



3-benzylidene camphor: Human health tier II assessment

12 December 2019

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Chemicals in this assessment

Chemical Name in the Inventory	CAS Number
Bicyclo[2.2.1]heptan-2-one, 1,7,7-trimethyl-3-(phenylmethylene)-	15087-24-8
Bicyclo[2.2.1]heptan-2-one, 1,7,7-trimethyl-3-(phenylmethylene)-, (+)-	36065-09-5
Bicyclo[2.2.1]heptan-2-one, 1,7,7-trimethyl-3-(phenylmethylene)-, (-)-	36275-29-3

Preface

This assessment was carried out by staff of the National Industrial Chemicals Notification and Assessment Scheme (NICNAS) using the Inventory Multi-tiered Assessment and Prioritisation (IMAP) framework.

The IMAP framework addresses the human health and environmental impacts of previously unassessed industrial chemicals listed on the Australian Inventory of Chemical Substances (the Inventory).

The framework was developed with significant input from stakeholders and provides a more rapid, flexible and transparent approach for the assessment of chemicals listed on the Inventory.

Stage One of the implementation of this framework, which lasted four years from 1 July 2012, examined 3000 chemicals meeting characteristics identified by stakeholders as needing priority assessment. This included chemicals for which NICNAS already held exposure information, chemicals identified as a concern or for which regulatory action had been taken overseas, and chemicals detected in international studies analysing chemicals present in babies' umbilical cord blood.

Stage Two of IMAP began in July 2016. We are continuing to assess chemicals on the Inventory, including chemicals identified as a concern for which action has been taken overseas and chemicals that can be rapidly identified and assessed by using

Stage One information. We are also continuing to publish information for chemicals on the Inventory that pose a low risk to human health or the environment or both. This work provides efficiencies and enables us to identify higher risk chemicals requiring assessment.

The IMAP framework is a science and risk-based model designed to align the assessment effort with the human health and environmental impacts of chemicals. It has three tiers of assessment, with the assessment effort increasing with each tier. The Tier I assessment is a high throughput approach using tabulated electronic data. The Tier II assessment is an evaluation of risk on a substance-by-substance or chemical category-by-category basis. Tier III assessments are conducted to address specific concerns that could not be resolved during the Tier II assessment.

These assessments are carried out by staff employed by the Australian Government Department of Health and the Australian Government Department of the Environment and Energy. The human health and environment risk assessments are conducted and published separately, using information available at the time, and may be undertaken at different tiers.

This chemical or group of chemicals are being assessed at Tier II because the Tier I assessment indicated that it needed further investigation.

For more detail on this program please visit: www.nicnas.gov.au

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ACRONYMS & ABBREVIATIONS

Grouping Rationale

3-Benzylidene camphor (3-BC) is referred to by 3 CAS Nos. 15087-24-8 (unspecified isomer), 36065-09-5 (1R, 4S) and 36275-29-3 (1S, 4R) (Scifinder), hereafter referred to as the chemical. The chemical is commonly referred to using the CAS No. for unspecified isomer (15087-24-8.) Unless stated otherwise, the chemical in this assessment refers to the unspecified isomer.

Import, Manufacture and Use

Australian

No specific Australian use, import, or manufacturing information has been identified.

International

The chemical (CAS No. 15087-24-8) has reported cosmetic uses as an ultraviolet (UV) light absorber (CosIng), a fragrance ingredient and light stabiliser (Personal Care Product Council).

The chemical (referred to by CAS Nos. 15087-24-8 and 36275-29-3) is listed on the International Fragrance Association (IFRA) transparency list (IFRA, 2019).

Restrictions

Australian

Use of the chemical in cosmetic sunscreens is restricted to sunscreens with SPF <4 and secondary sunscreens (such as skin moisturisers) with SPF <15 (TGA, 2016).

International

The following international restrictions apply to the chemical (Galleria Chemica):

- EU Cosmetics Regulation 1298/2015 Annex II—List of substances prohibited in cosmetic products;
- the ASEAN Cosmetic Directive Annex II Part 1: List of substances which must not form part of the composition of cosmetic products;
- New Zealand group standard—Schedule 8 List of permitted ultraviolet (UV) filters which cosmetic products may contain with a maximum authorised concentration of 2 %; and
- China hygienic standard for cosmetics - Restricted sunscreen agent for use in cosmetic products with a maximum allowable concentration of 2 %.

