Australian Government

Department of Health, Disability and Ageing

Australian Industrial Chemicals Introduction Scheme

2-Propenoic acid, 2-cyano-3,3-diphenyl-, 2-ethylhexyl ester (Octocrylene)

Evaluation statement (EVA00202)

1 April 2026

Draft

Table of contents

Contents

Evaluation statement

Subject of the evaluation

2-Propenoic acid, 2-cyano-3,3-diphenyl-, 2-ethylhexyl ester (Octocrylene)

Chemical in this evaluation

CAS name	CAS number
2-Propenoic acid, 2-cyano-3,3-diphenyl-, 2-ethylhexyl ester	6197-30-4

Reason for the evaluation

Evaluation selection analysis indicated a potential risk for environment.

Parameters of evaluation

The chemical is listed on the Australian Inventory of Industrial Chemicals (the Inventory).

This evaluation statement includes an environment risk assessment for all identified industrial uses of 2-propenoic acid, 2-cyano-3,3-diphenyl-, 2-ethylhexyl ester (octocrylene). The use of octocrylene in therapeutic sunscreens is not assessed in this evaluation because this is not an industrial use.

The risks posed to the environment associated with the industrial uses of octocrylene have been assessed according to the following parameters:

- Industrial uses listed in the 'Summary of introduction, use and end use' section.
- Expected emission to sewage treatment plants (STPs) following consumer and commercial use.

Summary of evaluation

Summary of introduction, use and end use

Based on Australian and international use data octocrylene has functional use as an ultraviolet (UV) filter. Personal care products (cosmetics) containing octocrylene, including skin-applied products such as face cream and lip balm, have been identified on Australian commercial websites.

The chemical also has reported non-industrial use in therapeutic sunscreens.

There is no information available on the Australian use volume of octocrylene. Reported volumes from international jurisdictions indicate that it is used in high volumes, in the order of 1,000–10,000 tons per year in both the European Economic Area (EEA) and the United

States of America (USA). However, these international use volumes include both therapeutic and industrial uses.

Environment

Summary of environmental hazard characteristics

Based on the information presented in this evaluation statement and according to the environmental hazard thresholds stated in the Australian Environmental Criteria for Persistent, Bioaccumulative and/or Toxic Chemicals, the chemical is:

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

Environmental hazard classification

This chemical satisfies the criteria for classification according to the Globally Harmonized System of Classification and Labelling of Chemicals (GHS) for environmental hazards as follows (UNECE 2017). This evaluation does not consider classification of physical hazards.

Environmental Hazard	Hazard Category	Hazard Statement
Hazardous to the aquatic environment (long-term)	Aquatic Chronic 1	H410: Very toxic to aquatic life with long lasting effects

Summary of environmental risk

The industrial uses of the chemical are expected to result mainly in releases into the environment via the sewer. For surface waters, sediment and soil, a risk quotient (RQ) less than 1 indicates that the chemical is not expected to pose a significant risk to the environment based on estimated diffuse emissions, as environmental concentrations are below levels likely to cause harmful effects.

Octocrylene may also be released directly to recreational waters by washing off the bodies of recreational water users. However, this exposure route is expected to be particularly relevant to therapeutic sunscreens. The environmental risks from the use of octocrylene in therapeutic sunscreen products are outside the parameters of this evaluation. However, their environmental exposure pathways are similar to industrial uses, so it is difficult to distinguish between environmental exposure from therapeutic versus industrial uses of octocrylene. International monitoring data suggest that some recreational water bodies, such as beaches and reefs that are near heavily populated areas or are visited by high numbers of tourists, may be subject to localised, transient elevated concentrations of octocrylene. Conservative worst-case risk estimates for these locations would result in RQs >1, indicating the presence of transient risks. However, there are no acute effects expected at the limit of water solubility, and the chemical will be dispersed within the water bodies, thus limiting the potential environmental risks. In the absence of Australian-specific monitoring data linking environmental concentrations to different classes of products, there is insufficient evidence to fully characterise the risk to the environment at these locations from either the industrial or the therapeutic uses of octocrylene.

The chemical has been categorised under domestic thresholds as persistent, not bioaccumulative, and toxic. There is some evidence that octocrylene may interact with endocrine systems. However, the current available data do not provide sufficient evidence of adverse effects of the chemical from an endocrine mode of action.

Conclusions

The Executive Director proposes to be satisfied that the identified risks to the environment from the introduction and use of the industrial chemical can be managed.

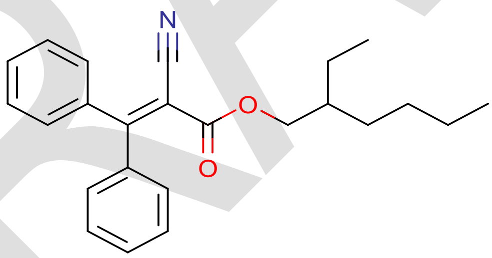
Note:

1. Obligations to report additional information about hazards under Section 100 of the *Industrial Chemicals Act 2019* apply.
2. A person introducing this chemical should be aware of their obligations under environmental, workplace health and safety and poisons legislation as adopted by the relevant state or territory

Supporting information

Chemical identity

Octocrylene is an α-cyanoester derived from diphenyl-methanone (benzophenone, CAS RN 119-61-9). Benzophenone is a known manufacturing impurity and degradation product of octocrylene (AICIS 2025):

CAS number	6197-30-4
CAS name	2-Propenoic acid, 2-cyano-3,3-diphenyl-, 2-ethylhexyl ester
Molecular formula	$C_{24}H_{27}NO_2$
Associated names	Octocrylene
	2-Ethylhexyl-2-cyano-3,3-diphenylacrylate
	Octocrilene
Molecular weight (g/mol)	361.48
SMILES (canonical)	N#CC(C(=O)OCC(CC)CCCC)=C(C=1C=CC=CC1)C=2C=CC=CC2
Structural formula	

Relevant physical and chemical properties

Physical and chemical properties were sourced from the REACH dossier for octocrylene (REACH n.d.). Calculated values were estimated using EPI Suite (US EPA 2017):

Physical form	Liquid
Melting point	-10°C (exp.)
Boiling point	Substance decomposes at > 300°C without boiling (exp.)
Vapour pressure	1.76×10^{-5} Pa (calc.)
Water solubility	40 µg/L (exp.)

