



Australian Government

Department of Health and Aged Care

Australian Industrial Chemicals Introduction Scheme

7-Nonenal, 6,8-dimethyl-

Assessment statement (CA09706)

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Final



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AICIS assessment statement (CA09706)

Chemical in this assessment

Name	CAS registry number
7-Nonenal, 6,8-dimethyl-	899810-84-5

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 Very Low to Low Risk type.

Defined scope of assessment

The chemical has been assessed:

- as a fragrance component imported into Australia at up to 1 tonne/year
- as imported in fragrance formulations at up to 1% concentration for reformulation of end use cosmetics and household products
- as imported or reformulated in continuous action air fresheners at up to 1% concentration, in fine fragrances at up to 0.2% concentration, in instant action air fresheners at up to 0.1% concentration, and in other cosmetic and household products at up to 0.02% concentration

Summary of assessment

Summary of introduction, use and end use

The assessed chemical will not be manufactured in Australia. It will be imported either in fragrance formulations at up to 1% concentration or in end use cosmetic and household products at various concentrations as shown below:

Product type	Proposed end use concentration (%)
Continuous action air fresheners	1.0
Fine fragrance	0.2
Instant action air fresheners	0.1
Other leave-on and rinse-off cosmetic products	0.02

Product type	Proposed end use concentration (%)
Other household products	0.02

The cosmetic and household end use products containing the chemical are proposed to be used by professional workers under industrial or non-industrial settings and by members of the general public.

Human health

Summary of health hazards

The submitted toxicological data on the assessed chemical (see **Supporting information** section) indicate that the assessed chemical is:

- of low acute oral toxicity
- slightly irritating to skin
- slightly irritating to eyes
- expected to be a weak skin sensitiser
- not expected to be genotoxic

The submitted data warrant hazard classification of skin sensitisation Cat. 1B for the assessed chemical (see section below).

No data on inhalation toxicity and repeated dose toxicity was provided.

Hazard classifications relevant for worker health and safety

The assessed chemical 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 as follows:

Health hazards	Hazard category	Hazard statement
Skin sensitisation	Skin Sens. 1B	H317: May cause an allergic skin reaction

Physical hazards	Hazard category	Hazard statement
Flammable Liquid*	Flam Liq Cat 4	H227: Combustible Liquid

* Classified based on measured flash point at 90.5°C (See **Supporting information** section)

Summary of health risk

Public

There will be widespread and repeated exposure of the public to the assessed chemical at up to 1% concentration through the use of a wide range of cosmetic and household products. The principal route of exposure will be dermal and inhalation, while incidental oral or ocular

exposure is also possible. Inhalation exposure occurs particularly from the use of air care products and other products applied by spray.

The assessed chemical in neat form is expected to be a weak skin sensitiser and is slightly irritating to skin and eyes. However, these effects are not expected to occur from use of the assessed chemical at the proposed low end use concentrations (up to 0.2%) in cosmetic and household products except for continuous action air fresheners (up to 1%). The continuous action air fresheners are not expected to come into direct contact with skin or eyes due to designed nature of the products.

No inhalation toxicity data were provided for the assessed chemical. Due to low concentrations of the assessed chemical in the end use products, it is not expected to pose health risk through inhalation when the assessed chemical is used according to the assessed use scenarios.

No repeated dose toxicity data were provided on the assessed chemical. Based on the quantitative risk assessment (QRA) for the worst case scenario, consumers simultaneously using multiple cosmetics and household products may be systemically exposed to the assessed chemical at approximately 63 µg/kg bw/day through repeated or prolonged exposure (see **Supporting information** section). Considering the low systemic exposure level to the assessed chemical, health risks from repeated exposure to the public are not expected.

Overall, this assessment does not identify any risks to public health that would require specific risk management measures if the assessed chemical is introduced and used in accordance with the terms of the assessment certificate.

Workers

Reformulation workers may be incidentally exposed to the assessed chemical at up to 1% concentration during reformulation processes mainly via the dermal route, while ocular and inhalation exposures are also possible. To mitigate potential repeated exposure risks to reformulation workers, control measures would be required (see **Means for managing risk**) to minimise the exposure. It is anticipated by the applicant that engineering controls such as enclosed and automated processes and local ventilation will be implemented where possible. Use of appropriate personal protective equipment (PPE) such as safety glasses, impervious chemical resistant gloves, protective clothing and respiratory protection will reduce worker exposure.