The chemical has been identified as a substance of very high concern (SVHC), based on environmental concerns, by the European Commission (EC) (EC, 2018).

Existing Worker Health and Safety Controls

Hazard Classification

The chemical is not listed on the Hazardous Chemical Information System (HCIS) (Safe Work Australia).

Exposure Standards

Australian

No specific exposure standards are available.

International

No specific exposure standards are available.

Health Hazard Information

Toxicokinetics

Based on human and animal studies, dermal absorption is expected to be low (SCCS, 2013). Species differences were noted in the metabolism of the chemical, with metabolism being more rapid in rats compared to other species.

Dermal absorption in humans was estimated to be approximately 3 % based on a study in 6 male volunteers (SCCS, 2013).

Following topical application of the chemical for 65 days at doses of 60, 180 or 540 mg/kg bw/day in rats, the chemical was mainly found in plasma and adipose tissue. Low levels of the chemical were detected in brain, liver, muscle and testes. Approximately 10 % of the total topically applied amount of the chemical was recovered in the tissues (SCCS, 2013).

After oral administration in rats, mice, rabbits and guinea pigs, the main metabolite identified was a 4-hydroxy derivative of the chemical. The metabolite was detectable in blood within 1 hour of administration and the parent compound was generally undetectable after 24 hours. In mice, the proportion of the metabolite (relative to the parent) was lower compared to rats, indicating species differences in the metabolism of the chemical (SCCS, 2013).

In an in vitro study in human and rat hepatocytes, the chemical was metabolised more rapidly in rat hepatocytes compared to human hepatocytes (SCCS, 2013).

Acute Toxicity

Oral

The chemical is expected to have low acute toxicity based on results from an OECD test guideline (TG) 401 study. The median lethal dose (LD50) in rats was >5000 mg/kg bw. No sub-lethal effects were reported (SCCS, 2013).

Dermal

No data are available.

Inhalation

No data are available.

Corrosion / Irritation

Skin Irritation

Based on the available data, the chemical is not expected to cause skin irritation at low concentrations.

In a skin irritation study in New Zealand White (NZW) rabbits, a 6 % solution of the chemical in isopropyl palmitate was applied to abraded or non-abraded skin under semi-occlusion for 24 hours. The chemical was reported to be a "mild irritant" (SCCS, 2013). No further details are available.

Eye Irritation

Based on the available data, the chemical is not expected to cause eye irritation at low concentrations.

In an eye irritation study in rabbits, a 6 % solution of the chemical in isopropyl palmitate was applied to 1 eye while the other eye served as the control. The reported irritation indices were 2.67, 0.67, and 0 (out of maximum 10) after 24, 48 and 72 hours, respectively (SCCS, 2013). No further details are available.

Sensitisation

Skin Sensitisation

Based on the available *in silico* and animal data, the chemical is unlikely to be a strong sensitiser (or photosensitiser). The absence of cases of sensitisation to the chemical in humans support this conclusion and suggest that the chemical is unlikely to induce skin sensitisation under the current use patterns.

Skin

In a non-guideline guinea pig adjuvant test in 20 Hartley guinea pigs (sex not specified), 0.5 g of the chemical was applied to the skin under occlusion for 48 hours, 3 days a week, for 10 applications (induction). An intradermal injection of 0.1 mL of Freund's complete adjuvant was given on days 1 and 10. Twelve days after the induction, 0.5 g of the chemical was applied topically to a naïve skin site. No skin reactions were observed (SCCS, 2013).

Quantitative Structure-Activity Relationship (QSAR) information

The QSAR modelling for skin sensitisation using the OECD QSAR Toolbox (version 4.2) indicated that there were protein-binding alerts for skin sensitisation via Michael conjugate addition.

The knowledge-based expert system Deductive Estimation of Risk from Existing Knowledge (DEREK) Nexus version 6.0.1 was utilised to estimate the sensitisation potential of BC-3. The chemical was predicted to be a moderate skin sensitiser with a predicted concentration of 4.9 % of the chemical producing a 3-fold increase in lymphocyte proliferation (EC3) in local lymph node assay (LLNA). The confidence level of the prediction was plausible. The prediction was supported by the mechanistic alert "480 alpha,beta-unsaturated ketone or precursor".

