Australian Government

Department of Health, Disability and Ageing
Australian Industrial Chemicals Introduction Scheme

Benzoic acid, 2-hydroxy-, 2-ethylhexyl ester (Ethylhexyl salicylate)

Evaluation statement (EVA00197)

3 October 2025

Draft

DRAFT

Table of contents

Contents

DRAFT

DRAFT

AICIS evaluation statement (EVA00197)

Subject of the evaluation

Benzoic acid, 2-hydroxy-, 2-ethylhexyl ester (Ethylhexyl salicylate)

Chemical in this evaluation

Name	CAS registry number
Benzoic acid, 2-hydroxy-, 2-ethylhexyl ester	118-60-5

Reason for the evaluation

Evaluation Selection Analysis indicated a potential environmental risk.

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 benzoic acid, 2-hydroxy-, 2-ethylhexyl ester (ethylhexyl salicylate). The use of ethylhexyl salicylate 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 ethylhexyl salicylate have been assessed according to the following parameters:

- A domestic introduction volume of 21 tonnes per year, based on industry consultation.
- 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

Ethylhexyl salicylate has a reported introduction volume in Australia of 21 tonnes per annum (for both therapeutic and industrial uses). Based on Australian and international use data the chemical has functional uses as a UV filter and as a fragrance ingredient. Personal care products (cosmetics) containing ethylhexyl salicylate including skin applied products such as face cream and lip balm have been identified as being available on Australian commercial websites.

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

DRAFT

DRAFT

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:

- Not Persistent (Not 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 chemical is expected to be mainly released 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. Particularly as environmental concentrations are below levels likely to cause harmful effects.

Ethylhexyl salicylate may also be released directly to recreational waters by washing off the bodies of recreational water users while in use. However, this exposure route is expected to be particularly relevant to therapeutic sunscreens. International monitoring data suggests 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 ethylhexyl salicylate. Conservative worst case treatment of 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, the chemical is rapidly degradable and 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 ethylhexyl salicylate.

The chemical has been categorised under domestic thresholds as not persistent, not bioaccumulative, and toxic.

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.

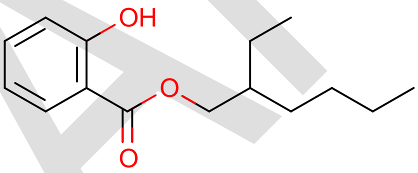
Note:

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.

DRAFT

Supporting information

Chemical identity

CAS number	118-60-5
CAS name	Benzoic acid, 2-hydroxy-, 2-ethylhexyl ester
Molecular formula	$C_{15}H_{22}O_3$
Associated names	Ethylhexyl salicylate 2-Ethylhexyl salicylate Octisalate Octyl salicylate
Molecular weight (g/mol)	250.33
SMILES (canonical)	O=C(OCC(CC)CCCC)C=1C=CC=CC1O
Structural formula	

Additional chemical identity information

The stereochemistry of the 2-ethylhexyl chain is not specified. The chemical is assumed to be composed of 2 enantiomers.

Relevant physical and chemical properties

Experimental (exp.) values are taken from the registration dossier for ethylhexyl salicylate submitted under the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH) legislation in the European Union (EU) (REACH n.d.-a). Calculated values were estimated using the following models: MCI method in EPISuite for K_{OC} (US EPA 2017), Chemaxon model in QSAR Toolbox for pKa (LMC 2021), and the Henry's Law Constant was calculated from the measured water solubility and vapour pressure values (US EPA, 2017):

Physical form	Liquid
Melting point	< -20 °C (exp.)
Boiling point	> 300 °C (exp.)
Vapour pressure	0.018 Pa (exp.)

DRAFT

Water solubility	0.074 mg/L at 20 °C (exp.)
Henry's law constant	61 Pa·m^3/mol (calc.)
Ionisable in the environment?	No
pKa	9.72 (calc.)
$\log K_{OW}$	5.94 at 25 °C (exp.)
K_{OC}	5,417 L/kg (calc.)

Introduction and use

Australia

Available information indicates that ethylhexyl salicylate has functional uses as a UV filter and as a fragrance ingredient. 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. Other secondary sunscreen products are excluded as therapeutic goods and are therefore industrial uses of the UV filters. 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, and the presence of other ingredients are scheduled in the *Poisons Standard* - *Standard for the Uniform Scheduling of Medicines and Poisons (SUSMP)* and pack size also apply to the product types above, as detailed in (TGA 2018).

An Australian voluntary call for information from industry in 2024 identified that approximately 21 tonnes of ethylhexyl salicylate are being introduced annually (for both therapeutic and industrial uses). For the more specific use as a fragrance ingredient, the use volume of ethylhexyl salicylate in 2023 was estimated to be less than 375 kg/year for Australia, based on data collected in the Asia-Pacific region by the International Fragrance Association (IFRA).

Personal care products (cosmetics) containing ethylhexyl salicylate including face cream and lip balm have been identified on Australian commercial websites.

The chemical has reported frequent use in therapeutic sunscreens (O'Malley 2020, TGA n.d.).

DRAFT

International

Ethylhexyl salicylate is primarily and commonly used as an active ingredient in personal care products (cosmetics) and sunscreens, where it functions as a UV-filter. The chemical is also used as a fragrance ingredient due to its scent, and as a skin conditioner. Based on international data, the majority of products containing ethylhexyl salicylate are primary sunscreens (Danish EPA 2015; De Lima Associates n.d.; EWG n.d.; INCI beauty n.d.). Primary sunscreens are regulated as therapeutic goods in Australia.

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

- perfumes
- skin care products
- make up products
- hair care products
- tanning products
- sun oil.

