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.

PHENOL & ACETIC ACID GLACIAL

The material may produce severe irritation to the eye causing pronounced inflammation. Repeated or prolonged exposure to irritants may produce conjunctivitis.

The material may produce severe skin irritation after prolonged or repeated exposure, and may produce a contact dermatitis (nonallergic). This form of dermatitis is often characterised by skin redness (erythema) thickening of the epidermis.

Histologically there may be intercellular oedema of the spongy layer (spongiosis) and intracellular oedema of the epidermis. Prolonged contact is unlikely, given the severity of response, but repeated exposures may produce severe ulceration.

CALCITONIN & WATER

No significant acute toxicological data identified in literature search.

| | | | |
|-----------------------------------|---|--------------------------|---|
| 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 either not available or does not fill the criteria for classification
 ✓ – Data available to make classification

SECTION 12 Ecological information**Toxicity**

| Calcitonin Salmon Injection USP,400USP Units/2ml (200 USP Units/ml) | Endpoint | Test Duration (hr) | Species | Value | Source |
|--|----------|--------------------|---------------|---------------|---------------|
| | | Not Available | Not Available | Not Available | Not Available |

| sodium chloride | Endpoint | Test Duration (hr) | Species | Value | Source |
|-----------------|-----------|--------------------|-------------------------------|-----------------|--------|
| | EC50 | 72h | Algae or other aquatic plants | 20.76-36.17mg/L | 4 |
| | EC50 | 48h | Crustacea | 0.004-0.006mg/L | 4 |
| | LC50 | 96h | Fish | 1000mg/L | 4 |
| | EC50 | 96h | Algae or other aquatic plants | 1110.36mg/L | 4 |
| | NOEC(ECx) | 6h | Fish | 0.001mg/L | 4 |

| phenol | Endpoint | Test Duration (hr) | Species | Value | Source |
|--------|-----------|--------------------|-------------------------------|-------------------|--------|
| | EC50 | 72h | Algae or other aquatic plants | 48.937-57.407mg/L | 4 |
| | EC50(ECx) | 24h | Crustacea | <0.001mg/L | 4 |
| | EC50 | 48h | Crustacea | 3.1mg/l | 1 |
| | LC50 | 96h | Fish | 0.002mg/L | 4 |
| | EC50 | 96h | Algae or other aquatic plants | 0.019-0.104mg/L | 4 |

| acetic acid glacial | Endpoint | Test Duration (hr) | Species | Value | Source |
|---------------------|-----------|--------------------|-------------------------------|---------------|--------|
| | EC50 | 72h | Algae or other aquatic plants | 29.23mg/l | 2 |
| | EC50 | 48h | Crustacea | 18.9mg/l | 2 |
| | EC50(ECx) | 24h | Algae or other aquatic plants | 0.08mg/l | 2 |
| | LC50 | 96h | Fish | 31.3-67.6mg/l | 2 |
| | EC50 | 96h | Algae or other aquatic plants | 73.4mg/L | 4 |

| sodium acetate, trihydrate | Endpoint | Test Duration (hr) | Species | Value | Source |
|----------------------------|-----------|--------------------|-------------------------------|-------------|--------|
| | EC50 | 72h | Algae or other aquatic plants | >417.92mg/l | 2 |
| | EC50 | 48h | Crustacea | >1000mg/l | 1 |
| | EC50(ECx) | 48h | Crustacea | >1000mg/l | 1 |
| | LC50 | 96h | Fish | >=100mg/l | 1 |

| calcitonin | Endpoint | Test Duration (hr) | Species | Value | Source |
|------------|----------|--------------------|---------------|---------------|---------------|
| | | Not Available | Not Available | Not Available | Not Available |

| water | Endpoint | Test Duration (hr) | Species | Value | Source |
|-------|----------|--------------------|---------------|---------------|---------------|
| | | Not Available | Not Available | Not Available | Not Available |

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

DO NOT discharge into sewer or waterways.