The chemical was predicted be a weak skin sensitiser using the QSAR model within Chemtunes ToxGPS (version 1.2). The prediction was within the applicability domain of the model.

Photosensitisation

In a guinea pig photosensitisation study (using adjuvant), 12 Hartley guinea pigs received topical applications of 4 % the chemical in olive oil followed by irradiation with ultraviolet light (UV). The induction was followed by challenges at a naive site with up to 2 % of the chemical and UV light. There was no evidence of photo-sensitisation (SCCS, 2013).

Repeated Dose Toxicity

Oral

The chemical is not expected to cause serious damage to health from repeated oral exposure, based on the low severity and reversibility of the reported effects.

In an oral study conducted according to OECD TG 408, Sprague Dawley (SD) rats (5/sex/dose) were given the chemical by gavage at doses of 0, 100, 250 or 500 mg/kg bw/day, 5 days a week for 6 or 13 weeks. The rats treated for 6 weeks served as a recovery group for the remainder of the study. There was no treatment-related mortality during the study. Ruffled and yellow stained fur and dose-dependent hair loss was observed in all dose groups. Body weight gain was reduced in males from the high-dose group and in females from the high- and mid-dose groups. Haemoglobin and red blood cell count were reduced in the high dose groups on day 13. Plasma lipids were increased in females at all dose levels. Cholesterol levels were increased in males at the high dose and in females at the mid and high dose. The changes in lipids and cholesterol levels were reversible in the recovery group. A no observed adverse effect level (NOAEL) was not reported (SCCS, 2013).

In a 6-week oral study conducted according to Good Laboratory Practice (GLP) guidelines, SD rats (10/sex/dose) were given the chemical by gavage at doses of 0, 25 or 50 mg/kg bw/day. There was no treatment-related mortality during the study. The main clinical finding was hair loss in high dose females. Body weights were unaffected. Absolute liver and adrenal weight were increased in females receiving the highest dose. No macroscopic abnormalities were found at necropsy. Follicular and epithelial thyroid hyperplasia and hypertrophy of the zona fasciculata in the adrenal cortex was observed in treated females. Cholesterol was reduced and lipids increased in all dosed groups. The thyroid hormone triiodothyronine (T3) was increased in males and thyroxine (T4) was increased in both males and females in a dose-dependent manner. Aspartate aminotransferase was reduced (dose-dependent) in females. A NOAEL was not reported from the study (SCCS, 2013).

In a 4-week oral study conducted according to OECD TG 407, rats (10/sex; strain not specified) were given the chemical in 1 % carboxymethylcellulose by gavage at doses of 0, 250, 375 or 550 mg/kg bw/day. There was no treatment-related mortality during the study. The only clinical finding was alopecia in females and males from the 375 mg/kg bw/day group. Body weights were significantly reduced in all dosed females; however, food consumption was not affected. Liver weights (absolute or relative not specified) were increased at all doses (dose-dependent). In females, there was a dose-dependent increase in weight of the adrenals. Haematological effects were observed in females and included reductions in haemoglobin and packed cell volume. Prothrombin time (a measure of clotting time) was significantly increased in all dosed groups (not dose-dependent). Cholesterol levels were significantly reduced in all dose groups. Bilirubin and protein levels were reduced in males (dose-dependent), and glucose, protein and alkaline phosphatase increased in all female dose groups (not dose-related). Urinalysis was normal in all groups. A NOAEL was not reported (SCCS, 2013).

The alopecia observed in rat studies was not observed in 6 and 8 week oral guinea pig studies at doses of 500 or 1000 mg/kg bw/day. Limited data are available for these studies (SCCS, 2013).

Dermal

No data are available.

Inhalation

No data are available.

Genotoxicity

Based on the limited in vitro and vivo data available, and in silico predictions, the chemical is not expected to be genotoxic. The chemical was negative in several bacterial strains. An in vitro chromosome aberration assay was positive; however, the chemical was negative in an in vivo micronucleus test (SCCS, 2013).

In vitro

The chemical was:

- negative in point mutation studies in *Salmonella typhimurium* strains TA98, TA100, TA1525 and TA1537 at concentrations up to 1000 µg/plate; and
- positive in a chromosome aberration assay in Chinese hamster ovary cells at concentrations without metabolic activation at doses up to 80 µg/mL and with metabolic activation at doses up to 25 µg/mL for 4 h.

