# IRM Liquid

## Dentsply Sirona Pty Ltd

Chemwatch Hazard Alert Code: **2**

Chemwatch: **8108-19**
Version No: **9.1**
Safety Data Sheet according to WHS Regulations (Hazardous Chemicals) Amendment 2020 and ADG requirements

Issue Date: **23/12/2022**
Print Date: **20/02/2023**
L.GHS.AUS.EN

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

### Product Identifier

| | |
|---|---|
| **Product name** | IRM Liquid |
| **Chemical Name** | Not Applicable |
| **Synonyms** | Not Available |
| **Chemical formula** | Not Applicable |
| **Other means of identification** | Not Available |

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

| | |
|---|---|
| **Relevant identified uses** | For dental use only. Intermediate restorative material Zinc eugenol cement. |

### Details of the manufacturer or supplier of the safety data sheet

| | |
|---|---|
| **Registered company name** | **Dentsply Sirona Pty Ltd** |
| **Address** | 11-21 Gilby Road Mount Waverley VIC 3149 Australia |
| **Telephone** | 1300 55 29 29 |
| **Fax** | 1300 55 31 31 |
| **Website** | www.dentsplysirona.com.au |
| **Email** | clientservices@dentsplysirona.com |

### Emergency telephone number

| **Association / Organisation** | **Dentsply Sirona Pty Ltd** | **CHEMWATCH EMERGENCY RESPONSE (24/7)** |
|---|---|---|
| **Emergency telephone numbers** | 1300 55 29 29 | +61 1800 951 288 |
| **Other emergency telephone numbers** | Not Available | +61 3 9573 3188 |

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

## SECTION 2 Hazards identification

### Classification of the substance or mixture

| | |
|---|---|
| **Poisons Schedule** | S6 |
| **Classification [1]** | Skin Corrosion/Irritation Category 2, Sensitisation (Skin) Category 1, Serious Eye Damage/Eye Irritation Category 2A, Sensitisation (Respiratory) Category 1 |
| ***Legend:*** | *1. Classified by Chemwatch; 2. Classification drawn from HCIS; 3. Classification drawn from Regulation (EU) No 1272/2008 - Annex VI* |

### Label elements

| | |
|---|---|
| **Hazard pictogram(s)** |  |
| **Signal word** | **Danger** |

**Page 1 continued...**

### Hazard statement(s)

| | |
|---|---|
| **H315** | Causes skin irritation. |
| **H317** | May cause an allergic skin reaction. |
| **H319** | Causes serious eye irritation. |
| **H334** | May cause allergy or asthma symptoms or breathing difficulties if inhaled. |

### Precautionary statement(s) Prevention

| | |
|---|---|
| **P261** | Avoid breathing mist/vapours/spray. |
| **P280** | Wear protective gloves, protective clothing, eye protection and face protection. |
| **P284** | [In case of inadequate ventilation] wear respiratory protection. |
| **P264** | Wash all exposed external body areas thoroughly after handling. |
| **P272** | Contaminated work clothing should not be allowed out of the workplace. |

### Precautionary statement(s) Response

| | |
|---|---|
| **P304+P340** | IF INHALED: Remove person to fresh air and keep comfortable for breathing. |
| **P342+P311** | If experiencing respiratory symptoms: Call a POISON CENTER/doctor/physician/first aider. |
| **P302+P352** | IF ON SKIN: Wash with plenty of water and soap. |
| **P305+P351+P338** | IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. |
| **P333+P313** | If skin irritation or rash occurs: Get medical advice/attention. |
| **P337+P313** | If eye irritation persists: Get medical advice/attention. |
| **P362+P364** | Take off contaminated clothing and wash it before reuse. |

### Precautionary statement(s) Storage

Not Applicable

### Precautionary statement(s) Disposal

| | |
|---|---|
| **P501** | Dispose of contents/container to authorised hazardous or special waste collection point in accordance with any local regulation. |

## SECTION 3 Composition / information on ingredients

### Substances

See section below for composition of Mixtures

### Mixtures

| CAS No | %[weight] | Name |
|---|---|---|
| 97-53-0 | >50 | eugenol |

| | |
|---|---|
| ***Legend:*** | *1. Classified by Chemwatch; 2. Classification drawn from HCIS; 3. Classification drawn from Regulation (EU) No 1272/2008 - Annex VI; 4. Classification drawn from C&L; * EU IOELVs available* |

## SECTION 4 First aid measures

### Description of first aid measures

| | |
|---|---|
| **Eye Contact** | If this product comes in contact with the eyes:<br>▸ Wash out immediately with fresh running water.<br>▸ 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.<br>▸ Seek medical attention without delay; if pain persists or recurs seek medical attention.<br>▸ Removal of contact lenses after an eye injury should only be undertaken by skilled personnel. |
| **Skin Contact** | If skin contact occurs:<br>▸ Immediately remove all contaminated clothing, including footwear.<br>▸ Flush skin and hair with running water (and soap if available).<br>▸ Seek medical attention in event of irritation. |
| **Inhalation** | ▸ If fumes, aerosols or combustion products are inhaled remove from contaminated area.<br>▸ Other measures are usually unnecessary. |
| **Ingestion** | ▸ Immediately give a glass of water.<br>▸ First aid is not generally required. If in doubt, contact a Poisons Information Centre or a doctor. |

**Continued...**

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

As in all cases of suspected poisoning, follow the ABCDEs of emergency medicine (airway, breathing, circulation, disability, exposure), then the ABCDEs of toxicology (antidotes, basics, change absorption, change distribution, change elimination).
For poisons (where specific treatment regime is absent):
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BASIC TREATMENT
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- Establish a patent airway with suction where necessary.
- Watch for signs of respiratory insufficiency and assist ventilation as necessary.
- Administer oxygen by non-rebreather mask at 10 to 15 L/min.
- Monitor and treat, where necessary, for pulmonary oedema.
- Monitor and treat, where necessary, for shock.
- Anticipate seizures.
- **DO NOT** use emetics. Where ingestion is suspected rinse mouth and give up to 200 ml water (5 ml/kg recommended) for dilution where patient is able to swallow, has a strong gag reflex and does not drool.

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ADVANCED TREATMENT
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- Consider orotracheal or nasotracheal intubation for airway control in unconscious patient or where respiratory arrest has occurred.
- Positive-pressure ventilation using a bag-valve mask might be of use.
- Monitor and treat, where necessary, for arrhythmias.
- Start an IV D5W TKO. If signs of hypovolaemia are present use lactated Ringers solution. Fluid overload might create complications.
- Drug therapy should be considered for pulmonary oedema.
- Hypotension with signs of hypovolaemia requires the cautious administration of fluids. Fluid overload might create complications.
- Treat seizures with diazepam.
- Proparacaine hydrochloride should be used to assist eye irrigation.