Persistence and degradability

| Ingredient | Persistence: Water/Soil | Persistence: Air |
|----------------------------|---------------------------|-----------------------------|
| sodium chloride | LOW | LOW |
| phenol | LOW (Half-life = 10 days) | LOW (Half-life = 0.95 days) |
| acetic acid glacial | LOW | LOW |
| sodium acetate, trihydrate | LOW | LOW |
| water | LOW | LOW |

Bioaccumulative potential

| Ingredient | Bioaccumulation |
|----------------------------|-----------------------|
| sodium chloride | LOW (LogKOW = 0.5392) |
| phenol | LOW (BCF = 17.5) |
| acetic acid glacial | LOW (LogKOW = -0.17) |
| sodium acetate, trihydrate | HIGH (BCF = 29100) |

Mobility in soil

| Ingredient | Mobility |
|-----------------|----------------------|
| sodium chloride | LOW (Log KOC = 14.3) |

Continued...

| Ingredient | Mobility |
|----------------------------|---------------------|
| phenol | LOW (Log KOC = 268) |
| acetic acid glacial | HIGH (Log KOC = 1) |
| sodium acetate, trihydrate | HIGH (Log KOC = 1) |

SECTION 13 Disposal considerations

Waste treatment methods

Product / Packaging disposal

- Containers may still present a chemical hazard/ danger when empty.
- Return to supplier for reuse/ recycling if possible.

Otherwise:

- If container can not be cleaned sufficiently well to ensure that residuals do not remain or if the container cannot be used to store the same product, then puncture containers, to prevent re-use, and bury at an authorised landfill.
- Where possible retain label warnings and SDS and observe all notices pertaining to the product.
- **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

| | Land transport (DOT): 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 |
|---|--|---|--|
| UN number: Not Applicable | | | |
| UN proper shipping name: Not Applicable | | | |
| Transport hazard class(es): Not Applicable | | | |
| Subsidiary Hazard: Not Applicable | | | |
| Packing group: Not Applicable | | | |

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

| Product name | Group |
|----------------------------|---------------|
| sodium chloride | Not Available |
| phenol | Not Available |
| acetic acid glacial | Not Available |
| sodium acetate, trihydrate | Not Available |
| calcitonin | Not Available |
| water | Not Available |

14.7.3. Transport in bulk in accordance with the IGC Code

| Product name | Ship Type |
|----------------------------|---------------|
| sodium chloride | Not Available |
| phenol | Not Available |
| acetic acid glacial | Not Available |
| sodium acetate, trihydrate | Not Available |
| calcitonin | Not Available |
| water | Not Available |

SECTION 15 Regulatory information

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

sodium chloride is found on the following regulatory lists

- US DOE Temporary Emergency Exposure Limits (TEELs)
- US Toxic Substances Control Act (TSCA) - Chemical Substance Inventory

phenol is found on the following regulatory lists

Continued...

- International Agency for Research on Cancer (IARC) - Agents Classified by the IARC Monographs - Not Classified as Carcinogenic
- US - California Hazardous Air Pollutants Identified as Toxic Air Contaminants
- US - Massachusetts - Right To Know Listed Chemicals
- US - New Jersey Right to Know Hazardous Substances
- US - Pennsylvania - Hazardous Substance List
- US ATSDR Minimal Risk Levels for Hazardous Substances (MRLs)
- US Clean Air Act - Hazardous Air Pollutants
- US CWA (Clean Water Act) - List of Hazardous Substances
- US CWA (Clean Water Act) - Priority Pollutants
- US CWA (Clean Water Act) - Toxic Pollutants
- US DOE Temporary Emergency Exposure Limits (TEELs)
- US EPA Integrated Risk Information System (IRIS)
- US EPCRA Section 313 Chemical List
- US New York City Community Right-to-Know: List of Hazardous Substances
- US NIOSH Recommended Exposure Limits (RELs)
- US OSHA Permissible Exposure Limits (PELs) Table Z-1
- US OSHA Permissible Exposure Limits (PELs) Table Z-1 (Spanish)
- US SARA Section 302 Extremely Hazardous Substances
- US Toxic Substances Control Act (TSCA) - Chemical Substance Inventory
- US TSCA Section 4/12 (b) - Sunset Dates/Status

acetic acid glacial is found on the following regulatory lists

- US - Massachusetts - Right To Know Listed Chemicals
- US - New Jersey Right to Know - Special Health Hazard Substance List (SHHSL): Corrosives
- US - New Jersey Right to Know Hazardous Substances
- US - Pennsylvania - Hazardous Substance List
- US CWA (Clean Water Act) - List of Hazardous Substances
- US DOE Temporary Emergency Exposure Limits (TEELs)
- US New York City Community Right-to-Know: List of Hazardous Substances
- US NIOSH Recommended Exposure Limits (RELs)
- US OSHA Permissible Exposure Limits (PELs) Table Z-1
- US OSHA Permissible Exposure Limits (PELs) Table Z-1 (Spanish)
- US Toxic Substances Control Act (TSCA) - Chemical Substance Inventory

sodium acetate, trihydrate is found on the following regulatory lists

- US DOE Temporary Emergency Exposure Limits (TEELs)
- US Toxic Substances Control Act (TSCA) - Chemical Substance Inventory

calcitonin is found on the following regulatory lists

- Not Applicable

water is found on the following regulatory lists

- US Toxic Substances Control Act (TSCA) - Chemical Substance Inventory

Additional Regulatory Information

Not Applicable

Federal Regulations

Superfund Amendments and Reauthorization Act of 1986 (SARA)

