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

Peroxide, bis(1-methyl-1-phenylethyl) (dicumyl peroxide)

Evaluation statement

26 June 2023

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AICIS evaluation statement

Subject of the evaluation

Peroxide, bis(1-methyl-1-phenylethyl) (dicumyl peroxide)

Chemical in this evaluation

Name	CAS registry number
Peroxide, bis(1-methyl-1-phenylethyl)	80-43-3

Reason for the evaluation

Evaluation Selection Analysis indicated potential human health risk.

Parameters of evaluation

The chemical is listed on the Australian Inventory of Industrial Chemicals (the Inventory). This evaluation is a human health risk assessment for all identified industrial uses of the chemical.

Summary of evaluation

Summary of introduction, use and end use

There is currently no specific information about the introduction, use or end use of the chemical in Australia. Based on international information, dicumyl peroxide (DCUP) is mainly used as an intermediate in the production of plastics, polymers, rubber products and silicones, including those used as food contact materials. The chemical also has reported use as a flame retardant synergist in polystyrene foams.

Human health

Summary of health hazards

The critical health effect is for risk characterisation developmental toxicity. The chemical may also be irritating to skin, eyes and the respiratory tract.

In a developmental toxicity study in rats (OECD TG 414), significantly increased post-implantation loss, decreased foetal weight, malrotated fore and hind limbs, and significantly increased skeletal malformations and variations in embryos were reported at 450 mg/kg body weight (bw)/day (highest dose tested). Maternal health effects included vaginal and uterine bleeding, enlarged adrenals and spleen, significantly reduced food consumption and body weight gain. However, an assessment of the effects in individual dams concluded there was no clear connection between maternal toxicity and the observed effects on developmental toxicity. Therefore, the observed developmental effects following exposure to

DCUP are not considered secondary consequences of maternal toxicity. Similar developmental effects were not observed in a study in rabbits. Limited information is available on the effects on fertility. No adverse effects relating to the sperm or oestrous cycle were observed in a 90 day oral toxicity study in rats.

The chemical is classified as hazardous for skin and eye irritation. Although effects observed in guideline studies indicated that the chemical only causes slight irritation, the conditions of the studies may not have adequately tested the irritation potential of the chemical. Nasal mucosa changes have been reported in a 4 week inhalation study in rabbits and effects in the nasal cavity have also been reported in workers exposed to the chemical.

Based on the available data, the chemical is:

- expected to have low acute toxicity
- not expected to have significant systemic toxicity following oral and inhalation exposure
- not considered to be a skin sensitiser
- not expected to have genotoxic potential.

Hazard classifications relevant to worker health and safety

The chemical satisfies the criteria for classification according to the Globally Harmonized System of Classification and Labelling of Chemicals (GHS) (UNECE 2017) for hazard classes relevant for work health and safety as follows. This does not consider classification of physical hazards and environmental hazards. These are the existing classification for the chemical (see **Existing Australian regulatory controls: Workers**).

Health hazards	Hazard category	Hazard statement
Skin irritation	Skin irrit. 2	H315: Causes skin irritation
Eye irritation	Eye irrit.2	H319: Causes serious eye irritation
Reproductive toxicity	Repr. 1B	H360D: May damage the unborn child

Summary of health risk

Public

Based on the available use information, it is unlikely that the public will be exposed to the chemical. The public could come into contact with coated surfaces and food contact articles manufactured with the chemical. Negligible residual amounts of the chemical are expected to remain.

Based on the available use information, there are no identified risks to the public that require management.

Workers

During product formulation and packaging, dermal, ocular and inhalation 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 chemical at lower concentrations could also occur while using

formulated products containing the chemical. The level and route of exposure will vary depending on the method of application and work practices employed.

Given the critical systemic long term health and potential local effects, the chemical could pose a risk to workers. Control measures to minimise dermal, ocular and inhalation exposure are needed to manage the risk to workers (see **Proposed means for managing risks**).

