1,2,4,5,7,8-Hexoxonane, 3,6,9-trimethyl-, 3,6,9-tris(Et and Pr) derivs.

Assessment statement (CA09751)

10 May 2024



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AICIS assessment statement (CA09751)

Chemical in this assessment

Name	CAS registry number
1,2,4,5,7,8-Hexoxonane, 3,6,9-trimethyl-, 3,6,9-tris(Et and Pr) derivs.	1613243-54-1

Reason for the assessment

An application for an assessment certificate under section 31 of the *Industrial Chemicals Act* 2019 (the Act).

Certificate Application type

AICIS received the application in a Health Focus type.

Defined scope of assessment

The chemical has been assessed:

- as imported into Australia at up to 20 tonnes/year
- as imported as a formulation containing the assessed chemical at up to 50% concentration
- as used as an initiator at 0.1% concentration in manufacturing of plastics in industrial settings
- as reformulated as a component of plastics at up to 0.005% concentration

Summary of assessment

Summary of introduction, use and end use

The assessed chemical will not be manufactured in Australia. It will be imported into Australia in a peroxide formulation at up to 50% concentration and will be used as an initiator at 0.1% concentration in manufacturing of plastics in industrial settings.

Imported formulations containing the assessed chemical will be transported in either 30 L cans, 205 L drums or 1,000 L plastic intermediate bulk containers (IBCs). At the end use site, the formulation will be transferred into the holding tank using pump or hose type equipment, and then added into the plastic manufacturing line. The plastic manufacturing process is expected to be within an enclosed system. Finished plastics are expected to contain 0-50ppm of the assessed chemical.

Human health

Summary of health and safety hazards

The submitted toxicological data on the assessed chemical as manufactured (in naphtha (petroleum), hydrotreated heavy at up to 50% concentration) and an analogue chemical as manufactured (solvent information not provided) (see **Supporting information**) indicate that the assessed chemical as manufactured is:

- of low acute oral and dermal toxicity
- not irritating to skin and eyes
- not expected to be genotoxic

The submitted data on an analogue (Analogue 1) indicates the assessed chemical as manufactured to be a skin sensitiser, warranting hazard classification (see section below).

Based on the available data from 2 repeated dose toxicity studies, the assessed chemical as manufactured may cause slight myocarditis (inflammation of the heart muscle) and some damage to the liver through prolonged or repeated exposure (see **Supporting information**). However, the severity of these effects was not sufficient to warrant hazard classification for specific target organ toxicity – repeated exposure. In addition, the dose level where adverse effects had occurred in the 90-day study were above the upper limit of classification for repeat dose toxicity.

Some reproductive toxicity effects (one total litter loss and reduction of litter size and offspring viability) were observed at 500 mg/kg bw/day. However, the study authors reported that these effects were not statistically significant, and these effects were seen at doses higher than maternal toxicity dose level (see **Supporting information**).

The applicant has classified the assessed chemical as manufactured as causing aspiration hazard (Category 1). This is supported by the same classification of Analogue 1 on ECHA C&L Inventory. Therefore, the assessed chemical as manufactured is classified for aspiration hazard (Category 1) (see section below).

No inhalation toxicity data were provided of the assessed chemical.

Hazard classifications relevant for worker health and safety

Based on the data provided by the applicant, the assessed chemical as manufactured satisfies the criteria for classification according to the *Globally Harmonized System of Classification and Labelling of Chemicals* (GHS) (UNECE 2017) for hazard classes relevant for worker health and safety as adopted for industrial chemicals in Australia.

Health hazards	Hazard category	Hazard statement
Aspiration hazard*	Asp. Haz. 1	H304: May be fatal if swallowed and enters airways
Skin sensitisation*	Skin Sens. 1B	H317: May cause an allergic skin reaction

Physical hazards	Hazard category	Hazard statement
Flammable liquid*	Flam. Liq. 4	H227: Combustible liquid
Self-reactive substances and mixtures; organic peroxides*	Org. Perox. D	H242: Heating may cause a fire

^{*}The assessed chemical cannot be separated from the manufacturing solvent which functions as a phlegmatizer. Therefore, the relevant studies used for the above classifications were conducted on the chemical in the solvent. Change of the manufacturing solvent may have an impact on the hazard classification of the assessed chemical (as manufactured), as it could not be separated from the manufacturing solvent.