Section 311/312 hazard categories

| | |
|--|----|
| Flammable (Gases, Aerosols, Liquids, or Solids) | No |
| Gas under pressure | No |
| Explosive | No |
| Self-heating | No |
| Pyrophoric (Liquid or Solid) | No |
| Pyrophoric Gas | No |
| Corrosive to metal | No |
| Oxidizer (Liquid, Solid or Gas) | No |
| Organic Peroxide | No |
| Self-reactive | No |
| In contact with water emits flammable gas | No |
| Combustible Dust | No |
| Carcinogenicity | No |
| Acute toxicity (any route of exposure) | No |
| Reproductive toxicity | No |
| Skin Corrosion or Irritation | No |
| Respiratory or Skin Sensitization | No |
| Serious eye damage or eye irritation | No |
| Specific target organ toxicity (single or repeated exposure) | No |
| Aspiration Hazard | No |
| Germ cell mutagenicity | No |
| Simple Asphyxiant | No |
| Hazards Not Otherwise Classified | No |

US. EPA CERCLA Hazardous Substances and Reportable Quantities (40 CFR 302.4)

| Name | Reportable Quantity in Pounds (lb) | Reportable Quantity in kg |
|---------------------|------------------------------------|---------------------------|
| phenol | 1000 | 454 |
| acetic acid glacial | 5000 | 2270 |

US. EPCRA Section 313 Toxic Release Inventory (TRI) (40 CFR 372)

This product contains the following EPCRA section 313 chemicals subject to the reporting requirements of section 313 of the Emergency Planning and Community Right-To-Know-Act of 1986 (40 CFR 372):

| CAS No | %[weight] | Name |
|----------|-----------|--------|
| 108-95-2 | <1 | phenol |

This information must be included in all SDSs that are copied and distributed for this material.

Additional Federal Regulatory Information

Not Applicable

State Regulations**US. California Proposition 65**

None Reported

Additional State Regulatory Information

Not Applicable

National Inventory Status

| National Inventory | Status |
|---|---|
| Australia - AIIC / Australia Non-Industrial Use | Yes |
| Canada - DSL | No (calcitonin) |
| Canada - NDSL | No (sodium chloride; phenol; acetic acid glacial; sodium acetate, trihydrate; calcitonin; water) |
| China - IECSC | Yes |
| Europe - EINEC / ELINCS / NLP | Yes |
| Japan - ENCS | No (calcitonin) |
| Korea - KECI | No (calcitonin) |
| New Zealand - NZIoC | No (calcitonin) |
| Philippines - PICCS | No (calcitonin) |
| USA - TSCA | TSCA Inventory 'Active' substance(s) (sodium chloride; phenol; acetic acid glacial; sodium acetate, trihydrate; water); No (calcitonin) |
| Taiwan - TCSI | Yes |
| Mexico - INSQ | No (calcitonin) |
| Vietnam - NCI | No (calcitonin) |
| Russia - FBEPH | No (calcitonin) |
| Legend: | 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: 13/12/2023

Initial Date: 24/11/2023

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
- DNEL: Derived No-Effect Level
- PNEC: Predicted no-effect concentration

- AIIC: Australian Inventory of Industrial Chemicals
- DSL: Domestic Substances List
- NDSL: Non-Domestic Substances List

- IECSC: Inventory of Existing Chemical Substance in China
- EINECS: European Inventory of Existing Commercial chemical Substances
- ELINCS: European List of Notified Chemical Substances
- NLP: No-Longer Polymers
- ENCS: Existing and New Chemical Substances Inventory
- KECI: Korea Existing Chemicals Inventory
- NZIoC: New Zealand Inventory of Chemicals
- PICCS: Philippine Inventory of Chemicals and Chemical Substances
- TSCA: Toxic Substances Control Act
- TCSI: Taiwan Chemical Substance Inventory
- INSQ: Inventario Nacional de Sustancias Químicas
- NCI: National Chemical Inventory
- FBEPH: Russian Register of Potentially Hazardous Chemical and Biological Substances

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