



SPE005 Sphere Fruit Blast Griffiths Equipment Limited

Chemwatch Hazard Alert Code: 2

Chemwatch: 5423-92
Version No: 3.1.1.1
Safety Data Sheet according to HSNO Regulations

Issue Date: 18/09/2020
Print Date: 20/09/2020
S.GHS.NZL.EN

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

Product Identifier

| | |
|-------------------------------|---------------------------|
| Product name | SPE005 Sphere Fruit Blast |
| Synonyms | SPE005 |
| Other means of identification | Not Available |

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

| | |
|--------------------------|---|
| Relevant identified uses | Air Freshener. Use according to manufacturer's directions. |
|--------------------------|---|

Details of the supplier of the safety data sheet

| | |
|-------------------------|--|
| Registered company name | Griffiths Equipment Limited |
| Address | 19 Bell Ave, Mount Wellington Auckland 1060 New Zealand |
| Telephone | +64 9 525 4575 |
| Fax | Not Available |
| Website | www.griffithsequipment.co.nz |
| Email | sales@griffithsequipment.co.nz |

Emergency telephone number

| | |
|-----------------------------------|-------------------------------|
| Association / Organisation | NZ NATIONAL POISONS CENTRE |
| Emergency telephone numbers | 0800 POISON or 0800 764-766 |
| Other emergency telephone numbers | International: +64 3 479-7227 |

SECTION 2 Hazards identification

Classification of the substance or mixture

| | |
|---|--|
| Classification [1] | Chronic Aquatic Hazard Category 3 |
| Legend: | 1. Classified by Chemwatch; 2. Classification drawn from CCID EPA NZ; 3. Classification drawn from Regulation (EU) No 1272/2008 - Annex VI |
| Determined by Chemwatch using GHS/HSNO criteria | 9.1C |

Label elements

| | |
|---------------------|----------------|
| Hazard pictogram(s) | Not Applicable |
| Signal word | Not Applicable |

Hazard statement(s)

| | |
|------|--|
| H412 | Harmful to aquatic life with long lasting effects. |
|------|--|

Precautionary statement(s) Prevention

| | |
|------|-----------------------------------|
| P273 | Avoid release to the environment. |
|------|-----------------------------------|

Precautionary statement(s) Response

Not Applicable

Precautionary statement(s) Storage

Not Applicable

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Precautionary statement(s) Disposal

| | |
|-------------|--|
| P501 | Dispose of contents/container to authorised hazardous or special waste collection point in accordance with any local regulation. |
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SECTION 3 Composition / information on ingredients

Substances

See section below for composition of Mixtures

Mixtures

| CAS No | %[weight] | Name |
|---------------|-----------|--|
| 104-67-6 | 1-5 | <u>gamma-undecalactone</u> |
| 93685-81-5 | 1-<5 | <u>dodecane, isomers</u> |
| 88-41-5 | 1-5 | <u>2-tert-butylcyclohexyl acetate</u> |
| 106-22-9 | 0.1-0.5 | <u>beta-citronellol</u> |
| 24720-09-0 | 0.1-0.5 | <u>rose ketones</u> |
| Not Available | 0.1-0.5 | reaction mass of 3,5-dimethylcyclohex-3-ene-1-carbaldehyde and 2,4-dimethylcyclohex-3-ene-1-carbaldehyde |
| 5989-27-5 | 0.1-0.5 | <u>d-limonene</u> |
| 91-64-5 | 0.1-0.5 | <u>coumarin</u> |
| Not Available | balance | Ingredients determined not to be hazardous |

SECTION 4 First aid measures

Description of first aid measures

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|---------------------|---|
| Eye Contact | <p>If this product comes in contact with the eyes:</p> <ul style="list-style-type: none"> ▶ Wash out immediately with fresh running water. ▶ Ensure complete irrigation of the eye by keeping eyelids apart and away from eye and moving the eyelids by occasionally lifting the upper and lower lids. ▶ Seek medical attention without delay; if pain persists or recurs seek medical attention. ▶ Removal of contact lenses after an eye injury should only be undertaken by skilled personnel. |
| Skin Contact | <p>If skin contact occurs:</p> <ul style="list-style-type: none"> ▶ 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 | <ul style="list-style-type: none"> ▶ If fumes, aerosols or combustion products are inhaled remove from contaminated area. ▶ Other measures are usually unnecessary. |
| Ingestion | <ul style="list-style-type: none"> ▶ Immediately give a glass of water. ▶ First aid is not generally required. If in doubt, contact a Poisons Information Centre or a doctor. ▶ If spontaneous vomiting appears imminent or occurs, hold patient's head down, lower than their hips to help avoid possible aspiration of vomitus. |

Indication of any immediate medical attention and special treatment needed

Treat symptomatically.

SECTION 5 Firefighting measures

Extinguishing media

- ▶ Alcohol stable 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

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|------------------------------|---|
| Fire Fighting | <ul style="list-style-type: none"> ▶ 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 courses. ▶ Use water delivered as a fine spray to control fire and cool adjacent area. ▶ DO NOT approach containers suspected to be hot. ▶ Cool fire exposed containers with water spray from a protected location. ▶ If safe to do so, remove containers from path of fire. ▶ Equipment should be thoroughly decontaminated after use. |
| Fire/Explosion Hazard | <ul style="list-style-type: none"> ▶ Combustible solid which burns but propagates flame with difficulty; it is estimated that most organic dusts are combustible (circa 70%) - according to the circumstances under which the combustion process occurs, such materials may cause fires and / or dust explosions. ▶ Organic powders when finely divided over a range of concentrations regardless of particulate size or shape and suspended in air or some other oxidizing medium may form explosive dust-air mixtures and result in a fire or dust explosion (including secondary explosions). ▶ Avoid generating dust, particularly clouds of dust in a confined or unventilated space as dusts may form an explosive mixture with air, and any source of ignition, i.e. flame or spark, will cause fire or explosion. Dust clouds generated by the fine grinding of the solid are a particular hazard; accumulations of fine dust (420 micron or less) may burn rapidly and fiercely if ignited - particles exceeding this limit will generally not form flammable dust clouds; once initiated, however, larger particles up to 1400 microns diameter will contribute to the propagation of an |

explosion.

- ▶ In the same way as gases and vapours, dusts in the form of a cloud are only ignitable over a range of concentrations; in principle, the concepts of lower explosive limit (LEL) and upper explosive limit (UEL) are applicable to dust clouds but only the LEL is of practical use; - this is because of the inherent difficulty of achieving homogeneous dust clouds at high temperatures (for dusts the LEL is often called the "Minimum Explosible Concentration", MEC).
- ▶ When processed with flammable liquids/vapors/mists, ignitable (hybrid) mixtures may be formed with combustible dusts. Ignitable mixtures will increase the rate of explosion pressure rise and the Minimum Ignition Energy (the minimum amount of energy required to ignite dust clouds - MIE) will be lower than the pure dust in air mixture. The Lower Explosive Limit (LEL) of the vapour/dust mixture will be lower than the individual LELs for the vapors/mists or dusts.
- ▶ A dust explosion may release of large quantities of gaseous products; this in turn creates a subsequent pressure rise of explosive force capable of damaging plant and buildings and injuring people.
- ▶ Usually the initial or primary explosion takes place in a confined space such as plant or machinery, and can be of sufficient force to damage or rupture the plant. If the shock wave from the primary explosion enters the surrounding area, it will disturb any settled dust layers, forming a second dust cloud, and often initiate a much larger secondary explosion. All large scale explosions have resulted from chain reactions of this type.
- ▶ Dry dust can be charged electrostatically by turbulence, pneumatic transport, pouring, in exhaust ducts and during transport.
- ▶ Build-up of electrostatic charge may be prevented by bonding and grounding.
- ▶ Powder handling equipment such as dust collectors, dryers and mills may require additional protection measures such as explosion venting.
- ▶ All movable parts coming in contact with this material should have a speed of less than 1-meter/sec.
- ▶ A sudden release of statically charged materials from storage or process equipment, particularly at elevated temperatures and/ or pressure, may result in ignition especially in the absence of an apparent ignition source.
- ▶ One important effect of the particulate nature of powders is that the surface area and surface structure (and often moisture content) can vary widely from sample to sample, depending of how the powder was manufactured and handled; this means that it is virtually impossible to use flammability data published in the literature for dusts (in contrast to that published for gases and vapours).
- ▶ Autoignition temperatures are often quoted for dust clouds (minimum ignition temperature (MIT)) and dust layers (layer ignition temperature (LIT)); LIT generally falls as the thickness of the layer increases.