BRONSTEIN, A.C. and CURRANCE, P.L.
EMERGENCY CARE FOR HAZARDOUS MATERIALS EXPOSURE: 2nd Ed. 1994

## SECTION 5 Firefighting measures

### Extinguishing media

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

### Special hazards arising from the substrate or mixture

| | |
|---|---|
| **Fire Incompatibility** | ‣ Avoid contamination with oxidising agents i.e. nitrates, oxidising acids, chlorine bleaches, pool chlorine etc. as ignition may result |

### Advice for firefighters

| | |
|---|---|
| **Fire Fighting** | ‣ Alert Fire Brigade and tell them location and nature of hazard.<br>‣ Wear full body protective clothing with breathing apparatus.<br>‣ Prevent, by any means available, spillage from entering drains or water course.<br>‣ Use water delivered as a fine spray to control fire and cool adjacent area.<br>‣ Avoid spraying water onto liquid pools.<br>‣ **DO NOT** approach containers suspected to be hot.<br>‣ Cool fire exposed containers with water spray from a protected location.<br>‣ If safe to do so, remove containers from path of fire. |
| **Fire/Explosion Hazard** | ‣ Combustible.<br>‣ Slight fire hazard when exposed to heat or flame.<br>‣ Heating may cause expansion or decomposition leading to violent rupture of containers.<br>‣ On combustion, may emit toxic fumes of carbon monoxide (CO).<br>‣ May emit acrid smoke.<br>‣ Mists containing combustible materials may be explosive.<br>Combustion products include:<br>carbon dioxide ($CO_2$)<br>other pyrolysis products typical of burning organic material.<br>May emit poisonous fumes.<br>May emit corrosive fumes. |
| **HAZCHEM** | Not Applicable |

**Continued...**

## 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**

- Remove all ignition sources.
- 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**

Chemical Class: phenols and cresols
For release onto land: recommended sorbents listed in order of priority.

| SORBENT TYPE | RANK | APPLICATION | COLLECTION | LIMITATIONS |
|---|---|---|---|---|
| LAND SPILL - SMALL | | | | |
| cross-linked polymer - particulate | 1 | shovel | shovel | R, W, SS |
| cross-linked polymer - pillow | 1 | throw | pitchfork | R, DGC, RT |
| wood fiber - pillow | 1 | throw | pitchfork | R, P, DGC, RT |
| foamed glass - pillow | 2 | shovel | shovel | R, W, P, DGC |
| sorbent clay - particulate | 2 | shovel | shovel | R, I, P |
| wood fibre - particulate | 3 | shovel | shovel | R, W, P, DGC |
| LAND SPILL - MEDIUM | | | | |
| cross-linked polymer - particulate | 1 | blower | skiploader | R,W, SS |
| cross-linked polymer - pillow | 2 | throw | skiploader | R, DGC, RT |
| sorbent clay - particulate | 3 | blower | skiploader | R, I, P |
| polypropylene - particulate | 3 | blower | skiploader | R, SS, DGC |
| wood fiber - particulate | 4 | blower | skiploader | R, W, P, DGC |
| expanded moneral - particulate | 4 | blower | skiploader | R, I, W, P, DGC |

Legend
DGC: Not effective where ground cover is dense
R; Not reusable
I: Not incinerable
P: Effectiveness reduced when rainy
RT:Not effective where terrain is rugged
SS: Not for use within environmentally sensitive sites
W: Effectiveness reduced when windy
Reference: Sorbents for Liquid Hazardous Substance Cleanup and Control;
R.W Melvold et al: Pollution Technology Review No. 150: Noyes Data Corporation 1988
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.
- No smoking, naked lights or ignition sources.
- Increase ventilation.
- Stop leak if safe to do so.
- Contain spill with sand, earth or vermiculite.
- Collect recoverable product into labelled containers for recycling.
- Absorb remaining product with sand, earth or vermiculite.
- Collect solid residues and seal in labelled drums for disposal.
- Wash area and prevent runoff into drains.
- 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

**Continued...**

## Precautions for safe handling

| | |
|---|---|
| **Safe handling** | ▸ **DO NOT** allow clothing wet with material to stay in contact with skin<br>▸ Avoid all personal contact, including inhalation.<br>▸ Wear protective clothing when risk of exposure occurs.<br>▸ Use in a well-ventilated area.<br>▸ Prevent concentration in hollows and sumps.<br>▸ **DO NOT** enter confined spaces until atmosphere has been checked.<br>▸ Avoid smoking, naked lights or ignition sources.<br>▸ Avoid contact with incompatible materials.<br>▸ When handling, **DO NOT** eat, drink or smoke.<br>▸ Keep containers securely sealed when not in use.<br>▸ Avoid physical damage to containers.<br>▸ Always wash hands with soap and water after handling.<br>▸ Work clothes should be laundered separately.<br>▸ Use good occupational work practice.<br>▸ Observe manufacturer's storage and handling recommendations contained within this SDS.<br>▸ Atmosphere should be regularly checked against established exposure standards to ensure safe working conditions. |
| **Other information** | ▸ Store in original containers.<br>▸ Keep containers securely sealed.<br>▸ No smoking, naked lights or ignition sources.<br>▸ Store in a cool, dry, well-ventilated area.<br>▸ Store away from incompatible materials and foodstuff containers.<br>▸ Protect containers against physical damage and check regularly for leaks.<br>▸ Observe manufacturer's storage and handling recommendations contained within this SDS. |

## Conditions for safe storage, including any incompatibilities

| | |
|---|---|
| **Suitable container** | ▸ Metal can or drum<br>▸ Packaging as recommended by manufacturer.<br>▸ Check all containers are clearly labelled and free from leaks. |
| **Storage incompatibility** | ▸ Avoid reaction with oxidising agents |

## SECTION 8 Exposure controls / personal protection

### Control parameters

#### Occupational Exposure Limits (OEL)

#### INGREDIENT DATA

Not Available

#### Emergency Limits

| Ingredient | TEEL-1 | TEEL-2 | TEEL-3 |
|---|---|---|---|
| IRM Liquid | Not Available | Not Available | Not Available |

| Ingredient | Original IDLH | Revised IDLH |
|---|---|---|
| eugenol | Not Available | Not Available |