In vivo

The chemical was negative in a micronucleus test in Oncins France 1 (OF-1) mice. No significant increases in micronucleated polychromatic erythrocytes were observed at 24, 48 and 72 hours after intraperitoneal (i.p.) administration of 700 or 1400 mg/kg in males or 800 or 1600 mg/kg in females.

In silico

No structural alerts for mutagenicity or clastogenicity were observed for the chemical or its metabolites (rat liver S9) using the OECD QSAR Toolbox (version 4.2).

The knowledge-based expert system DEREK Nexus version 6.0.1 was utilised to estimate the genotoxicity potential of the chemical. The chemical or its metabolites did not match any structural alerts or examples for (bacterial in vitro) mutagenicity. Additionally, the chemical structure did not contain any unclassified or misclassified features and was; therefore, predicted negative for genotoxicity.

Carcinogenicity

No data are available.

Reproductive and Developmental Toxicity

Data from the available reproductive studies are insufficient to determine reproductive toxicity potential of the chemical. In rats, any developmental effects were generally only observed secondary to maternal toxicity. Rabbits and mice were less sensitive to the effects of the chemical. In the absence of more comprehensive information, hazard classification is not warranted for reproductive or developmental effects.

In an oral developmental toxicity study conducted according to GLP, pregnant SD rats (22–24/dose) were administered the chemical in 1 % carboxymethylcellulose by gavage at 0, 15, 50, 100 or 150 mg/kg bw/day from gestation day (GD) 6–15 and euthanised on GD 21. Maternal toxicity was apparent at doses ≥ 50 mg/kg bw/day. One female mortality occurred at the highest dose. Vaginal discharge attributed to increased resorptions was observed in dams receiving 50 mg/kg bw/day. Bodyweight gain and food intake were reduced in dams receiving ≥ 50 mg/kg bw/day. Abnormal findings in these dams included enlarged spleens; haemorrhagic uteri; haemorrhagic and necrotic placentae; pale liver and kidneys. There was an increased foetal loss at doses ≥ 50 mg/kg bw/day. Foetal abnormalities (details not specified) were observed at doses ≥ 100 mg/kg. The abnormalities were attributed to delayed development and in utero pressure, and likely related to maternal toxicity. The reported NOAEL for maternal and developmental toxicity was 15 mg/kg bw/day (SCCS, 2013).

When pregnant Cesarean derived (CD)-1 mice (23–26/dose) were administered the chemical in 1 % carboxymethylcellulose by gavage at 0, 15, 50, 100 or 250 mg/kg bw/day from GD 6–15. No maternal or developmental toxicity attributed to the chemical was observed. A NOAEL of 250 mg/kg bw/day was reported (SCCS, 2013).

Pregnant Himalayan rabbits (11–12/dose), were administered the chemical in 2 % polysorbate 80 at 0, 50, 150 or 450 mg/kg bw/day. No mortality occurred. One dam receiving 150 mg/kg bw/days showed necrosis and uterine haemorrhage, and loss of all foetuses. No other abnormalities were found in pups or in the remaining dams (SCCS, 2013).

In a non-guideline study with limited study details available, Long Evans rats (12–18/dose) received the chemical in diet at 0, 0.24, 2.4 or 7 mg/kg bw/day from at least 10 weeks before mating, during pregnancy (females) and lactation (females). The offspring (F1) were fed the chemical until adulthood. Rats exposed during adult life only (P0) did not show any overt signs of toxicity. Litter size was decreased at the highest dose (7 mg/kg bw/day) and perinatal survival decreased at 2.4 or 7 mg/kg bw/day (Schlumpf et al., 2004). Females (F1) had changes in oestrous cycles and altered sexual behaviour (when mated with unexposed males). Whether these changes affected the reproductive function of the females was not reported (Faass, 2009). Female adult bodyweight was increased at 0.24 mg/kg bw/day and decreased at 2.4 and 7 mg/kg bw/day. Uterus weight was decreased at the highest dose (7 mg/kg bw/day). Delays in puberty (preputial separation) were reported in males (F1) receiving 2.4 or 7 mg/kg bw/day. No other parameters related to puberty or data from the perinatal period were reported. In adult males, bodyweight was reduced at the highest dose. Epididymis and seminal vesicle weight were reduced at 2.4 mg/kg bw/day but not 7 mg/kg bw/day (Schlumpf et al., 2004). The number of animals and litters studied were not clearly reported; therefore, it was not possible to evaluate the statistical power of the study. The reliability of the study was also difficult to assess since the outcomes were published in different research publications with limited methodological details available (SCCS, 2013).