Henry's law constant	0.00030 Pa·m^3/mol (calc.)
Ionisable in the environment?	No
log K_{ow}	6.1 at 23 °C (exp.)
K_{OC}	48,898 L/kg (exp.)

Introduction and use

Australia

Octocrylene is an ultraviolet (UV) filter which absorbs primarily UVB radiation and short UVA wavelengths. It is used in various cosmetic products to either provide sun protection in sunscreen products or to protect cosmetic formulations – such as photosensitive pigments from UV radiation. The chemical is commonly used in both:

- cosmetics, which are regulated under the *Industrial Chemicals Act 2019,* and
- therapeutic sunscreens, which are regulated under the *Therapeutic Goods Act 1989*.

Therapeutic sunscreens include primary sunscreens and some secondary sunscreens. Uses of octocrylene in therapeutic sunscreens are not assessed in this evaluation. Other secondary sunscreen products are excluded as therapeutic goods and are therefore industrial uses of the UV filters. These uses are assessed in this evaluation. Excluded goods are defined under the Therapeutic Goods (Excluded Goods) Determination 2018 (TGA 2018). They generally include the following products that contain sunscreen:

- products applied to the lips (such as lipsticks and lip balms)
- tinted bases and foundations (including liquids, pastes, and powders)
- moisturising skin care products
- sunbathing skin care products.

Limitations relating to sun protection factor (SPF), product type, the presence of other ingredients scheduled in the *Poisons Standard - Standard for the Uniform Scheduling of Medicines and Poisons (SUSMP)* and pack size apply to the product types above (TGA 2018).

Industrial uses of octocrylene in personal care products (cosmetics), including face cream, moisturiser, nail polish, suntan products (that are not primary sunscreens) and lip balm, have been identified on Australian commercial websites.

However, a significant proportion of the introduction volume of octocrylene is expected to consist in therapeutic uses. The chemical has reported frequent use in therapeutic sunscreens (O'Malley 2020; TGA n.d.).

International

High volumes of octocrylene are used internationally (AICIS 2025). The reported use volumes include both industrial and therapeutic uses. For example, in the EEA, octocrylene is currently registered for use in the range of 1,000–10,000 t/year (REACH n.d.), and in the USA in the range of about 454–9,070 t/year (US EPA 2020).

The predominant use of octocrylene internationally is in primary sunscreens. For example, up to 80% by weight of octocrylene is used to formulate primary sunscreens in the European Union (ECHA 2025a; ECHA 2025b). Octocrylene can be found in various other consumer products, especially cosmetics products, and to a lesser extent in plastics products and soil covers. Octocrylene is used in the manufacture of these products mostly for its UV absorbing, UV filtering, and light stabilising properties. It also functions as a solvent for other crystalline and oil soluble UV filters (ECHA 2025a; ECHA 2025b).

The chemical has reported cosmetic uses in a range of personal care products including:

- face cream
- foundation
- lip balm
- body wash
- shampoo
- nail polish and remover
- hand cream
- concealer
- massage products
- perfume/eau de toilette
- tanning products (that are not primary sunscreens).

Additional use information on the type of cosmetics containing octocrylene is presented in the AICIS human health evaluation for octocrylene (AICIS 2025).

The proportions of products containing octocrylene in different categories of cosmetics have been detailed in the ECHA Restriction Report and Appendix, demonstrating use in a wide range of products. Notably, octocrylene is an ingredient in 30% of lip balms with SPF available on the market. The chemical is also present in a small proportion of facial moisturisers (3.9%), anti-ageing creams (6.2%), foundation/BB cream (2.6%), and nail polishes (2.7%) (ECHA 2025a; ECHA 2025b).

Octocrylene is on the International Fragrance Association Transparency List (IFRA n.d.).

The chemical is also used at industrial sites and by professional workers, as a photochemical, in sealants, in adhesives, coatings, paints, thinners and paint removers. Octocrylene is also used in printing and recorded media reproduction and for the manufacturing of plastics (including plastisol) and rubber products (ECHA 2025a; ECHA 2025b). The above uses are expected to account for a minor proportion of octocrylene use volumes.

Existing Australian regulatory controls

Environment

The reported industrial use of octocrylene is not subject to any specific national environmental regulations.

International regulatory status

European Union

The chemical is listed in entry 3 of Annex VI of the EU Cosmetic Regulation (EC) No. 1223/2009 – List of substances which cosmetic products must not contain except subject to the restrictions laid down. Octocrylene is permitted in propellant spray products at a concentration of 9% and 10% in other products. Benzophenone as an impurity or degradation product should be kept at a trace level of 0.5% (EC n.d.).

In September 2025, ECHA (2025c) published a proposal to restrict 'the placing on the market of finished cosmetic product containing octocrilene in a concentration equal to or greater than 0.001% w/w.' The ECHA reason for the proposed restriction is that 'Octocrilene is a hazardous substance for aquatic and sediment species. Octocrilene is persistent and very persistent, is toxic for the environment and has the ability to bioaccumulate to some extent. Octocrilene is a suspected endocrine disruptor for the environment.' This was published alongside an Annex XV Restriction Report (ECHA 2025a) and Appendix to the Annex XV Restriction Report (ECHA 2025b). The ECHA reports are used as supporting information for the purposes of this AICIS evaluation.