Professional workers in cleaning or cosmetic businesses may experience exposure via dermal, inhalation and accidental ocular exposure to the assessed chemical during the use of cleaning or cosmetic products containing the assessed chemical at up to 0.2% concentration. The professional workers may wear some PPE (including gloves, safety glasses, coveralls and face masks). If PPE is used, exposure of such workers is expected to be of a similar or lesser extent than that experienced by consumers using the same end use products containing the assessed chemical, requiring no specific risk management measures for these workers.

Environment

Summary of environmental hazard characteristics

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

- Not Persistent (Not P)

- Not Bioaccumulative (Not B)
- Toxic (T)

Environmental hazard classification

The chemical satisfies the criteria for classification according to the GHS (UNECE 2017) as Acute Category 1 (H400) based on the toxicity data for algae.

Environmental Hazard	Hazard Category	Hazard Statement
Hazardous to the aquatic environment (acute / short-term)	Aquatic Acute 1	H400: Very toxic to aquatic life

Summary of environmental risk

The assessed chemical will be introduced as a fragrance ingredient for use in a variety of cosmetic and household products. These end uses will result in the release of the assessed chemical to sewers and to air.

The assessed chemical is readily biodegradable and is not persistent. The assessed chemical has a low potential for bioaccumulation and is toxic to aquatic organisms.

As the assessed chemical does not meet all three PBT criteria it is unlikely to have unpredictable long-term effects and its risk may be estimated by the risk quotient method ($RQ = PEC \div PNEC$). Based on the expected RQ values < 1 for the river and ocean compartments, it is expected that the environmental risk from the introduction and use of the assessed chemical can be managed.

Means for managing risk

Workers

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.

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 following control measures should be implemented to manage the risk arising from exposure to the assessed chemical during reformulation:
 - Use of engineering controls such as
 - automated and enclosed systems where possible
 - adequate workplace ventilation to avoid accumulation of vapours, mists, or aerosols

- Use of safe work practices to
 - avoid contact with eyes and skin
 - avoid inhalation of vapours, mists or aerosols
- Use of personal protective equipment (PPE)
 - overalls
 - gloves
 - respiratory protection if required
- These 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.
- A copy of the Safety Data Sheet (SDS) should be easily accessible to workers.

Conclusions

The conclusions of this assessment are based on the information described in this statement.

Considering the means of managing risks, the Executive Director is satisfied that when the assessed chemical is introduced and used in accordance with the terms of the assessment certificate the human health and environment risks can be managed within existing risk management frameworks. This is provided that all requirements are met under environmental, workplace health and safety, and poisons legislation as adopted by the relevant state or territory, and the means for managing the risks identified during this assessment are implemented.

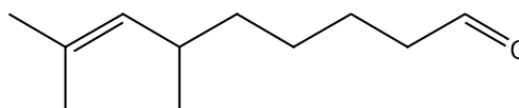
Note: Obligations to report additional information about hazards under section 100 of the *Industrial Chemicals Act 2019* apply.

Supporting information

Chemical identity

Chemical name	7-Nonenal, 6,8-dimethyl-
CAS No.	899810-84-5
Synonyms	6,8-Dimethyl-7-nonenal
Molecular formula	C ₁₁ H ₂₀ O
Molecular weight (g/mol)	168.28
SMILES (Canonical)	O=CCCCC(C=C(C)C)C
Purity	> 90 - < 100% (w/w)

Representative Structure:



Chemical description

The assessed chemical is a mixture of two stereoisomers (R and S).

Relevant physical and chemical properties

Physical form	Pale-yellow liquid
Melting point	-121.1 ± 0.1 °C
Boiling point	202.4 ± 0.4 °C
Density	0.848 g/mL at 20.3 °C
Vapour pressure	0.068 kPa at 20 °C, 0.085 kPa at 25 °C
Water solubility	34.8 mg/L at 20 °C, pH 7.02 - 7.05
Ionisable in the environment	No
log K _{ow}	3.87 at 20 °C
log K _{oc}	1.95 - 2.84 (calc)

Flash point

90.5 °C (close cup)

Human exposure

Public

There will be widespread and repeated exposure of the public to the assessed chemical at up to 0.2% concentration through the use of a range of cosmetic and household products and up to 1% concentration when using continuous action air fresheners. The main routes of exposure will be dermal and inhalation, while incidental oral or ocular exposures are also possible.

Dermal exposure

Data on typical use patterns of cosmetic products (SCCS 2012; Cadby et al. 2002; ACI 2010; Loretz et al. 2006) in which the assessed chemical may be used are shown in the following table. A dermal absorption (DA) rate of 100% was used as a worst-case scenario along with a combined average body weight (BW) for males and females of 70 kg (enHealth 2012) for calculation purposes.