Proposed means for managing risk

Workers

Information relating to safe introduction and use

The information in this statement including recommended hazard classifications, should be used by a person conducting a business or undertaking at a workplace (such as an employer) to determine the appropriate controls under the relevant jurisdiction Work Health and Safety laws.

Control measures that could be implemented to manage the risk arising from exposure to the chemical include, but are not limited to:

- using closed systems or isolating operations
- using local exhaust ventilation to prevent these chemicals from entering the breathing zone of any worker
- minimising manual processes and work tasks through automating processes
- adopting work procedures that minimise splashes and spills
- cleaning equipment and work areas regularly
- using protective equipment that is designed, constructed, and operated to ensure that the worker does not come into contact with the chemical.

Measures required to eliminate or manage risk arising from storing, handling and using this hazardous chemical depend on the physical form and how this chemical is used.

These control measures may need to be supplemented with:

- conducting health monitoring for any worker who is at significant risk of exposure to the chemical, if valid techniques are available to monitor the effect on the worker's health.

Personal protective equipment should not solely be relied upon to control risk and should only be used when all other reasonably practicable control measures do not eliminate or sufficiently minimise risk.

Model codes of practice, available from the Safe Work Australia website, provide information on how to manage the risks of hazardous chemicals in the workplace, prepare an SDS and label containers of hazardous chemicals. Your Work Health and Safety regulator should be contacted for information on Work Health and Safety laws and relevant Codes of Practice in your jurisdiction.

Conclusions

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

Considering the proposed means of managing risks, the Executive Director is satisfied that the identified human health risks can be managed within existing risk management frameworks. This is provided that all requirements are met under environmental, workplace health and safety and poisons legislation as adopted by the relevant state or territory and the proposed means of managing the risks identified during this evaluation are implemented.

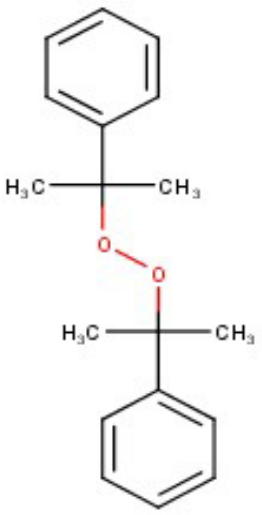
Note: Obligations to report additional information about hazards under *Section 100* of the *Industrial Chemicals Act 2019* apply.

Supporting information

Chemical identity

Chemical name	peroxide, bis(1-methyl-1-phenylethyl)
CAS No.	80-43-3
Synonyms	dicumyl peroxide DCUP bis(α,α-dimethylbenzyl) peroxide 1,1'-(dioxydipropane-2,2-diyl)dibenzene
Molecular formula	C18H22O2
Molecular weight (g/mol)	270.37
SMILES	O(OC(C=1C=CC=CC1)(C)C)C(C=2C=CC=CC2)(C)C

Structural formula:



Relevant physical and chemical properties

The chemical is a white, granular powder with low water solubility of 0.43 mg/L at 20°C and octanol-water partition coefficient (log K_{OW}) of 5.6 at 25°C. It is a highly combustible unstable solid that decomposes on heating (Government of Canada 2019; OECD 2012; Sigma-Aldrich SDS n.d.).

Introduction and use

Australia

No specific information on the introduction, use and end use of the chemical in Australia has been identified.

International

The following international uses have been identified through:

- international assessments and reports (ECHA 2017; Government of Canada 2019; OECD 2012)
- European Union Registration, Evaluation and Authorisation of Chemicals (EU REACH) dossiers
- Substances in preparations in Nordic countries (SPIN) database
- the US Chemical Data Reporting under the Toxic Substances Control Act 2012/2016.

The chemical has mainly site limited uses as an intermediate (catalyst, vulcanisation agent, cross-linking agent) in the manufacture of:

- natural and synthetic rubber
- plastics and polymers
- silicone materials
- electrical and electronic products.

Any unreacted chemical is reported to thermally decompose following its use in the manufacture of plastics and rubbers (OECD 2002).

The chemical also has commercial use as a flame retardant synergist in polystyrene foams.