Environmental exposure

Octocrylene has non-industrial use in therapeutic sunscreens and industrial use in a variety of personal care products. It has additional uses as described in the **Introduction and use** section; however, those uses are expected to have minimal environmental release as compared to uses in personal care products and sunscreens. The environmental risks from the use of octocrylene in therapeutic sunscreen products are outside the parameters of this evaluation. However, as outlined in the summary above their environmental exposure pathways are similar to industrial uses, so it is difficult to distinguish between environmental exposure from therapeutic versus industrial uses of octocrylene.

Chemicals used in personal care products are typically released to wastewater (e.g. through shower wash off). Some fraction of the quantity of chemicals in wastewater entering sewage treatment plants (STPs) can be emitted to:

- the air compartment
- rivers or oceans in treated effluent
- soil by application of biosolids to agricultural land (Struijs 2014).

Down the drain release of octocrylene is expected to be the main environmental exposure pathway related to its use as an industrial chemical. Octocrylene may also be released directly to recreational waters, washing off the bodies of recreational water users. However, this exposure route is expected to be particularly relevant to therapeutic sunscreens. One study indicated that less than 1.4% of applied octocrylene is detected in seawater samples from rinse-off during use (Saxe et al. 2021).

Environmental fate

Partitioning

Octocrylene is expected to mostly partition to sediment when released into the environment, with some remaining in water. This is confirmed in a sediment/water simulation study, where octocrylene rapidly partitioned to the sediment (> 80% to sediment within 7 days) (ECHA 2025a; ECHA 2025b).

Octocrylene is only very slightly soluble, and the Henry's law constant indicates very slight volatility from water and moist soil. Octocrylene has high lipophilicity, which promotes partitioning from water to organic matter, including biota, soil, and sediment. The average measured K_{OC} of 48,898 L/kg, with a range of 29,934 to 79,018 L/kg depending on the type of soil, indicates that octocrylene will be immobile once it partitions to soil and sediment.

Degradation

Octocrylene is expected to persist in the environment as it is not readily biodegradable, not readily photodegradable, and it is not hydrolysable. Octocrylene has long half-lives for ultimate degradation in sediment and water simulation tests. It also has been found to be not readily biodegradable in water in several standard test guideline studies.

Octocrylene has half-lives > 60 days in water and > 180 days in sediment based on simulation tests in water sediment systems. The rate and route of degradation of radio-labelled octocrylene was investigated in both freshwater and estuarine aquatic sediment systems at 12 °C under aerobic conditions, according to OECD TG 308 (REACH n.d.). From the analysis of these tests by ECHA (ECHA 2025a; ECHA 2025b), the degradation kinetics of octocrylene in the whole system resulted in the ultimate half-lives for mineralisation of 1,810 days in the freshwater system and 1,870 days in the estuarine system, based on mineralisation amounts of 3.3% after 100 days. The distribution of radioactivity indicated that partitioning to sediment and formation of degradants were the primary processes in the disappearance of the parent test material from water. 2-Cyano-3,3-diphenylpropanoic acid and 2-cyano-3,3-diphenylpropenoic acid were the main degradants identified in the study.

The OECD TG 308 test results are supported by a literature study that found no degradation of octocrylene in marine sediment after 100 days of incubation (Fagervold et al. 2025).

According to 2 studies based on oxygen consumption performed in compliance with EU method C.4 -D (0% degradation after 28 days) and OECD TG 301F (0–10% degradation after 28 days), octocrylene is not readily biodegradable (REACH n.d.).

The REACH dossier additionally contains reports of recent studies conducted in 2023 and 2024:

- two prolonged OECD TG 301B studies of ready biodegradability
- two OECD TG 302B inherent biodegradability studies
- one prolonged OECD TG 301F ready biodegradability study (REACH n.d.).

The results of these studies are not included in the weight of evidence as they are considered unreliable based on an unclear source of adapted inoculum and uncertainties or errors in the degradation calculations.

Conflicting data are available on the photostability of octocrylene in water. One literature study by Albini et al. (1998) found a primary photodegradation half-life of 96 hours based on a test performed in a solar simulator. A more recent literature study found octocrylene to be resistant against both photodegradation and biodegradation, with no significant changes over time in the 144 hour study period (O'Malley et al. 2021).

Bioaccumulation

Octocrylene does not meet the Australian thresholds for bioaccumulation.

Based on the results of 3 OECD TG 305 fish bioaccumulation studies (exposure via water and water + diet), the substance is not bioaccumulative as bioconcentration factors (BCFs) and bioaccumulation factors (BAFs) are below 2,000 and biomagnification factors (BMFs) are below 1. Some literature data indicates that octocrylene does accumulate in biota and within food chains to some extent, but results are mixed.

Guideline studies

The bioaccumulation of octocrylene in zebra fish, *Danio rerio,* was investigated using a flow through system set up according to OECD TG 305. The fish were exposed via the water to the radio-labelled test substance for 28 days. After a depuration period of 15 days the test was terminated and a mean growth and lipid corrected BCF of 858 L/kg based on the whole-body wet weight was determined (REACH n.d.).

The bioaccumulation of octocrylene in rainbow trout, *Oncorhynchus mykiss*, was investigated in a modified OECD TG 305 study based on dietary exposure. Significant biotransformation was observed, substantially reducing bioaccumulation potential in trout. The average BAF (misreported as BCF) for octocrylene was 1,267 L/kg, while the average dietary biomagnification factor (BMF) was 0.0084 (Saunders et al. 2019).

Another OECD TG 305 fish bioaccumulation study using rainbow trout and dietary exposure was carried out with radio-labelled test substance (1 µg/g feed) for 14 days. The resulting lipid and growth corrected kinetic BMF was 0.034 (REACH n.d.).

Literature studies

Identified literature studies show inconsistent results alongside some methodological limitations.