Combustion products include:

- carbon monoxide (CO)
- carbon dioxide (CO₂)
- 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 | <ul style="list-style-type: none"> ▶ Clean up waste regularly and abnormal spills immediately. ▶ Avoid breathing dust and contact with skin and eyes. ▶ Wear protective clothing, gloves, safety glasses and dust respirator. ▶ Use dry clean up procedures and avoid generating dust. ▶ Vacuum up or sweep up. NOTE: Vacuum cleaner must be fitted with an exhaust micro filter (HEPA type) (consider explosion-proof machines designed to be grounded during storage and use). ▶ Dampen with water to prevent dusting before sweeping. ▶ Place in suitable containers for disposal. |
| Major Spills | <p>Moderate hazard.</p> <ul style="list-style-type: none"> ▶ CAUTION: Advise personnel in area. ▶ Alert Emergency Services and tell them location and nature of hazard. ▶ Control personal contact by wearing protective clothing. ▶ Prevent, by any means available, spillage from entering drains or water courses. ▶ Recover product wherever possible. ▶ IF DRY: Use dry clean up procedures and avoid generating dust. Collect residues and place in sealed plastic bags or other containers for disposal. IF WET: Vacuum/shovel up and place in labelled containers for disposal. ▶ ALWAYS: Wash area down with large amounts of water 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

Precautions for safe handling

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| Safe handling | <ul style="list-style-type: none"> ▶ Organic powders when finely divided over a range of concentrations regardless of particulate size or shape and suspended in air or some other oxidizing medium may form explosive dust-air mixtures and result in a fire or dust explosion (including secondary explosions) ▶ Minimise airborne dust and eliminate all ignition sources. Keep away from heat, hot surfaces, sparks, and flame. ▶ Establish good housekeeping practices. ▶ Remove dust accumulations on a regular basis by vacuuming or gentle sweeping to avoid creating dust clouds. ▶ Use continuous suction at points of dust generation to capture and minimise the accumulation of dusts. Particular attention should be given to overhead and hidden horizontal surfaces to minimise the probability of a "secondary" explosion. According to NFPA Standard 654, dust layers 1/32 in.(0.8 mm) thick can be sufficient to warrant immediate cleaning of the area. ▶ Do not use air hoses for cleaning. ▶ Minimise dry sweeping to avoid generation of dust clouds. Vacuum dust-accumulating surfaces and remove to a chemical disposal area. Vacuums with explosion-proof motors should be used. ▶ Control sources of static electricity. Dusts or their packages may accumulate static charges, and static discharge can be a source of ignition. ▶ Solids handling systems must be designed in accordance with applicable standards (e.g. NFPA including 654 and 77) and other national guidance. |
|----------------------|--|

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| | <ul style="list-style-type: none"> ▶ Do not empty directly into flammable solvents or in the presence of flammable vapors. ▶ The operator, the packaging container and all equipment must be grounded with electrical bonding and grounding systems. Plastic bags and plastics cannot be grounded, and antistatic bags do not completely protect against development of static charges. <p>Empty containers may contain residual dust which has the potential to accumulate following settling. Such dusts may explode in the presence of an appropriate ignition source.</p> <ul style="list-style-type: none"> ▶ Do NOT cut, drill, grind or weld such containers. ▶ In addition ensure such activity is not performed near full, partially empty or empty containers without appropriate workplace safety authorisation or permit. ▶ Limit all unnecessary personal contact. ▶ Wear protective clothing when risk of exposure occurs. ▶ Use in a well-ventilated area. ▶ Avoid contact with incompatible materials. ▶ When handling, DO NOT eat, drink or smoke. ▶ Keep containers securely sealed when not in use. ▶ Avoid physical damage to containers. ▶ Always wash hands with soap and water after handling. ▶ Work clothes should be laundered separately. ▶ 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 | <ul style="list-style-type: none"> ▶ Store in original containers. ▶ Keep containers securely sealed. ▶ Store in a cool, dry area protected from environmental extremes. ▶ 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. <p>For major quantities:</p> <ul style="list-style-type: none"> ▶ Consider storage in banded areas - ensure storage areas are isolated from sources of community water (including stormwater, ground water, lakes and streams). ▶ Ensure that accidental discharge to air or water is the subject of a contingency disaster management plan; this may require consultation with local authorities. |

Conditions for safe storage, including any incompatibilities

| | |
|--------------------------------|---|
| Suitable container | <ul style="list-style-type: none"> ▶ Polyethylene or polypropylene container. ▶ Packing as recommended by manufacturer. ▶ Check all containers are clearly labelled and free from leaks. |
| Storage incompatibility | <ul style="list-style-type: none"> ▶ Avoid reaction with oxidising agents, bases and strong reducing agents. ▶ Avoid strong acids, acid chlorides, acid anhydrides and chloroformates. |

SECTION 8 Exposure controls / personal protection

Control parameters

Occupational Exposure Limits (OEL)

INGREDIENT DATA

Not Available

Emergency Limits

| Ingredient | Material name | TEEL-1 | TEEL-2 | TEEL-3 |
|------------|---------------|------------|-----------|----------|
| d-limonene | Limonene, d- | 15 ppm | 67 ppm | 170 ppm |
| coumarin | Coumarin | 0.88 mg/m3 | 9.7 mg/m3 | 58 mg/m3 |


| Ingredient | Original IDLH | Revised IDLH |
|--------------------------------|---------------|---------------|
| gamma-undecalactone | Not Available | Not Available |
| dodecane, isomers | Not Available | Not Available |
| 2-tert-butylcyclohexyl acetate | Not Available | Not Available |
| beta-citronellol | Not Available | Not Available |
| rose ketones | Not Available | Not Available |
| d-limonene | Not Available | Not Available |
| coumarin | Not Available | Not Available |

Occupational Exposure Banding

| Ingredient | Occupational Exposure Band Rating | Occupational Exposure Band Limit |
|--------------------------------|-----------------------------------|----------------------------------|
| gamma-undecalactone | E | ≤ 0.1 ppm |
| dodecane, isomers | E | ≤ 0.1 ppm |
| 2-tert-butylcyclohexyl acetate | E | ≤ 0.1 ppm |
| beta-citronellol | E | ≤ 0.1 ppm |
| rose ketones | E | ≤ 0.1 ppm |
| d-limonene | E | ≤ 0.1 ppm |
| coumarin | E | ≤ 0.01 mg/m ³ |

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.

Exposure controls

| | |
|---|--|
| Appropriate engineering controls | General exhaust is adequate under normal operating conditions. |
| Personal protection |  |
| Eye and face protection | No special equipment for minor exposure i.e. when handling small quantities. OTHERWISE: <ul style="list-style-type: none"> ▶ Safety glasses with side shields. ▶ 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 | No special equipment needed when handling small quantities. OTHERWISE: Wear general protective gloves, e.g. light weight rubber gloves. |
| Body protection | See Other protection below |
| Other protection | No special equipment needed when handling small quantities. OTHERWISE: <ul style="list-style-type: none"> ▶ Overalls. ▶ Skin cleansing cream. ▶ Eyewash unit. ▶ Do not spray on hot surfaces. |

Recommended material(s)

GLOVE SELECTION INDEX

Glove selection is based on a modified presentation of the:

"Forsberg Clothing Performance Index".

The effect(s) of the following substance(s) are taken into account in the **computer-generated** selection:

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| Material | CPI |
|----------|-----|
| NITRILE | A |
| PVA | A |
| VITON | A |

* CPI - Chemwatch Performance Index

A: Best Selection

B: Satisfactory; may degrade after 4 hours continuous immersion

C: Poor to Dangerous Choice for other than short term immersion

NOTE: As a series of factors will influence the actual performance of the glove, a final selection must be based on detailed observation. -

* Where the glove is to be used on a short term, casual or infrequent basis, factors such as "feel" or convenience (e.g. disposability), may dictate a choice of gloves which might otherwise be unsuitable following long-term or frequent use. A qualified practitioner should be consulted.

Respiratory protection

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

| Required Minimum Protection Factor | Half-Face Respirator | Full-Face Respirator | Powered Air Respirator |
|------------------------------------|----------------------|----------------------|------------------------|
| up to 10 x ES | A P1 Air-line* | - | A PAPR-P1 |
| up to 50 x ES | Air-line** | A P2 | A PAPR-P2 |
| up to 100 x ES | - | A P3 | - |
| | | Air-line* | - |
| 100+ x ES | - | Air-line** | A PAPR-P3 |

* - Negative pressure demand ** - Continuous flow

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)

- ▶ Respirators may be necessary when engineering and administrative controls do not adequately prevent exposures.
- ▶ The decision to use respiratory protection should be based on professional judgment that takes into account toxicity information, exposure measurement data, and frequency and likelihood of the worker's exposure - ensure users are not subject to high thermal loads which may result in heat stress or distress due to personal protective equipment (powered, positive flow, full face apparatus may be an option).
- ▶ Published occupational exposure limits, where they exist, will assist in determining the adequacy of the selected respiratory protection. These may be government mandated or vendor recommended.
- ▶ Certified respirators will be useful for protecting workers from inhalation of particulates when properly selected and fit tested as part of a complete respiratory protection program.
- ▶ Use approved positive flow mask if significant quantities of dust becomes airborne.
- ▶ Try to avoid creating dust conditions.

