Phenol, 2,2'-methylenebis[6-(1,1-dimethylethyl)-4-methyl-: Human health tier II assessment

21 April 2016

CAS Number: 119-47-1

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.

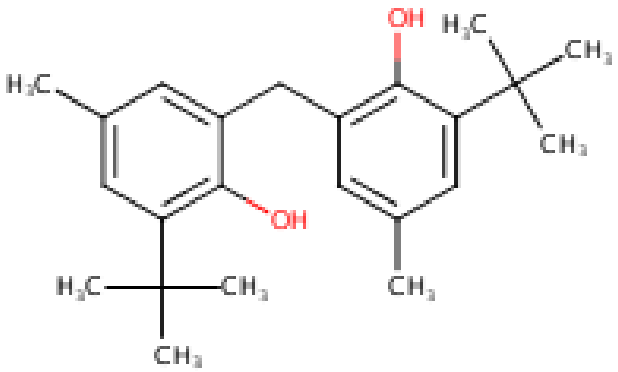
This chemical or group of chemicals are being assessed at Tier II because the Tier I assessment indicated that it needed further investigation.

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

Disclaimer

Acronyms & Abbreviations

Chemical Identity

Synonyms	2,2-methylenebis[4-methyl-6-tert-butylphenol p-cresol, 2,2'-methylenebis(6-tert- butyl- antioxidant 2246 bisalkofen BP methylene di-t-butylcresol
Structural Formula	
Molecular Formula	C23H32O2
Appearance and Odour (where available)	Off-white powder
SMILES	C(C)(C)(C)c1c(O)c(Cc2c(O)c(C(C)(C)C)cc(C)c2)cc(C)c1

Import, Manufacture and Use

Australian

The following uses were identified based on several material safety data sheets (MSDS) for the chemical or articles containing the chemical sold in Australia:

The chemical has reported commercial uses including:

- in adhesives;
- as a rubber antioxidant; and
- as a binder in polymers.

In addition, the chemical was identified as an anti-oxidant in explosives by the Australian Government, Department of Defence (Australian Government, 2003).

The chemical was also reported to have use in sealant products.

International

The following uses were identified through, Handbook of Preservatives (Ash and Ash, 2004), Galleria Chemica (Galleria Chemica), United States (US) Occupational Health Database (HazMap), Health Canada (2009), International Agency for Research on Cancer (IARC, 1982), The International Fragrance Association (IFRA) Use Survey (IFRA, 2011), Registration, Evaluation, Authorisation and Restriction of Chemicals dossier (REACH), The Organisation for Economic Co-operation and Development (OECD, 2001), the Substances in Preparations In Nordic Countries (SPIN), Cosmetic Ingredients and Substances Database (CosIng) and United States (US) National Library of Medicine Hazardous Substances Data Bank (HSBD).

The chemical has reported cosmetic use as an antioxidant in cosmetics and fragrances.

The chemical has reported commercial uses as:

- an antioxidant in lubricants, fuels, hydraulic fluids, rubber and polymer preparations; and
- a stabiliser for rubber and polymer preparations.

The chemical has reported site-limited use as an intermediate.

The non-industrial use of the chemical as an inert ingredient in pesticides has also been identified.

Restrictions

Australian

No known restrictions have been identified.

International

The chemical is listed on the following (Galleria Chemica):

- Europe Commission Regulation (EU) No 10/2011 of 14 January 2011 on plastic materials and articles intended to come into contact with food - Annex I - Table 1. Group total specific migration limit (SML(T)) No (13) = 1.5 mg/kg;

- Switzerland Ordinance of the Federal Department of Home Affairs (FDHA) on articles and materials - Annex 6, List of additives, Part A: evaluated substances. SML(T) 1.5 mg/kg in total for CAS No 119-47-1 and CAS No 88-24-4; and
- US FDA Indirect Food Additives: Adhesives and Components of Coatings - Substances for Use Only as Components of Adhesives.