Summary of health risk

Public

The imported formulation containing the assessed chemical will not be available for use by the public. Once bound into plastics, the assessed chemical will not be available for exposure. When introduced and used in the proposed manner, it is unlikely that the public will be exposed to the assessed chemical.

This assessment does not identify any risks to public health that require specific risk management measures.

Workers

Workers may experience dermal, inhalation and incidental ocular exposure to the assessed chemical at up to 50% concentration during handling of formulations containing the assessed chemical. To mitigate the risks to workers from any sensitising effects, aspiration hazards, and repeated exposure, control measures to minimise exposure are required to manage the risks to workers (see **Means for managing risk** section).

Environment

Summary of environmental hazard characteristics

According to domestic environmental hazard thresholds and based on the available data the chemical is:

- Persistent (P)
- Bioaccumulative (B)
- Not Toxic (not T)

Environmental hazard classification

The assessed chemical as manufactured is not toxic to aquatic life up to its limit of solubility. The assessed chemical as manufactured satisfies the criteria for classification as Chronic Category 4 (H413) under the *Globally Harmonized System of Classification and Labelling of Chemicals* (GHS) (UNECE 2017) with consideration given to degradation and bioaccumulation factors.

Environmental Hazard	Hazard Category	Hazard Statement
Hazardous to the aquatic environment (long-term)*	Aquatic Chronic 4	H413: May cause long lasting harmful effects to aquatic life

^{*}The assessed chemical cannot be separated from the manufacturing solvent which functions as a phlegmatizer. The relevant studies for the above classification were conducted on the chemical in the solvent. Change of the manufacturing solvent may have an impact on the hazard classification.

Summary of environmental risk

No significant release of the assessed chemical is expected to occur as a result of its use in the manufacture of articles. The assessed chemical is expected to share the fate of the article it is incorporated into and be disposed of to landfill or collected for recycling at the end of its useful life.

Based on the biodegradation study, the assessed chemical as manufactured is not readily biodegradable and is persistent. The assessed chemical as manufactured has a potential to bioaccumulate. The assessed chemical as manufactured is not toxic to aquatic organisms.

Although the assessed chemical as manufactured is persistent and bioaccumulative, it does not meet all three PBT criteria. It is unlikely to have unpredictable long-term effects. Based on its low hazards and the assessed use pattern, the environmental risks from the introduction of the assessed chemical can be managed.

Means for managing risk

Workers

Recommendation to Safe Work Australia

• It is recommended that Safe Work Australia (SWA) update the *Hazardous Chemical Information System* (HCIS) to include classifications relevant to work health and safety (see **Hazard classifications relevant for worker health and safety**).

Information relating to safe introduction and use

The information in this statement, including recommended hazard classifications, should be used by a person conducting a business or undertaking at a workplace (such as an employer) to determine the appropriate controls under the relevant jurisdiction Work Health and Safety laws.

The following control measures could be implemented to manage the risk arising from exposure to the assessed chemical during handling of formulations containing the assessed chemical:

- Use of engineering controls such as
 - Enclosed and automated systems where possible
 - Adequate workplace ventilation to avoid accumulation of vapours, mists or aerosols

- Use of safe work practices to
 - Avoid contact with skin and eyes
 - Avoid inhalation of vapours, mists or aerosols
- Use of personal protective equipment (PPE)
 - Impervious gloves
 - Protective clothing
 - Safety glasses
 - Respiratory protection
- As the assessed chemical as manufactured is a skin sensitiser, the control measures
 may need to be supplemented with health monitoring for any worker who is at
 significant risk of exposure to the chemical, if valid techniques are available to monitor
 the effect on the worker's health.
- The storage of the assessed chemical should be in accordance with the Safe Work Australia Code of Practice for Managing Risks of Hazardous Chemicals in the Workplace (SWA 2023) or relevant State or Territory Code of Practice.
- A copy of the Safety Data Sheet (SDS) should be easily accessible to workers.

Conclusions

The Executive Director is satisfied that the risks to human health and the environment associated with the introduction and use of the industrial chemical can be managed.