#### Occupational Exposure Banding

| Ingredient | Occupational Exposure Band Rating | Occupational Exposure Band Limit |
|---|---|---|
| eugenol | E | ≤ 0.1 ppm |
| ***Notes:*** | *Occupational exposure banding is a process of assigning chemicals into specific categories or bands based on a chemical's potency and the adverse health outcomes associated with exposure. The output of this process is an occupational exposure band (OEB), which corresponds to a range of exposure concentrations that are expected to protect worker health.* | |

#### 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.<br>The basic types of engineering controls are:<br>Process controls which involve changing the way a job activity or process is done to reduce the risk.<br>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. |

**Continued...**

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: | Air Speed: |
|---|---|
| solvent, vapours, degreasing etc., evaporating from tank (in still air). | 0.25-0.5 m/s (50-100 f/min.) |
| 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) | 0.5-1 m/s (100-200 f/min.) |
| direct spray, spray painting in shallow booths, drum filling, conveyer loading, crusher dusts, gas discharge (active generation into zone of rapid air motion) | 1-2.5 m/s (200-500 f/min.) |
| grinding, abrasive blasting, tumbling, high speed wheel generated dusts (released at high initial velocity into zone of very high rapid air motion). | 2.5-10 m/s (500-2000 f/min.) |

Within each range the appropriate value depends on:

| Lower end of the range | Upper end of the range |
|---|---|
| 1: Room air currents minimal or favourable to capture | 1: Disturbing room air currents |
| 2: Contaminants of low toxicity or of nuisance value only. | 2: Contaminants of high toxicity |
| 3: Intermittent, low production. | 3: High production, heavy use |
| 4: Large hood or large air mass in motion | 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.
- Contact lenses may pose a special hazard; soft contact lenses may absorb and concentrate irritants. A written policy document, describing the wearing of lenses or restrictions on use, should be created for each workplace or task. This should include a review of lens absorption and adsorption for the class of chemicals in use and an account of injury experience. Medical and first-aid personnel should be trained in their removal and suitable equipment should be readily available. In the event of chemical exposure, begin eye irrigation immediately and remove contact lens as soon as practicable. Lens should be removed at the first signs of eye redness or irritation - lens should be removed in a clean environment only after workers have washed hands thoroughly. [CDC NIOSH Current Intelligence Bulletin 59], [AS/NZS 1336 or national equivalent]

**Skin protection**

See Hand protection below

**Hands/feet protection**

- Wear chemical protective gloves, e.g. PVC.
- Wear safety footwear or safety gumboots, e.g. Rubber

**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.
- Contaminated leather items, such as shoes, belts and watch-bands should be removed and destroyed.

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).

**Continued...**

| | |
|---|---|
| | · 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.<br>· 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.<br>· Some glove polymer types are less affected by movement and this should be taken into account when considering gloves for long-term use.<br>· Contaminated gloves should be replaced.<br>As defined in ASTM F-739-96 in any application, gloves are rated as:<br>· Excellent when breakthrough time > 480 min<br>· Good when breakthrough time > 20 min<br>· Fair when breakthrough time < 20 min<br>· Poor when glove material degrades<br>For general applications, gloves with a thickness typically greater than 0.35 mm, are recommended.<br>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.<br>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.<br>Note: Depending on the activity being conducted, gloves of varying thickness may be required for specific tasks. For example:<br>· 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.<br>· 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<br>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.<br>‣ P.V.C apron.<br>‣ Barrier cream.<br>‣ Skin cleansing cream.<br>‣ Eye wash unit. |

### Respiratory protection

Type A-P Filter of sufficient capacity. (AS/NZS 1716 & 1715, EN 143:2000 & 149:2001, ANSI Z88 or national equivalent)

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

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

* - Continuous Flow ** - Continuous-flow or positive pressure demand
A(All classes) = Organic vapours, B AUS or B1 = Acid gasses, B2 = Acid gas or hydrogen cyanide(HCN), B3 = Acid gas or hydrogen cyanide(HCN), E = Sulfur dioxide(SO2), G = Agricultural chemicals, K = Ammonia(NH3), Hg = Mercury, NO = Oxides of nitrogen, MB = Methyl bromide, AX = Low boiling point organic compounds(below 65 degC)

- 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.
- Cartridge performance is affected by humidity. Cartridges should be changed after 2 hr of continuous use unless it is determined that the humidity is less than 75%, in which case, cartridges can be used for 4 hr. Used cartridges should be discarded daily, regardless of the length of time used

## SECTION 9 Physical and chemical properties

### Information on basic physical and chemical properties

| | |
|---|---|
| **Appearance** | Yellowish colour liquid with characteristic odour; does not mix with water. |

| | | | |
|---|---|---|---|
| **Physical state** | Liquid | **Relative density (Water = 1)** | 1.06 |

**Continued...**

| | | | |
|---|---|---|---|
| **Odour** | Not Available | **Partition coefficient n-octanol / water** | Not Available |
| **Odour threshold** | Not Available | **Auto-ignition temperature (°C)** | Not Available |
| **pH (as supplied)** | Not Available | **Decomposition temperature (°C)** | Not Available |
| **Melting point / freezing point (°C)** | -10 | **Viscosity (cSt)** | Not Available |
| **Initial boiling point and boiling range (°C)** | 254 | **Molecular weight (g/mol)** | Not Applicable |
| **Flash point (°C)** | 116 | **Taste** | Not Available |
| **Evaporation rate** | Not Available | **Explosive properties** | Not Available |
| **Flammability** | Not Applicable | **Oxidising properties** | Not Available |
| **Upper Explosive Limit (%)** | Not Available | **Surface Tension (dyn/cm or mN/m)** | Not Available |
| **Lower Explosive Limit (%)** | Not Available | **Volatile Component (%vol)** | Not Available |
| **Vapour pressure (kPa)** | Negligible | **Gas group** | Not Available |
| **Solubility in water** | Immiscible | **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.<br>‣ Product is considered stable.<br>‣ 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.<br>Inhalation hazard is increased at higher temperatures. |
| **Ingestion** | Although ingestion is not thought to produce harmful effects (as classified under EC Directives), 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** | The material produces severe skin irritation; evidence exists, or practical experience predicts, that the material either:<br>‣ produces severe inflammation of the skin in a substantial number of individuals following direct contact, and/or<br>‣ produces significant and severe 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.<br>‣ 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.<br><br>**NOTE:** Prolonged contact is unlikely, given the severity of response, but repeated exposures may produce severe ulceration.<br>Open cuts, abraded or irritated skin should not be exposed to this material<br>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** | Evidence exists, or practical experience predicts, that the material may cause eye irritation in a substantial number of individuals and/or may produce significant ocular lesions which are present twenty-four hours or more after instillation into the eye(s) of experimental animals. |

