Australian Government
Department of Health and Aged Care
Australian Industrial Chemicals Introduction Scheme

9-Decen-2-one

Assessment statement (CA09709)

25 September 2023

Final

Table of contents

AICIS assessment statement (CA9709)

Chemical in this assessment

Name	CAS registry number
9-Decen-2-one	35194-30-0

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 cosmetic or household products
- as imported or reformulated in continuous action air fresheners at up to 0.5% concentration, in fine fragrances and instant action air fresheners at up to 0.05% 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	0.5
Fine fragrance	0.05
Instant action air fresheners	0.05
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**) indicate that the assessed chemical:

- is slightly irritating to skin and eyes
- is expected to be a weak skin sensitiser
- is not expected to cause systemic effects following repeated exposure (up to 500 mg/kg bw/day in rats)
- is not mutagenic in a bacteria reverse mutation assay

The submitted data warrant hazard classification of specific target organ toxicity - single exposure (STOT SE) Cat. 3 for the assessed chemical (see section below).

No data on inhalation toxicity of the chemical was provided.

Hazard classifications relevant for worker health and safety

The 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
Specific target organ toxicity (single exposure)	STOT Single Exp. 3	H336: May cause drowsiness or dizziness

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

* Classified based on measured flash point at 88 °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 0.5% 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 is slightly irritating to skin and eyes. However, irritation effects are not expected to occur from use of the assessed chemical at the proposed low end use concentrations in cosmetic and household products (up to 0.05%) except for continuous action air fresheners (up to 0.5%). 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 are 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.

Considering the low end use concentrations in various products and the toxicological profile of the chemical, the above exposure level to the assessed chemical is not expected to pose health risk to the public through normal use of the cosmetic and household products.

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 dose 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 0.02% concentration. The professional workers may wear some PPE (including gloves, coveralls, safety glasses or 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

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

Environmental hazard classification

The chemical satisfies the criteria for classification according to the *Globally Harmonized System of Classification and Labelling of Chemicals* (GHS) (UNECE 2017) as Acute Category 3 (H402) based on the toxicity data for invertebrates and algae.

Environmental Hazard	Hazard Category	Hazard Statement
Hazardous to the aquatic environment (acute / short-term)	Aquatic Acute 3	H402: Harmful to aquatic life

Summary of environmental risk

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

The assessed chemical is readily degradable and is not persistent. The assessed chemical is not expected to bioaccumulate and cause toxic effects in aquatic organisms.

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

Means for managing risk

The information in this statement 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 mists or aerosols
    - Use of safe work practices to
        - avoid inhalation of mists or aerosols
    - Use of personal protective equipment (PPE)
        - respiratory protection if required
- 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.

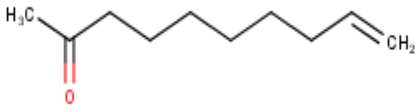
Note: Obligations to report additional information about hazards under section 100 of the *Industrial Chemicals Act 2019* apply.

Supporting information

Chemical identity

Chemical name	9-Decen-2-one
CAS No.	35194-30-0
Molecular formula	$C_{10}H_{18}O$
Molecular weight (g/mol)	154.25
SMILES (Canonical)	O=C(C)CCCCCCC=C

Structure:



Chemical description
The assessed chemical has a degree of purity between 95% and 100% (w/w).

Relevant physical and chemical properties

Physical form	Colourless liquid
Melting point	-17.5 ± 0.2 °C
Boiling point	206.3 ± 0.4 °C
Density	841 kg/m^3 at 20.0 °C
Vapour pressure	0.0298 kPa at 25°C (calculated)
Water solubility	272 mg/L at 20°C, pH 6.9
Ionisable in the environment	No
log K_{ow}	3.06 at 20°C, pH 6.2
log K_{oc}	2.21 - 2.81 (calculated)
Flash point	88 °C (close cup)
Auto-ignition temperature	234 °C at 99.4 kPa

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
Rabbit, skin irritation	OECD TG 404	Slightly irritating
Rabbit, eye irritation	OECD TG 405	Slightly irritating
Skin sensitisation – Local lymph node assay (mice)	OECD TG 429	Weak sensitiser
Rat, repeat dose oral toxicity, 28 days	OECD TG 407	NOAEL = 500 mg/kg bw/day
Mutagenicity – bacterial reverse mutation	OECD TG 471	Non mutagenic

Acute toxicity

Oral

In an acute oral toxicity study (OECD TG 423), the assessed chemical was administered by oral gavage to 6 Sprague Dawley (SD) rats at a single dose of 2,000 mg/kg bw. One mortality occurred on Day 4 of the study. Prior to the death of the animal, a decrease in spontaneous activity, dyspnea, hypothermia, piloerection, decrease in muscle tone, absence of Preyer's reflex and righting reflex were observed from the 24-hour observation to the 72-hour observation. Necroscopy of the animal revealed a thinning of the corpus and the forestomach, and the presence of black foci at the level of the corpus.