(Danish EPA 2015; De Lima Associates n.d.; EWG n.d.; INCI beauty n.d.; REACH n.d.-a).

High volumes of ethylhexyl salicylate are used internationally. The annual use volume of ethylhexyl salicylate in the USA is 454–9,070 tonnes for 2017–2019 (US EPA 2020). In the European Economic Area (EEA), ethylhexyl salicylate is registered for use in the range of 1,000–10,000 t/year (REACH n.d.-a).

The chemical is listed on the IFRA Transparency List (IFRA n.d.). Based on data collected by IFRA, the use volume of ethylhexyl salicylate as a fragrance ingredient in the Asia-Pacific region was approximately 7.5 tonnes in 2023.

Existing Australian regulatory controls

Environment

The industrial use of ethylhexyl salicylate is not subject to any specific national environmental regulations.

Environmental exposure

Ethylhexyl salicylate has non-industrial use in therapeutic sunscreens and industrial use in a variety of personal care products. The environmental risks from the use of ethylhexyl salicylate in therapeutic sunscreen products are outside the scope of this evaluation. However, their environmental exposure pathways are similar to industrial uses, so it is difficult to distinguish between environmental exposure from therapeutic and industrial uses of ethylhexyl salicylate.

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

DRAFT

- soil by application of biosolids to agricultural land (Struijs 1996).

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

Environmental fate

Dissolution, speciation and partitioning

Ethylhexyl salicylate is expected to mostly partition to sediment when released into the environment, with some remaining in water.

Ethylhexyl salicylate is only very slightly soluble, and based on its calculated pKa of 9.72, some speciation to the phenolate anion is expected in alkaline waters (16% at pH 9). The Henry's law constant indicates moderate volatility from water and moist soil. Ethylhexyl salicylate has high lipophilicity, which promotes partitioning from water to organic matter, including biota and sediment. The calculated K_{OC} of 5,417 L/kg indicates that ethylhexyl salicylate will be immobile once it partitions to soil and sediment.

Degradation

Ethylhexyl salicylate is not persistent. The chemical is readily biodegradable in water and has an estimated half-life of less than 2 days in air.

The key ready biodegradation study in the REACH registration dossier was conducted in a closed bottle evolution test in accordance with EU Method C.4-E (similar to OECD TG 301 D) over a testing period of 28 days. The test was valid according to the criteria given in the testing guideline. A degradation of 89% of the test substance was found at the end of the testing period and the 10 day window period was fulfilled (REACH n.d.-a). The results indicate that ethylhexyl salicylate is readily biodegradable in water.

Ethylhexyl salicylate is expected to degrade in the atmosphere through reaction with photogenerated hydroxyl radicals. Calculations performed assuming a typical hydroxyl radical concentration of 1.5×10^6 molecules/cm^3 resulted in a half-life of 5.9 h (US EPA 2017a).

Bioaccumulation

Ethylhexyl salicylate is not expected to bioaccumulate in aquatic life. Ethylhexyl salicylate has a log K_{OW} of 5.94 indicating a potential to bioaccumulate and/or undergo trophic magnification in some aquatic food webs. However, both measured and calculated data indicate that biotransformation occurs at a faster rate than uptake. Bioconcentration factors (BCFs) and bioaccumulation factors (BAFs) of ethylhexyl salicylate, and similar chemicals, are below the domestic threshold for categorisation as bioaccumulative (EPHC 2009).

DRAFT

Field bioaccumulation studies

Tang et al. (2019) measured ethylhexyl salicylate BAFs in wild fish from Lake Chaohu, China. These values were erroneously reported as BCFs in the paper. The mean BAF value observed across 6 species of fish was 16.2 L/kg ww, with a range of 8.3–59 L/kg ww. These values are below the domestic threshold of 2,000 L/kg (EPHC 2009).

Laboratory and calculated bioconcentration studies

Ethylhexyl salicylate has an estimated biotransformation half-life of less than one day in fish (US EPA 2017a). Therefore, a model considering bioelimination from the organism is most suitable and the method of Arnot and Gobas (Arnot and Gobas 2006) was used in EPISuite (US EPA 2017a). The calculated BCF estimate in fish (upper trophic level) is 123.7 L/kg ww (REACH n.d.-a). The lower trophic level BCF for fish is 174.4 L/kg ww (US EPA 2017a). Calculated BCF values for ethylhexyl salicylate are supported by measured BCF values for the analogue chemical cyclohexyl salicylate (log K_{OW} = 4.7, CAS No. 25485-88-5). Cyclohexyl salicylate has a measured BCF between 600 and 900 L/kg ww in *Danio rerio* in steady state, flow-through conditions according to OECD TG 305E (REACH n.d.-c).

Environmental transport

Ethylhexyl salicylate is not expected to undergo long range transport based on its short half life in the environment. Although, the chemical has been detected in samples of Arctic snow more information is required to distinguish between local and long range sources of the chemical in remote regions.

In a study by D’Amico et el. (2024) the atmospheric transport of ethylhexyl salicylate was considered by analysing analyte concentrations in 25 snow samples collected from glaciers and the vicinity of a research centre in the Svalbard area in the Arctic. Ethylhexyl salicylate was one of the most abundant UV filters detected in the samples. Total concentrations (dissolved + particulate phase) ranging from below the limit of detection (0.9 ng/L) to 61.9 ng/L, with a mean of 15.7 ng/L, were measured. Local and long range sources, as well as direct contamination by scientists’ visits, were cited as possible sources of the chemical in snow samples.

In another study conducted by Tsui et al. (2014a), ethylhexyl salicylate was not detected in surface seawater samples from the Arctic Ocean and Chukchi Sea.