SECTION 9 Physical and chemical properties

Information on basic physical and chemical properties

| | | | |
|-------------------------|---|--|---------------|
| Appearance | Orange solid with a characteristic fruit blast odour; insoluble in water. | | |
| Physical state | Solid | 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 Available |
| pH (as supplied) | Not Applicable | Decomposition temperature | Not Available |

Continued...

| | | | |
|--|----------------|----------------------------------|----------------|
| Melting point / freezing point (°C) | Not Available | Viscosity (cSt) | Not Available |
| Initial boiling point and boiling range (°C) | Not Applicable | Molecular weight (g/mol) | Not Applicable |
| Flash point (°C) | Not Available | Taste | Not Available |
| Evaporation rate | Not Available | Explosive properties | Not Available |
| Flammability | Not Available | Oxidising properties | Not Available |
| Upper Explosive Limit (%) | Not Available | Surface Tension (dyn/cm or mN/m) | Not Applicable |
| Lower Explosive Limit (%) | Not Available | Volatile Component (%vol) | Not Available |
| Vapour pressure (kPa) | Not Available | Gas group | Not Available |
| Solubility in water | Immiscible | pH as a solution (1%) | Not Applicable |
| Vapour density (Air = 1) | Not Available | VOC g/L | Not Available |

SECTION 10 Stability and reactivity

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|------------------------------------|--|
| Reactivity | See section 7 |
| Chemical stability | <ul style="list-style-type: none"> ▶ Unstable in the presence of incompatible materials. ▶ Product is considered stable. ▶ Hazardous polymerisation will not occur. |
| Possibility of hazardous reactions | See section 7 |
| Conditions to avoid | See section 7 |
| Incompatible materials | See section 7 |
| Hazardous decomposition products | See section 5 |

SECTION 11 Toxicological information

Information on toxicological effects

| | |
|--------------|--|
| Inhaled | The material is not thought to produce respiratory irritation (as classified by EC Directives using animal models). Nevertheless inhalation of dusts, or fumes, especially for prolonged periods, may produce respiratory discomfort and occasionally, distress. |
| Ingestion | Accidental ingestion of the material may be damaging to the health of the individual. |
| Skin Contact | Open cuts, abraded or irritated skin should not be exposed to this material Entry into the blood-stream, through, for example, cuts, abrasions or lesions, may produce systemic injury with harmful effects. Examine the skin prior to the use of the material and ensure that any external damage is suitably protected. There is some evidence to suggest that this material can cause inflammation of the skin on contact in some persons. |
| Eye | There is some evidence to suggest that this material can cause eye irritation and damage in some persons. |
| Chronic | There is limited evidence that, skin contact with this product is more likely to cause a sensitisation reaction in some persons compared to the general population. A number of common flavor and fragrance chemicals can form peroxides surprisingly fast in air. Antioxidants can in most cases minimize the oxidation. Fragrance terpenes are easily oxidized in air. Non-oxidised forms are very weak sensitizers; however, after oxidation, the hydroperoxides are strong sensitizers which may cause allergic reactions. Autooxidation of fragrance terpenes contributes greatly to fragrance allergy. There is the need to test for compounds the patients are actually exposed to, not only the ingredients originally applied in commercial formulations. |

| | | |
|--------------------------------|--|---|
| SPE005 Sphere Fruit Blast | TOXICITY | IRRITATION |
| | Not Available | Not Available |
| gamma-undecalactone | TOXICITY | IRRITATION |
| | Oral (rat) LD50: 18500 mg/kg ^[2] | Skin (guinea pig): 100 mg/24h-mod Skin (rabbit): 100 mg/24h-SEVERE |
| dodecane, isomers | TOXICITY | IRRITATION |
| | Not Available | Not Available |
| 2-tert-butylcyclohexyl acetate | TOXICITY | IRRITATION |
| | Dermal (rabbit) LD50: >5000 mg/kg ^[2] Oral (rat) LD50: 4600 mg/kg ^[2] | Eye: no adverse effect observed (not irritating) ^[1] Skin: no adverse effect observed (not irritating) ^[1] |
| beta-citronellol | TOXICITY | IRRITATION |
| | Dermal (rabbit) LD50: 2650 mg/kg ^[2] Oral (rat) LD50: 3450 mg/kg ^[2] | Eye: adverse effect observed (irritating) ^[1] Skin (guin.pig): 100mg/24h-SEVERE Skin (man): 16 mg/48h - mod Skin (rabbit): 100 mg/24h-SEVERE Skin: adverse effect observed (irritating) ^[1] |

| | TOXICITY | IRRITATION |
|----------------|---|--|
| rose ketones | Oral (mouse) LD50: 1821 mg/kg ^[2] | Eye: no adverse effect observed (not irritating) ^[1] |
| | Oral (rat) LD50: 2920 mg/kg ^[2] | Skin: adverse effect observed (irritating) ^[1] |
| | Oral (rat) LD50: 2920 mg/kg ^[2] | Skin: no adverse effect observed (not irritating) ^[1] |
| | Oral (rat) LD50: 2920 mg/kg ^[2] | |
| d-limonene | Dermal (rabbit) LD50: >5000 mg/kg ^[2] | Eye: no adverse effect observed (not irritating) ^[1] |
| | Inhalation (rat) LC50: 90.86 mg/l ^{e[2]} | Skin (rabbit): 500mg/24h moderate |
| | Oral (rat) LD50: >2000 mg/kg ^[1] | Skin: no adverse effect observed (not irritating) ^[1] |
| | Oral (rat) LD50: >4800 mg/kg ^[2] | |
| | Oral (rat) LD50: 4400 mg/kg ^[2] | |
| | Oral (rat) LD50: 5300 mg/kg ^[2] | |
| coumarin | TOXICITY | IRRITATION |
| | Oral (rat) LD50: 293 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 | |

| | |
|---------------------------------------|--|
| GAMMA-UNDECALACTONE | <p>Gamma-butyrolactone may cause thymus atrophy, brain damage, severe weakness and low body weight in rats. It causes no foetal development defects but may decrease testicular weight in the male rat. There is insufficient evidence from animal testing to show that gamma-butyrolactone has cancer-causing effects.</p> <p>The material may cause severe skin irritation after prolonged or repeated exposure and may produce on contact skin redness, swelling, the production of vesicles, scaling and thickening of the skin. Repeated exposures may produce severe ulceration.</p> <p>This is a member or analogue of a group of lactones generally considered as safe (GRAS).</p> <p>Aliphatic lactones occur naturally at high concentrations (up to 100 parts per million) in food having a high fat content such as meat, cheese, milk and coconuts.</p> |
| DODECANE, ISOMERS | <p>Equivocal tumorigen by RTECS criteria.</p> <p>Animal studies indicate that normal, branched and cyclic paraffins are absorbed from the gastrointestinal tract and that the absorption of n-paraffins is inversely proportional to the carbon chain length, with little absorption above C30. With respect to the carbon chain lengths likely to be present in mineral oil, n-paraffins may be absorbed to a greater extent than iso- or cyclo-paraffins.</p> <p>The major classes of hydrocarbons are well absorbed into the gastrointestinal tract in various species. In many cases, the hydrophobic hydrocarbons are ingested in association with fats in the diet. Some hydrocarbons may appear unchanged as in the lipoprotein particles in the gut lymph, but most hydrocarbons partly separate from fats and undergo metabolism in the gut cell. The gut cell may play a major role in determining the proportion of hydrocarbon that becomes available to be deposited unchanged in peripheral tissues such as in the body fat stores or the liver.</p> <p>Animal testing showed exposure to high concentrations (over 3500 parts per million) of C9 to C13 alkanes in air caused inco-ordination, seizures and spasms. Cerebellar damage was found on autopsy in some animals. It appears that exposure may possibly damage the central nervous system.</p> <p>No significant acute toxicological data identified in literature search.</p> <p>The safety of isoparaffins as used in cosmetic products was reviewed by the Cosmetic Ingredient Review (CIR) Expert Panel.</p> <p>These ingredients function mostly as solvents and also function as emollients in the 0001% to 90% concentration range. The CIR Expert Panel has reviewed relevant animal and clinical data and concluded that these ingredients are safe in the present practices of use and concentration.</p> <p>The CIR Expert Panel noted that most of the available data related to oral or inhalation exposure to isoparaffins, but the dermal and ocular exposure data that were available, suggested mild ocular irritation, mild-to-severe irritation, no sensitization or photosensitization, and no phototoxicity. No significant toxicity was identified in oral or inhalation exposure studies of the following end points: genotoxicity, reproductive and developmental toxicity, or carcinogenicity. Nephrotoxicity, however, was a concern. The Expert Panel noted the involvement of a2u-globulin in the mechanism for isoparaffin-induced nephrotoxicity/renal tubule cell proliferation in male rats of various strains in oral and inhalation exposure studies. Humans lack this protein and, thus, the Panel agreed that findings associated with the a2u-globulin protein in male rats were not relevant to humans. This view was consistent with the US EPA position that it was not possible for the agency to derive an oral RfD for chronic oral exposure or a reference concentration for chronic inhalation exposure to isooctane because the available studies were limited, in that they were designed to only investigate the endpoints specific to a2u-globulin-associated nephropathy. The EPA also concluded that there was inadequate evidence to assess the carcinogenic potential of isooctane, based on the absence of human epidemiological studies and chronic bioassays on this compound. However, the CIR Expert Panel noted that no significant tumor incidence was found following life-time dermal application of petrolatum (15% in isooctane) to mice and also found no evidence of any concern regarding carcinogenic potential from exposure to isoparaffins as used in cosmetics.</p> <p>The potential adverse effects of inhaled aerosols depend on the specific chemical species, the concentration and the duration of the exposure and their site of deposition within the respiratory system. In practice, aerosols should have at least 99% of their particle diameters in the 10 to 110 mm range and the mean particle diameter in a typical aerosol spray has been reported as ~38 mm. Particles with an aerodynamic diameter of <10 mm are respirable. After reviewing the positive acute and subchronic inhalation toxicity data the Expert Panel determined that isoparaffins can be used safely in hair sprays, because the product particle size is not respirable.</p> <p>International Journal of Toxicology 31 (Supplement 3) 269S-295S 2012</p> |
| 2-TERT-BUTYLCYCLOHEXYL ACETATE | <p>There are no safety concerns regarding cyclic acetates under the present declared levels of use, for the reasons outlined below.</p> <p>Cyclic acetates have low acute toxicity. Cyclic acetates and cyclic alcohols also have low whole-body toxicity, after repeated application to skin. At concentrations encountered in current use, minimal, if any, skin irritation occurs. These substances have little or no sensitizing potential. Available data does not indicate that these substances cause genetic toxicity or mutations, so they are unlikely to cause cancer. They have a very wide safety margin.</p> |
| BETA-CITRONELLOL | <p>With few exceptions* (see below), there are no safety concerns regarding certain cyclic and non-cyclic terpene alcohols **, as fragrance ingredients, under present declared levels of use and exposure, because</p> <ul style="list-style-type: none"> - They have low acute toxicity - No significant toxicity was observed in repeat dose toxicity tests - They were not found to cause mutations or genetic toxicity - Substances in this group are processed similarly in the body - There is no indication of persistent breakdown products causing severe toxicity - They practically do not irritate the skin - They have a generally low potential for sensitization |