**Continued...**

| | |
|---|---|
| | Repeated or prolonged eye contact may cause inflammation characterised by temporary redness (similar to windburn) of the conjunctiva (conjunctivitis); temporary impairment of vision and/or other transient eye damage/ulceration may occur. |
| **Chronic** | Practical evidence shows that inhalation of the material is capable of inducing a sensitisation reaction in a substantial number of individuals at a greater frequency than would be expected from the response of a normal population.<br>Pulmonary sensitisation, resulting in hyperactive airway dysfunction and pulmonary allergy may be accompanied by fatigue, malaise and aching. Significant symptoms of exposure may persist for extended periods, even after exposure ceases. Symptoms can be activated by a variety of nonspecific environmental stimuli such as automobile exhaust, perfumes and passive smoking.<br>Practical experience shows that skin contact with the material is capable either of inducing a sensitisation reaction in a substantial number of individuals, and/or of producing a positive response in experimental animals.<br>Substances that can cause occupational asthma (also known as asthmagens and respiratory sensitisers) can induce a state of specific airway hyper-responsiveness via an immunological, irritant or other mechanism. Once the airways have become hyper-responsive, further exposure to the substance, sometimes even to tiny quantities, may cause respiratory symptoms. These symptoms can range in severity from a runny nose to asthma. Not all workers who are exposed to a sensitiser will become hyper-responsive and it is impossible to identify in advance who are likely to become hyper-responsive.<br>Substances than can cuase occupational asthma should be distinguished from substances which may trigger the symptoms of asthma in people with pre-existing air-way hyper-responsiveness. The latter substances are not classified as asthmagens or respiratory sensitisers<br>Wherever it is reasonably practicable, exposure to substances that can cuase occupational asthma should be prevented. Where this is not possible the primary aim is to apply adequate standards of control to prevent workers from becoming hyper-responsive.<br>Activities giving rise to short-term peak concentrations should receive particular attention when risk management is being considered. Health surveillance is appropriate for all employees exposed or liable to be exposed to a substance which may cause occupational asthma and there should be appropriate consultation with an occupational health professional over the degree of risk and level of surveillance.<br><br>Some phenol-based naturally occurring substances, (e.g. phenol, guaiacol, tannic acid, eugenol) undergo conversion to produce derivatives which produce skin (and possibly respiratory) sensitisation. Each of these compounds has phenolic hydroxyl groups which are readily oxidized to produce reactive quinone-like compounds. Phenol is converted in the body to quinone whilst guaiacol (ortho-methoxyphenol) and eugenol (2-allylguaiacol) are converted to the ortho-quinone. Both eugenol and isoeugenol (4-propenylguaiacol) are pro-haptens that require biotransformation to become protein-reactive haptens. Although they are close structural isomers they show markedly different levels of sensitisation and are weakly cross-reactive in in vivo tests. Isoeugenol is a strong sensitiser and eugenol is moderate. It appears that neither share a common mechanism for sensitisation although structural similarities exist. This relates to different mechanisms of biotransformation.<br><br>Cinnamaldehyde and cinnamic acid are structurally related to eugenol and isoeugenol; they seen to generate a common hapten and appear to produce simultaneous sensitisation to eugenol and isoeugenol despite being metabolised via different pathways. Buckley et al British Jnl of Dermatology 2006 Vol 154 pp 885-884<br><br>The phenolics and related substances permeate the dermis where they undergo bio-distribution. Phenolic permeation is related to liphophilicity and molecular volume. Phenols are metabolised by cutaneous enzymes or other processes to form reactive metabolites or may be chemically modified through the reaction of UV light. The skin has a wide-ranging metabolic capability which can perform essentially all the metabolic transformation which are know to be carried out in the liver. Metabolic by-products may be haptens and produce sensitisation. Eugenol although a weak sensitiser, in its own right, is oxidised to the highly reactive ortho-quinone. The sensitising principal in poison ivy, a catechol know as urishiol, appears to undergo similar oxidation to produce a reactive hapten. These reactive haptens bind to dermal proteins (haptens are often electrophilic and bind covalently with -NH2 and -SH groups on proteins, modifying the protein which when exposed to the immune system, will react with antigen-presenting cells in the dermis.<br><br>Axillary dermatitis is common and over represented in people with contact allergy to fragrances. Many people suspect their deodorants to be the incriminating products. In order to investigate the significance of isoeugenol in deodorants for the development of axillary dermatitis when used by people with and without contact allergy to isoeugenol, patch tests with deodorants and ethanol solutions with isoeugenol), as well as repeated open application tests (ROAT) with roll-on deodorants with and without isoeugenol at various concentrations, were performed in 35 dermatitis patients, 10 without and 25 with contact allergy to isoeugenol. A positive ROAT was observed only in patients hypersensitive to isoeugenol and only in the axilla to which the deodorants containing isoeugenol had been applied. Deodorants containing isoeugenol in the concentration range of 0.0063-0.2% used 2 times daily on healthy skin can thus elicit axillary dermatitis within a few weeks in people with contact allergy to isoeugenol. Bruze et al ; Contact Dermatitis Vol 52, May 2005 pp 7<br>On the basis, primarily, of animal experiments, concern has been expressed that the material may produce carcinogenic or mutagenic effects; in respect of the available information, however, there presently exists inadequate data for making a satisfactory assessment.<br>Intolerance to perfumes, by inhalation, may occur if the perfume contains a sensitising principal. Symptoms may vary from general illness, coughing, phlegm, wheezing, chest-tightness, headache, exertional dyspnoea, acute respiratory illness, hayfever, and other respiratory diseases (including asthma). Perfumes can induce hyper-reactivity of the respiratory tract without producing an IgE-mediated allergy or demonstrable respiratory obstruction. This was shown by placebo-controlled challenges of nine patients to "perfume mix". The same patients were also subject to perfume provocation, with or without a carbon filter mask, to ascertain whether breathing through a filter with active carbon would prevent symptoms. The patients breathed through the mouth, during the provocations, as a nose clamp was used to prevent nasal inhalation. The patient's earlier symptoms were verified; breathing through the carbon filter had no protective effect. The symptoms were not transmitted via the olfactory nerve but they may have been induced by trigeminal reflex via the respiratory tract or by the eyes.<br>Cases of occupational asthma induced by perfume substances such as isoamyl acetate, limonene, cinnamaldehyde and benzaldehyde, tend to give persistent symptoms even though the exposure is below occupational exposure limits.<br>Inhalation intolerance has also been produced in animals. The emissions of five fragrance products, for one hour, produced |