Existing Work Health and Safety Controls

Hazard Classification

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

Exposure Standards

Australian

No specific exposure standards are available.

International

No specific exposure standards for the chemical are available. However, the following exposure standard was identified for cresols and all isomers (Galleria Chemica):

- Occupational Exposure Limit (OEL) of 5 ppm (22 mg/m^3) – South Africa (SA Occupational Exposure limits for Airborne Pollutants).

Health Hazard Information

Acute Toxicity

Oral

The chemical exhibits low acute toxicity via the oral route in animal tests as evidenced by reported oral median lethal dose (LD50) in rats of >5000 mg/kg body weight (bw).

In a non-guideline study, albino rats (10 males) received 10000 mg/kg bw of the chemical via oral gavage. No deaths occurred during the study. Depressive behaviour in animals was described six to 24 hours after the administration of the chemical. No other adverse effects were reported. LD50 was estimated to be >10000 mg/kg bw (OECD, 2001; REACH).

In another non-guideline studies, Wistar male and female rats (10 per sex) received 5000 mg/kg bw of the chemical in olive oil and Sprague-Dawley male and female rats (10 /sex/dose) received 1000, 2500, 5000 mg/kg bw of the chemical in corn oil via oral gavage. No deaths occurred during the studies. LD50 was determined to be > 5000 mg/kg bw for both sexes (OECD, 2001; REACH).

In addition, oral LD50 value of 11000 mg/kg bw was reported for mouse (ChemIDPlus).

Dermal

The chemical has low acute toxicity based on results from animal tests following dermal exposure.

The LD50 values of >5000 mg/kg bw and >10000 mg/kg bw were reported in rabbits (REACH).

Inhalation

Only limited data are available.

Inhalation exposure to 100 mg/m^3 for four hours did not induce any toxic effects in experimental animals (species and sex unspecified) (OECD, 2001; REACH).

In another inhalation study, one rabbit, one guinea pig, two rats and four mice were exposed to the chemical via inhalation (whole body) for four hours (no further details available). Four grams of the chemical was heated up to 180°C in a room with the capacity of 400 litres. There were no deaths, but all animals had abnormal breathing during exposure and breathing difficulties after exposure. The breathing difficulties were reversible (REACH).

Corrosion / Irritation

Skin Irritation

Based on the available data, the chemical is not considered a skin irritant.

In a OECD Test Guideline (TG) 404 study, New Zealand White rabbits (2 males, 1 female) were treated with the chemical (semiocclusive coverage) on shaved skin for 24 hours and observed for 72 hours. The test material, did not produce any irritation (REACH).

In a non-guideline study, rabbits were exposed via dermal application of 0.4 mg/kg bw as a 10% solution in Wesson oil for 18 hours. The chemical caused slight erythema that disappeared in 48 hours (REACH).

In other non-guideline studies, either no irritation, or reversible local irritation, was reported in rabbits and guinea pigs. No other study details are available (OECD 2001, REACH).

Eye Irritation

Based on the available data, the chemical is considered to be a slight eye irritant.

In a guideline (OECD TG 405) study, New Zealand White rabbits (1 male, 2 females) were treated with 0.1 ml of the chemical on one eye of each animal for 72 hours. No corneal effects were noted during the study. Iridial inflammation was present in two treated eyes and minimal to moderate conjunctival irritation was noted in all treated eyes one hour after application. The effects were reversible and treated eyes appeared normal 24 or 48 hours after application. No effects were noted at 72 hours (REACH).

In other non-guideline studies, either no eye irritation or mild to moderate, reversible eye irritation were reported in rabbits and guinea pigs. No other study details were available (OECD, 2001; REACH).

Sensitisation

Skin Sensitisation

The chemical is not considered a skin sensitiser.