Other Health Effects

Endocrine Disruption

The chemical is reported to possess oestrogenic activity, although at much lower potency than endogenously produced oestrogens. There are currently no established adverse outcome pathways for weak oestrogenic activity. Observed anti-androgenic properties were equivocal and anti-progestogenic potency was very low. At this stage there is no evidence of these weak endocrine activities causing adverse effects in mammals or humans.

In vitro

In vitro studies indicate that the chemical can increase the proliferation rate in transformed or cancerous cell lines at concentrations in the μM range. The potency of the natural ligand, 17β -oestradiol is within the pM range, hence the chemical is approximately 80000 times less potent than the natural ligand (SCCS, 2013). Oestrogen receptor binding studies demonstrated

that the chemical preferentially binds to oestrogen receptor β (ER β) (Schlumpf, 2004; SCCS, 2013). In yeast cells which are less metabolically active than cancerous cells, the oestrogenic activity of the chemical was much lower. This indicates that a metabolite of the chemical may be responsible for the observed oestrogenic activity (EC, 2016).

Mixed results were found in anti-androgenic studies (SCCS, 2013). Anti-androgenic effects were noted in the μM range in one study in AR CALUX® cells ($\text{EC}_{50} = 4.6 \mu\text{M}$, 50 times less potent than the androgen antagonist vinclozolin). No anti-androgenic effects were observed in MDA46 kb2 human tumour cells at concentrations up to $10 \mu\text{M}$ (Schlumpf, 2004; SCCS, 2013).

The chemical demonstrated weak antagonism ($\text{IC}_{50} = 0.4 \mu\text{M}$) towards the progesterone receptor (PR); however, it was 100000 times less potent than the anti-progestogenic drug mifepristone ($\text{IC}_{50} = 4.9 \mu\text{M}$) (Schreurs et al., 2005). The chemical also inhibited progesterone-induced Ca^{2+} signalling in sperm cells at a relatively high concentration ($10 \mu\text{M}$) (Rehfeld et al., 2016).

In vivo

In a uterotrophic assay (reported as a guideline study but with limited details available), rats (strain not specified) received the chemical by oral gavage at 9 doses between 0.8–300 mg/kg bw/day for 3 days. Doses above 0.8 mg/kg bw/day caused a significant increase in uterine weight in immature rats (SCCS, 2013).

Risk Characterisation

Critical Health Effects

No critical health effects associated with the chemical has been established; although, the chemical possess the ability to interact with hormone receptors.

Public Risk Characterisation

The main source of exposure is expected to be from cosmetic products with sun protection. However, the concentration of the chemical is expected to be low due to current restrictions (see **Australian restrictions**). There are also international restrictions and prohibitions (see **International Restrictions**) that are expected to limit the use and exposure to the chemical. Furthermore, absorption through the skin is anticipated to be low (see **Toxicokinetics**). The available data do not indicate any health hazards associated with human exposure to the chemical at these low concentrations.

While the chemical has weak oestrogenic activity, and potentially weak anti-androgenic and anti-progestogenic activities, no adverse health effects in an intact organism or its progeny related to these endocrine activities have been clearly demonstrated.

Therefore, the chemical is not considered to pose an unreasonable risk to public health.

Should additional information associated with the weak endocrine activity become available, further assessment of the chemical may be required.

Occupational Risk Characterisation

During product formulation, dermal, oral and ocular exposure might occur, particularly where manual or open processes are used. These could include transfer and blending activities, quality control analysis, and cleaning and maintaining equipment. Worker exposure to the chemicals at lower concentrations could also occur while using formulated products containing the chemicals. The level and route of exposure will vary depending on the method of application and work practices employed.

Given the lack critical health effects, the risk to workers from this chemical is not considered to be unreasonable. Information in this report can be used by a person conducting a business or undertaking (PCBU) at a workplace (such as an employer) to determine the appropriate controls. The chemical currently has no hazard classification for worker health and safety; this is considered appropriate based on the available data.

NICNAS Recommendation

Current risk management measures are considered adequate to protect public and workers' health and safety, provided that all requirements are met under workplace health and safety, and poisons legislation as adopted by the relevant state or territory.