Note:

- 1. Obligations to report additional information about hazards under s 100 of the *Industrial Chemicals Act 2019* apply.
- 2. You should be aware of your obligations under environmental, workplace health and safety and poisons legislation as adopted by the relevant state or territory.

Supporting information

Chemical identity

Chemical name 1,2,4,5,7,8-Hexoxonane, 3,6,9-trimethyl-, 3,6,9-

tris(Et and Pr) derivs.

CAS No. 1613243-54-1

Molecular formula Unspecified

Chemical description

The assessed chemical is an unknown or variable composition, complex reaction product or biological material (UVCB).

Relevant physical and chemical properties

Physical form* Clear liquid

Freezing point* - 26 °C at 101.3 kPa

Boiling point* Decomposes at ~110 °C

Density* 887 kg/m³ at 20 °C

Vapour pressure* 66 Pa at 25 °C (calculated)

Water solubility* 0.06 - 3.1 mg/L

Ionisable in the environment? No

 $\log K_{ow}^*$ 5 – 6 at 30 °C

 $\log K_{\rm oc}^*$ 1.9

Flash point* 63 °C

Dynamic viscosity* 3.2 mPa.s at 20 °C

Kinematic viscosity^ 3.6 mm²/s at 20 °C (calculated)

^{*} The test substance was the assessed chemical in naphtha (petroleum), hydrotreated heavy; (CAS No. 64742-48-9) at up to 50% concentration, as manufactured.

[^] The kinematic viscosity was calculated from the dynamic viscosity measured at 20 °C. Because the GHS criteria for aspiration hazard refers to the kinematic viscosity at 40 °C, no definite category for aspiration hazard could be determined.

Human exposure

Workers

Professional workers may experience dermal, inhalation or incidental ocular exposure to formulations containing the assessed chemical at up to 50% concentration at end use sites when the initiator formulation is transferred from the import containers into the holding tank of machines and during cleaning and maintenance of equipment. The plastic manufacturing process is expected to be within an enclosed system. It is anticipated by the applicant that engineering controls such as enclosed and automated systems and local ventilation will be implemented where possible. Use of appropriate personal protective equipment (PPE) such as impervious gloves, safety glasses, protective clothing, and respiratory protection (where local ventilation may be inadequate) will reduce worker exposure.

Health hazard information

Toxicokinetics

No study data on toxicokinetics, metabolism and distribution of the assessed chemical were provided. Based on the molecular weight (< 500 g/mol) of the assessed chemical, there is potential for the chemical to cross biological membranes. However, absorption is expected to be limited, based on the low water solubility and high partition coefficient of the assessed chemical.

In two repeat dose oral toxicity studies conducted in rats, treatment-related effects were observed in the organs of treated animals, indicating that absorption through the oral route can occur, possibly after hydrolysis of the assessed chemical into more readily absorbed metabolites under physiologically relevant conditions. Chemicals with molecular weights > 100 g/mol would have limited absorption through the dermal route.

Acute toxicity

Oral

In an acute oral toxicity study (OECD TG 423), the test substance (the assessed chemical in naphtha (petroleum), hydrotreated heavy at up to 50% concentration) was administered to two groups of female Wistar rats (n = 3 per group) at a single dose of 2,000 mg/kg bw via oral gavage. All animals survived during the 14-day observation period and no signs of systemic toxicity were noted. All animals showed expected body weight gains and no treatment-related gross necropsy findings were observed. The acute oral median lethal dose (LD50) of the test substance was determined to be > 2,000 mg/kg bw.

Dermal

In an acute dermal toxicity study (OECD TG 402), three female Sprague-Dawley rats had the test substance (the assessed chemical in naphtha (petroleum), hydrotreated heavy at up to 50% concentration) applied at 2,000 mg/kg bw for a 24-hour contact period under semi-occlusive conditions. All animals survived during the 14-day observation period. No signs of treatment-related systemic toxicity were noted. Erythema was observed on the treated site in 2/3 animals, but had recovered by Day 4. All animals showed expected body weight gains over

the study period. The acute dermal LD50 of the test substance was determined to be > 2,000 mg/kg bw.

Corrosion/Irritation

Skin irritation

In an *in vitro* skin irritation study (OECD TG 439 - EPISKIN™ model) conducted on the assessed chemical as manufactured (in naphtha (petroleum), hydrotreated heavy at up to 50% concentration), the relative mean viability of the test substance-treated tissues was 54.1% after a 15-minute exposure period and a 42-hour incubation period. As the tissue viability was > 50%, the test substance is identified as not requiring classification for skin irritation.