Product type	Amount (mg/day)	C (%)	RF	Daily systemic exposure (µg/kg bw/day)
Body lotion	7,820	0.02	1	22
Face cream	1,540	0.02	1	4
Hand cream	2,160	0.02	1	6
Fine fragrances	750	0.2	1	21
Deodorant (non-spray)	1,500	0.02	1	4
Shampoo	10,460	0.02	0.01	0
Conditioner	3,920	0.02	0.01	0
Shower gel	18,670	0.02	0.01	1
Hand wash soap	20,000	0.02	0.01	1
Hair styling products	4,000	0.02	0.1	1
Total				61

C = maximum intended concentration of assessed chemical; RF = retention factor

Daily systemic exposure = (Amount × C × RF × DA)/BW

Dermal exposure from using household cleaning products and wearing clothes will result in additional 1 µg/kg bw/day systemic exposure, considering low concentrations and retention factors of these products.

Inhalation exposure

Hairspray was taken as a worst-case scenario example for the inhalation exposure assessment. A 2-zone approach was used (Steiling et al. 2014; Rothe et al. 2011; Earnest Jr. 2009). An adult inhalation rate of 20 m³/day (enHealth 2012) was used and it was conservatively assumed that the fraction of the assessed chemical inhaled is 50%.

Amount of hairspray applied	9.89 g/day
Maximum intended concentration of the chemical	0.02 %
Inhalation rate of the user	20 m ³ /day
Exposure duration in zone 1	1 minutes
Exposure duration in zone 2	20 minutes
Fraction inhaled by the user	50 %
Volume of zone 1	1 m ³
Volume of zone 2	10 m ³
Daily systemic exposure	1 µg/kg bw/day

C = maximum intended concentration of assessed chemical

Total daily systemic exposure = Daily systemic exposure in zone 1 [(amount × C × inhalation rate × exposure duration (zone 1) × fraction inhaled)/(volume (zone 1) × body weight)] + Daily systemic exposure in zone 2 [(amount × C × inhalation rate × exposure duration (zone 2) × fraction inhaled)/(volume (zone 2) × body weight)]

It is acknowledged that inhalation exposure to the assessed chemical from use of other cosmetic and household products may also occur.

Overall, the worst-case scenario estimation is for a person who is a simultaneous user of all products listed in the above tables that contain the assessed chemical at the maximum intended concentrations specified in various product types. This would result in a combined internal dose of 63 µg/kg bw/day (= 0.063 mg/kg bw/day) for the assessed chemical. This low level of worst-case systemic exposure is unlikely to pose health risk to the public with repeated use of products containing the assessed chemical.

Health hazard information

The results from toxicological investigations conducted on the assessed chemical provided by the applicant are summarised in the following table.

Endpoint	Test guideline	Results and Conclusion
Rat, acute oral toxicity	OECD TG 423	LD50 > 2,000 mg/kg bw; low toxicity
Rabbit, skin irritation	OECD TG 404	Slightly irritating
Rabbit, eye irritation	OECD TG 405	Slightly irritating
Skin sensitisation – Guinea pig maximisation test	OECD TG 406	Evidence of sensitisation
Skin sensitisation – LLNA	OECD TG 429	Weak sensitiser
Mutagenicity – bacterial reverse mutation	OECD TG 471	Non mutagenic
Genotoxicity – in vitro mammalian chromosome aberration test	OECD TG 473	Non clastogenic

Acute toxicity

Oral

In the acute toxicity study (OECD TG 423), the assessed chemical was administered by oral gavage to 6 Sprague Dawley rats at the single dose of 2,000 mg/kg bw. No mortality occurred during the study. Clinical observations included a decrease in spontaneous activity (6/6) at the 1-hour observation, which persisted until the 4-hour observation. Piloerection (2/6) was also observed at the 4-hour observation. No clinical signs were noted at the 24-hour observation. Changes in body weight in all animals were comparable to control. No treatment-related macroscopic changes were observed in any treated animals at the end of the study. Based on the results of this study, the assessed chemical is of low acute oral toxicity.

Corrosion/Irritation

Skin irritation

The assessed chemical was tested in rabbits (OECD TG 404). A single 4-hour, semi-occluded application of the chemical to the intact skin of 3 rabbits produced well-defined erythema and slight oedema in all animals at the 1-hour observation. Well-defined erythema (maximum score of 2) and very slight to slight oedema (maximum score of 2) were observed in all animals until the 72-hour observation. Dryness at the test site was noted in 2 animals at the Day 3 observation and in the remaining animal at the Day 6 observation. At the 14-day observation, slight dryness of the skin was observed in one animal at the test site. Under the conditions of this study, the assessed chemical is slightly irritating to the skin but does not meet the GHS criteria as adopted by Australia for industrial chemicals.