Predicted environmental concentration (PEC)

Based on its use, ethylhexyl salicylate is expected to be mainly released into the environment via the sewer with some release directly from the bodies of recreational water users. The chemical has been measured in concentrations ranging from ng/L to low µg/L in a variety of waters internationally, with the highest concentrations observed in recreational waters affected by direct release of therapeutic uses of the chemical from the bodies of swimmers. In a study of estuary waters in Victoria, Australia, a maximum concentration of 31.6 ng/L was detected. However, a maximum of 266 ng/L in Japanese streams has been selected as a conservative PEC for surface waters. A modelled PEC in soil of 0.24 mg/kg dw has been selected, in the absence of measured data in this compartment. Ethylhexyl salicylate has also been measured in a variety of sediment studies, up to a maximum concentration of 20 ng/g dw in river sediment in Spain. 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 ethylhexyl salicylate have also been detected in biota, and these have been reported for information purposes in this section.

DRAFT

Surface waters

Ethylhexyl salicylate is released to surface waters both via sewers and directly from the bodies of recreational water users. Therefore, it has been detected in a range of aquatic environments including beaches, reefs, rivers, lakes, and streams as summarised in the following paragraphs.

Ethylhexyl salicylate has been measured in a variety of surface waters internationally. Tsui et al (2014b) investigated the removal efficiency of the chemical in different sewage treatment plants and treatment techniques. Ethylhexyl salicylate showed almost complete removal from the effluent following secondary treatment. Tashiro and Kameda (2013) measured the concentrations of UV filters at 4 beaches, 2 reefs, and one river on Okinawa Island, Japan. Ethylhexyl salicylate concentrations ranged from not detected up to 10 ng/L. A maximum concentration of 266 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). In Korean rivers, ethylhexyl salicylate was detected in the range of about 25 to 150 ng/L (Ekpeghere et al. 2016).

Allinson et al. (2018) measured ethylhexyl salicylate concentrations in the range from 18.0 to 31.6 ng/L in Victorian estuary sites in Australia. Despite this Australian monitoring data, the predicted environmental concentration in domestic surface waters from diffuse release via STPs is conservatively taken to be 266 ng/L as reported for Japanese streams. This value was the highest found internationally that was not attributed to transient and localised direct releases. As such, it is conservatively representative of the release of ethylhexyl salicylate to surface waters from industrial uses of the chemical.

Other international monitoring of ethylhexyl salicylate levels in the surface waters of cities, beaches and reefs is available. Tsui et al (2014a) measured the occurrence of UV filters in surface waters in Hong Kong, Tokyo, Bangkok, New York, Los Angeles, the Arctic, Shantou, and Chaozhou. Total UV filter concentrations generally decreased with population density. Ethylhexyl salicylate was detected in 59% of the 60 Hong Kong Harbour samples in the range of 61–1,030 ng/L. The concentrations of ethylhexyl salicylate exceeding 1,000 ng/L were in surface water samples collected on hot summer days with strong UV radiation in June and August 2013 at a popular beach in Hong Kong, indicating use and wash off from sunscreens high in ethylhexyl salicylate content. Given the significant population density in this region, the monitoring values are unlikely to be relevant to Australian conditions. Concentrations of ethylhexyl salicylate in the other major cities studied ranged 28–128 ng/L (Tsui et al. 2014a). Tsui et al. (2019) reported ethylhexyl salicylate concentrations between 0.85 and 27.8 ng/L in the coastal regions of the South China Sea. In a study by García-Pimentel et al. (2023) assessing concentrations of UV filters in waters of the Mar Menor lagoon and Ebro Delta Spain, seasonal fluxes in ethylhexyl salicylate were observed. Mar Menor lagoon is a semi enclosed coastal area that is impacted by agriculture, tourism, urban land uses and mining, and Ebro Delta is impacted by industrial activities, urban and agricultural land uses. The maximum ethylhexyl salicylate concentration in Mar Menor was 1,034 ng/L in summer and 22.6 ng/L in winter. In the Ebro Delta river and bays, the maximum ethylhexyl salicylate concentration decreased from > 2,000 ng/L (above the linearity of the calibration curve) in summer to 30.8 ng/L in winter. As swimming and other recreational activities are popular in these areas, the major contributing source to the high summer concentrations is likely wash off from therapeutic sunscreens. For coral reef locations, Mitchelmore et al. (2019) reported ethylhexyl salicylate concentrations up to about 120 ng/L at reefs off Oahu, Hawaii.

DRAFT

Soil

No monitoring data for ethylhexyl salicylate in soil were identified. The PEC for this compartment was estimated using STP modelling for the application of biosolids to agricultural land. Based on a reported introduction volume of 21 tonnes/annum, 100% release to sewers, and modelled sewage treatment, a concentration of 0.76 µg/L is predicted in STP effluent. Modelled partitioning to primary and surplus sludge predicts a concentration of 7.93 mg/kg in the combined sludge (SimpleTreat 4.1) (Stuijs 2014). This biosolid concentration, under a standard model of application of biosolids to agricultural land, produces a worst case PEC in soil of 0.24 mg/kg dw. The predicted effluent concentration and soil PEC are expected to be overestimates of the concentrations resulting from industrial uses as the reported Australian volume is for both industrial and therapeutic uses of the chemical.

Sediment

Being lipophilic, ethylhexyl salicylate partitions to sediment and biota. Therefore, it has been measured in a range of aquatic sediments and biota around the world, as reported below.