Eye irritation

In an *in vitro* eye irritation study (OECD TG 492 - EpiOcularTM model) conducted on the assessed chemical as manufactured (in naphtha (petroleum), hydrotreated heavy at up to 50% concentration), the relative mean viability of the test substance-treated tissues was 97.2% after 30 minutes of exposure. As the tissue viability was > 60%, the test substance is identified as not requiring classification for eye irritation.

In an *in vitro* eye irritation study (OECD TG 437) conducted on the assessed chemical as manufactured (in naphtha (petroleum), hydrotreated heavy at up to 50% concentration), the *in vitro* irritancy score (IVIS) of the test substance was calculated as 0.1, after a 10-minute exposure period and a 120-minute incubation period. As the IVIS was \leq 3, the test substance is identified as not requiring classification for eye irritation.

Sensitisation

Skin sensitisation

No skin sensitisation data were submitted on the assessed chemical. In a skin sensitisation study (OECD TG 406 - Magnusson-Kligman Test) conducted on an analogue, 1,2,4,5,7,8-hexoxonane, 3,6,9-triethyl-3,6,9-trimethyl- (CAS No. 24748-23-0) as manufactured (solvent information not provided), 10 male guinea pigs (Dunkin-Hartley Albino) were injected with the test substance (at 10% concentration). Seven days after injection, the animals were topically applied with the test substance (at 100% concentration). Three weeks after the topical induction, the animals were challenged with the test substance applied topically at both 75% and 100% concentrations. Of the animals challenged at 100% concentration, 5/10 showed positive skin reactions (discrete, patchy erythema) at the 24- and 48-hour observations while no skin reactions were noted in the control group. Based on the results of the analogue, the assessed chemical is expected to be a skin sensitiser, warranting hazard classification for skin sensitisation (Category 1B, H317: May cause an allergic skin reaction) according to the GHS criteria.

Repeat dose toxicity and reproductive and development toxicity

Oral

In a combined repeated dose toxicity study with the reproduction/developmental toxicity screening test (OECD TG 422), the assessed chemical as manufactured (in naphtha

(petroleum), hydrotreated heavy at up to 50% concentration) was administered to Wistar rats (n = 12/sex/group) by oral gavage at 0, 50, 150 and 500 mg/kg bw/day for up to 56 days.

There were no unscheduled deaths. Increased salivation was observed in some animals treated at 150 and 500 mg/kg bw/day. A reduction in body weight gain was observed in animals of both sexes treated at 500 mg/kg bw/day at different stages of the study. Animals of either sexes treated at 500 mg/kg bw/day and males treated at 150 mg/kg bw/day showed reductions in various haemoglobin-related parameters. Females treated at 500 mg/kg bw/day showed increases in erythrocyte count, lymphocytes and total leukocyte count. Animals of either sexes treated at 500 mg/kg bw/day showed increases in total protein and alanine aminotransferase. Females treated at 500 mg/kg bw/day also showed increases in bile acid, bilirubin, cholesterol and aspartate aminotransferase. Males treated at 500 mg/kg bw/day showed an increase in blood sodium concentration. Females treated at 150 or 500 mg/kg bw/day showed a reduction in albumin/globulin ratio.

Of the males treated at 500 mg/kg bw/day, 7/12 had an enlarged liver, 5/12 had a dark liver, 6/12 had mottled kidneys and 4/12 had enlarged kidneys. Of the females treated at 500 mg/kg bw/day, 4/12 had an enlarged liver and 3/12 had a dark liver. Animals of either sex in the 500 mg/kg bw/day dose group and males in the 150 mg/kg bw/day dose group showed a statistically significant increase in absolute and relative liver and spleen weights. Males from the 150 and 500 mg/kg bw/day dose group also showed a statistically significant increase in absolute and relative kidney weights. Myocarditis (inflammation of the heart muscle) was observed in all male treatment groups. It was noted in 3/5 males of the low dose group, 4/5 of the mid dose group and 5/5 of the high dose group. However, the severity was graded as minimal to mild in all three groups. A variety of effects in the liver, including hypertrophy, bile duct hyperplasia, pigment in bile ducts, peribiliary inflammation, single cell necrosis and increased glycogen were observed in both sexes treated at 500 mg/kg bw/day. Most of the liver findings were also observed in both sexes treated at 150 mg/kg bw/day and males treated at 50 mg/kg bw/day. The severity of the single cell necrosis was reported to be of a minimal degree and the severity of the other findings was indicated to be minimal to mild and up to moderate at 500 mg/kg bw/day. Hypertrophy was also observed in females treated at 50 mg/kg bw/day, but the study authors considered the finding to be an adaptive response. Hyaline droplets were evident in the kidneys of all male treatment males. Tubular basophilia were observed in males treated at 150 or 500 mg/kg bw/day and granular casts were observed in males treated at 500 mg/kg bw/day.