In a GLP, guideline (OECD TG 429; Local Lymph Node Assay) study, NMRI female mice (6/dose) received 0, 2, 10 or 50 % chemical in acetone/olive oil (4:1 v/v). As stimulation indexes (SI)s were < 3, EC3 value could not be determined. Therefore, the chemical did not produce allergic skin reaction(REACH).

Observation in humans

Ten or 50 human volunteers were treated with 20% antioxidant 2246 (CAS No 119-47-1) in polyethylene glycol for 48 hours. Treatment of 10 men under a gauze patch did not cause irritation (0/10) while subsequent, occlusive patch test on 50 males with repeated applications to a site irritated by freezing caused weak sensitisation in one participant (1/50) (REACH).

In patch-test, human volunteers (contact dermatitis patients; sex not specified) were treated with epicutaneous, occlusive patches containing the chemical at 0.1, 1 or 10 %. The test material was negative (0/13) in a patch-test with contact dermatitis patients (REACH).

The substance was not irritating or allergenic in human volunteers (25 males) in a maximisation test (epicutaneous, occlusive exposure) (OECD, 2001).

In patch-test of human contact dermatitis patients (3 females), epicutaneous, occlusive exposure to 2 % of chemical in petrolatum produced skin erythema in one patient (1/3), while negative results were seen in the other in two patients (2/3) (REACH).

Repeated Dose Toxicity

Oral

Based on the results of several repeated dose toxicity studies ranging from 28 days to 18 months, the chemical is not expected to cause severe effects following repeated oral exposure. However, toxic effects following repeated exposure were observed, mainly in the reproductive organs. The reproductive effects are described elsewhere in this report (see Reproductive & Developmental Toxicity).

In a well-documented chronic toxicity study, Wistar rats (30/sex/dose) were exposed via diet to 0, 100, 300 or 1000 ppm of the chemical for 18 weeks. Suppression of the body weight gain and increase in the relative liver weight in both sexes was reported at 1000 ppm (corresponding to 42.3 mg/kg bw/day for males and 54.2 mg/kg bw/day for females) (OECD, 2001; REACH). Therefore, the no observable adverse effect level (NOAEL) for non-reproductive organ effects are considered as 300 ppm in both males (12.7 mg/kg bw/day) and females (15.1 mg/kg bw/day).

In another non-guideline subchronic study, male and female Nelson albino rats (25/dose) were exposed via a diet containing 0, 330, 1000 or 3000 ppm of the chemical for three months. The males and females treated with 1000 (75 mg/kg bw/day for males and 113 mg/kg bw/day for females) or above of the chemical had significant increases in mean liver weights (REACH). Therefore, the NOAEL for non-reproductive organ effects is considered to be 330 ppm.

In a 28-day repeated dose toxicity study conducted in accordance with a Japanese Government guideline, Crj:CD Sprague-Dawley (SD) rats (6 or 12/dose/sex) were treated with the chemical via oral gavage at 0, 12.5, 50, 200, 800 mg/kg bw/day. A prolongation in prothrombin time (PT) and activated partial thromboplastin time (APTT) were seen in males in all treatment groups and in females at 200 mg/kg bw/day and higher. All doses increased liver weights in both sexes. Histopathological lesions of the liver were seen in both sexes at 200 mg/kg bw/day and higher. In females an increase in adrenal weights was reported at 200 mg/kg bw/day and higher (REACH). Therefore, a lowest observable adverse effect level (LOAEL) for non-reproductive organ effects in this study is considered to be 12.5 mg/kg bw/day.

Dermal

Limited data suggest that the chemical is not expected to cause severe systemic effects following repeated dermal exposure.

Repeated application of the chemical at 400 mg/kg bw/day (length of exposure not specified) on rabbit's skin resulted in no signs of systemic toxicity, while some skin irritation was observed (REACH).

Inhalation

Limited existing data suggest that the chemical is not expected to cause severe systemic effects following repeated inhalation exposure.