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|---|---|
| | various combinations of sensory irritation, pulmonary irritation, decreases in expiratory airflow velocity as well as alterations of the functional observational battery indicative of neurotoxicity in mice. Neurotoxicity was found to be more severe after mice were repeatedly exposed to the fragrance products, being four brands of cologne and one brand of toilet water. |

| | | |
|---|---|---|
| **IRM Liquid** | **TOXICITY** | **IRRITATION** |
| | Dermal (Rabbit) LD50: 212000 mg/kg[2] | Not Available |
| | Oral (None) LD50: 2683 mg/kg[2] | |
| **eugenol** | **TOXICITY** | **IRRITATION** |
| | Oral (Rat) LD50: 1930 mg/kg[2] | Eye: adverse effect observed (irritating)[1] |
| | | Skin (human) 40 mg/24h - mild |
| | | Skin (man): 16 mg/48h - moderate |
| | | Skin (rabbit): 100 mg/24h-SEVERE |
| | | Skin: no adverse effect observed (not irritating)[1] |
| ***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* | |

**EUGENOL**

Equivocal tumorigen by RTECS criteria
The following information refers to contact allergens as a group and may not be specific to this product.
Contact allergies quickly manifest themselves as contact eczema, more rarely as urticaria or Quincke's oedema. The pathogenesis of contact eczema involves a cell-mediated (T lymphocytes) immune reaction of the delayed type. Other allergic skin reactions, e.g. contact urticaria, involve antibody-mediated immune reactions. The significance of the contact allergen is not simply determined by its sensitisation potential: the distribution of the substance and the opportunities for contact with it are equally important. A weakly sensitising substance which is widely distributed can be a more important allergen than one with stronger sensitising potential with which few individuals come into contact. From a clinical point of view, substances are noteworthy if they produce an allergic test reaction in more than 1% of the persons tested.
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.
Allergic reactions which develop in the respiratory passages as bronchial asthma or rhinoconjunctivitis, are mostly the result of reactions of the allergen with specific antibodies of the IgE class and belong in their reaction rates to the manifestation of the immediate type. In addition to the allergen-specific potential for causing respiratory sensitisation, the amount of the allergen, the exposure period and the genetically determined disposition of the exposed person are likely to be decisive. Factors which increase the sensitivity of the mucosa may play a role in predisposing a person to allergy. They may be genetically determined or acquired, for example, during infections or exposure to irritant substances. Immunologically the low molecular weight substances become complete allergens in the organism either by binding to peptides or proteins (haptens) or after metabolism (prohaptens). Particular attention is drawn to so-called atopic diathesis which is characterised by an increased susceptibility to allergic rhinitis, allergic bronchial asthma and atopic eczema (neurodermatitis) which is associated with increased IgE synthesis.
Exogenous allergic alveolitis is induced essentially by allergen specific immune-complexes of the IgG type; cell-mediated reactions (T lymphocytes) may be involved. Such allergy is of the delayed type with onset up to four hours following exposure.
Adverse reactions to fragrances in perfumes and in fragranced cosmetic products include allergic contact dermatitis, irritant contact dermatitis, photosensitivity, immediate contact reactions (contact urticaria), and pigmented contact dermatitis. Airborne and connubial contact dermatitis occur.
Intolerance to perfumes, by inhalation, may occur if the perfume contains a sensitising principal. Symptoms may vary from general illness, coughing, phlegm, wheezing, chest-tightness, headache, exertional dyspnoea, acute respiratory illness, hayfever, and other respiratory diseases (including asthma). Perfumes can induce hyper-reactivity of the respiratory tract without producing an IgE-mediated allergy or demonstrable respiratory obstruction. This was shown by placebo-controlled challenges of nine patients to "perfume mix". The same patients were also subject to perfume provocation, with or without a carbon filter mask, to ascertain whether breathing through a filter with active carbon would prevent symptoms. The patients breathed through the mouth, during the provocations, as a nose clamp was used to prevent nasal inhalation. The patient's earlier symptoms were verified; breathing through the carbon filter had no protective effect. The symptoms were not transmitted via the olfactory nerve but they may have been induced by trigeminal reflex via the respiratory tract or by the eyes.
Cases of occupational asthma induced by perfume substances such as isoamyl acetate, limonene, cinnamaldehyde and benzaldehyde, tend to give persistent symptoms even though the exposure is below occupational exposure limits.
Inhalation intolerance has also been produced in animals. The emissions of five fragrance products, for one hour, produced various combinations of sensory irritation, pulmonary irritation, decreases in expiratory airflow velocity as well as alterations of the functional observational battery indicative of neurotoxicity in mice. Neurotoxicity was found to be more severe after mice were repeatedly exposed to the fragrance products, being four brands of cologne and one brand of toilet water.
Contact allergy to fragrances is relatively common, affecting 1 to 3% of the general population, based on limited testing with eight