Eye irritation

The assessed chemical was tested for eye irritation using 3 rabbits (OECD TG 405). A single application of the chemical produced no iridial effects. Slight to moderate conjunctival irritation (maximum score of 2) was noted in treated eyes 24 hours after treatment, which persisted until the 72-hour observation. Slight corneal opacity was observed in 1 animal at the 48-hour

observation. Treated eyes appeared normal at the 7-day observation. Based on the results of this study, the assessed chemical was considered slightly irritating to the eyes.

Sensitisation

Skin sensitisation

The skin sensitisation potential of the assessed chemical was tested using a guinea pig maximisation test (GPMT) (OECD TG 406). Following preliminary tests, an intradermal induction concentration of 6.25% and topical induction concentration of 100% were used, with a single topical application at 6.25% and 12.5% concentrations used for challenge after 10 days rest period following induction.

Slight to moderate erythema was present in 5/10 animals at 24 hours after challenge with 12.5% concentration, with slight erythema remaining in 3/10 animals at the 48-hour time point and 1/10 at the 72-hour time point. Slight to moderate erythema was recorded in 1/10 animals at all time points (24, 48 and 72 hour) after the challenge with 6.25% concentration, indicating the test substance as a skin sensitiser.

The skin sensitisation potential of the assessed chemical was further assessed using a local lymph node assay (LLNA) in mice (OECD TG 429). The mice were treated by daily application of 25 µL of the assessed chemical at concentrations of 25%, 50% or 100% using acetone/olive oil 4:1 as vehicle to the dorsal surface of each ear for 3 consecutive days.

There were no signs of systemic toxicity and body weights were comparable to controls. Slight dryness of the eye, an increase in ear thickness (18.9%) and ear weight (8.3%) was observed at Day 6 observation in the group treated with 100% of the assessed chemical. The stimulation index (SI) at the 25%, 50% and 100% concentrations were 1.40, 1.71 and 1.79, respectively. The concentration of the test substance expected to cause a 1.4-fold increase in lymph node cell number (EC1.4 value) was calculated (by linear interpolation) to be 25%. According to the study author, the assessed chemical is a weak skin sensitiser.

Based on the results of these studies, the assessed chemical is considered a skin sensitiser requiring hazard classification for Skin Sensitisation (Cat 1B: H317: May cause an allergic skin reaction) according to GHS criteria.

Genotoxicity

The assessed chemical was found to be non mutagenic in a bacterial reverse mutation assay (OECD TG 471). The assessed chemical was also found to be non clastogenic in an in vitro mammalian chromosome aberration test using human peripheral blood lymphocytes (OECD TG 473).

Environmental exposure

The assessed chemical will be imported into Australia for use as a fragrance in end use cosmetic and household products, or as a component of fragrance formulations for reformulation into the end use products. Reformulation and repackaging will occur in both closed and open processes. Significant releases of the assessed chemical to the environment are not expected during reformulation, transport or storage.

The assessed chemical will be included in a wide range of products, resulting in a variety of potential exposure scenarios.

Consumer and professional end use of the assessed chemical in polish and wax blends, cosmetic products, washing, cleaning and disinfection products is expected to result in the release of the assessed chemical “down the drain” and into the sewers. Consequently, the assessed chemical will be treated at sewage treatment plants (STPs) before release to surface waters.

Use of the assessed chemical in air-care products will result in direct release of the assessed chemical into the air compartment.

Environmental fate

Partitioning

The assessed chemical is moderately soluble in water (water solubility = 34.8 mg/L at 20 °C). If the assessed chemical is released to surface water, a proportion of the assessed chemical is expected to remain in the water compartment and a proportion of the chemical is expected to partition to sediments based on its moderate water solubility and high log K_{OW} value (log K_{OW} = 3.87).

The assessed chemical is volatile (vapour pressure = 85 Pa at 25 °C). A moderate proportion of the assessed chemical is expected to partition to air during STP processing based on SimpleTreat 3.0 model outputs (Struijs, 1996). Additionally, when the assessed chemical is released to air it is not expected to partition to other compartments.

Degradation

Based on its measured degradation in water, the assessed chemical is categorised as not persistent.

The result of a supplied biodegradation study conducted using the OECD 301D test guideline (oxygen consumption) demonstrated 75% degradation of the assessed chemical in 28 days, fulfilling the 14-day window criterion for ready biodegradability. Therefore, the assessed chemical is categorised as readily biodegradable in water.