A total litter loss was observed in one female treated at 500 mg/kg bw/day. Reduction in litter size and offspring viability was slightly reduced in females treated at 500 mg/kg bw/day, but these reductions were not statistically significant. Litter weight, offspring body weight gain and male offspring body weight from females treated at 500 mg/kg bw/day had a statistically significant reduction. Statistically significant reduction in surface righting reflex and increase in number of dead or missing pups were also observed in females treated at 500 mg/kg bw/day.

The No Observed Adverse Effect Level (NOAEL) for systemic toxicity was reported as 50 mg/kg bw/day for females. No NOAEL for males was reported as all treatment groups showed myocarditis and changes in the liver. The NOAEL for reproductive and developmental toxicity was considered by the study authors to be 150 mg/kg bw/day, based on reductions in offspring viability, offspring body weight gain, litter size and litter weights on Days 1 and 4 *post partum* at 500 mg/kg bw/day.

In a repeated dose oral toxicity study (OECD TG 408), the assessed chemical as manufactured (in naphtha (petroleum), hydrotreated heavy at up to 50% concentration) was administered to Wistar rats (n = 10/sex/group) by oral gavage at 0, 10, 30 and 120 mg/kg bw/day for 90 days.

There were no unscheduled deaths. Males and females treated at 120 mg/kg bw/day showed a statistically significant increase in absolute (5% for males and 13% for females) and relative (13% for males and 22% for females) liver weight. Males treated with 120 mg/kg bw/day had a statistically significant increase in absolute and relative kidney weight. Some of the liver effects persisted during the recovery period. Related histopathological changes found in these animals included:

- minimal to mild bile duct hyperplasia in 5/10 males (persisted but at a lower incidence and severity following the recovery period)
- minimal to moderate pigment deposits in the bile ducts of 7/10 males (still observed in 5 males following the recovery period but at a minimal degree)
- minimal centrilobular hypertrophy in livers of 5/10 males and 7/10 females (completely recovered following the recovery period)

Based on the following results, the NOAELs were reported as 30 mg/kg bw/day for males and 120 mg/kg bw/day for females, as the liver changes observed in females were considered by the study authors to be adaptive responses.

Genotoxicity

A mixture containing the assessed chemical in naphtha (petroleum), hydrotreated heavy at up to 50% concentration was found to be non-mutagenic in a bacterial reverse mutation assay (OECD TG 471) using TA1535, TA1537, TA98 and TA100 strains of *Salmonella typhimurium* and WP2*uvrA* strain of *Escherichia coli*.

The mixture was also negative in an *in vitro* mammalian cell gene mutation test (OECD TG 476) using the thymidine kinase (TK +/-) locus of the L5178Y mouse lymphoma cell line.

Environmental exposure

The assessed chemical as manufactured will be imported into Australia as a component of an initiator for the modification of plastics. Significant releases of the assessed chemical from transport or transfer are not expected. If spills or accidental releases of the assessed chemical do occur, they are expected to be collected by suitable absorbents and disposed of in accordance with State and local government regulations.

The assessed chemical will be used in the manufacture of articles at industrial sites. The assessed chemical will be mixed with other components, automatically dispensed to moulds, and allowed to cure. Once cured into the matrix of the article, there will be limited exposure to the aquatic environment. The assessed chemical is expected to share the fate of the article it is incorporated into and be disposed of to landfill at the end of its useful life.