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common fragrance allergens and about 16 % of patients patch tested for suspected allergic contact dermatitis.
Contact allergy to fragrance ingredients occurs when an individual has been exposed, on the skin, to a suffcient degree of fragrance contact allergens. Contact allergy is a life-long, specifically altered reactivity in the immune system. This means that once contact allergy is developed, cells in the immune system will be present which can recognise and react towards the allergen. As a consequence, symptoms, i.e. allergic contact dermatitis, may occur upon re-exposure to the fragrance allergen(s) in question. Allergic contact dermatitis is an inflammatory skin disease characterised by erythema, swelling and vesicles in the acute phase. If exposure continues it may develop into a chronic condition with scaling and painful fissures of the skin. Allergic contact dermatitis to fragrance ingredients is most often caused by cosmetic products and usually involves the face and/or hands. It may affect fitness for work and the quality of life of the individual. Fragrance contact allergy has long been recognised as a frequent and potentially disabling problem. Prevention is possible as it is an environmental disease and if the environment is modified (e.g. by reduced use concentrations of allergens), the disease frequency and severity will decrease Fragrance contact allergy is mostly non-occupational and related to the personal use of cosmetic products. Allergic contact dermatitis can be severe and widespread, with a significant impairment of quality of life and potential consequences for fitness for work. Thus, prevention of contact sensitisation to fragrances, both in terms of primary prevention (avoiding sensitisation) and secondary prevention (avoiding relapses of allergic contact dermatitis in those already sensitised), is an important objective of public health risk management measure.
**Hands:** Contact sensitisation may be the primary cause of hand eczema, or may be a complication of irritant or atopic hand eczema. The number of positive patch tests has been reported to correlate with the duration of hand eczema, indicating that long-standing hand eczema may often be complicated by sensitisation .Fragrance allergy may be a relevant problem in patients with hand eczema; perfumes are present in consumer products to which their hands are exposed. A significant relationship between hand eczema and fragrance contact allergy has been found in some studies based on patients investigated for contact allergy. However, hand eczema is a multi-factorial disease and the clinical significance of fragrance contact allergy in (severe) chronic hand eczema may not be clear.
**Axillae Bilateral axillary** (underarm) dermatitis may be caused by perfume in deodorants and, if the reaction is severe, it may spread down the arms and to other areas of the body. In individuals who consulted a dermatologist, a history of such first-time symptoms was significantly related to the later diagnosis of perfume allergy.
**Face** Facial eczema is an important manifestation of fragrance allergy from the use of cosmetic products (16). In men, after-shave products can cause an eczematous eruption of the beard area and the adjacent part of the neck and men using wet shaving as opposed to dry have been shown to have an increased risk of of being fragrance allergic.
**Irritant reactions (including contact urticaria):** Irritant effects of some individual fragrance ingredients, e.g. citral are known. Irritant contact dermatitis from perfumes is believed to be common, but there are no existing investigations to substantiate this, Many more people complain about intolerance or rashes to perfumes/perfumed products than are shown to be allergic by testing. This may be due to irritant effects or inadequate diagnostic procedures. Fragrances may cause a dose-related contact urticaria of the non-immunological type (irritant contact urticaria). Cinnamal, cinnamic alcohol, and Myroxylon pereirae are well recognised causes of contact urticaria, but others, including menthol, vanillin and benzaldehyde have also been reported . The reactions to Myroxylon pereirae may be due to cinnamates. A relationship to delayed contact hypersensitivity was suggested , but no significant difference was found between a fragrance-allergic group and a control group in the frequency of immediate reactions to fragrance ingredients in keeping with a nonimmunological basis for the reactions seen.
**Pigmentary anomalies:** The term “pigmented cosmetic dermatitis” was introduced in 1973 for what had previously been known as melanosis faciei feminae when the mechanism (type IV allergy) and causative allergens were clarified.. It refers to increased pigmentation, usually on the face/neck, often following sub-clinical contact dermatitis. Many cosmetic ingredients were patch tested at non-irritant concentrations and statistical evaluation showed that a number of fragrance ingredients were associated: jasmine absolute, ylang-ylang oil, cananga oil, benzyl salicylate, hydroxycitronellal, sandalwood oil, geraniol, geranium oil.
**Photo-reactions** Musk ambrette produced a considerable number of allergic photocontact reactions (in which UV-light is required) in the 1970s and was later banned from use in the EU. Nowadays, photoallergic contact dermatitis is uncommon . Furocoumarins (psoralens) in some plant-derived fragrance ingredients caused phototoxic reactions with erythema followed by hyperpigmentation resulting in Berloque dermatitis. There are now limits for the amount of furocoumarins in fragrance products. Phototoxic reactions still occur but are rare.
**General/respiratory:** Fragrances are volatile and therefore, in addition to skin exposure, a perfume also exposes the eyes and naso-respiratory tract. It is estimated that 2-4% of the adult population is affected by respiratory or eye symptoms by such an exposure. It is known that exposure to fragrances may exacerbate pre-existing asthma . Asthma-like symptoms can be provoked by sensory mechanisms. In an epidemiological investigation, a significant association was found between respiratory complaints related to fragrances and contact allergy to fragrance ingredients, in addition to hand eczema, which were independent risk factors in a multivariate analysis.
Fragrance allergens act as haptens, i.e. low molecular weight chemicals that are immunogenic only when attached to a carrier protein. However, not all sensitising fragrance chemicals are directly reactive, but require previous activation. A prehapten is a chemical that itself is non- or low-sensitising, but that is transformed into a hapten outside the skin by simple chemical transformation (air oxidation, photoactivation) and without the requirement of specific enzymatic systems. A prohapten is a chemical that itself is non- or low-sensitising but that is transformed into a hapten in the skin (bioactivation) usually via enzyme catalysis. It is not always possible to know whether a particular allergen that is not directly reactive acts as a prehapten or as a prohapten, or both, because air oxidation and bioactivation can often give the same product (geraniol is an example). Some chemicals might act by all three pathways.
**Prohaptens**
Compounds that are bioactivated in the skin and thereby form haptens are referred to as prohaptens.
In the case of prohaptens, the possibility to become activated is inherent to the molecule and activation cannot be avoided by extrinsic measures. Activation processes increase the risk for cross-reactivity between fragrance substances. Crossreactivity has been shown for certain alcohols and their corresponding aldehydes, i.e. between geraniol and geranial (citral) and between cinnamyl alcohol and cinnamal.
The human skin expresses enzyme systems that are able to metabolise xenobiotics, modifying their chemical structure to increase hydrophilicity and allow elimination from the body. Xenobiotic metabolism can be divided into two phases: phase I and phase II. Phase I transformations are known as activation or functionalisation reactions, which normally introduce or unmask hydrophilic functional groups. If the metabolites are sufficiently polar at this point they will be eliminated. However, many phase I

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products have to undergo subsequent phase II transformations, i.e. conjugation to make them sufficiently water soluble to be eliminated. Although the purpose of xenobiotic metabolism is detoxification, it can also convert relatively harmless compounds into reactive species. Cutaneous enzymes that catalyse phase I transformations include the cytochrome P450 mixed-function oxidase system, alcohol and aldehyde dehydrogenases, monoamine oxidases, flavin-containing monooxygenases and hydrolytic enzymes. Acyltransferases, glutathione S-transferases, UDP-glucuronosyltransferases and sulfotransferases are examples of phase II enzymes that have been shown to be present in human skin . These enzymes are known to catalyse both activating and deactivating biotransformations, but the influence of the reactions on the allergenic activity of skin sensitisers has not been studied in detail. Skin sensitising prohaptens can be recognised and grouped into chemical classes based on knowledge of xenobiotic bioactivation reactions, clinical observations and/or in vivo and in vitro studies of sensitisation potential and chemical reactivity.