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. However, ethylhexyl salicylate was not detected in any samples. Sanchez-Brunete et al. (2011) detected ethylhexyl salicylate up to 20 ng/g dw in river sediment in Spain. Gu et al. (2025) detected ethylhexyl salicylate concentrations up to a maximum of 6.43 ng/g dw in sediments from Taihu Lake China in November 2015 and 2016. Apel et al. (2018) detected ethylhexyl salicylate in the surface sediment of the Bohai Sea and Yellow Sea up to 1.35 ng/g dw. Pintado-Herrera et al. (2017) found ethylhexyl salicylate in sediments of Cadiz Bay and Huelva Estuary in Andalusia, Spain up to 7.7 ng/g dw. Tovar-Salvador et al. (2023) detected ethylhexyl salicylate in coastal sediment samples in the Atacama Region of Chile up to 2.33 ng/g dw. Mitchelmore et al. (2021) conducted a review of UV filters around coral reefs and reported the highest as a median of 2.65 ng/g dw of ethylhexyl salicylate in sediments near Hawaiian coral reefs (Mitchelmore et al. 2019). The maximum value of 20 ng/g dw is conservatively selected as the PEC for sediment in Australia.

Biota

Ethylhexyl salicylate has also been detected in a range of aquatic biota globally. As reported in Mitchelmore et al. (2021), Mitchelmore et al. (2019) measured a median of 331 ng/g dw in corals around Hawaii, USA. Tang et al (2019) found concentrations of ethylhexyl salicylate in the muscle of wild fish from Lake Chaohu, China, ranging 0.46 to 8.87 ng/g dw. Cunha et al. (2018) studied levels of ethylhexyl salicylate in seafood, reporting the highest levels in wild mussels at 72.1 ng/g dw. Petrarca et al. (2022) measured ethylhexyl salicylate at 6.1–79.2 ng/g dw in Atlantic Ocean estuary fish muscle samples. This data shows that ethylhexyl salicylate 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}, ethylhexyl salicylate is a difficult to test substance. Acute ecotoxicity testing, using ethylhexyl salicylate reported in the REACH

DRAFT

registration dossier for fish, invertebrates, and algae found no effects at saturation (REACH n.d.-a).

Additional non-guideline studies on fish and freshwater and marine invertebrates support the absence of acute effects at exposure concentrations up to the water solubility of ethylhexyl salicylate (0.074 mg/L at 20 °C) (Layton 2015, Thorel et al. 2020, Zhao et al. 2023).

Chronic toxicity

The following measured no observed effect concentration (NOEC) values were retrieved from the REACH registration dossier for ethylhexyl salicylate (REACH n.d.-a). A calculated chronic endpoint has been included for fish using ECOSAR (US EPA 2017b):

Taxon	Endpoint	Method
Fish	NOEC = 0.005 mg/L	ECOSAR Chronic Value Esters Class Calculated for ethylhexyl salicylate
Invertebrates	21 d NOEC = 0.0061 mg/L	*Daphnia magna* (water flea) Reproduction Measured concentrations OECD TG 211
Algae	72 h NOEC ≥ 0.011 mg/L	*Raphidocelis subcapitata* (green algae) Growth rate Measured concentrations OECD TG 201

The standardised OECD TG 211 study (*Daphnia magna* reproduction test) referenced above found an overall LOEC based on survival, growth, and reproduction of 0.014 mg/L. The effects were not attributed to a specific mode of action.

The chronic calculated endpoint for fish has been included as ECOSAR has been shown to give the most conservative value from multiple models, which has been verified with comparison to experimental values for other salicylate analogues (REACH n.d.-a, REACH n.d.-b, REACH n.d.-c).

Thorel et al. (2020) conducted a 7 day study and found a 24% decrease in growth rate for algae exposed to 1 mg/L ethylhexyl salicylate, with significant effects at 0.010 mg/L for a non-apical endpoint. Although it is noted that this was not a guideline study, not conducted in a GLP laboratory, and a solvent was used, the observed effects add weight to the chronic classification for toxicity.

Effects on sediment dwelling life

No ecotoxicity data are currently available for effects on sediment dwelling life. For the purposes of this risk assessment the ecotoxicity has been estimated via the equilibrium partitioning method (EPHC 2009), to give an indication of levels in sediment that may produce effects on sediment dwelling and/or aquatic life (see **Predicted no effect concentration (PNEC)** section). Lucas et al. (2022) studied zebrafish larvae developed from eggs exposed to sediment spiked with ethylhexyl salicylate for 96 hr and with a test concentration of 10 µg/g sediment. They found that ethylhexyl salicylate significantly

DRAFT

increased (by 19.7%) the cardiac frequency of larvae zebrafish for fish embryos developed under these exposure conditions.

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 ethylhexyl salicylate exposure. Stien et al. (2020) found that ethylhexyl salicylate alters the concentration of a coral sterol at 50 µg/L for the coral *Pocillopora damicornis*. Further metabolomic analyses suggested a stress/inflammatory response at 300 µg/L and above. No coral bleaching was observed at concentrations up to 300 µg/L. However, there are no standardised tests available, and the practical significance of these findings is unclear.

Effects on terrestrial life

No terrestrial ecotoxicity data are currently available for ethylhexyl salicylate. Cyclohexyl salicylate (CAS No. 25485-88-5) is an acceptable analogue for read across based on physical and chemical similarity, with data available for 3 trophic levels (ECHA Chem n.d.-c).

A LC50 value between 560 and 1,000 mg cyclohexyl salicylate/kg soil dw was reported for *Eisenia fetida* (earthworm) mortality after 14 days exposure, as per OECD TG 207 (REACH n.d.-c). This corresponds to an LC50 of 636–1137 mg ethylhexyl salicylate/kg soil dw when converted based on molecular weight. No mortality was recorded at 560 mg cyclohexyl salicylate/kg soil dw and 60% mortality was observed on day 7 for 1,000 mg cyclohexyl salicylate/kg soil dw.