- The margin of safety is more than 100 times the maximum daily exposure.

*Safety concerns exist for the following substances for the following reasons:

- 6,7-dihydrogeraniol, hydroabietyl alcohol and 2-isopropyl-2-decahydronaphthalenol are potent skin sensitizers.
- Farnesol is a weak sensitizer.
- Scaleryl and linalool may contain impurities and/or oxidation products that are strong sensitizers.
- No sensitization test results were available for 2(10)-pinen-3-ol, 2,6-dimethyloct-3,5-dien-2-ol, and 3,7-dimethyl-4,6-octadien-3-ol. These materials should be regarded as potential sensitizers until tested.

** The common characteristic structural element of acyclic -noncyclic- and cyclic terpene alcohols is the typically branched isoprene unit 2-methyl-1,3-butadiene

Citronellol, geraniol, nerol, and geranyl acetate are currently generally regarded as safe by the US FDA for their intended use as flavouring substances. They are ubiquitous in the plant kingdom. Terpenoid alcohol, formed in the gastrointestinal tract, as a result of hydrolysis, is rapidly absorbed, metabolised and excreted via the urine. It has no repeat dose effect, no genetic and cancer causing effect but may harm the unborn child of a pregnant woman.

Current opinion holds that there are no safety concerns regarding the branched chain unsaturated non-cyclic alcohols, as fragrance ingredients, at current declared levels of use and exposure; however, use of these materials at higher maximum levels of skin or whole-body exposure requires re-evaluation.

At current declared levels of use, there was no evidence or only minimal evidence of skin irritation in humans. Sensitising hydroperoxides may be formed by contact with air. It should be ensured that oxidation reactions are prevented in the end product. The use of these materials under the declared levels of use and exposure will not induce sensitization. These compounds generally have low acute toxicity. The branched chain, unsaturated alcohols tested had low whole-body toxicity after repeated application. In animals, repeated exposure at high doses caused liver changes and kidney damage.

There was little or no evidence of adverse effects on fertility or development. Data on cancer-causing potential is not available, but they are not of primary concern.

Alkyl alcohols of chain length C6-13 are absorbed from skin, when inhaled or swallowed but show evidence of little harm. They are broken down and rapidly excreted by the body.

ROSE KETONES

These should not be used as fragrance ingredients at concentrations more than 0.02%, individually or in combination with other isomers of damascone. This is based on data showing potential for sensitisation and evidence of cross-reactivity.

Beta-ionone is absorbed after oral exposure. Metabolism takes place mainly in the liver, and beta-ionone is excreted via urine. It produces abnormal liver, kidney and thyroid changes, and may cause depression and tremors. It causes dose dependent eye and skin irritation but no evidence of cancer-causing effect, nerve or genetic toxicity was observed.

For ionones and rose ketones, when used as fragrance ingredients:

Ionones have low to moderate toxicity if swallowed. Acute toxicity by skin contact is low. Animal testing has not shown subchronic toxicity. Under intended conditions of use as fragrance ingredients, they do not have significant potential for genetic, reproductive or developmental toxicity. Ionones are non-irritating when used as fragrance ingredients, while the rose ketones have limited irritation potential in sensitive subjects. The ionones are considered to be without significant potential to sensitise the skin, while the rose ketones are sensitizers when present at concentrations greater than 0.2%. The safety margin is considered to be high.

A member or analogue of a group of aliphatic and alicyclic terpenoid tertiary alcohols and structurally related substances generally regarded as safe.

Most alicyclic substances used as flavour ingredients are mono- and bicyclic terpenes which occur naturally in a wide variety of foods. With the exception of pulegone, alicyclic substances show very low oral acute toxicity. In most subchronic studies performed on animals, no adverse effects were observed at any dose level.

A member or analogue of EFSA Chemical Group 10 secondary aliphatic saturated or unsaturated alcohols, ketones, ketals and esters with a secondary or tertiary oxygenated functional group used as flavourings

No safety concern would arise for the consumer from the use of these compounds up to the highest proposed level in feeds.

Hazards for skin and eye contact and respiratory exposure are recognised for the majority of the compounds under application. Most are classified as irritating to the respiratory system.

Aliphatic acyclic and alicyclic alpha-diketones and alpha-hydroxyketones are generally used as flavouring agents up to average maximum levels of 200 ppm.

In rats and mice, orally administered aliphatic alpha-diketones are rapidly absorbed from the gastrointestinal tract. It is anticipated that at low levels of exposure, humans will metabolize aliphatic acyclic alpha-diketone principally by alpha-hydroxylation and subsequent oxidation of the terminal methyl group to yield the corresponding ketocarboxylic acid. The acid may undergo oxidative decarboxylation to yield carbon dioxide and a simple aliphatic carboxylic acid, which may be completely metabolized in the fatty acid pathway and citric acid cycle. At high concentrations, another detoxification pathway is used which involves reduction to the diol and subsequent conjugation with glucuronic acid. Acyclic alpha-diketones and alpha-hydroxyketones without a terminal methyl group and alicyclic diketones and hydroxyketones are mainly metabolized by reduction to the corresponding diol, followed by glucuronic acid conjugation and excretion

Compounds belonging to CG 10 are absorbed from the gastrointestinal tract and share common pathways of metabolism: (i) hydrolysis of esters by carboxylesterases, (ii) reduction of ketones to alcohols, (iii) oxidation of alcohols to acids, (iv) alpha-hydroxylation of the terminal methyl group to yield corresponding ketocarboxylic acids, (v) oxidative decarboxylation to yield carbon dioxide and an aliphatic carboxylic acid, and (vi) conjugation of alpha-hydroxyketones or their diol metabolites with glucuronic acid. Aliphatic acyclic diketones and alpha-hydroxyketones, which contain a carbonyl function at the 2-position (i.e. a methyl ketone) are expected to undergo alpha-hydroxylation and subsequent oxidation of the terminal methyl group to eventually yield corresponding ketocarboxylic acids. These compounds are intermediary metabolites (e.g. alpha-ketoacids), which may undergo oxidative decarboxylation to yield carbon dioxide and an aliphatic carboxylic acid. The acid is then metabolised via beta-oxidation and the citric acid cycle. beta-Ketoacids and derivatives readily undergo decarboxylation to yield breakdown products, which are incorporated into normal biochemical pathways. Alternatively, the methyl-substituted diketones may be successively reduced to the corresponding hydroxyketones and diols, which are excreted in the urine as glucuronic acid conjugates. This pathway is favoured at elevated in vivo concentrations, especially for longer chain length ketones. If the carbonyl function is located elsewhere on the chain, reduction is the predominant pathway. alpha-hydroxyketones or their diol metabolites may be excreted as glucuronic acid conjugates. Low concentrations of aliphatic acyclic methyl ketones are mainly metabolised by oxidation of the terminal methyl group. At higher concentrations, acyclic alpha-diketones are metabolised via a reduction pathway to the diol and subsequent conjugation with glucuronic acid

In a 13-week study in rats (males/females, 15 animals/group), 3-hydroxybutan-2-one was administered with the diet at doses of 0, 85, 330 and 1,345 mg/kg bw per day. No treatment-related effects on body weight gain, haematological and urinary parameters, serum chemistry, organ weight and histopathology were seen up to 330 mg/kg bw per day. Several effects were observed at the highest dose tested, i.e. a reduction in body weight gain associated with a reduction in food and water consumption, an increase in relative liver weight and a slight anaemia. From this study, a no observed adverse effect level (NOAEL) of 330 mg/kg bw per day could be derived.