The chemical has been shown to have weak endocrine activity. However, the available data do not demonstrate the potential of the chemical to cause adverse effects via this endocrine activity. NICNAS will continue to monitor the availability of high quality data emerging on the chemical and determine if further assessment may be required.

Regulatory Control

Public Health

No specific controls are required.

Work Health and Safety

The chemical is not recommended for classification and labelling aligned with the Globally Harmonized System of Classification and Labelling of Chemicals (GHS). This does not consider classification of physical hazards and environmental hazards.

Advice for industry

Obligations under workplace health and safety legislation

Information in this report should be taken into account to help meet obligations under workplace health and safety legislation as adopted by the relevant state or territory. This includes, but is not limited to:

- ensuring that hazardous chemicals are correctly classified and labelled;
- ensuring that (material) safety data sheets ((M)SDS) containing accurate information about the hazards (relating to both health hazards and physicochemical (physical) hazards) of the chemical is prepared; and
- managing risks arising from storing, handling and using a hazardous chemical.

Your work health and safety regulator should be contacted for information on the work health and safety laws in your jurisdiction.

Information on how to prepare an (M)SDS and how to label containers of hazardous chemicals are provided in relevant codes of practice such as the Preparation of safety data sheets for hazardous chemicals—Code of practice and Labelling of workplace hazardous chemicals—Code of practice, respectively. These codes of practice are available from the Safe Work Australia website.

A review of the physical hazards of the chemical has not been undertaken as part of this assessment.

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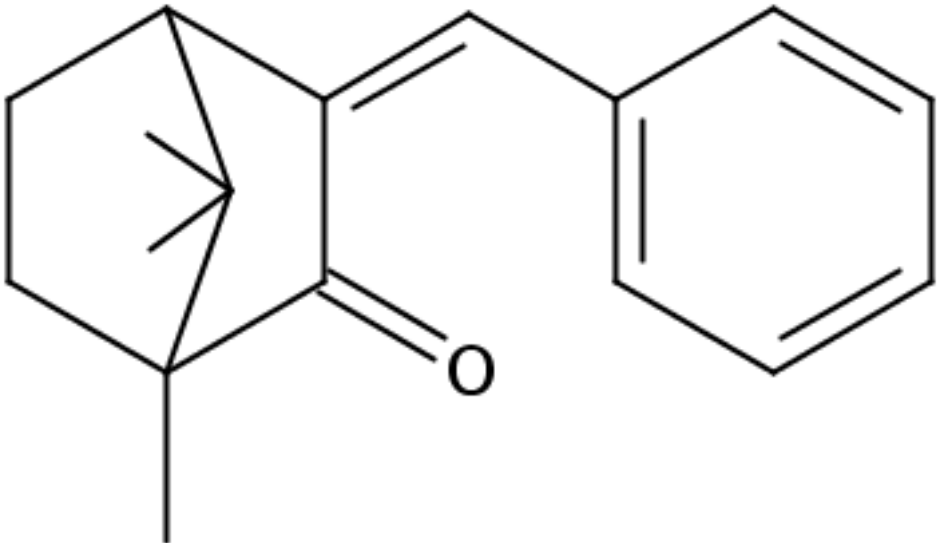
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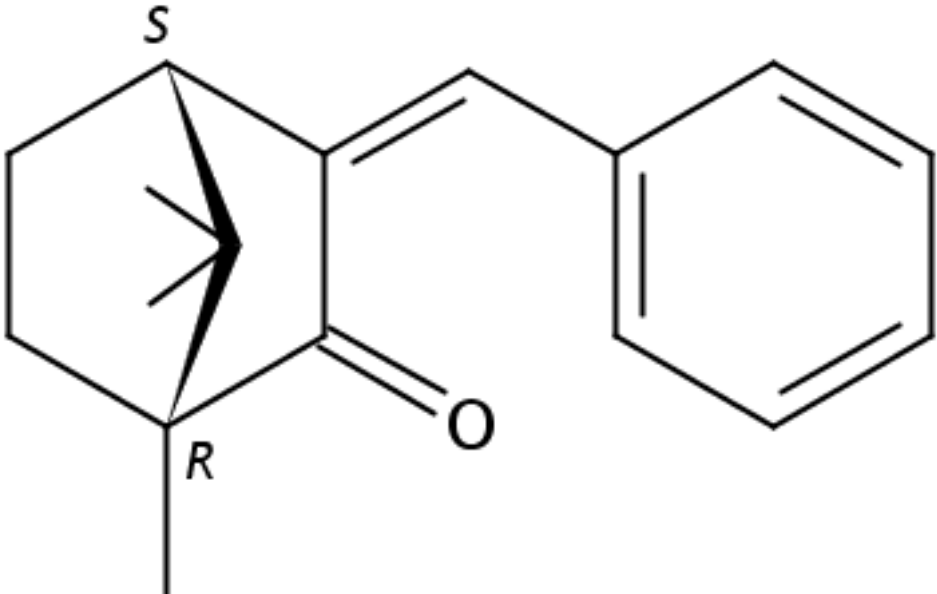
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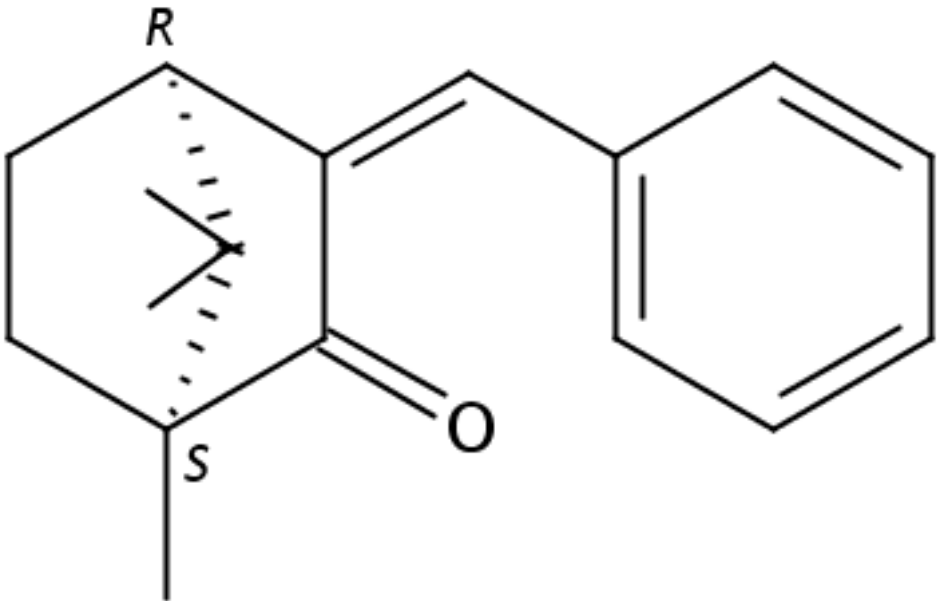
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Chemical Identities