Clinical observations in the remaining rats included decreased spontaneous activity (5/5), mydriasis (2/5) and decreased righting reflex (1/5) between the 30-minute and 4-hour observations. All effects fully reversed by the 72-hour observation. No treatment-related macroscopic changes were observed in the remaining treated animals at the end of the study.

As the assessed chemical caused a decrease in righting reflex in rats during the study, the chemical warrants a hazard classification for STOT SE Cat 3 (H336: May cause drowsiness or dizziness) according to GHS criteria.

Corrosion/Irritation

Skin irritation

The assessed chemical was tested in rabbits for skin irritation (OECD TG 404). A single 4-hour, semi-occluded application of the chemical to the intact skin of 3 rabbits produced slight to well-defined erythema (maximum score of 2) in all treated animals from the 1-hour observation until the 72-hour observation. Very slight oedema (maximum score of 1) was also observed in 2 animals at the 1-hour observation. At the 48-hour and 72-hour observations, very slight to slight oedema (maximum score of 2) was observed in all treated animals. Slight dryness at the test site was noted in all animals on Day 2, 3, 6 to 10 or 13 observations. At the 14-day observation, the skin of all animals appeared normal. Based on the results, the

assessed chemical is slightly irritating to 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 conjunctival irritation (maximum score of 1) was noted in all treated animals 1 hour after treatment and persisted in two animals until the 24-hour observation. Slight corneal opacity (maximum score of 1) was observed in two animals at the 24-hour observation. Treated eyes appeared normal at the 48-hour 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 local lymph node assay (LLNA) in mice (OECD TG 429). The mice were treated by daily application of 25 µL of the chemical at concentrations of 25%, 50% or 100% (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 eyes was observed at Day 6 observation in the group treated with 100% of the chemical. The stimulation index (SI) at the 25%, 50% and 100% concentrations were 1.04, 1.67 and 2.23, 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 39.29%. Based on the results of this study, the study authors have classified the assessed chemical for skin sensitisation Cat 1 (H317: May cause an allergic skin reaction).

Repeat dose toxicity

In a repeated dose oral toxicity study (OECD TG 407), the assessed chemical was administered to Wistar rats (n=5/sex/dose) by oral gavage for 28 days at dose levels of 250, 500 and 1,000 mg/kg bw/day. An additional group of rats (n = 5/sex) were administered the assessed chemical at 1,000 mg/kg bw/day to assess the reversibility of any effects following a 14-day recovery period.

There were no clinical signs of toxicity, mortality or test substance-related effects on general appearance, body weight, food consumption, behavioural parameters, functional performance, and sensory reactivity throughout the treatment and recovery period for all tested concentrations of the assessed chemical.

<u>Laboratory Findings – Clinical Chemistry, Haematology, Urinalysis</u>

In the treatment groups, a statistically significant decrease in total white blood cells (52%) in high dose females was noted but not considered by the study authors to be toxicologically relevant as there were no clear dose-related responses. There were also some haematology and clinical chemistry parameters with statistically significant differences but were within the historical control data for this strain of rats.

By the end of the recovery period, only the following statistically significant effects were observed when compared to controls:

- decrease in haematocrit level (9%), mean corpuscular volume (6%) and glucose level (13%) in males
- increase in potassium level (17%) in males
- decrease in aspartate transferase (26%), calcium (12%) and phosphorus (19%) in females

Effects on Organs

During treatment, increases in absolute liver (9%), relative liver (25%), absolute kidney (8%) and relative kidney (18%) weights was observed in high dose males when compared to control. In high dose females, decreases in absolute liver (10%), relative liver (15%), absolute spleen (34%) and relative spleen (28%) weights was observed in comparison to controls.

After recovery, decreases in absolute liver (11%) and spleen (35%) weight was observed in females and a decrease in relative kidney weight (3%) was observed in males. Although the study authors considered these changes to be spontaneous and not treatment related, the absolute liver and spleen weight effects were persistent in the high dose recovery females and should be considered adverse.

No test substance-related abnormalities were observed at macroscopic examinations of organs.