Vidal-Liñán et al. (2018) studied the bioaccumulation kinetics of octocrylene in wild *Mytilus galloprovincialis* mussels. The kinetics of bioaccumulation of octocrylene fitted to an asymptotic model from which a BCF value of 2,210 L/kg dry weight (dw) was derived. This value may have been underestimated as steady state was not reached. However, while it is common for mussels' data to be expressed in dry weight, the bioaccumulation criterion is based on a BCF value expressed in wet weight (ww). The converted BCF based on ww concentrations is expected to be below 2,000 L/kg ww.

In another study, Cadena-Aizaga et al. (2022) found octocrylene from 33.1 to 1,735 ng/g dw in primary marine consumers, calculating very large log BAFs of 5.4-8.4 (misreported as log BCFs) and BMFs from 0.01 to 0.3. However, there are several limitations to this study such as calculations being based on dry weight and not wet weight in the biota, using filtered water concentrations which will underestimate exposure through diet for filter-feeding biota, and different sampling periods for the water and the biota.

Other results in the literature include:

- BCFs of 56–81 L/kg for zebrafish exposed to 29–1249 µg/L of octocrylene (Zhang et al. 2016),
- BCFs of 41–136 L/kg for zebrafish exposed to 100–2,000 µg/L octocrylene (Blüthgen et al. 2014),
- a BAF of 187 L/kg for red swamp crayfish, *Procambarus clarkii*, (He et al. 2021),
- a BCF of 1,440 L/kg ww in a study of Daphnia resting eggs (ephippia) by Chiaia-Hernandez et al. (2013), and
- BAFs of 1.5–1,122 L/kg in a study of coral communities in the South China Sea (Pei et al. 2023).

Contrasting results are found for studies of octocrylene biomagnification in freshwater food chains.

Yang et al. (2020) investigated the concentrations of various chemicals in the Nanjing Qinhuai River system in China. A trophic magnification factor (TMF) of 2.04 was calculated for octocrylene across the 14 species sampled. However, the reliability of this TMF is uncertain, as biota concentrations were not normalised, and TMFs should be based on normalised concentrations (typically normalised to lipid contents) (Gobas et al. 2009).

Peng et al. (2017) investigated the concentrations of UV absorbents in the Pearl River Estuarine in the South China Sea. The study sampled 24 species. Calculated biota-sediment accumulation factors were below 1 for octocrylene and no positive correlation between trophic level and concentration in biota was found. One specific predator-prey pair had a BMF of 1.05.

Lyu et al. (2022) found that concentrations of octocrylene did not correlate with trophic level in a freshwater lake and they did not calculate a TMF.

Environmental transport

Octocrylene may undergo long range transport due to its long half-life in water. However, partitioning to sediment is likely to mitigate long-range transport. Monitoring studies in remote regions have been complicated by potential local contamination sources.

In a study by D'Amico et al. (2024), octocrylene concentrations were analysed in 25 snow samples collected from glaciers and the vicinity of a research centre in the Svalbard area in the Arctic. Octocrylene was detected in the samples at total concentrations (dissolved + particulate phase) ranging from below the limit of detection (0.2 ng/L) to 19.6 ng/L, with a mean of 3.7 ng/L. Local and long range sources, as well as direct contamination by scientists' visits, were cited as possible sources of the chemical in these snow samples.

In another study, octocrylene was detected in 43% of surface seawater samples from the Arctic Ocean and Chukchi Sea at 26–31 ng/L. The presence of octocrylene in these samples may be due to long range or local transport from wastewater runoff in Alaska, via oceanic currents (Tsui et al. 2014b).

Predicted environmental concentration (PEC)

The PEC of octocrylene in surface waters is 109 ng/L based on Australian monitoring data for STPs and estuaries.

A PEC in soil of 0.014 mg/kg dw has been estimated, based on a measured biosolids concentration and modelled application of biosolids to soil.

Octocrylene has also been measured in a variety of sediment studies, up to a maximum concentration of 635 ng/g dw in the sediment of Japanese streams. This value will be used as a conservative PEC for sediment for risk characterisation purposes in Australia.

Given its presence in waters and sediment, levels of octocrylene have also been detected in biota, and a selection of these have been reported for information purposes in this section.

Surface waters

Concentrations of octocrylene in the Australian environment are expected to result from both industrial and non-industrial uses of octocrylene. Octocrylene has been detected in a range of aquatic environments, both in Australia and internationally, including beaches, reefs, rivers, lakes, and streams.

Octocrylene in urban STPs and surface waters may originate from industrial uses in personal care products and plastic products, and from non-industrial uses in therapeutic sunscreens, for example, from shower wash-off of sunscreens.

Octocrylene in recreational swimming areas is expected to predominantly originate from non-industrial use in therapeutic sunscreens, with very minimal contributions from industrial uses in cosmetics. Therefore, the dominant source of octocrylene in recreational swimming areas will be non-industrial.

Monitoring studies from urban STPs and surface waters have the highest chance of detecting octocrylene contributions from industrial uses. However, these studies cannot differentiate between industrial and non-industrial sources of octocrylene. Therefore, measured concentrations in surface waters affected by urban STP emissions are considered a worst-case estimate of levels arising from industrial uses.

In Australia, monitoring data are available for STPs and surface waters affected by STP emissions. Allinson et al. (2018) measured octocrylene concentrations ranging from 2.0 to 109 ng/L in 4 Victorian estuary sites. The catchments at the sampling sites include mixed urban, agricultural, and forested areas, with discharge from STP effluents, stormwater run-off and potentially sewer overflows. Liu et al. (2012) measured octocrylene concentrations during STP processing in South Australia. Octocrylene was reported at 88–89 ng/L in the influent and removed to below the limit of detection (3.4 ng/L) in the effluent water, demonstrating high removal from wastewater.