A 28 day test on *Avena sativa* (oats) per OECD TG 208 reported a NOEC value of 300 mg cyclohexyl salicylate/kg soil dw and LOEC value of 1,000 mg cyclohexyl salicylate/kg soil dw (REACH n.d.-c). The NOEC value correlates to 341 mg/kg soil dw for ethylhexyl salicylate.

In a 28 day test on soil microorganisms as per OECD TG 216 no effects were observed up to the final test value of 100 mg/kg soil dw (REACH n.d.-c). The final test value converts to 114 mg/kg soil dw for ethylhexyl salicylate.

Endocrine effects

There is limited evidence that ethylhexyl salicylate may interact with endocrine systems. However, the current available data do not provide evidence of an adverse effect of the chemical from an endocrine mode of action.

Endocrine activity

Ethylhexyl salicylate has been found to interact with the thyroid hormone system in fish, based on a study in zebrafish. Interactions with the oestrogen and androgen receptors were also observed in some *in vitro* assays, although at potencies several magnitudes lower than endogenously produced hormones.

Exposure to ethylhexyl salicylate was observed to affect thyroid hormone levels in fish. However, there are currently no standardised test guidelines for thyroid related effects in fish. The OECD has highlighted challenges in identifying relevant endpoints for the testing of these effects in fish (OECD 2023). Ka et al. (2024) tested effects of ethylhexyl salicylate on the thyroid hormone system of zebrafish embryos and larvae. At 30 µg/L a significant increase in thyroxine (T4) was observed.

DRAFT

Kunz et al. (2006) found minimal oestrogenic activity for ethylhexyl salicylate in the rainbow trout oestrogen receptor alpha (rtERα) *in vitro* and no effect for *in vivo* vitellogenin induction for fish.

Kunz and Fent (2006) found that ethylhexyl salicylate did not exhibit oestrogenic activity but showed anti-oestrogenic, androgenic activity and anti-androgenic activity in human oestrogen receptor (hERα) and androgen receptor (hAR) assays. The concentrations at which effects were observed significantly exceed the water solubility limit of ethylhexyl salicylate.

Adverse effects in whole organisms

The available data do not provide evidence that ethylhexyl salicylate causes adverse effects as a consequence of an endocrine mode of action. Ethylhexyl salicylate has chronic effects on *Daphnia magna* reproduction and is expected to be chronically toxic to fish. However, the mode of action for these effects has not been demonstrated.

In the Ka et al. (2024) study, reduced hatching rates, larvae survival and body length were observed at 300 µg/L after 96 h exposure to ethylhexyl salicylate, a concentration that exceeds the normal water solubility of the chemical. These adverse effects may be due to thyroid activity induced by the chemical. However, the measured effects are non-specific endpoints for thyroid hormone system disruption and may be influenced by generalised non-endocrine toxicity. No adverse effects were observed below the water solubility of the chemical.

Predicted no-effect concentration (PNEC)

A freshwater PNEC of 0.61 µg/L (610 ng/L) is derived for ethylhexyl salicylate from the measured invertebrate chronic ecotoxicity endpoint (Chronic Value = 0.0061 mg/L or 6.1 µg/L), using an assessment factor of 10. This assessment factor was selected based on the following considerations:

- absence of acute effects up to the water solubility of the chemical
- a weight of evidence approach for chronic effects, based on reliable chronic endpoints for 2 trophic levels, and a conservative modelled estimation of the chronic toxicity to fish supported by a comparison between experimental and calculated data for analogue chemicals (EPHC 2009).

A sediment PNEC of 130 µg/kg dw has been derived for ethylhexyl salicylate by the equilibrium partitioning method using the aquatic PNEC of 0.61 µg/L, the calculated K_{OC} of 5,417 L/kg, and default values (EPHC, 2009).

A soil PNEC of 6.82 mg/kg dw (6,820 µg/kg dw) is derived for ethylhexyl salicylate based on the analogue derived NOEC of 341 mg/kg dw soil for terrestrial plants and an assessment factor of 50. This assessment factor was chosen as terrestrial ecotoxicity data for the suitable analogue, cyclohexyl salicylate, was available for a short term test and 2 long term tests for 3 trophic levels (EPHC, 2009).

DRAFT

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 the ready biodegradability of the chemical, ethylhexyl salicylate is categorised as Not Persistent.

Bioaccumulation

Not Bioaccumulative (Not B). Based on measured and calculated BCF and BAF values in fish, and evidence of biotransformation, ethylhexyl salicylate is categorised as Not Bioaccumulative.

Toxicity

Toxic (T). Based on chronic toxicity values below 0.1 mg/L, ethylhexyl salicylate 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 ethylhexyl salicylate to surface waters, sediments, and soils:

Compartment	PEC	PNEC	RQ
Surface water	266 ng/L	610 ng/L	0.44
Soil	240 µg/kg dw	6,820 µg/kg dw	0.035
Sediment	20 µg/kg dw	130 µg/kg dw	0.15

For surface waters, sediment and soil, an RQ less than 1 indicates that ethylhexyl salicylate is not expected to pose a significant risk to the environment based on estimated diffuse emissions and environmental monitoring, as environmental concentrations are below levels likely to cause harmful effects. However, re-evaluation of ethylhexyl salicylate may be required if new Australian monitoring data with environmental concentrations higher than those considered in this Evaluation Statement or relevant ecotoxicity data for the sediment compartment become available.

Ethylhexyl salicylate is categorised as not persistent, not bioaccumulative and toxic. The chemical is readily biodegradable in water. The log K_{OW} of ethylhexyl salicylate indicates bioaccumulation potential, but the bioaccumulation factors (BAFs) for ethylhexyl salicylate and bioconcentration factors (BCFs) obtained from calculations and a suitable analogue are below the domestic threshold for categorisation as bioaccumulative. Although the chemical does not induce any acute effects up to its solubility limit, it is chronically toxic to aquatic life.