**QSAR prediction:** The relationships between molecular structure and reactivity that form the basis for structural alerts are based on well established principles of mechanistic organic chemistry. Examples of structural alerts are aliphatic aldehydes (alerting to the possibility of sensitisation via a Schiff base reaction with protein amino groups), and alpha,beta-unsaturated carbonyl groups, C=C-CO- (alerting to the possibility of sensitisation via Michael addition of protein thiol groups). Prediction of the sensitisation potential of compounds that can act via abiotic or metabolic activation (pre- or prohaptens) is more complex compared to that of compounds that act as direct haptens without any activation. The autoxidation patterns can differ due to differences in the stability of the intermediates formed, e.g. it has been shown that autoxidation of the structural isomers linalool and geraniol results in different major haptens/allergens. Moreover, the complexity of the prediction increases further for those compounds that can act both as pre- and prohaptens. In such cases, the impact on the sensitisation potency depends on the degree of abiotic activation (e.g. autoxidation) in relation to the metabolic activation

For eugenol:

**Acute toxicity:** The acute oral, dermal and inhalation toxicity in mammals of eugenol is low .

Acute toxic effects at high doses include destruction of the gastric mucosa, capillary hemorrhaging in dogs, gastric inflammation and depression of secretory capacity, liver discoloration and mottling in rats, and liver congestion in dogs.

Single-dose studies in rats were used to determine the level at which no toxic effects were observed, and 250 mg/kg was selected as the NOAEL-equivalent by WHO. This dose was used to develop the acceptable daily intake (ADI) of 2.5 mg/kg-day for humans, dividing the NOAEL by the intra- and inter-species factors of 10.

Eugenol has been found to produce reversible, dose-dependent anaesthetic effects in rats at moderate doses (5-60 mg/kg)

Eugenol is readily absorbed through the skin. Products containing eugenol or clove oil may cause irritation to the skin and eyes.

The vapour pressure of eugenol is moderately high (0.0226 mm Hg at 25 C), indicating that inhalation may contribute substantially to exposure, especially for workers.

Eugenol produces cardiovascular effects; it possesses vasorelaxant properties. The relaxant effects of eugenol at 300 micromoles per liter (uM) were comparable to those induced by nifedipine, a selective Ca2+ channel blocker, at 0.01 uM, producing similar relaxant effects. The authors of this study concluded that eugenol produces smooth muscle relaxation resulting from the blockade of both voltagesensitive and receptor-operated channels that are modulated by endothelial-generated nitric oxide.

A second study evaluated the effects of injections of 1-10 mg eugenol/kg on vascular relaxation. Dose-dependent hypotension and bradycardia were observed. The authors indicate that “The bradycardia appears dependent upon the presence of an intact and functional parasympathetic nerve drive to the heart while the hypotension is due to an active vascular relaxation rather than withdrawal of sympathetic tone.” These authors concluded that nitric oxide from vascular endothelial cells was *not* involved in the mediation of eugenol-induced hypotension.

**Repeat dose toxicity:** The subchronic toxicity of eugenol is low, with most studies showing no effects until a very high dose regime is entered. Up to 1.0% eugenol in the diet did not cause adverse effects. At intermediate doses by gavage, reduced weight gains, erosion of the epithelium in the stomach, and liver damage were observed. At the highest doses (10–12% of the diet), most of the test animals died.

**Genotoxicity:** The mutagenic and chromosomal effects of eugenol have also been investigated in *in vitro* studies. Findings are contradictory, reflecting the results of the *in vivo* studies. Mutagenesis assays using *Salmonella* both with and without activation with the S9 fraction of the liver were negative.

An assay using Syrian hamster embryo (SHE) cells found that eugenol induces chromosome aberrations.75 Similar results were observed in V79 cells at higher doses The S9 fraction of the liver increased the induction of chromosome aberrations in a dose-dependent manner. The results confirm that eugenol is genotoxic and raises the possibility of it having topoisomerase II inhibiting activity. Topoisomerases are involved in the unwinding of the DNA helix during the replication process.

Eugenol has been found to inhibit the inducible cyclooxygenase (COX2) enzyme that has been implicated in the processes of inflammation and carcinogenesis. Potential COX2 inhibitors have been considered as anti-inflammatory or cancer chemopreventive agents.

Eugenol produced a positive recombinagenic response in the somatic mutation and recombination test (SMART) assay using *Drosophila*, which is related to a high cytochrome P450-dependent activation capacity. The authors suggest that this family of enzymes is involved in the activation of eugenol rather than in its detoxification

**Carcinogenicity:** Eugenol was not carcinogenic to rats; in mice, significant increases in liver tumors were observed. Eugenol gave both positive and negative results in mutagenesis tests, induced chromosomal aberrations and increased sister chromatid exchanges in *in vitro* tests. Based on the limited and conflicting evidence of carcinogenicity, neither IARC nor NTP listed eugenol as a carcinogen.

Eugenol was reported to inhibit the carcinogenicity of benzo(a)pyrene when the compounds were applied together in a carcinogenic skin-painting study. In a limited study in mice, eugenol did not potentiate the tumourigenic effects of methylcholanthrene

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.

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.

**Continued...**

| | | | |
|---|---|---|---|
| **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

**IRM Liquid**

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

**eugenol**

| Endpoint | Test Duration (hr) | Species | Value | Source |
|---|---|---|---|---|
| EC0(ECx) | 48h | Crustacea | 0.36mg/l | 2 |
| EC50 | 72h | Algae or other aquatic plants | 23mg/l | 2 |
| EC50 | 48h | Crustacea | 1.05mg/l | 2 |
| LC50 | 96h | Fish | 13mg/l | 2 |