Octocrylene was found at a mean concentration of 465 ng/g dw in the biosolids of a South Australian STP (Liu et al. 2012). This biosolids value is used to calculate a modelled PEC in agricultural soil with biosolids applied.

High removal of octocrylene from wastewater in STPs is also apparent in international data:

- Tsui et al. (2014a) investigated the removal efficiency of the chemical in different sewage treatment plants and treatment techniques. Octocrylene showed almost complete removal from the effluent following secondary treatment.
- Amankwah et al. (2024) reported a maximum octocrylene concentration of 4,100 ng/L in STP influent and a maximum of 78 ng/L in the effluent (98% removal) of STPs in the Czech Republic.

- Balmer et al. (2005) reported 88% to more than 99% removal in Swiss STPs employing tertiary or higher treatment with a maximum influent concentration of 12,000 ng/L and a maximum effluent concentration of 300 ng/L.

Octocrylene has been measured in a variety of international surface waters impacted by STP emissions. For example, a maximum concentration of 14 ng/L was found in streams, STP effluents, lakes, and moderately and heavily polluted rivers in a study within an urban area in Saitama Prefecture, Japan (Kameda et al. 2011).

Other Australian and international monitoring studies have focussed on areas that are affected by direct release to waters from recreational users. Environmental levels in these locations are expected to arise mostly from therapeutic sunscreen wash off, which is outside the parameters of this evaluation. A selection of studies is reported for information only.

In Australia, two studies involving direct release of octocrylene to recreational waters are available. Octocrylene was the highest measured UV filter in samples taken 30 cm below the surface in a Queensland freshwater swimming area, with time-of-day dependent concentrations ranging from 1,380–4,660 ng/L related to swimming activity (O'Malley et al. 2021). In another study of Queensland freshwater reservoirs with variable recreational activity, octocrylene was detected from 0.39–2.77 ng/L in samples taken 3 m below the surface (Verhagen et al. 2025).

International monitoring of octocrylene in the surface waters of islands, beaches, cities, coastal regions, lagoons, and reefs in a number of worldwide locations is available. The reported concentrations in these surface waters vary greatly, from 2.15 ng/L in a coastal region of the South China Sea to a maximum of 7,301 ng/L at a popular Norwegian beach in summer (García-Pimentel et al. 2023; Langford and Thomas 2008; Mitchelmore et al. 2019; Schaap and Slijkerman 2018; Tashiro and Kameda 2013; Tsui et al. 2014b; Tsui et al. 2019). The concentrations exceeding 1,000 ng/L were correlated with high recreational activity at the time of sampling (García-Pimentel et al. 2023; Langford and Thomas 2008; Tsui et al. 2014b). Spatial and temporal variations in octocrylene concentrations suggest that high levels are localised and transient. For example, at a popular beach in the Caribbean, octocrylene was measured at 1,950 ng/L in the surface microlayer and 810 ng/L at a depth of 30 cm. On a different date, concentrations at this location were at or below 160 ng/L. Samples collected at a nearby mangrove and reef contained octocrylene in concentrations at or below 30 ng/L on both sampling dates (Schaap and Slijkerman 2018).

Soil

No monitoring data for octocrylene in soil were identified. The PEC for this compartment was estimated using STP modelling for the application of biosolids to agricultural land, based on the measured Australian STP biosolids concentration of 0.465 mg/kg (Liu et al. 2012). This biosolid concentration, under a standard model of application of biosolids to agricultural land, produces a worst-case PEC in soil of 0.014 mg/kg dw.

Sediment

Octocrylene has been measured in a range of aquatic sediments internationally:

- Kameda et al. (2011) measured the concentrations of UV filters in the sediment of streams, STP effluents, and moderately and heavily polluted rivers in Japan. The maximum concentration of octocrylene was 635 ng/g in the sediment of streams.
- Gu et al. (2025) detected octocrylene concentrations up to a maximum of 22.2 ng/g dw in sediments from Taihu Lake China in November 2015 and 2016.

- Apel et al. (2018) detected octocrylene in the surface sediment of the Bohai Sea and Yellow Sea up to 9.7 ng/g dw.
- Pintado-Herrera et al. (2017) found octocrylene in sediments of Cadiz Bay and Huelva Estuary in Andalusia, Spain with a 90th percentile concentration of 43.6 ng/g dw.
- Tovar-Salvador et al. (2023) detected octocrylene in coastal sediment samples in the Atacama Region of Chile up to 33.39 ng/g dw.
- Mitchelmore et al. (2019) reported a maximum of 19.8 ng/g in sediment around Hawaiian coral reefs.

Octocrylene was investigated but not reported (limit of reporting 1.0 µg/kg dw) in the sediment in the study of Victorian estuary waters (Allinson et al. 2018), so the maximum value of 635 ng/g dw is conservatively selected as the PEC for sediment in Australia.

Biota

Octocrylene has been detected in a range of aquatic biota globally:

- As reported in Mitchelmore et al. (2021), Mitchelmore et al. (2019) measured a median of 48.4 ng/g dw in corals around Hawaii, USA.
- Tang et al. (2019) found concentrations of octocrylene in the muscle of wild fish from Lake Chaohu, China, ranging 0.73 to 13.7 ng/g dw.
- Cunha et al. (2018) studied levels of octocrylene in seafood, reporting the highest levels in farmed seabream at 103.3 ng/g dw.
- Pintado-Herrera et al. (2024) reported up to 2,698 ng/g dw in muscle samples of Atlantic bluefin tuna from the Gulf of Cadiz.
- Gago-Ferrero et al. (2013) reported octocrylene levels up to 782 ng/g lipid weight in Franciscana dolphins.
- Molins-Delgado et al. (2017) measured octocrylene levels up to 65.2 ng/g dw in black-headed gull eggs.