A NOAEL of 90 mg/kg bw per day was derived from a 13-week study in rats (15 males/15 females each group), in which diacetyl [07.052] was administered by gavage at nominal doses of 0, 10, 30, 90 and 540 mg/kg bw per day. No adverse effects were seen at the three low doses tested on haematological and urinary parameters, serum chemistry, absolute and relative organ weight and histopathology. Several effects were observed at the highest dose tested (540 mg/kg bw), i.e. a decrease in weight gain associated with an increase in water consumption, anaemia, increased leucocyte count, increased relative weights of the liver, kidneys, adrenals and pituitary glands. At the same dose, stomach lesions seen at necropsy revealed necrosis with infiltration by inflammatory cells.

A trial was conducted to assess the chronic toxicity of 3-ethylcyclopentan-1,2-dione ((due to keto-enol tautomerism this substance can exist as two isomers; the keto-isomer is 3-ethylcyclopentan-1,2-dione a synonym for the keto-isomer is ethylcyclopentenolone) on reproduction and development in rats (male and female Charles River CD-COBS) following administration to three successive generations. In each generation, rats received diet containing 3-ethylcyclopentan-1,2-dione corresponding to dose levels of 0 (untreated controls), 0 (propylene glycol vehicle), 30, 80, and 200 mg/kg body weight/day. The F0 group (20 animals/sex/treatment) entered the study at weaning and were mated on day 64. Animals from the control groups and the high-dose group were

maintained on trial for 12 months. The F1 generation 50 animals/sex per treatment except control, 100 animals/sex) was exposed to the test substance in utero, via milk until weaning and then through the diet for a further 23 months. The final examination of the F1 generation included ophthalmology, clinical chemistry, haematology and a full histopathology. The F1 generation was bred twice (days 99 and 155) and 20 litters/treatment group from the first mating selected to provide the F2 generation which were in turn mated at day 84. The F3 generation were killed after weaning. Survival, food consumption, growth, reproductive performance, haematological and clinical chemistry parameters were not adversely affected. Gross pathological and histopathological examination revealed no significant treatment-related effects. The incidence of benign or malignant tumours in treated animals was not significantly different to that in controls in the F0 and F1 generations. From this study, it is concluded that ethylcyclopentan-1,2-dione was not carcinogenic in rats under the study conditions and that a NOAEL of 200 mg/kg body weight (the highest dose tested) can be derived for chronic and developmental effects.

A structural alert for genotoxicity is overruled for 3-ethyl-2-hydroxy-2-cyclopenten-1-one as well as for the nine structurally related substances (alpha,beta-unsaturated alicyclic ketones and their precursors)

Maltol and ethyl maltol were considered separately because in contrast to the other substances in this subgroup they contain a ring-oxygen atom.

Ethyl maltol induced gene mutations in bacteria

Maltol induced gene mutations in bacteria and sister chromatid exchanges (SCE) in human lymphocytes In vivo, maltol induced micronuclei in mouse bone marrow after intraperitoneal application. Negative results were obtained in a sex-linked recessive lethal mutation assay in *Drosophila*. However, the micronucleus assay is considered more relevant than the *Drosophila* assay. Ethyl maltol induced gene mutations in bacteria

EFSA Scientific Opinion October 2016: Safety and efficacy of secondary aliphatic saturated or unsaturated alcohols, ketones, ketals and esters with a second secondary or tertiary oxygenated functional group belonging to chemical group 10 when used as flavourings for all animal species Safety Evaluation of Aliphatic, Acyclic and Alicyclic alpha-Diketones and related Hydroxyketones; WHO Food Additive Series Joint FAO/ WHO Expert Committee on Food Additives 1999

The alpha,beta-unsaturated aldehyde and ketone structures are considered by the Panel to be structural alerts for genotoxicity.

Flavouring Group Evaluation 213: alpha,beta-Unsaturated alicyclic ketones and precursors from chemical subgroup 2.7 of FGE.19: Scientific Opinion of the Panel on Food Contact Materials, Enzymes, Flavourings and Processing Aids (CEF)

D-LIMONENE

d-Limonene is readily absorbed by inhalation and swallowing. Absorption through the skin is reported to be lower than by inhalation. It is rapidly distributed to different tissues in the body, readily metabolized and eliminated, primarily through the urine.

Limonene shows low acute toxicity by all three routes in animals. Limonene is a skin irritant in both experimental animals and humans. Limited data is available on the potential to cause eye and airway irritation. Autooxidised products of d-limonene have the potential to sensitize the skin. Limited data is available on the potential to cause respiratory sensitization in humans. Limonene will automatically oxidize in the presence of light in air, forming a variety of oxygenated monocyclic terpenes. When contact with these oxidation products occurs, the risk of skin sensitization is high.

Limonene does not cause genetic toxicity of birth defects, and it is not toxic to the reproductive system.

Monomethyltin chloride, thioglycolate esters, and tall oil ester reaction product:

Monomethyltin trichloride (MMTC, CAS RN: 993-16-8), monomethyltin tris[2-ethylhexylmercaptoacetate (MMT (EHTG); MMT (2-EHMA), CAS RN: 57583-34-3), monomethyltin tris[isooctylmercaptoacetate (MMT(IOTG), CAS RN: 54849-38-6) and methyltin reverse ester tallate reaction product (TERP, CAS RNs: 201687-58-3, 201687-57-2, 68442-12-6, 151436-98-5) are considered one category of compounds for mammalian studies via the oral route. The justification for this category is based on structural similarities and the demonstrated rapid conversion of all of the esters to the MMTC when placed in simulated mammalian gastric contents [0.07M HCl] under physiological conditions. For the MMT(EHTG) >90% conversion to MMTC occurred within 0.5 hours. For TERP, 68% of the monomethyltin portion of the compound was converted to MMTC within 1 hour. Thus, MMTC is the appropriate surrogate for mammalian toxicology studies via the oral route.

TERP is a reaction product of MMTC and dimethyltin dichloride (DMTC), Na₂S, and tall oil fatty acid [a mixture of carboxylic acids, predominantly C-18]. The reaction product is a mixture of carboxylic esters and includes short oligomers of mono/dimethyltins bridged by sulfide groups.

Although the tall oil component of TERP is not structurally similar to EHTG, TERP's conversion to MMTC justifies its inclusion. While the contribution of the various ligands to the overall toxicity may vary, the contribution is expected to be small relative to that of the MMTC. Further, the EHTG ligand from MMT(EHTG) is likely to be more toxic than the oleic or linoleic acid from TERP so inclusion of TERP in the category is a rather conservative approach. The other possible degradate of tall oil and EHTG is 2-mercaptoethanol (2-ME), and it is common to both ligands. Data for MMT(EHTG) and MMT(IOTG) are used interchangeably because they are isomers differing only slightly in the structure of the C-8 alcohol of the mercaptoester ligand. In addition, the breakdown products of MMT(EHTG) and MMT(IOTG) are the thioglycolate esters (EHTG and IOTG), which have the common degradates, thioglycolic acid and C-8 alcohols (either 2-ethylhexanol or isooctanol). EHTG and IOTG also have similar physicochemical and toxicological properties.

The chemistry of the alkyl organotin has been well studied. For organotin, like MMT(EHTG), the alkyl groups are strongly bound to tin and remain bound to tin under most reaction conditions. However, other ligands, such as carboxylates or sulfur based ligands (EHTG), are more labile and are readily replaced under mild reaction conditions. To assess the reactivity of MMT(EHTG) under physiological conditions simulating the mammalian stomach, an in-vitro hydrolysis test was performed. This in vitro test provides chemical information that strongly suggests both the probable in vivo metabolic pathway and the toxicokinetics of the MMT(EHTG) substance. This result verifies that under physiological conditions MMT(EHTG) is rapidly and essentially completely converted to the corresponding monomethyltin chloride, MMTC.

Acute toxicity:

The majority of toxicology studies were conducted with commercial mixtures having high monoalkyltin to dialkyltin ratios.

Gastric hydrolysis studies were conducted with TERP and MMT(EHTG) in which simulated gastric fluid [0.07M HCl under physiological conditions] converted these substances to methyltin chloride and the respective organic acids. Based on data for DMTC and DMT esters the dermal penetration of MMTC and its esters is expected to be low.

Oral:

Acute oral LD50 values for MMTC, MMT(EHTG), MMT(IOTG), and TERP indicated low to moderate toxicity; the most reliable data place the LD50s in the range of 1000 mg/kg.