DRAFT

International monitoring data suggests that some recreational water bodies, such as popular beaches and reefs, may be subject to transient elevated concentrations of ethylhexyl salicylate 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, the chemical is rapidly degradable and will be dispersed within the water bodies, thus limiting the potential for environmental risks. These concentrations include contributions from the wash off of 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 ethylhexyl salicylate.

Uncertainty

This evaluation was conducted based on a set of information that may be incomplete or limited in scope. 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 ethylhexyl salicylate is based on the most relevant international monitoring data that is available. There is limited Australian monitoring data for ethylhexyl salicylate.
    - 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.
- There are no standard ecotoxicity data on sediment dwelling organisms or terrestrial species available for ethylhexyl salicylate. Additionally, the ecotoxicity to other potentially sensitive aquatic organisms, such as coral, has been studied but not fully characterised by standardised international methods.
    - The ECHA Chem dossier for ethylhexyl salicylate states that the screening assessment indicates the need to investigate further the effects on sediment organisms, and a testing proposal for a Sediment-Water Lumbriculus Toxicity Using Spiked Sediment according to OECD TG 225 is proposed. Depending on the results of the OECD 225 study further sediment toxicity tests might be suggested. The ECHA Chem dossier and the risk assessment will be updated as soon as the results are available (ECHA Chem n.d.-a).
    - Further evaluation may be required if new ecotoxicity data become available indicating that ethylhexyl salicylate is more hazardous than considered in this evaluation.
- The endocrine activity and effects of ethylhexyl salicylate have been studied but not fully characterised by standardised international methods.
    - Further evaluation may be required if new relevant data become available.
- The identities and environmental effects of the degradation products of ethylhexyl salicylate have not been fully assessed as part of this evaluation.
    - Further evaluation may be required if more information becomes available in the future to indicate the potential for any environmental metabolites or degradants to cause harm in the environment.

DRAFT

References

AICIS (2024) *Salicylic acid and its salts*, AICIS, accessed 22 July 2025.

Allinson M, Kameda Y, Kimura K and Allinson G (2018) 'Occurrence and assessment of the risk of ultraviolet filters and light stabilizers in Victorian estuaries', *Environmental Science and Pollution Research,* **25**(12), pp 12022-12033, doi:10.1007/s11356-018-1386-7.

Apel C, Tang J and Ebinghaus R (2018) ‘Environmental occurrence and distribution of organic UV stabilizers and UV filters in the sediment of Chinese Bohai and Yellow Seas’, *Environmental Pollution*, 235: 85-94, doi:10.1016/j.envpol.2017.12.051.

Arnot J and Gobas F (2006) 'A review of bioconcentration factor (BCF) and bioaccumulation factor (BAF) assessments for organic chemicals in aquatic organisms', *Environmental Reviews,* 14: 257-297, doi:10.1139/A06-005.

Commonwealth of Australia (2019) *Industrial Chemicals Act 2019*, accessed 22 July 2025.

Cunha SC, Trabalón L, Jacobs S, Castro M, Fernandez-Tejedor M, Granby K, Verbeke W, Kwadijk C, Ferrari F, Robbens J, Sioen I, Pocurull E, Marques A, Fernandes JO and Domingo JL (2018). UV-filters and musk fragrances in seafood commercialized in Europe Union: Occurrence, risk and exposure assessment. *Environmental research*, 161: 399–408, doi:10.1016/j.envres.2017.11.015.

Danish EPA (The Danish Environmental Protection Agency) (2015) *Survey and health assessment of UV filters*, Danish EPA, accessed 22 July 2025.

D'Amico M, Kallenborn R, Scoto F, Gambaro A, Gallet JC, Spolaor A and Vecchiato M (2024) 'Chemicals of Emerging Arctic Concern in north-western Spitsbergen snow: Distribution and sources', *Science of The Total Environment,* 908, 168401, doi: 10.1016/j.scitotenv.2023.168401.

Danovaro, R, Bongiorni, L, Corinaldesi, C, Giovannelli, D, Damiani, E, Astolfi, P, Greci, L, & Pusceddu, A. (2008). Sunscreens cause coral bleaching by promoting viral infections. *Environmental health perspectives*, *116*(4), 441–447. doi:10.1289/ehp.10966

DeLima Associates (n.d.) Consumer Product Information Database, *DeLima Associates website*, accessed 22 July 2025.

Ekpeghere K, Kim U, Sung-Hee O, Hee-Young Kim, Jeong-Eun Oh (2016) ‘Distribution and seasonal occurrence of UV filters in rivers and wastewater treatment plants in Korea’, *Science of The Total Environment*, 542, 121-128, doi:10.1016/j.scitotenv.2015.10.033.

EPHC (Environment Protection and Heritage Council) (2009) *Environmental Risk Assessment Guidance Manual for Industrial Chemicals*, EPHC, accessed 22 July 2025.

EWG (Environmental Working Group) (n.d.) *Octisalate*, EWG website, accessed 22 July 2025.

García-Pimentel M, Campillo JA, Castaño-Ortiz JM, Llorca M and León VM (2023) 'Occurrence and distribution of contaminants of legacy and emerging concern in surface waters of two Western Mediterranean coastal areas: Mar Menor Lagoon and Ebro Delta', *Marine Pollution Bulletin*, 187, 114542, doi:10.1016/j.marpolbul.2022.114542.