Existing Australian regulatory controls

AICIS

No specific controls are currently available for the chemical. The chemical is listed on the Australian Industrial Chemicals Introduction Scheme (AICIS) – List of chemicals with high hazards for categorisation.

Public

No specific controls are currently available for the chemical.

Workers

The chemical is listed in the Hazardous Chemical Information System HCIS (Safe Work Australia, SWA) with following hazard category and statements for human health:

Health hazards	Hazard category	Hazard statement
Skin irritation	Skin irrit. 2	H315: Causes skin irritation
Eye irritation	Eye irrit. 2	H319: Causes serious eye irritation
Reproductive toxicity	Repr. 1B	H360D: May damage the unborn child

No specific exposure standards are available for the chemical (SWA n.d.).

International regulatory status

Exposure standards

The following Protective Action Criteria (PAC) (formerly known as Temporary Emergency Exposure Limits (TEELs) are available for the chemical (Chemwatch n.d.; US DOE 2013):

- PAC-1 = 3.0E+01 mg/m^3;
- PAC-2 = 5.0E+01 mg/m^3; and
- PAC-3 = 2.52E+02 mg/m^3

Canada

The chemical is listed on the Canada Cosmetic Ingredient Hotlist – List of Ingredients that are restricted for use in Cosmetic Products.

European Union

The chemical is listed on EU Regulation (EC) No 1223/2009 of the European Parliament and of the Council of 30 November 2009 on cosmetic products - Annex II – List of Substances Prohibited in Cosmetic Products.

The chemical is listed on EU Regulation No 10/2011 on Control of Aids to Polymerisation for Plastic materials and Articles – Limits for finished articles with limit of 0.05 mg/kg (EC 2011).

United States of America

The chemical is listed on the US FDA List of Indirect Additives Used in Food Contact Substances (US FDA 2018); Substances for Use Only as Components of Adhesives; Substances for use as Components of Coatings (21CFR175) – Resinous and polymeric Coatings; and Polymers (21CFR177) - Substances for Use Only as Components of Articles Intended for Repeated Use - Rubber articles intended for repeated use as vulcanisation materials (accelerators total not to exceed 1.5% by weight of rubber product (US FDA 2018).

Health hazard information

Toxicokinetics

Information on the oral, dermal and inhalation absorption of the chemical is not available.

Based on the physico-chemical properties, the chemical is expected to have low absorption via the dermal route. Systemic effects in oral repeat dose studies with the chemical suggest absorption occurs following oral exposure. Reduction of organic peroxides to corresponding alcohols and water is expected to be catalysed by glutathione peroxidases in vivo (OECD 2012).

Acute toxicity

Oral

Based on the available data, the chemical has low acute oral toxicity with a reported median lethal dose (LD50) of >2000 mg/kg bw in animal studies.

In an acute oral toxicity study conducted according to OECD TG 401, an LD50 >2000 mg/kg bw in Crj:CD rats was reported (OECD 2012; REACH n.d.).

Dermal

Based on the available data, the chemical is expected to have low acute dermal toxicity.

An LD50 of >2000 mg/kg bw in Wistar rats was derived from an acute dermal toxicity study (OECD TG 402) (REACH n.d.).

Inhalation

Limited data are available for acute inhalation toxicity. A median lethal concentration (LC50) of >0.1 mg/L air (nominal) was reported in a non-guideline study in rats, guinea pigs and mice. The animals (2 per species) were exposed to 0.1 mg/L of the chemical (vapour) for 4 hours (REACH n.d.).

Corrosion/Irritation

Skin irritation

The chemical is classified as hazardous (Skin Irritation – Cat 2; H315 (Causes skin irritation)) in the HCIS (SWA n.d.). While the limited available data do not support this classification, in the absence of more comprehensive information, there is insufficient evidence to warrant an amendment to this classification.