The acute oral LD50 of MMT(2-EHMA) was 880 mg/kg in rats. Clinical observations included depression, comatose, piloerection, eye squinting, hunched posture, laboured breathing, ataxia, faecal/urine stains, and masticatory movement. No gross pathological changes were reported in surviving animals.

Dermal

Acute dermal LD50 values were =1000 mg/kg bw, and inhalation LC50 was >200 mg/L. MMTC was corrosive to skin and assumed corrosive to eyes.

The acute dermal LD50 of MMT(2-EHMA) in rabbits was 1000 (460 to 2020) mg/kg for females and 2150 (1000 to 4620) mg/kg for males. There were no deaths at 215 and 464 mg/kg, 0/2 males and 1/2 females died at 1000 mg/kg and 1/2 males and 2/2 females died at 2150 mg/kg. All animals died at 4640 and 10 000 mg/kg. A variety of clinical abnormalities were observed and disappeared in surviving animals by the end of the exposure period. Clinical signs included death, uncoordinated movements, shaking, and hypersensitivity to external stimuli.

Gross necropsy results for animals that died during the study included irritated intestines; blanched stomach; reddened lungs; pale or congested kidneys; and oral, ocular and/or nasal discharges

Inhalation:

The acute inhalation LC50 of MMT(2-EHMA) was 240 mg/L.

The study reported an acute inhalation LC50 of 240 (212 to 271) mg/L in a 1-hr aerosol exposure to male and female rats. The mortality rate was 2/10, 6/10, 9/10 and 10/10 animals at dose levels of 200, 250, 300 and 250 mg/L/hr, respectively. Gross findings included blood in lungs, dark spleen, pale kidneys, fluid in the chest cavity, and heart failure. The slope of the dose-response curve was 1.22 (1.04 to 1.43).

Irritation:

MMT(IOTG)/(EHTG) are irritating to skin, but not to eyes.

Sensitisation:

No data on sensitization are available on MMT(EHTG)/(IOTG), but the hydrolysis products EHTG or IOTG are sensitizers. No primary irritation data were available for TERP, but it was a sensitizer in the mouse Local Lymph Node Assay.

Topical application with 5, 25 and 50 % v/v MMT(2-EHMA) elicited a stimulation index (SI) of 2.13, 7.25 and 9.05, respectively in a local lymph node assay (OECD 429), thus the material is a sensitiser.

Repeat dose toxicity:

There are no repeated-dose studies for the category members via the dermal or inhalation routes.

In a 90-day repeated-dose oral study of MMTC, treatment-related changes were limited to the high dose group (750 ppm in diet; 50 mg/kg bw/d with some gender-related variation). Organ weight changes (adrenal, kidney, thymus, spleen, brain, epididymides), haematology, clinical chemistry, and urinalysis changes were noted, but histopathology only confirmed effects in the thymus and brain. The critical toxic effects were neurotoxicity and thymic atrophy. Both sexes had decreased cortex/medulla ratios in the thymus. In the brain there was loss of perikarya of neuronal cells in the pyramidal layer of the Hippocampus CA1/2 in both sexes, and in males there was loss of perikarya in the piriform cortex.

The NOAEL was 150 ppm (10 mg/kg bw/d). Another 90-day dietary study using MMTC showed increased relative kidney weights and slight to moderate epithelial hyperplasia of the bladder in females at the lowest dose (NOAEL <20 ppm in diet [$<1\text{-}3.6\text{ mg/kg bw/d}$]) and additional effects including increased relative thymus weights in females and urinalysis results in both sexes at higher doses.

A 90-day dietary study with dose levels of 30, 100, 300, and 1000 ppm TERP in the diet resulted in slightly decreased food intake, body and organ weight changes, and decreased specific gravity of the urine at the highest dose. The NOAEL was 300 ppm in diet (equivalent to 15 mg/kg bw/d). A 28-day gavage study using TERP showed changes in clinical chemistry and slight differences in haematology at 150 mg/kg bw/d and higher. The NOAEL was 50 mg/kg bw/d.

The effects of MMT(IOTG) were evaluated in a 90-day dietary study using doses of 100, 500, and 1500 ppm (decreased from 2500 ppm) in the diet. Based on clinical chemistry effects at 500 ppm and other effects at higher doses, the NOAEL was 100 ppm in diet (approximately 6-21 mg/kg bw/d).

Neurotoxicity:

In a guideline 90-day subchronic dietary study conducted in Wistar rats, effects occurred at the high dose of 750 ppm MMT(2-EHMA, (equivalent to 49.7 mg/kg bw/day in males and 53.6 mg/kg bw/day in females), which consisted of changes in neurobehavioral parameters and associated brain histopathology. The NOAEL was the next lower dose of 150 ppm (equivalent to 9.8 mg/kg bw/day in males and 10.2 mg/kg bw/day in females).

Immunotoxicity:

Immune function was assessed in male Sprague-Dawley rats exposed to the mixture of organotins used in PVC pipe production.

Adult male rats were given drinking water for 28 d containing a mixture of dibutyltin dichloride (DBTC), dimethyltin dichloride (DMTC), monobutyltin trichloride (MBT), and monomethyltin trichloride (MMT) in a 2:2:1:1 ratio, respectively, at 3 different concentrations (5:5:2.5:2.5, 10:10:5:5, or 20:20:10:10 mg organotin/L). Rats were also exposed to MMT alone (20 or 40 mg MMT/L) or plain water as a control. Delayed-type hypersensitivity, antibody synthesis, and natural killer cell cytotoxicity were evaluated in separate endpoint groups immediately after exposure ended.

The evaluated immune functions were not affected by the mixture or by MMT alone. The data suggest that immunotoxicity is unlikely to result from the concentration of organotins present in drinking water delivered via PVC pipes, as the concentrations used were several orders of magnitude higher than those expected to leach from PVC pipes.

Genotoxicity:

In a guideline 90-day subchronic dietary study in rats, with MMT(2-EHMA), based on the changes in neurobehavioral parameters and associated brain histopathology that occurred at the high dose of 750 ppm (equivalent to 49.7 mg/kg bw/day in males and 53.6 mg/kg bw/day in females), as well as changes in haematology, clinical chemistry, urinalysis, organ weights, and pathology of the thymus at the same dose, the NOAEL was the next lower dose of 150 ppm (equivalent to 9.8 mg/kg bw/day in males and 10.2 mg/kg bw/day in females).

The monomethyltin compounds as a class are not mutagenic in the Ames test. TERP was positive in a human lymphocyte assay. MMTC was equivocal for induction of micronucleated polychromatic erythrocytes (MPEs) in an in vivo rat micronucleus test (OECD 474). In this study a statistically significant increase in MPE was observed only at 24 h and not at 48 h after treatment and there was no dose-response. Based on these observations the overall conclusion is that MMTC does not have genotoxic potential.

From the results obtained in a micronucleus test with MMT(2-EHMA), it was demonstrated that the substance was weakly genotoxic to bone marrow cells of rats and that the substance has the potential to induce damage to the mitotic spindle apparatus of the bone marrow target cells.

Carcinogenicity:

In a limited carcinogenicity study, MMT(EHTG) produced no compound-related macroscopic or microscopic changes in rats fed 100 ppm in the diet for two years.

Toxicity to reproduction:

In the reproductive satellite portion of the 90-day study using MMTC (with dose levels of 30, 150, and 750 ppm in the diet), post-implantation loss, decreased litter size and increased neonatal mortality occurred at 750 ppm (26-46 mg/kg bw/d for females). Maternal gestational body weights were transiently suppressed and other maternal toxicity was inferred from the repeated dose results at this dose. There were no malformations observed at any dose. The NOAEL for maternal toxicity, and reproductive, and foetotoxic effects was 150 ppm in the diet (6-12 mg/kg bw/d).

SIDS Initial Assessment Profile (SIAM 23 2006)

ECHA Registration Dossier for MMT(2-EHMA) (ethylhexyl 10-ethyl-4-[[2-((2-ethylhexyl)oxy)-2-oxoethyl]thio]-4-methyl-7-oxo-8-oxa-3,5-dithia-4-stannatetradecanoate)

Tumorigenic by RTECS criteria

GAMMA-UNDECALACTONE & DODECANE, ISOMERS & 2-TERT-BUTYLCYCLOHEXYL ACETATE & BETA-CITRONELLOL & COUMARIN

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.

GAMMA-UNDECALACTONE & BETA-CITRONELLOL & ROSE KETONES & D-LIMONENE & COUMARIN

Adverse reactions to fragrances in perfumes and fragranced cosmetic products include allergic contact dermatitis, irritant contact dermatitis, sensitivity to light, immediate contact reactions, and pigmented contact dermatitis. Airborne and conjugal contact dermatitis occurs. Contact allergy is a lifelong condition, so symptoms may occur on re-exposure. Allergic contact dermatitis can be severe and widespread, with significant impairment of quality of life and potential consequences for fitness for work.

If the perfume contains a sensitizing component, intolerance to perfumes by inhalation may occur. Symptoms may include general unwellness, coughing, phlegm, wheezing, chest tightness, headache, shortness of breath with exertion, acute respiratory illness, hayfever, asthma and other respiratory diseases. Perfumes can induce excess reactivity of the airway without producing allergy or airway obstruction. Breathing through a carbon filter mask had no protective effect.