DRAFT

DRAFT

Gu W, Sun S, Cai Y, Du Z, Shan X, Liang M, Guo M, Zhou L and Zhang Y (2025) 'Occurrences, spatial distributions, and ecological risks of organic ultraviolet absorbents in surface sediments from Taihu Lake, China', *Emerging Contaminants,* 11(2), 100466, doi: 10.1016/j.emcon.2024.100466.

IFRA (International Fragrance Association) (n.d.) *Transparency List*, IFRA website, accessed 22 July 2025.

INCI beauty (Internation Nomenclature Cosmetic Ingredient) (n.d.) *Ethylhexyl salicylate*, INCI beauty website, accessed 22 July 2025.

Ka Y, Lee I and Ji K (2024) 'Thyroid and growth hormone endocrine disruption and mechanisms of homosalate and octisalate using wild-type, thrα-/-, and dre-miR-499-/- zebrafish embryo/larvae', *Ecotoxicology and Environmental Safety,* 286, 117170, doi: 10.1016/j.ecoenv.2024.117170.

Kameda Y, Kimura K and Miyazaki M (2011) ‘Occurrence and profiles of organic sun-blocking agents in surface waters and sediments in Japanese rivers and lakes’, *Environmental Pollution*, 159(6): 1570-1576, doi:10.1016/j.envpol.2011.02.055.

Kunz PY and Fent K (2006). ‘Multiple hormonal activities of UV filters and comparison of in vivo and in vitro estrogenic activity of ethyl-4-aminobenzoate in fish’. *Aquatic Toxicology*, *79*(4): 305–324, doi:10.1016/j.aquatox.2006.06.016.

Kunz PY, Galicia HF and Fent K (2006). Comparison of in vitro and in vivo estrogenic activity of UV filters in fish. *Toxicological Sciences*, *90*(2): 349–361, doi:10.1093/toxsci/kfj082.

Layton SM (2015) ‘UV filters as common organic water contaminants: A toxicological study of selected UV filters on Daphnia magna, a monitoring study of selected Oklahoma lakes, and the development of an undergraduate endocrine disruption authentic research lab’, Doctoral thesis, Oklahoma State University, accessed 22 July 2025.

LMC (2021) *The OECD QSAR Toolbox, (Version 4.4.1)*, [Computer software], Laboratory of Mathematical Chemistry (LMC), University "Prof. Dr. Assen Zlatarov", accessed 22 July 2025.

Lucas J, Logeux V, Rodrigues A, Stien D and Lebaron P (2022) ‘Impact of Egg Exposure to UV Filter-Spiked Sediment on the Survival, Hatching Success, Cardiac Frequency and Metabolic Scope of Zebrafish Embryos.’ *Oceans*, 3: 84-93, doi:10.3390/oceans3010008f

Mitchelmore CL, He K, Gonsior M, Hain E, Heyes A, Clark C, Younger R, Schmitt-Kopplin P, Feerick A, Conway A and Blaney L (2019). ‘Occurrence and distribution of UV-filters and other anthropogenic contaminants in coastal surface water, sediment, and coral tissue from Hawaii.’ *Science of the Total Environment*, 670: 398–410, doi:10.1016/j.scitotenv.2019.03.034.

Mitchelmore CL, Burns EE, Conway A, Heyes A and Davies IA (2021). ‘A Critical Review of Organic Ultraviolet Filter Exposure, Hazard, and Risk to Corals.’ *Environmental Toxicology and Chemistry,* 40: 967– 988, doi:10.1002/etc.4948

Moeller, Mareen & Pawlowski, Sascha & Petersen-Thiery, Mechtild & Miller, Ingo & Nietzer, Samuel & Heisel-Sure, Yannik & Kellermann, Matthias & Schupp, Peter. (2021). Challenges in Current Coral Reef Protection – Possible Impacts of UV Filters Used in Sunscreens, a Critical Review. *Frontiers in Marine Science*. 8: 665548, doi:10.3389/fmars.2021.665548.

OECD (Organisation for Economic Co-operation and Development) (1995) *Guidance document for aquatic effects assessment*, OECD, Paris.

OECD (The Organisation for Economic Co-operation and Development) (2019) *Guiding Principles and Key Elements for Establishing a Weight of Evidence for Chemical Assessment, Series on Testing and Assessment No. 311, Environment, Health and Safety Division, Environment Directorate*, OECD, accessed 22 July 2025.

OECD (The Organisation for Economic Co-operation and Development) (2023) *Detailed review paper (DRP) on the thyroid hormone system in fish and identification of potential thyroid hormone system related endpoints for inclusion in existing OECD fish Test Guidelines, Series on Testing and Assessment No. 381, Environment Directorate*, OECD, accessed 17 September 2025.

O'Malley EJ (2020) *Assessing sources, fate, and the potential risk of UV filters in the aquatic environment*, Doctoral thesis, University of Queensland, accessed 22 August 2024.

Petrarca MH, Fernandes JO, Marmelo I, Marques A, Cunha SC (2022). Multi-analyte gas chromatography-mass spectrometry method to monitor bisphenols, musk fragrances, ultraviolet filters, and pesticide residues in seafood. *Journal of Chromatography A,*1663: 462755. doi:10.1016/j.chroma.2021.462755.

Pintado-Herrera MG, Combi T, Corada-Fernández C, González-Mazo E and Lara-Martín PA (2017) 'Occurrence and spatial distribution of legacy and emerging organic pollutants in marine sediments from the Atlantic coast (Andalusia, SW Spain)'. *Science of the Total Environment*, 605: 980–994, doi:10.1016/j.scitotenv.2017.06.055.

REACH (Registration, Evaluation, Authorisation and Restriction of Chemicals) (n.d.-a) *ECHA Chem dossier for ethylhexyl salicylate (CAS RN 118-60-5),* European Chemicals Agency, accessed 22 July 2025.