This data shows that octocrylene makes its way from the environment into biota at low levels.

Environmental effects

Effects on aquatic Life

Acute toxicity

With low water solubility and a high log K_{OW}, octocrylene is a difficult to test substance. Octocrylene does not exhibit toxicity up to the limits of water solubility in acute toxicity tests on fish, invertebrates and algae performed according to standard test guidelines (REACH n.d.). Literature studies detailed in the ECHA Restriction Report and Appendix support the absence of acute effects in aquatic organisms within the solubility limit of octocrylene (ECHA 2025a; 2025b).

Chronic toxicity

The following measured no observed effect concentration (NOEC), and 10% effective concentration (EC10) values were retrieved from the REACH registration dossier for octocrylene (REACH n.d.):

Taxon	Endpoint	Method
Invertebrates	21 d NOEC = 0.00266 mg/L	*Daphnia magna* (Water flea) Reproduction Mean measured concentration Semi-static TG 211
Algae	72 h EC10 = 0.4 mg/L	*Chlorella vulgaris* (green algae) Growth rate Nominal concentrations, DMSO used as solvent Static OECD TG 201

Read across with etocrilene (CAS No. 5232-99-5) has been proposed for fish in the REACH registration dossier, with a 36 d survival NOEC of 0.09 mg/L for zebrafish in an OECD TG 210 study (ECHA 2025a; ECHA 2025b). While etocrilene has a similar chemical structure and UV-absorbing properties to octocrylene, its alkyl chain is significantly shorter. The lower lipophilicity of etocrilene is expected to affect tissue distribution and long-term effects in aquatic organisms. Therefore, reading across to etocrilene may underestimate the chronic toxicity of octocrylene to fish.

An OECD Guideline 241 (The Larval Amphibian Growth and Development Assay (LAGDA)) study using octocrylene produced a 113 day overall NOEC of 0.0032 mg/L (REACH n.d.).

Long term toxicity studies from the scientific literature, as detailed in ECHA Restriction Report and Appendix (ECHA 2025a; ECHA 2025b), are considered to be supportive data and indicate that octocrylene can affect fish reproduction at doses as low as 0.0027 mg/L (Yan et al. 2020), as discussed further in **Endocrine Effects**. However, the study by Yan et al. is not a standardised test, and the observed effects are not dose dependent, so the invertebrates' endpoint reported in the table is considered the most reliable and pivotal endpoint.

Effects on sediment dwelling life

The following measured NOEC or EC10 values were retrieved from the REACH registration dossier for octocrylene (REACH n.d.):

Taxon	Endpoint	Method
Annelids	28 d EC10 = 46.3 mg/kg dw	*Lumbriculus variegatus* (Blackworm) Biomass Nominal concentration Static OECD TG 225
Aquatic plants	14 d NOEC ≥ 1,000 mg/kg dw	*Myriophyllum spicatum* (Spiked water milfoil) Growth rate Nominal concentrations Static OECD TG 239

Additional scientific literature studies for sediment toxicity have been evaluated in detail in the ECHA Restriction Report and Appendix (ECHA 2025a; ECHA 2025b) and found in support of the annelids endpoint above being pivotal for the sediment compartment. In an invertebrates (harlequin fly) OECD TG 233 study, a 28 day NOEC greater than or equal to 1,000 mg/kg dw for emergence rate was reported in the registration dossier. This study has been discounted as it likely overestimates the effective exposure concentrations. The exposure route was not modified from spiked sediment to contaminated food, as is required for strongly absorbing substances such as octocrylene (ECHA 2025a; ECHA 2025b).

Some UV filters have been investigated for hazards to corals (see reviews by Mitchelmore et al. (2021) and Moeller et al. (2021)). Danovaro et al. (2008) did not observe any coral bleaching due to octocrylene exposure. Stien et al. (2019) found that octocrylene alters mitochondrial function and the concentration of a coral sterol at 50 µg/L for the coral *Pocillopora damicornis*. However, there are no standardised tests available, and the significance of these findings is unclear.

Effects on terrestrial Life

An NOEC value of 125 mg/kg soil dw was reported for *Eisenia fetida* (earthworm) reproduction after 56 days exposure, as per OECD TG 222 (REACH n.d.).

A 21 day test on terrestrial plants per OECD TG 208 reported an NOEC (=LOEC/2) value of 6.15 mg/kg soil dw for mung beans shoot weight. This value corresponds to an NOEC of 19.5 mg/kg dw after normalisation to a standard soil organic carbon content of 2% (ECHA 2025a; ECHA 2025b).

In a 28 day test on soil microorganisms as per OECD TG 216 no effects were observed up to the final test value of 1,000 mg/kg soil dw (REACH n.d.).

An additional 2 scientific literature studies for soil toxicity have been evaluated in detail in the ECHA Restriction Report and Appendix (ECHA 2025a; ECHA 2025b) and found in support of the above terrestrial plant's endpoint being pivotal for the soil compartment.

Endocrine effects

Octocrylene causes chronic effects in fish and invertebrates at low exposure concentrations, including causing impacts on reproductive success. There is some evidence that octocrylene may interact with endocrine systems. However, the available data do not provide sufficient evidence of an adverse effect of the chemical from an endocrine mode of action.

Most studies considered in this evaluation have not been performed to OECD test guidelines, but they are considered reliable for weight of evidence consideration in line with the OECD conceptual framework for evaluating chemicals for endocrine disruption (OECD 2018). The study design, including exposure concentrations, was also considered when determining the reliability and relevance of studies below.

For environmental endocrine activity, many studies observe the effects of exposure on thyroid hormones in fish. However, there are currently no standardised test guidelines for thyroid related effects in fish, and the OECD has highlighted challenges in identifying relevant endpoints for the testing of these effects (OECD 2023).