In a skin irritation study conducted according to OECD TG 404 (deviation: no vehicle used), 0.5 mg of the chemical was applied to the skin of 3 New Zealand White (NZW) rabbits for 4 hours under semi-occlusive conditions. Observations were recorded at 24, 48 and 72 hours after patch removal. The following mean scores were reported for individual animals: 0/0.6/0.3 for erythema and 0/0.3/0 for oedema at 24, 48 and 72 hours. These effects were fully reversed within 72 hours (ECHA 2017; OECD 2012; REACH n.d.). Organic peroxides are assumed to be skin irritants unless evidence suggests otherwise. As the chemical was administered in a crystalline state (without a vehicle) it may not have been sufficiently bioavailable in the test and the results may not reflect the irritation potential of the chemical (ECHA 2017).

Eye irritation

The chemical is classified as hazardous (Eye irritation – Cat 2; H319 (Causes serious eye irritation)) in the HCIS (SWA n.d.). While the limited available data do not support this classification, in the absence of more comprehensive information, there is insufficient evidence to warrant an amendment to this classification.

In a GLP compliant eye irritation study (with deviations) conducted in according to OECD TG 405, the chemical (100 mg) was applied to the conjunctival sac of one eye each of 3 Himalayan rabbits. Deviations included presence of impurities, lack of information on purity, application of anaesthesia, and use of Himalayan rabbits instead of albino rabbits. The eyes were rinsed one hour after administration and observed at 1, 24, 48, 72 hours, 14 days. Slight irritation was reported with mean scores reported at 24, 48 and 72 hours: 0.3/3 for conjunctivae; 0/4 for corneal opacity; 0/4 for chemosis; and 0/2 for iris reactions. All reactions were fully reversed within 72 hours (ECHA 2017; REACH n.d.). However, the study may not have adequately tested the irritation effects of the chemical as an appropriate vehicle was not used (ECHA 2017)

The chemical was reported to be slightly irritating to the rabbit eyes in one other non-guideline study at 0.1 mL of 50% chemical in corn oil (REACH n.d.).

Respiratory irritation

Limited data are available for the chemical. Nasal mucosa changes have been reported in a 4 week inhalation study in rabbits and effects in the nasal cavity have also been reported in workers exposed the chemical (see **Repeated dose toxicity**).

Sensitisation

Skin sensitisation

Based on weight of evidence from available data, the chemical is not expected to be a skin sensitiser.

In a modified local lymph Node Assay (LLNA) conducted similar to OECD TG 429, female CBA mice (6/group) were treated with the chemical at concentrations of 10, 25 or 50% in acetone/olive oil (3+1 v/v). The study was performed using the lymph node weight and lymph node cell count to assess cell proliferation along with ear weight and ear thickness measurements to determine the skin irritation potential of the chemical (Ehling et al. 2005). Reported stimulation indices of 1, 1.086, 1.339, and 1.384 at 0, 10, 25 and 50% concentrations, respectively. No evidence of sensitisation was observed (OECD 2012; REACH n.d.).

The chemical did not give protein binding alerts for skin sensitisation and respiratory sensitisation based on their molecular structures as profiled (in silico) by the OECD Quantitative Structure–Activity Relationship (QSAR) Toolbox v4.4.

Observation in humans

In a human patch test (200 volunteers), slight skin irritation but no sensitisation was reported following patch testing with technical grade DCUP (90% purity). No further study details were available (REACH n.d.).

Repeat dose toxicity

Based on the available data, the chemical is not expected to cause significant systemic health effects following repeated oral and inhalation exposure.

Oral

In a GLP compliant 28 day oral toxicity study, similar to OECD TG 407, Crj:CD (SD) rats (5/sex/dose) were administered DCUP at 60, 200 or 600 mg/kg bw/day by gavage for 28 days. Observations during a 14 day recovery period were made for an additional 5 rats/sex (satellite groups) in the 0 and 600 mg/kg bw/day groups. No mortalities occurred in treated rats. An increase in relative liver weight in female rats and hypertrophy of hepatocytes in males and females was observed at 200 mg/kg bw/day. At the highest dose (600 mg/kg bw/day), increased relative liver weights, hypertrophy and degeneration of hepatocytes, decreased absolute and relative thymus weights and increased serum gamma glutamyl transpeptidase (GTP) were observed in both male and female rats. Kupffer cell mobilisation, and increased alanine aminotransferase (ALT) were also noted in male rats. All effects were reversed during the recovery period. A no observed adverse effect level (NOAEL) of 60 mg/kg bw/day was derived based on this study (OECD 2012; REACH n.d.).