In a non-guideline study, rats, guinea pigs and dogs were exposed to the chemical via inhalation (dust) for 60 times over a period of 84 days. No significant signs of toxicity were observed throughout the study (REACH).

Genotoxicity

The chemical is not considered to be genotoxic. The chemical tested negative in several in vitro tests and in one in vivo micronucleus assay.

The chemical was not mutagenic in the following in vitro studies:

- In a bacterial reverse mutation assay (OECD TG 471 and OECD TG 472), the chemical was not mutagenic in *Salmonella typhimurium* strains TA 100, TA 1535, TA98, TA1537, or *Escherichia coli* WP2 uvrA, with or without metabolic activation, at doses up to 5000 µg/plate (REACH).
- In a guideline study (similar to OECD TG 476), the chemical did not induce gene mutations at the hypoxanthine phosphoribosyltransferase (HPRT) locus in V79 cells, with or without metabolic activation (REACH).
- In a mammalian chromosome aberration test (OECD TG 473), no cytogenetic effects were detected, with and without metabolic activation (REACH).

The chemical was not mutagenic in an in vivo mammalian erythrocyte micronucleus assay (OECD TG 474). No significant treatment-related increase of micronucleated polychromatic erythrocytes was observed in NMRI male and females mice at 24, 48, and 72 hours following treatment by a single application of the chemical at 5000 mg/kg bw by gavage (OECD, 2001; REACH).

Carcinogenicity

There is limited data available that is insufficient to reach conclusion on the carcinogenicity.

In a well conducted study, Wistar rats (30/dose/sex) were exposed to the chemical via the diet at 0, 0.01, 0.03 or 0.1 % (1000 ppm) for 18 months. No tumours were observed in the study. However, the study was not designed for carcinogenicity and was carried out with relatively small number of animals (OECD, 2001).

Reproductive and Developmental Toxicity

The chemical is recommended for classification as hazardous, a Category 2 substance toxic to reproduction with the risk phrases ‘May impair fertility’ (T; R60) in HSIS (Safe Work Australia). The available data support this classification.

Based on the consistent results of toxicity studies in rats, a reported no observed adverse effect level (NOAEL) of 12.5 mg/kg bw/day was determined for male reproductive toxicity (testicular toxicity) and 50 mg/kg bw/day for female reproductive toxicity. The NOAEL for developmental toxicity was 200 mg/kg bw/day. See study details below.

Reproductive toxicity

In an OECD TG 421 (reproduction/developmental toxicity) study, Crj:CD(SD) rats (12/dose/sex) were treated with the chemical via oral gavage at 0, 12.5, 50, 200, 800 mg/kg bw/day. Duration of treatment was 50-52 days in males and 40-48 days in females (starting 14 days before mating). Atrophy of the testes and epididymides leading to reduced absolute and relative testis

and epididymis weights was reported at 200 mg/kg bw/day and above. Histological examination revealed giant cell formation in the testes of males treated at 50 mg/kg bw/day and above and degeneration of the seminiferous tubules was seen at 200 mg/kg bw/day and above. The sperm motility ratio, sperm viability ratio, sperm survivability ratio, and number of sperm in the cauda epididymis were reduced, and the abnormal sperm ratio was increased at 50 and above. An atrophy of the seminal vesicles was reported at 800 mg/kg bw/day. Reduction in the number of corpora lutea, implantation scars, and pups was reported at 200 and 800 mg/kg bw. In addition, one dam was unable to deliver pups at 800 mg/kg bw/day. Based on the findings of this study, the NOAEL for reproductive toxicity was established at 50 mg/kg bw/day for females and 12.5 mg/kg bw/day for males (OECD, 2001; REACH).

In a well-documented chronic toxicity study, male and female Wistar rats (30/sex/dose) were exposed via diet containing 0, 100, 300 or 1000 ppm of the chemical for 18 weeks. Decrease of the absolute and relative testes weights and atrophy of testicular tubules as well as a spermatogenic arrest and epididymis hypospermia were observed at 1000 ppm (corresponding to 42.3 mg/kg bw/day) (REACH).