REACH (Registration, Evaluation, Authorisation and Restriction of Chemicals) (n.d.-b) *ECHA Chem dossier for homosalate (CAS RN 118-56-9),* European Chemicals Agency, accessed 22 July 2025.

REACH (Registration, Evaluation, Authorisation and Restriction of Chemicals) (n.d.-c) *ECHA Chem dossier for cyclohexyl salicylate (CAS RN 25485-88-5),* European Chemicals Agency, accessed 22 July 2025.

Sánchez-Brunete C, Miguel E, Ibero B, Tadeo JL, (2011) 'Analysis of salicylate and benzophenone-type UV filters in soils and sediments by simultaneous extraction cleanup and gas chromatography–mass spectrometry', *Journal of Chromatography A*, 1218(28), 4291-4298, doi:10.1016/j.chroma.2011.05.030.

Saxe JK, Dean S, Jones RL, Mullins LA and Reynertson KA (2021). Development of a novel rinse-off method for improved sunscreen exposure assessment. *Integrated Environmental Assessment and Management* , 17(5): 961–966, doi:10.1002/ieam.4451.

Stien D, Suzuki M, Rodrigues AMS, Yvin M, Clergeaud F, Thorel E and Lebaron P (2020) 'A unique approach to monitor stress in coral exposed to emerging pollutants'. *Scientific Reports*, 10(1): 9601, doi:10.1038/s41598-020-66117-3.

DRAFT

Struijs J (2014), *SimpleTreat 4.1: A model to predict fate and emission of chemicals in wastewater treatment plants: Background report describing equations*, National Institute of Public Health and the Environment (RIVM).

SWA (Safe Work Australia) (n.d.) *Hazardous Chemical Information System* (HCIS), SWA website, accessed 22 July 2025.

Tang Z, Zhong F, Cheng J, Nie Z, Han X, Han Y and Yang Y (2019) 'Concentrations and tissue-specific distributions of organic ultraviolet absorbents in wild fish from a large subtropical lake in China', *Science of the Total Environment,* 647: 1305-1313, doi:10.1016/j.scitotenv.2018.08.117.

Tashiro Y and Kameda Y (2013) 'Concentration of organic sun-blocking agents in seawater of beaches and coral reefs of Okinawa Island, Japan', *Marine Pollution Bulletin*, 77(1–2): 333-340, doi:10.1016/j.marpolbul.2013.09.013.

TGA (Therapeutic Goods Administration) (n.d.), Australian Register of Therapeutic Goods (ARTG), accessed 8 September 2025.

TGA (Therapeutic Goods Administration) (1989) *Therapeutic Goods Act 1989*, accessed 22 August 2024.

TGA (Therapeutic Goods Administration) (2018) *Therapeutic Goods (Excluded Goods) Determination 2018*, accessed 22 August 2025.

Thorel E, Clergeaud F, Jaugeon L, Rodrigues AMS, Lucas J, Stien D and Lebaron P (2020) 'Effect of 10 UV Filters on the Brine Shrimp *Artemia salina* and the Marine Microalga *Tetraselmis* sp.' *Toxics*, 8(2): 29, doi:10.3390/toxics8020029.

Tovar-Salvador ML, Pintado-Herrera MG, Lara-Martín PA and Bonnail E (2023) 'Occurrence, sources and environmental risk assessment of organic micropollutants in coastal sediments from the Atacama Region (Chile)', *Science of The Total Environment,* 900, 165871, doi:10.1016/j.scitotenv.2023.165871.

Tsui MM, Leung HW, Wai TC, Yamashita N, Taniyasu S, Liu W, Lam PK and Murphy MB (2014a) 'Occurrence, distribution and ecological risk assessment of multiple classes of UV filters in surface waters from different countries.' *Water Research*, 67: 55–65, doi: 10.1016/j.watres.2014.09.013.

Tsui MM, Leung HW, Lam PK and Murphy MB (2014b) 'Seasonal occurrence, removal efficiencies and preliminary risk assessment of multiple classes of organic UV filters in wastewater treatment plants', *Water Research*, 53: 58-67, doi:10.1016/j.watres.2014.01.014.

Tsui MM, Chen L, He T, Wang Q, Hu C, Lam JC and Lam PJ (2019) 'Organic ultraviolet (UV) filters in the South China sea coastal region: Environmental occurrence, toxicological effects and risk assessment', *Ecotoxicology and Environmental Safety*,181: 26-33, doi: 10.1016/j.ecoenv.2019.05.075.

UNECE (United Nations Economic Commission for Europe) (2017) *Globally Harmonized System of Classification and Labelling of Chemicals (GHS), Seventh Revised Edition*, UNECE, accessed 22 July 2025.

US EPA (United States Environmental Protection Agency) (2017a) *Estimation Programs Interface (EPI) Suite^{TM} for Microsoft Windows®, v 4.11.* US EPA, accessed 22 July 2025.

DRAFT

US EPA (United States Environmental Protection Agency) (2017b) *The ECOSAR (ECOlogical Structure Activity Relationship) Class Program for Microsoft Windows® v2.0.* US EPA, accessed 22 July 2025.

US EPA (United States Environmental Protection Agency) (2020) *2020 CDR Industrial Processing and Use*, US EPA, accessed 22 July 2025.

Zhao G, Gao M, Guo S, Zeng S, Ye C, Wang M, Anwar Z, Hu B and Hong Y (2023) 'UV filter ethylhexyl salicylate affects cardiovascular development by disrupting lipid metabolism in zebrafish embryos', *Science of The Total Environment,* 888, 164073, doi:10.1016/j.scitotenv.2023.164073.

DRAFT

DRAFT