Microscopic analysis of recovery animals revealed chronic inflammatory foci in the liver, perivascular lymphocytic aggregation, foam cells and haemorrhages in the lungs, cysts and lymphocytic infiltration in the kidneys, granular cysts in the stomach and sub-mucosal lymphocytic infiltration of the rectum. As these effects were either spontaneous or comparable to controls, these effects were not considered adverse by the study authors.

Under the conditions of this study, a no observed adverse effect level (NOAEL) of 500 mg/kg bw/day should be considered based on the greater than 10% decreases in absolute liver and spleen weights in the high dose females which were not recovered at the end of the study.

Genotoxicity

The assessed chemical was found to be non mutagenic in a bacterial reverse mutation assay (OECD TG 471).

Environmental exposure

The assessed chemical will be imported into Australia for use as a fragrance in consumer end use 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 consumer products, resulting in a variety of potential exposure scenarios.

Consumer and professional end use of the assessed chemical in cosmetic and household 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 partitioning of the assessed chemical was not determined. The chemical is treated as if it is mobile in the environment as a worst-case scenario.

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 EU Method C.4-E test guideline (oxygen consumption) demonstrated 71% degradation of the assessed chemical in 21 days, fulfilling the 10-day window criterion for ready biodegradability. Therefore, the assessed chemical is categorised as readily biodegradable in water.

Bioaccumulation

No bioaccumulation information was provided for the assessed chemical. The experimental partition coefficient of the assessed chemical (log K_{OW} = 3.06) 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 the maximum allowable introduction volume for environmental exposure band 2 (1,000 kg/annum) with a release reduction factor of 1 for down-the-drain style end use scenarios. Correspondingly, 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 was not calculated as a worst-case scenario.

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	L/person/day

Population of Australia	25.423	Million
Removal within STP	0%	Mitigation
Daily effluent production	5,085	ML/day
Dilution Factor - River	1	
Dilution Factor - Ocean	10	
PEC - River	0.54	µg/L
PEC - Ocean	0.05	µg/L

Environmental effects

Effects on aquatic Life

Acute toxicity

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

Taxon	Endpoint	Method
Invertebrate	48 h EC50 = 12 mg/L	*Daphnia magna* (water flea) Growth rate iSafeRat HA-QSAR v1.8 Ecotox module Calculated concentration
Algae	72 h EC50 = 11 mg/L	*Desmodesmus subspicatus* (green algae) Growth rate iSafeRat HA-QSAR v1.8 Ecotox module Calculated concentration

Chronic toxicity

The following calculated no-effect concentration (NOEC) values for model organisms were supplied for the assessed chemical:

Taxon	Endpoint	Method
Algae	72 h NOEC = 3.7 mg/L	*Desmodesmus subspicatus* (green algae) Growth rate iSafeRat HA-QSAR v1.8 Ecotox module Calculated concentration

Predicted no-effect concentration (PNEC)

The predicted no-effect concentration is expected to be greater than 0.54 µg/L.

The available standard acute ecotoxicity endpoints for this chemical are greater than 0.54 mg/L. With a conservative assessment factor of 1,000, the lowest calculable PNEC is > 0.54 µg/L.

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 low measured log K_{ow} value, the assessed chemical is categorised as Not Bioaccumulative.

Toxicity

Not Toxic (Not T). Based on calculated ecotoxicity values above 1 mg/L chemical is categorised as Not Toxic.

Environmental risk characterisation

The assessed chemical does not meet any of the PBT criteria. It is hence unlikely to have unpredictable long-term effects (EPHC 2009). An estimate of risk may therefore be determined using the risk quotient method.

Compartment	PEC	PNEC	RQ
River	< 0.54 µg/L	> 0.54 µg/L	< 1
Ocean	< 0.05 µg/L	> 0.54 µg/L	< 0.1

The risk quotient for the aquatic compartment is expected to be less than 1. This is based on a conservative PEC, assuming 100% release of 1 tonne/annum to STPs and no removal from the aqueous stream during STP processes, and a conservative PNEC based on an assessment factor of 1,000 and acute aquatic toxicity endpoints for the chemical that each exceed 0.54 mg/L.

Therefore, based on the expected RQ < 1 the assessed chemical is not expected to pose a significant risk to the environment. As such, the environmental risks associated with 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.

UNECE (United Nations Economic Commission for Europe) (2017). Globally Harmonized System of Classification and Labelling of Chemicals (GHS), Seventh Revised Edition. UNECE.