Occupational asthma caused 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. Prevention of contact sensitization to fragrances is an important objective of public health risk management.

Hands: Contact sensitization may be the primary cause of hand eczema or a complication of irritant or atopic hand eczema. However hand eczema is a disease involving many factors, and the clinical significance of fragrance contact allergy in severe, chronic hand eczema may not be clear.

Underarm: Skin inflammation of the armpits 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 skin specialist, a history of such first-time symptoms was significantly related to the later diagnosis of perfume allergy.

Face: An important manifestation of fragrance allergy from the use of cosmetic products is eczema of the face. In men, after-shave products can cause eczema around the beard area and the adjacent part of the neck. Men using wet shaving as opposed to dry have been shown to have an increased risk of allergic to fragrances.

Irritant reactions: Some individual fragrance ingredients, such as citral, are known to be irritant. Fragrances may cause a dose-related contact

| | |
|--|---|
| | <p>urticaria (hives) which is not allergic; cinnamal, cinnamic alcohol and Myroxylon pereirae are known to cause hives, but others, including menthol, vanillin and benzaldehyde have also been reported.</p> <p>Pigmentary anomalies: Type IV allergy is responsible for "pigmented cosmetic dermatitis", referring to increased pigmentation on the face and neck. Testing showed a number of fragrance ingredients were associated, including jasmine absolute, ylang-ylang oil, cananga oil, benzyl salicylate, hydroxycitronellal, sandalwood oil, geraniol and geranium oil.</p> <p>Light reactions: Musk ambrette produced a number of allergic reactions mediated by light and was later banned from use in Europe.</p> <p>Furocoumarins (psoralens) in some plant-derived fragrances have caused phototoxic reactions, with redness. There are now limits for the amount of furocoumarins in fragrances. Phototoxic reactions still occur, but are rare.</p> <p>General/respiratory: Fragrances are volatile, and therefore, in addition to skin exposure, a perfume also exposes the eyes and the nose / airway. 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. A significant association was found between respiratory complaints related to fragrances and contact allergy to fragrance ingredients and hand eczema.</p> |
| GAMMA-UNDECALACTONE & COUMARIN | <p>Fragrance allergens act as haptens, low molecular weight chemicals that cause an immune response only when attached to a carrier protein. However, not all sensitizing fragrance chemicals are directly reactive, but require previous activation. A prohaptens is a chemical that itself causes little or no sensitization, but 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 prohaptens or a prohaptens, or both.</p> <p>Prohaptens: Compounds that are bioactivated in the skin and thereby form haptens are referred to prohaptens. The possibility of a prohaptens being activated cannot be avoided by outside measures. Activation processes increase the risk for cross-reactivity between fragrance substances. Various enzymes play roles in both activating and deactivating prohaptens. Skin-sensitizing prohaptens can be recognized and grouped into chemical classes based on knowledge of xenobiotic bioactivation reactions, clinical observations and/or studies of sensitization. QSAR prediction: Prediction of sensitization activity of these substances is complex, especially for those substances that can act both as pre- and prohaptens.</p> |
| BETA-CITRONELLOL & ROSE KETONES & D-LIMONENE & COUMARIN | <p>The following information refers to contact allergens as a group and may not be specific to this product.</p> <p>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.</p> |
| BETA-CITRONELLOL & ROSE KETONES & D-LIMONENE | <p>Fragrance allergens act as haptens, which are small molecules that cause an immune reaction only when attached to a carrier protein. However, not all sensitizing fragrance chemicals are directly reactive, but some require previous activation. A prohaptens is a chemical that itself causes little or no sensitization, but it is transformed into a hapten outside the skin by a chemical reaction (oxidation in air or reaction with light) without the requirement of an enzyme.</p> <p>For prohaptens, it is possible to prevent activation outside the body to a certain extent by different measures, for example, prevention of air exposure during handling and storage of the ingredients and the final product, and by the addition of suitable antioxidants. When antioxidants are used, care should be taken that they will not be activated themselves, and thereby form new sensitizers.</p> <p>Prohaptens: Most terpenes with oxidisable allylic positions can be expected to self-oxidise on air exposure. Depending on the stability of the oxidation products that are formed, the oxidized products will have differing levels of sensitization potential. Tests shows that air exposure of lavender oil increased the potential for sensitization.</p> <p>Prohaptens: Compounds that are bioactivated in the skin and thereby form haptens are referred to prohaptens. The possibility of a prohaptens being activated cannot be avoided by outside measures. Activation processes increase the risk for cross-reactivity between fragrance substances. Various enzymes play roles in both activating and deactivating prohaptens. Skin-sensitizing prohaptens can be recognized and grouped into chemical classes based on knowledge of xenobiotic bioactivation reactions, clinical observations and/or studies of sensitization. QSAR prediction: Prediction of sensitization activity of these substances is complex, especially for those substances that can act both as pre- and prohaptens.</p> |
| D-LIMONENE & COUMARIN | <p>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.</p> |

| | | | |
|--|---|---------------------------------|---|
| 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

| SPE005 Sphere Fruit Blast | Endpoint | Test Duration (hr) | Species | Value | Source |
|---------------------------|---------------|--------------------|-------------------------------|---------------|---------------|
| | Not Available | Not Available | Not Available | Not Available | Not Available |
| gamma-undecalactone | Endpoint | Test Duration (hr) | Species | Value | Source |
| | LC50 | 96 | Fish | 5.5mg/L | 2 |
| | EC50 | 48 | Crustacea | 4mg/L | 2 |
| | EC50 | 96 | Algae or other aquatic plants | 5mg/L | 2 |
| NOEC | 504 | Crustacea | 0.138mg/L | 2 | |
| dodecane, isomers | Endpoint | Test Duration (hr) | Species | Value | Source |
| | LC50 | 96 | Fish | >0.0028mg/L | 2 |
| | EC50 | 48 | Crustacea | >1-mg/L | 2 |
| | EC50 | 72 | Algae or other aquatic plants | >0.0225mg/L | 2 |
| NOEC | 504 | Crustacea | 0.011mg/L | 2 | |

Continued...

| | Endpoint | Test Duration (hr) | Species | Value | Source |
|------|--------------------------------|--------------------|-------------------------------|-----------|-----------|
| | 2-tert-butylcyclohexyl acetate | LC50 | 96 | Fish | 5.6mg/L |
| EC50 | | 48 | Crustacea | 17mg/L | 2 |
| EC50 | | 72 | Algae or other aquatic plants | 4.2mg/L | 2 |
| EC10 | | 792 | Fish | 0.91mg/L | 2 |
| NOEC | | 72 | Algae or other aquatic plants | 0.57mg/L | 2 |
| | Endpoint | Test Duration (hr) | Species | Value | Source |
| | beta-citronellol | LC50 | 96 | Fish | 14.66mg/L |
| EC50 | | 48 | Crustacea | 17.48mg/L | 2 |
| EC50 | | 72 | Algae or other aquatic plants | 2.4mg/L | 2 |
| EC20 | | 72 | Algae or other aquatic plants | 1.1mg/L | 2 |
| NOEC | | 48 | Crustacea | 3.1mg/L | 2 |
| | Endpoint | Test Duration (hr) | Species | Value | Source |
| | rose ketones | EC50 | 48 | Crustacea | 9.5mg/L |
| EC50 | | 72 | Algae or other aquatic plants | 8.8mg/L | 2 |
| LC50 | | 96 | Fish | 1.09mg/L | 2 |
| EC50 | | 48 | Crustacea | 9mg/L | 2 |
| EC50 | | 72 | Algae or other aquatic plants | 8.3mg/L | 2 |
| LC50 | | 96 | Fish | 1.09mg/L | 2 |
| EC50 | | 48 | Crustacea | 2.37mg/L | 2 |
| EC50 | | 72 | Algae or other aquatic plants | 5mg/L | 2 |
| EC50 | | 48 | Crustacea | 2.32mg/L | 2 |
| EC50 | | 72 | Algae or other aquatic plants | 2.45mg/L | 2 |
| EC10 | | 72 | Algae or other aquatic plants | 1.14mg/L | 2 |
| LC50 | | 96 | Fish | 0.97mg/L | 2 |
| EC50 | | 72 | Algae or other aquatic plants | 2.47mg/L | 2 |
| NOEC | 504 | Crustacea | 0.35mg/L | 2 | |
| | Endpoint | Test Duration (hr) | Species | Value | Source |
| | d-limonene | LC50 | 96 | Fish | 0.46mg/L |
| EC50 | | 48 | Crustacea | 0.307mg/L | 2 |
| NOEC | | 504 | Crustacea | 0.05mg/L | 2 |
| | Endpoint | Test Duration (hr) | Species | Value | Source |
| | coumarin | LC50 | 96 | Fish | 1.324mg/L |
| EC50 | | 48 | Crustacea | 8.012mg/L | 2 |
| EC50 | | 96 | Algae or other aquatic plants | 1.452mg/L | 2 |
| NOEC | | 72 | Algae or other aquatic plants | 0.431mg/L | 2 |

Legend: *Extracted from 1. IUCLID Toxicity Data 2. Europe ECHA Registered Substances - Ecotoxicological Information - Aquatic Toxicity 3. EPIWIN Suite V3.12 (QSAR) - Aquatic Toxicity Data (Estimated) 4. US EPA, Ecotox database - Aquatic Toxicity Data 5. ECETOC Aquatic Hazard Assessment Data 6. NITE (Japan) - Bioconcentration Data 7. METI (Japan) - Bioconcentration Data 8. Vendor Data*

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.