The AICIS 2025 human health evaluation reviewed the endocrine effects of octocrylene relevant to human health. Data indicated that the chemical interacts with the oestrogen, androgen and progesterone receptors in some *in vitro* assays, although at potencies several magnitudes lower than endogenously produced hormones (AICIS 2025; SCCS 2021). The evaluation also reviewed data on effects on the thyroid and concluded that octocrylene may interfere with the thyroid hormone system although effects were not observed consistently across studies. The observed effects may be mediated by changes to the thyroidal signalling as a result of liver enzymatic induction (AICIS 2025).

In the ECHA Restriction Report and Appendix for octocrylene (ECHA 2025a; ECHA 2025b), endocrine activity via a thyroid mode of action is discussed and evidence is presented in relation to endocrine effects relevant to human health. For the environment, results from studies of thyroid activity in rats were identified as potentially relevant for environmental species, since it is acknowledged that thyroid signalling, regulation, and development are highly conserved in vertebrates. However, they also report that none of the identified studies provide information on apical and adverse effects specific to a thyroid modality in other taxonomic groups. To investigate this, a Larval Amphibian Growth and Development Assay (LAGDA, OECD TG 241) study was requested. The results of the LAGDA study were not available to ECHA for their assessment, but they are now available and are discussed below along with other endocrine data specific to environmental species.

Endocrine activity

Octocrylene has been found to interact with the thyroid hormone system in fish, based on studies in zebrafish. Oestrogenic and androgenic activity was also observed in some *in vitro* assays and *in vivo* testing, although not consistently.

Octocrylene has been reported to significantly lower thyroid hormone levels (TSH, TT4, TT3, FT4, and FT3) in zebrafish larvae (Reum Kwon et al. 2024).

In a study of the effects of octocrylene on adult Japanese medaka (*Oryzias latipes*) at exposure concentrations of 2.7–233 µg/L for 28 days, impacts on the hormone levels were observed. Increases in vitellogenin and oestradiol (E2) were observed in males at all exposure concentrations, and in females exposed to 14 µg/L and 233 µg/L octocrylene. 11-ketotestosterone (11-KT) increased in females at all exposure concentrations. 11-KT levels in males varied, with increases and decreases observed across exposure levels (Yan et al. 2020).

Octocrylene has been shown to activate the oestrogen receptor pathway, in both *in vivo* (zebrafish larvae) and *in vitro* (zebrafish liver cell line) models (Meng et al. 2021).

Kunz et al. (2006) found no binding or response effects on oestrogenic activity for octocrylene in the rainbow trout oestrogen receptor alpha (rtERα) *in vitro*.

Ozáez et al. (2013) investigated effects of octocrylene on endocrine signalling genes following *in vivo* exposure to *Chironomus riparius* (harlequin fly) and found that it did not alter the ecdysone receptor, ultraspiracle, or oestrogen related receptor genes at the exposure conditions tested. In their later study on *Chironomus riparius* embryos and larvae, they found that octocrylene provoked an overexpression of the ecdysone receptor and triggered transcriptional activities. The same did not occur in larvae (Ozáez et al. 2016).

Adverse effects in whole organisms

Octocrylene causes chronic effects on fish, invertebrates and frogs, including impacts on reproductive success. However, available endpoints are potentially influenced by general toxicity, and the relative contribution of endocrine and non-endocrine effects cannot be determined.

A Larval Amphibian Growth and Development Assay (LAGDA, OECD TG 241) was conducted using African Clawed Frogs, *Xenopus laevis*, over 16 weeks (REACH n.d.). The study is a Level 4 assay under the OECD conceptual framework on endocrine disruptors testing and assessment. Adult frogs and tadpoles were exposed to octocrylene at concentrations ranging from 1.3 to 20 µg/L, and multiple endpoints indicative of both generalised toxicity and endocrine toxicity modes of actions were measured. An overall NOEC of 3.2 µg/L and an overall LOEC of 8.0 µg/L based on significant effects on oviduct stage (females; decrease) and male kidneys (increase in fibrosis) were observed. This suggested a potential generalised toxicity from exposure to octocrylene. Time to metamorphosis and sex ratios (phenotypic and genotypic) were not significantly impacted. No difference between phenotypic and genotypic gender nor asynchronous development were observed. No effects were observed in all thyroid endpoints, including histopathology (REACH n.d.). This standard test did not provide any evidence of apical adverse effects from an endocrine mode of action.

Zhang et al. (2016) studied the effects of three octocrylene accumulation levels on adult *Danio rerio* (zebrafish). Slightly increased gonadosomatic index (GSI) was observed at the highest accumulation level. No other significant effects in whole organisms were observed for any accumulation level. The exposure concentrations and body burdens in the study of Zhang et al. (2016) (up to 3,000 µg/L and 70,593 ng/g ww, respectively) are extremely high when compared to the environmental levels reported in the **Predicted environmental concentration (PEC)** section above.

Yan et al. (2020) studied the effects of octocrylene on adult and embryonic Japanese medaka (*Oryzias latipes*) reproduction and development. Adult fish (F0 generation) were exposed to octocrylene at measured concentrations of 2.7, 14 and 233 µg/L for 28 days before breeding. The subsequent offspring (F1 generation) were either reared in clean test water or exposed to the same octocrylene concentrations for 14 days. Observed significant effects on reproduction include:

- Reduced fecundity (number of produced eggs) in the parent (F0) generation for all test concentrations.
- Reduced survival of offspring (F1) reared in clean water for a parental (F0) exposure of 233 µg/L.
- Increased time to hatch, increased rate of morphological abnormalities, and reduced body weight in all offspring (F1) reared in octocrylene, for all exposure concentrations.
- Reduced survival of offspring (F1) reared in octocrylene for all exposure concentrations.

No significant effects on mortality, fertility rate, body length, or body weight were observed in parent (F0) fish.