Environmental fate

Partitioning

The assessed chemical as manufactured is slightly soluble in water and if released into the environment, it is expected to partition to soils and sediments. This is supported by the partition coefficient (Log Kow = 5 - 6) for the assessed chemical as manufactured.

The assessed chemical as manufactured is moderately volatile (vapour pressure = 66 Pa at 25 °C). A considerable proportion of the assessed chemical is expected to evaporate and partition to air when released to water.

Degradation

Based on the measured biodegradation in water, the assessed chemical as manufactured is persistent.

Degradation studies conducted on the assessed chemical as manufactured indicate that the mixture is not readily biodegradable. Test results demonstrated 7% degradation after 28 days (OECD TG 301D).

Bioaccumulation

Based on its log Kow value, the assessed chemical as manufactured has the potential to bioaccumulate.

No bioaccumulation information was provided for the assessed chemical. The experimental partition coefficient of the assessed chemical as manufactured is in the range of log Kow 5 - 6, which is above the domestic bioaccumulation threshold of log Kow = 4.2 (EPHC, 2009).

Predicted environmental concentration (PEC)

The predicted environmental concentration (PEC) has not been calculated as release of the assessed chemical to the aquatic environment will be negligible based on its assessed use pattern.

Environmental effects

Effects on aquatic Life

Acute toxicity

The following key measured median lethal loading (LL50) and effective loading (EL50) values for model organisms were supplied for the assessed chemical as manufactured:

Taxon	Endpoint	Method
Fish	96 h LL50 > 100 mg/L (WAF)	Oncorhynchus mykiss (Rainbow trout), Mortality OECD TG 203 Semi-static conditions Measured concentration
Invertebrate	48 h EL50 > 116.3 mg/L (WAF)	Daphnia magna (water flea) Immobility OECD TG 202 Semi-static conditions Nominal concentration
Algae	72 h EL50 > 608.5 mg/L (WAF)	Raphidocelis subcapitata (green algae) Growth rate OECD TG 201 Static conditions Nominal concentration

Chronic toxicity

The following measured 10th-percentile effective concentration (EC10) and effective loading values for model organisms were supplied by the applicant for the assessed chemical as manufactured.

Taxon	Endpoint	Method
Invertebrates	21 d EC10 = 2.7 mg/L (WAF)	Daphnia magna (water flea) Reproduction OECD TG 211 Semi-static conditions Measured concentration
Algae	72 h ErL10 = 18.6 mg/L (WAF)	Raphidocelis subcapitata (green algae) Growth rate OECD TG 201 Static conditions Nominal concentration

Predicted no-effect concentration (PNEC)

A Predicted no-effect concentration was not calculated for the assessed chemical as the assessed chemical as manufactured was not harmful to aquatic life across all trophic levels in the studies supplied.

Categorisation of environmental hazard

The categorisation of the environmental hazards of the assessed chemical as manufactured according to domestic environmental hazard thresholds is presented below:

Persistence

Persistent (P). Based on measured degradation studies, the assessed chemical as manufactured is categorised as Persistent.

Bioaccumulation

Bioaccumulative (B). Based on the measured log K_{OW} value indicating a potential to bioaccumulate, the assessed chemical as manufactured is categorized as Bioaccumulative.

Toxicity

Not toxic (Not T). Based on available acute ecotoxicity values above 1 mg/L and a chronic ecotoxicity value above 0.1 mg/L, the assessed chemical as manufactured is categorised as Not Toxic.

Environmental risk characterisation

Although the assessed chemical as manufactured is persistent and bioaccumulative, the mixture does not meet all three PBT criteria and is hence unlikely to have unpredictable long-term effects (EPHC 2009). A Risk Quotient (PEC/PNEC) for the aquatic compartment could not be calculated. However, the assessed chemical as manufactured is not expected to be harmful to aquatic life, and release of the assessed chemical to the aquatic environment will be negligible based on its assessed use pattern.

Thus, based on the low hazard of the assessed chemical as manufactured and the assessed use pattern, the risk from the assessed chemical can be managed.

References

EPHC (2009) Environment Protection and Heritage Council, Environmental Risk Assessment Guidance Manual for industrial chemicals, Prepared by: Chris Lee-Steere Australian Environment Agency Pty Ltd, February 2009. ISBN 978-1-921173-41-7.

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