DO NOT discharge into sewer or waterways.

Persistence and degradability

| Ingredient | Persistence: Water/Soil | Persistence: Air |
|--------------------------------|-------------------------|------------------|
| gamma-undecalactone | LOW | LOW |
| 2-tert-butylcyclohexyl acetate | HIGH | HIGH |
| beta-citronellol | LOW | LOW |
| rose ketones | HIGH | HIGH |
| d-limonene | HIGH | HIGH |
| coumarin | LOW | LOW |

Bioaccumulative potential

| Ingredient | Bioaccumulation |
|--------------------------------|--------------------------|
| gamma-undecalactone | LOW (LogKOW = 3.0583) |
| 2-tert-butylcyclohexyl acetate | MEDIUM (LogKOW = 4.4225) |

SPE005 Sphere Fruit Blast

| Ingredient | Bioaccumulation |
|------------------|--------------------------|
| beta-citronellol | MEDIUM (LogKOW = 3.91) |
| rose ketones | MEDIUM (LogKOW = 4.4235) |
| d-limonene | HIGH (LogKOW = 4.8275) |
| coumarin | LOW (LogKOW = 1.39) |

Mobility in soil

| Ingredient | Mobility |
|--------------------------------|-------------------|
| gamma-undecalactone | LOW (KOC = 476.5) |
| 2-tert-butylcyclohexyl acetate | LOW (KOC = 528.1) |
| beta-citronellol | LOW (KOC = 70.79) |
| rose ketones | LOW (KOC = 668.6) |
| d-limonene | LOW (KOC = 1324) |
| coumarin | LOW (KOC = 146.1) |

SECTION 13 Disposal considerations

Waste treatment methods

| | |
|-------------------------------------|---|
| Product / Packaging disposal | <ul style="list-style-type: none"> ▶ 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. |
|-------------------------------------|---|

Ensure that the hazardous substance is disposed in accordance with the Hazardous Substances (Disposal) Notice 2017

Disposal Requirements

Packages that have been in direct contact with the hazardous substance must be only disposed if the hazardous substance was appropriately removed and cleaned out from the package. The package must be disposed according to the manufacturer's directions taking into account the material it is made of. Packages which hazardous content have been appropriately treated and removed may be recycled.

The hazardous substance must only be disposed if it has been treated by a method that changed the characteristics or composition of the substance and it is no longer hazardous. Do not dispose to the environment any component, which may be bioaccumulative or not rapidly degradable. Only discharge the substance to the environment if an environmental exposure limit has been set for the substance.

Only deposit the hazardous substance into or onto a landfill or sewage facility or incinerator, where the hazardous substance can be handled and treated appropriately.

SECTION 14 Transport information

Labels Required

| | |
|-------------------------|----------------|
| Marine Pollutant | NO |
| HAZCHEM | Not Applicable |

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

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

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

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

Not Applicable

SECTION 15 Regulatory information

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

This substance is to be managed using the conditions specified in an applicable Group Standard

| HSR Number | Group Standard |
|------------|--|
| HSR002578 | Food Additives and Fragrance Materials (Subsidiary Hazard) Group Standard 2017 |

gamma-undecalactone is found on the following regulatory lists

Chemical Footprint Project - Chemicals of High Concern List

New Zealand Approved Hazardous Substances with controls

New Zealand Hazardous Substances and New Organisms (HSNO) Act - Classification of Chemicals

New Zealand Hazardous Substances and New Organisms (HSNO) Act - Classification of Chemicals - Classification Data

New Zealand Inventory of Chemicals (NZIoC)

dodecane, isomers is found on the following regulatory lists

New Zealand Inventory of Chemicals (NZIoC)

2-tert-butylcyclohexyl acetate is found on the following regulatory lists

New Zealand Inventory of Chemicals (NZIoC)

beta-citronellol is found on the following regulatory lists

New Zealand Approved Hazardous Substances with controls
New Zealand Hazardous Substances and New Organisms (HSNO) Act - Classification of Chemicals

New Zealand Hazardous Substances and New Organisms (HSNO) Act - Classification of Chemicals - Classification Data
New Zealand Inventory of Chemicals (NZIoC)

rose ketones is found on the following regulatory lists

New Zealand Inventory of Chemicals (NZIoC)

d-limonene is found on the following regulatory lists

International Agency for Research on Cancer (IARC) - Agents Classified by the IARC Monographs

New Zealand Approved Hazardous Substances with controls

New Zealand Hazardous Substances and New Organisms (HSNO) Act - Classification of Chemicals

New Zealand Hazardous Substances and New Organisms (HSNO) Act - Classification of Chemicals - Classification Data

New Zealand Inventory of Chemicals (NZIoC)

coumarin is found on the following regulatory lists

International Agency for Research on Cancer (IARC) - Agents Classified by the IARC Monographs

New Zealand Approved Hazardous Substances with controls

New Zealand Hazardous Substances and New Organisms (HSNO) Act - Classification of Chemicals

New Zealand Hazardous Substances and New Organisms (HSNO) Act - Classification of Chemicals - Classification Data

New Zealand Inventory of Chemicals (NZIoC)

Hazardous Substance Location

Subject to the Health and Safety at Work (Hazardous Substances) Regulations 2017.

| Hazard Class | Quantity (Closed Containers) | Quantity (Open Containers) |
|----------------|------------------------------|----------------------------|
| Not Applicable | Not Applicable | Not Applicable |

Certified Handler

Subject to Part 4 of the Health and Safety at Work (Hazardous Substances) Regulations 2017.

| Class of substance | Quantities |
|--------------------|----------------|
| Not Applicable | Not Applicable |

Refer Group Standards for further information

Tracking Requirements

Not Applicable

National Inventory Status

| National Inventory | Status |
|-------------------------------|---|
| Australia - AIIC | No (dodecane, isomers) |
| Australia Non-Industrial Use | No (gamma-undecalactone; dodecane, isomers; 2-tert-butylcyclohexyl acetate; beta-citronellol; rose ketones; d-limonene; coumarin) |
| Canada - DSL | Yes |
| Canada - NDSDL | No (gamma-undecalactone; dodecane, isomers; 2-tert-butylcyclohexyl acetate; beta-citronellol; d-limonene; coumarin) |
| China - IECSC | Yes |
| Europe - EINEC / ELINCS / NLP | Yes |
| Japan - ENCS | No (dodecane, isomers) |
| Korea - KECI | Yes |
| New Zealand - NZIoC | Yes |
| Philippines - PICCS | Yes |
| USA - TSCA | No (dodecane, isomers) |
| Taiwan - TCSI | Yes |
| Mexico - INSQ | No (dodecane, isomers) |
| Vietnam - NCI | Yes |
| Russia - ARIPS | No (dodecane, isomers) |
| Legend: | Yes = All CAS declared ingredients are on the inventory No = One or more of the CAS listed ingredients are not on the inventory and are not exempt from listing (see specific ingredients in brackets) |

SECTION 16 Other information

| | |
|----------------------|------------|
| Revision Date | 18/09/2020 |
| Initial Date | 15/09/2020 |

SDS Version Summary

| Version | Issue Date | Sections Updated |
|---------|------------|--------------------------------|
| 3.1.1.1 | 18/09/2020 | Chronic Health, Classification |

Other information

Classification of the preparation and its individual components has drawn on official and authoritative sources as well as independent review by the Chemwatch Classification

committee using available literature references.

The SDS is a Hazard Communication tool and should be used to assist in the Risk Assessment. Many factors determine whether the reported Hazards are Risks in the workplace or other settings. Risks may be determined by reference to Exposures Scenarios. Scale of use, frequency of use and current or available engineering controls must be considered.

Definitions and abbreviations

PC—TWA: Permissible Concentration-Time Weighted Average
PC—STEL: Permissible Concentration-Short Term Exposure Limit
IARC: International Agency for Research on Cancer
ACGIH: American Conference of Governmental Industrial Hygienists
STEL: Short Term Exposure Limit
TEEL: Temporary Emergency Exposure Limit.
IDLH: Immediately Dangerous to Life or Health Concentrations
OSF: Odour Safety Factor
NOAEL :No Observed Adverse Effect Level
LOAEL: Lowest Observed Adverse Effect Level
TLV: Threshold Limit Value
LOD: Limit Of Detection
OTV: Odour Threshold Value
BCF: BioConcentration Factors
BEI: Biological Exposure Index

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