Chemical Name in the Inventory and Synonyms	Bicyclo[2.2.1]heptan-2-one, 1,7,7-trimethyl-3-(phenylmethylene)- 3-benzylidene-2-bornanone 1,7,7-trimethyl-3-(phenylmethylene)bicyclo(2.2.1)heptan-2-one bicyclo(2.2.1)heptan-2-one, 1,7,7-trimethyl-3-(phenylmethylene)-
CAS Number	15087-24-8

Structural Formula	
Molecular Formula	C ₁₇ H ₂₀ O
Molecular Weight	240.35

Chemical Name in the Inventory and Synonyms	Bicyclo[2.2.1]heptan-2-one, 1,7,7-trimethyl-3-(phenylmethylene)-, (+)- (+)-1,7,7-trimethyl-3-(phenylmethylene)bicyclo(2.2.1)heptan-2-one bicyclo(2.2.1)heptan-2-one, 1,7,7-trimethyl-3-(phenylmethylene)-, (1R,4S)-
CAS Number	36065-09-5
Structural Formula	
Molecular Formula	C ₁₇ H ₂₀ O
Molecular Weight	240.35

Chemical Name in the Inventory and Synonyms	Bicyclo[2.2.1]heptan-2-one, 1,7,7-trimethyl-3-(phenylmethylene)-, (-)- (-)-1,7,7-trimethyl-3-(phenylmethylene)bicyclo(2.2.1)heptan-2-one bicyclo(2.2.1)heptan-2-one, 1,7,7-trimethyl-3-(phenylmethylene)-, (-)-
CAS Number	36275-29-3
Structural Formula	
Molecular Formula	C ₁₇ H ₂₀ O
Molecular Weight	240.35

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