***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*

Harmful to aquatic organisms, may cause long-term adverse effects in the aquatic environment.
Do NOT allow product to come in contact with surface waters or to intertidal areas below the mean high water mark. Do not contaminate water when cleaning equipment or disposing of equipment wash-waters.
Wastes resulting from use of the product must be disposed of on site or at approved waste sites.
for eugenol:
**Environmental fate:**
Eugenol is a very weak organic acid, with pKa of 10.19. In aqueous solution, the acid is not substantially dissociated.
Eugenol is a volatile liquid at room temperature and has moderate water solubility (2,463 mg/L at 25 deg C). The octanol-water partition coefficient, Kow, for eugenol is 186, indicating low solubility in water relative to organic solvents and low to moderate potential for bioaccumulation, with an estimated bioconcentration factor of 31
The organic-carbon-adjusted soil adsorption coefficient (Koc) of eugenol is 409 mL/g, a value that indicates that, in a mix of soil and water, eugenol is distributed in both media, with a slight preference for binding to soil. As a result, eugenol has moderate mobility in soils, adsorbing to soils and sediments to some extent.
Eugenol is anticipated to be short-lived in the environment, and is rapidly dissipated and degraded via volatilisation and atmospheric decomposition. Soil and water biodegradation data are not available. Photolysis is not anticipated to be a major degradation pathway.Eugenol does not hydrolyse readily in water, but will volatilize from water over time if microbial degradation or adsorption to sediments does not occur. No half-lives are available for eugenol in soil or water; however data on the half-life of the related compound methyl eugenol is available. The study found that methyl eugenol has a dissipation half-life of 4-4.5 days from cigarette filters placed in or on top of the soil. Shorter half-lives were found for methyl eugenol in soil (0.33-0.5 days) and water (0.5-1.5 days).
Eugenol can be degraded or transported away from an application site through a number of different processes. The most important known processes for dissipation of eugenol are volatilisation and degradation by reaction with ozone and hydroxyl radicals in the atmosphere, and adsorption to soils and sediments.
When dissolved in water, eugenol volatilises slowly to the air, as dictated by its low Henry s law constant of 2.0 x 10-6 atmm 3/mol. The modeled volatilisation half-life from a river was calculated to be 24 days;
volatilisation from a lake was estimated to occur with a 177-day half-life. Volatilisation is also expected to occur from wet soils, although the rate of microbial degradation may be competitive. Vapour phase eugenol reacts rapidly with hydroxyl radicals and ozone in the atmosphere, with estimated half-lives of six hours and 23 hours (dependent on ozone concentration), respectively
Eugenol is degraded by microbes, although specific data for microbial degradation in soils is not available. One laboratory study found that *Pseudomonas fluorescens* bacteria degraded eugenol; the responsible enzyme was isolated and characterized.131 This same reaction has been used commercially to transform eugenol into the flavour molecule vanillin.Transformation is relatively rapid, with the process being used commercially to produce vanillin. Since *Pseudomonas sp.* is a common soil bacterium, it is anticipated that microbial degradation of eugenol will be relatively rapid in soils.
**DO NOT** discharge into sewer or waterways.

### Persistence and degradability

| Ingredient | Persistence: Water/Soil | Persistence: Air |
|---|---|---|
| eugenol | HIGH | HIGH |

### Bioaccumulative potential

**Continued...**

| Ingredient | Bioaccumulation |
|---|---|
| eugenol | LOW (LogKOW = 2.27) |

### Mobility in soil

| Ingredient | Mobility |
|---|---|
| eugenol | LOW (KOC = 1124) |

## SECTION 13 Disposal considerations

### Waste treatment methods

| | |
|---|---|
| **Product / Packaging disposal** | ▸ Containers may still present a chemical hazard/ danger when empty.<br>▸ Return to supplier for reuse/ recycling if possible.<br>Otherwise:<br>▸ 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.<br>▸ Where possible retain label warnings and SDS and observe all notices pertaining to the product.<br>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.<br>A Hierarchy of Controls seems to be common - the user should investigate:<br>▸ Reduction<br>▸ Reuse<br>▸ Recycling<br>▸ Disposal (if all else fails)<br>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.<br>▸ **DO NOT** allow wash water from cleaning or process equipment to enter drains.<br>▸ It may be necessary to collect all wash water for treatment before disposal.<br>▸ In all cases disposal to sewer may be subject to local laws and regulations and these should be considered first.<br>▸ Where in doubt contact the responsible authority.<br>▸ Recycle wherever possible or consult manufacturer for recycling options.<br>▸ Consult State Land Waste Authority for disposal.<br>▸ Bury or incinerate residue at an approved site.<br>▸ Recycle containers if possible, or dispose of in an authorised landfill. |

## 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

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

| Product name | Group |
|---|---|
| eugenol | Not Available |

### Transport in bulk in accordance with the IGC Code

| Product name | Ship Type |
|---|---|
| eugenol | Not Available |

## SECTION 15 Regulatory information

**Continued...**

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

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

Australia Hazardous Chemical Information System (HCIS) - Hazardous Chemicals
Australia Standard for the Uniform Scheduling of Medicines and Poisons (SUSMP) - Schedule 5
Australia Standard for the Uniform Scheduling of Medicines and Poisons (SUSMP) - Schedule 6
Australian Inventory of Industrial Chemicals (AIIC)
International Agency for Research on Cancer (IARC) - Agents Classified by the IARC Monographs - Not Classified as Carcinogenic

## National Inventory Status

| National Inventory | Status |
|---|---|
| Australia - AIIC / Australia Non-Industrial Use | Yes |
| Canada - DSL | Yes |
| Canada - NDSL | No (eugenol) |
| China - IECSC | Yes |
| Europe - EINEC / ELINCS / NLP | Yes |
| Japan - ENCS | Yes |
| Korea - KECI | Yes |
| New Zealand - NZIoC | Yes |
| Philippines - PICCS | Yes |
| USA - TSCA | Yes |
| Taiwan - TCSI | Yes |
| Mexico - INSQ | Yes |
| Vietnam - NCI | Yes |
| Russia - FBEPH | Yes |
| ***Legend:*** | *Yes = All CAS declared ingredients are on the inventory*<br>*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** | 23/12/2022 |
| **Initial Date** | 11/08/2004 |

## SDS Version Summary

| Version | Date of Update | Sections Updated |
|---|---|---|
| 8.1 | 01/05/2020 | Toxicological information - Acute Health (inhaled), Toxicological information - Acute Health (skin), Toxicological information - Acute Health (swallowed), First Aid measures - Advice to Doctor, Toxicological information - Chronic Health, Hazards identification - Classification, Disposal considerations - Disposal, Exposure controls / personal protection - Engineering Control, Ecological Information - Environmental, Exposure controls / personal protection - Exposure Standard, Firefighting measures - Fire Fighter (fire/explosion hazard), First Aid measures - First Aid (swallowed), Exposure controls / personal protection - Personal Protection (hands/feet), Physical and chemical properties - Physical Properties, Accidental release measures - Spills (major), Toxicological information - Toxicity and Irritation (Other) |
| 9.1 | 23/12/2022 | Classification review due to GHS Revision change. |

## 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

**Continued...**

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
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



**end of SDS**