In a 90 day oral toxicity study, conducted according to OECD TG 408, Wistar rats (10/sex/dose) were administered DCUP in sunflower oil at 0, 20, 80 or 320 mg/kg bw/day by oral gavage. Observations during a 14 day recovery period were made for an additional 5 rats/sex (satellite groups) in the 0 and 320 mg/kg bw/day groups. No treatment related mortality was reported. Reduced body weight and changes in body weight gain, and reversible changes in liver and kidney weights were noted in male and female rats at 320 mg/kg bw/day. Elevated serum levels of ALT, alkaline phosphatase (ALP), total bilirubin and albumin were also noted at this dose. In males, significant changes in absolute and relative weights of thymus and adrenals at 80 mg/kg bw/day, and of heart, spleen, testes, adrenals and thyroids at 320 mg/kg bw/day, were reported. From the study details reported, a dose response relationship or the extent of reversibility of effects could not be determined. No adverse effects were seen on the oestrous cycle. No treatment related effects were overserved in the sperm cells at the highest dose. The lowest observed adverse effect level (LOAEL) of 320 mg/kg bw/day and an NOAEL of 80 mg/kg bw/day was reported (REACH n.d.).

Dermal

No data are available for this chemical.

Inhalation

In a 4 week inhalation toxicity study with limited data available, Albino Swedish rabbits (numbers not stated) were exposed (by direct instillation in the right nostril) to 50 µL of phosphate-buffered saline containing either:

- the chemical or
- a dust mixture containing the chemical.

The chemical and dust mixture were tested at concentrations of 10 or 25 ppm. The animals were treated 3 times daily for 4 weeks followed by a 2 month recovery period. Clinical signs of toxicity included local irritation, increased amount of mucus at one hour post exposure, and increased number of blood vessels at one week and one month post exposure. Visible

blood vessels remained at the end of the recovery period. Changes to the mucosal membrane and absence of cilia were noted at end of the 2 month recovery period (Hans-Arne Hansson and Bjorn Petursson 1986; REACH n.d.).

Observation in humans

Limited data are available for this chemical. In an occupational study, 18 workers were exposed to dust measuring 0.9 mg/m^3 during routine work. Nine exposed and 2 control group workers had visible blood vessels in the mucosa of the anterior nasal septum. The reliability of this study was not assignable due to limited number of workers investigated and exposure not being measured (Bjorn and Jarvholm 1986; REACH n.d.).

Genotoxicity

Based on the available data, the chemical is not expected to have genotoxic potential.

In vitro

In a bacterial reverse mutation test (OECD TG 471), the chemical was not mutagenic in *Salmonella typhimurium* strains TA 98, TA 100, TA 1535, TA 1537 and *Escherichia coli* WP2 at concentrations up to 5000 µg/plate, with or without metabolic activation (REACH n.d.).

In a mammalian cell gene mutation test (OECD TG 476) in Chinese hamster lung fibroblasts (V79), the chemical was not mutagenic at the hprt locus for up to 156.3 µg/mL, with or without metabolic activation (REACH n.d.).

In a mammalian chromosome aberration test (OECD TG 473) in Chinese hamster lung (CHL/IU) cells, the chemical was not clastogenic at up to 225 µg/mL (10 mM), with or without metabolic activation (REACH n.d.).

In vivo

In a mammalian DNA damage (non-compliant) study in female Sencar mice, no effects were observed after 2 topical applications of the chemical at 2.5 mg (REACH n.d.).

Carcinogenicity

Limited data are available to evaluate carcinogenicity.