The GSI and the hepatosomatic index (HSI) of adult male (F0) fish were not significantly different at any exposure concentration. A significant increase in GSI and HSI was observed for adult female (F0) fish exposed to 233 µg/L octocrylene. No increase in the proportion of spermatogonia was observed in the testes of adult male (F0) fish. A significant reduction in spermatozoa cells was observed; however, this did not impact the fertility rate. Some statistically significant differences in the proportions of ovary cells were observed in the ovaries of adult female (F0) fish at some exposure concentrations. However, the overall gonadal staging of these fish was considered to be similar when using the OECD gonadal staging criteria (OECD 2010).

While impacts on hormones were observed alongside effects on reproduction, no significant effects on gonads were observed that are indicative of endocrine modalities. As the observed effects on reproduction and on gonads may be impacted by non-endocrine modes of action, these effects are likely to be due to standard toxic modes of action (Yan et al. 2020).

Blüthgen et al. (2014) exposed zebrafish embryos (for 6 days) and adult males (for 8 or 16 days) to octocrylene in water (22–925 µg/L). Octocrylene showed no overt toxicity to zebrafish. No statistically significant effects on survival, phenotype, behaviour, condition factors, 11-KT concentrations, and GSI were observed in adult males. Octocrylene did not significantly affect survival and hatching rate in embryos (Blüthgen et al. 2014).

Predicted no-effect concentration (PNEC)

A freshwater PNEC of 0.266 µg/L (266 ng/L) is derived for octocrylene from the measured invertebrate chronic ecotoxicity endpoint (chronic value = 0.00266 mg/L or 2.66 µg/L), using an assessment factor of 10. This assessment factor was chosen due to the availability of chronic ecotoxicity endpoints for invertebrates supported by toxicity data for fish (EPHC n.d.). A higher assessment factor for the marine environment is not considered because marine and freshwater species generally show similar sensitivity to chemicals (Yanagihara et al. 2022) and the marine environment is considered to be more diluted at the outflow of STP effluent. Direct marine exposure to octocrylene is not considered to be significant from industrial uses of octocrylene.

For sediment, a PNEC is 0.926 mg/kg dw is derived from the lowest EC10 is 46.3 mg/kg dw and an assessment factor of 50. This assessment factor is chosen because there are 2 reliable long term tests with species representing different living and feeding conditions (EPHC n.d.).

For soil, a PNEC is 1.95 mg/kg dw is derived from the lowest NOEC is 19.5 mg/kg dw and an assessment factor of 10. This assessment factor is chosen because there are three long term tests with species representing three trophic levels (EPHC n.d.).

Categorisation of environmental hazard

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

Persistence

Persistent (P). Based on a lack of measured biodegradability in water and a long half-life for ultimate biodegradation in water-sediment systems, octocrylene is categorised as Persistent.

Bioaccumulation

Not Bioaccumulative (Not B). Based on measured bioconcentration factors (BCF) in fish, octocrylene is categorised as Not Bioaccumulative.

Toxicity

Toxic (T). Based on available chronic ecotoxicity values below 0.1 mg/L, octocrylene is categorised as Toxic.

Environmental risk characterisation

Based on the PEC and PNEC values determined above, the following Risk Quotients (RQ = PEC ÷ PNEC) have been calculated for release of octocrylene to surface waters, sediments, and soils:

Compartment	PEC	PNEC	RQ
Surface water (effluent, rivers, etc)	109 ng/L	266 ng/L	0.41
Sediment	635 µg/kg dw	926 µg/kg dw	0.69
Soil	14 µg/kg dw	1,950 µg/kg dw	0.007

For surface waters, sediment, and soil, an RQ less than 1 indicates that octocrylene is not expected to pose a significant risk to the environment based on estimated diffuse emissions, as environmental concentrations are below levels likely to cause harmful effects.

The RQ calculations rely on concentrations from Australian and international monitoring data which may include contributions from both industrial and non-industrial uses. As such, the RQ calculations are expected to be conservative for the industrial uses of octocrylene.

International monitoring data suggest that some recreational water bodies, such as popular beaches and reefs, are often subject to transient elevated concentrations of octocrylene through its use in personal care products and sunscreens. The highest monitoring values were identified for areas that were subject to high population densities and/or heavy recreational use, particularly in summer months. Conservative worst-case assumptions for these locations would result in localised RQs > 1, indicating the presence of transient risks. However, there are no acute effects expected at the limit of water solubility, and the chemical will be dispersed within the water bodies, thus limiting the potential for environmental risks. These concentrations include contributions from the wash off therapeutic sunscreens, which are not regulated as industrial chemicals in Australia. In the absence of Australian-specific monitoring data linking concentrations to different classes of products, there is insufficient evidence to fully characterise the risk to the environment at these locations from either the industrial or the therapeutic uses of octocrylene.

Uncertainty

This evaluation was conducted based on a set of information that may be incomplete or limited in parameters. Some relatively common data limitations can be addressed through use of conservative assumptions (OECD 2019) or quantitative adjustments such as assessment factors (OECD 1995). Others must be addressed qualitatively, or on a case-by-case basis (OECD 2019).

The most consequential areas of uncertainty for this evaluation are discussed below:

- The risk characterisation for octocrylene is based on the most relevant Australian and international monitoring data that is available. However, there is limited Australian monitoring data for octocrylene.
    - Further evaluation may be required if new Australian monitoring or exposure data become available to indicate that it may be present in Australian surface waters, sediments, or soils at concentrations above the levels of concern.
- The ecotoxicity to potentially sensitive aquatic organisms, such as coral, has been studied but not fully characterised by standardised international methods. Additionally, the endocrine activity and effects of octocrylene, and its degradants, may continue to be investigated yielding additional information.
    - Further evaluation may be required if new ecotoxicity data become available indicating that octocrylene is more hazardous than considered in this evaluation.

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