The half-life of the assessed chemical in air is calculated to be 1.082 hours, based on reactions with hydroxyl radicals (US EPA, 2012; calculated using AOPWIN v1.92). As its calculated half-life in air is below the domestic threshold value of 2 days, the assessed chemical is not expected to persist in the air compartment.

Bioaccumulation

No bioaccumulation information was provided for the assessed chemical. The experimental partition coefficient of the assessed chemical (log K_{OW} = 3.87) is below the domestic bioaccumulation threshold of log K_{OW} = 4.2 (EPHC, 2009). Therefore, bioaccumulation of the assessed chemical is not expected.

Predicted environmental concentration (PEC)

A predicted environmental concentration (PEC) for Australian waters was calculated assuming 100% of the introduction volume is released into sewage treatment plants (STP) over 365 days

per annum. The extent to which the assessed chemical is removed from the effluent in STP processes is based on its physicochemical properties, modelled by SimpleTreat 3.0 (Struijs, 1996).

Based on the partitioning and biodegradability of the assessed chemical, most of the assessed chemical is expected to volatilise (46%) or biodegrade (34%) with a minor amount partitioning to sludge (15%). Total removal during STP treatment is estimated to be 96%. Therefore, 4% of the total introduction volume is estimated to be released to the aquatic environment.

This calculated value is conservative as not all uses of the assessed chemical are expected to result in release to STP.

The calculation of the PEC is detailed in the table below:

Total Annual Import Volume	1,000	kg/year
Proportion expected to be released to sewer	100%	
Annual quantity of chemical released to sewer	1,000	kg/year
Days per year where release occurs	365	days/year
Daily chemical release	2.74	kg/day
Water use	200.0	L/person/day
Population of Australia	25.423	Million
Removal within STP	96%	Mitigation
Daily effluent production	5,085	ML/day
Dilution Factor - River	1	
Dilution Factor - Ocean	10	
PEC - River	0.03	µg/L
PEC - Ocean	0.003	µg/L

Environmental effects

Effects on aquatic Life

Acute toxicity

The following calculated median lethal concentration (LC50) and calculated median effective concentration (EC50) values for model organisms were supplied for the assessed chemical:

Taxon	Endpoint	Method
Fish	96 h LC50 = 1.9 mg/L	<i>Danio rerio</i> (zebra fish) Mortality iSafeRat HA-QSAR v1.8 Ecotox module Calculated concentration
Invertebrate	48 h EC50 = 1.2 mg/L	<i>Daphnia magna</i> (water flea) Growth rate iSafeRat HA-QSAR v1.8 Ecotox module Calculated concentration
Algae	72 h EC50 = 0.43 mg/L	<i>Desmodesmus subspicatus</i> (green algae) Growth rate iSafeRat HA-QSAR v1.8 Ecotox module Calculated concentration

Predicted no-effect concentration (PNEC)

A predicted no-effect concentration (PNEC) of 0.43 µg/L was calculated for the assessed chemical in the aquatic environment. This value was derived using the endpoint value for algae (0.43 mg/L). An assessment factor of 1,000 was applied to this endpoint as only in silico acute toxicity data were provided for all three trophic levels (EPHC, 2009).

Categorisation of environmental hazard

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

Persistence

Not Persistent (Not P). Based on a measured degradation study, the assessed chemical is categorised as Not Persistent.

Bioaccumulation

Not Bioaccumulative (Not B). Based on a measured log K_{OW} value, below domestic threshold, the assessed chemical is categorised as Not Bioaccumulative.

Toxicity

Toxic (T). Based on an ecotoxicity value below 1 mg/L, the assessed chemical is categorised as Toxic.

Environmental risk characterisation

Although the assessed chemical is toxic, it does not meet all three PBT criteria. It is hence unlikely to have unpredictable long-term environmental effects (EPHC 2009). An estimate of risk may therefore be determined using the risk quotient method.

Based on the PEC and PNEC values determined above, Risk Quotients (RQ = PEC ÷ PNEC) have been calculated for release of the assessed chemical to water, soil and sediment:

Compartment	PEC	PNEC	RQ
River	0.03	0.43	0.063
Ocean	0.003	0.43	0.006

For the river and ocean compartments, a RQ less than 1 indicates that introduction of the assessed chemical, in line with the terms outlined in this assessment statement, is not expected to pose a significant risk to the environment. As such, the risk from the assessed chemical can be managed, based on consideration of the environmental hazard characteristics and estimated releases.

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