The chemical was reported to induce short term markers of tumour promotions (epidermal hyperplasia, ornithine decarboxylase and dark basal keratinocytes) (REACH n.d.). In a 60 week tumour initiation/promotion study in mice, the chemical only had weak tumour promoting potential. Following initiation with 7,12-dimethylbenz(a)anthracene (DMBA), the chemical induced 0.13 and 0.44 papillomas per mouse at 6 and 20 mg, respectively, and one spindle cell carcinoma at 60 mg (REACH n.d.).

Reproductive and development toxicity

No specific data are available on effects on sexual function and fertility. No treatment related effects were seen on the oestrous cycle and sperm cells in a 90 day oral toxicity study (see **Repeated dose toxicity**). Based on the available data, DCUP is expected to cause specific adverse effects on development following oral exposure. The chemical is classified as

hazardous ‘Reproductive toxicity— Category 1B (H360D: May damage the unborn child)’. The data are consistent with this classification.

In a GLP compliant prenatal developmental study, similar to OECD TG 414, pregnant Wistar rats (n=24/group) were administered the chemical by gavage in sunflower oil at 0, 50, 150 or 450 mg/kg bw/day on gestational days (GD) 5–19. Maternal toxicity with treatment related clinical signs and associated necropsy findings were observed only at the highest dose (450 mg/kg bw/day). Mortality was reported in one female on GD 20; salivation in 8/17 dams; piloerection in 3/17 dams; alopecia in 3/17 dams. Reduced activity, vaginal bleeding, hypotonicity and red colouration around eyes were observed in the deceased dam. Necropsy observations in the highest dose group were enlarged adrenals (4/17 dams); blood in uterus (3/17) and enlarged spleen (2/17). Dose dependent decrease in average food consumption and reduction in body weight gain were reported at 150 and 450 mg/kg bw/day.

Effects on the F1 generation from the high dose dams included increased post implantation loss, decrease in foetal weight, malrotated fore and hind limbs, and significant skeletal malformations of the pectoral girdle and extremities and fore- and hindlimbs, increase in skeletal variations and dark brownish discoloured placentas with fibrinoid degeneration. A LOAEL of 450 mg/kg bw/day and an NOAEL of 150 mg/kg bw/day for maternal and developmental health effects were determined (REACH). A further assessment of the relationship between the individual dams with symptoms of maternal toxicity and the individual pups with symptoms of developmental toxicity was conducted by the Norwegian Environment Agency. The assessment concluded that there no clear connection between maternal toxicity and post-implantation loss, intrauterine mortality, body weight retardation and foetal malformations. Therefore, the observed developmental effects following exposure to DCUP are not considered a secondary consequence of maternal toxicity (ECHA 2017; Government of Canada 2019; REACH n.d.).

In a GLP compliant prenatal developmental study, similar to OECD TG 414, female NZW rabbits (n=20/group) were administered the chemical by gavage in sunflower oil at 0, 20, 50, 150 or 250/325 mg/kg bw/day on GD 6–27. Highest dose level was reduced from 325 mg/kg bw/day to 250 mg/kg bw/day on GD 22. Dams were sacrificed on GD 28 and the foetuses examined. There was no mortality, clinical signs, body weight changes reported at doses up to 150 mg/kg bw/day. Mortality in 2 females and morbidity in 13 females were reported at 250/325 mg/kg bw/day due to the adverse effects including, malnutrition, reduced spontaneous activity, loss of body weight and abortion. There were no treatment related effects on post-implantation loss, intrauterine mortality, body weight retardation in pups and foetal malformations. An NOAEL of 150 mg/kg bw/day for maternal and developmental toxicity were reported (REACH n.d.).

In a non-guideline supporting study, 3 day old white leghorn chicken embryos were injected with the chemical in the inner shell membrane of air chamber at 0.38, 0.75, 1.5 or 3.0 micromole/egg, 30 eggs/dose for 14 days. High frequency of malformation including defects of the right eye and right wing, twisting and stunting of the back, and defects of the coelomic walls were reported (ECHA 2017).

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