In another non-guideline subchronic study, male and female Nelson albino rats were exposed via a diet containing 0, 330, 1000 or 3000 ppm of the chemical. Atrophy of the testis was reported in males treated at 1000 ppm or 3000 ppm (REACH).

In a 28-day repeated dose toxicity study conducted in accordance with a Japanese Government guideline, Crj:CD(SD) rats (6 or 12/dose/sex) were treated with the chemical via oral gavage at 0, 12.5, 50, 200, 800 mg/kg bw. Lesions of the testis were noted at 200 mg/kg bw/day and above, and sperm abnormalities were reported at 50 mg/kg bw/day and above (REACH).

In another subchronic feeding study, comparable to guideline study, male and female Wistar rats (10 sex/dose) were fed at 0,100, 330, 1000 or 3000 ppm of the chemical in the diet daily for 13 weeks. Males receiving 1000 ppm and 3000 ppm (approximately 76 and 282 mg/kg bw/day) showed a significant reduction of testes weights and a severe atrophy of the testes. The weight of the epididymis was reduced at the highest dose group (3000 ppm). In female rats, a reduction of the uterus weight and an atrophy of both horns of the uterus were seen at 3000 ppm (approximately 345 mg/kg bw/day) (REACH).

In another non-guideline study, rats were exposed to the chemical at 10 or 50 mg/kg bw/day for four and ten months. Decreased fertility and atrophy of the testes was reported. No other details were available (REACH).

In another well conducted non-guideline study, F344/DuCrj (Fischer) rats (8 males) and Slc:Wistar rats (8 males) were exposed to the chemical via diet at 0.06 % (approx. 40 to 60 mg/kg/day) for two months. Effects such as reduced relative testicular and epididymal weights and histopathological changes including vacuolisation of Sertoli cells, disappearance of basement membrane and degeneration of spermatids were reported. Daily sperm production (DSP) was significantly decreased. Serum testosterone levels were not significantly affected by the treatment when compared with controls (REACH).

Developmental toxicity

A reproduction/developmental toxicity study (OECD TG 421) was conducted as detailed in the previous section. Body weight gain in dams was suppressed in the 200 mg/kg bw/day treatment group during the lactation period, while the 800 mg/kg bw/day treatment suppressed body weight gain during pregnancy and lactation. Lower food consumption was reported in the 200 and 800 mg/kg bw/day groups during pre-mating, pregnancy, and lactation periods. Low body weight gain of offspring and increased number of stillbirths were observed at 800 mg/kg bw/day, but not at 200 mg/kg. No external anomalies were found in any of the pups evaluated. Maternal toxicity was observed at 200 mg/kg bw/day and the NOAEL for pup development was 200 mg/kg bw/day (REACH). The chemical is therefore not considered to cause developmental effects.

In a teratogenicity study, Wistar rats (15-23 dams/dose) were exposed to the chemical by oral gavage at doses of 0, 93.5, 187 and 375 mg/kg bw/day between gestation days (GDs) 7 and 17. Maternal toxicity including suppression of body weight were detected at 187 mg/kg bw/day and above. Foetal toxicity including foetal deaths was noted at 375 mg/kg bw/day. There were no external, visceral and skeletal effects reported (OECD, 2001).

Other Health Effects

Endocrine Disruption

The chemical had no oestrogenic activity when tested in an in vitro ER alpha-binding assay (REACH).

Risk Characterisation

Critical Health Effects

The critical health effects for risk characterisation include systemic long-term effects (reproductive toxicity).

Public Risk Characterisation

Based on the international use information, the chemical could be used as an antioxidant in cosmetics, fragrances and domestic products. However, the REACH dossier (REACH) does not identify cosmetic use and the chemical is not listed in the Compilation of Ingredients Used in Cosmetics in the United States (CIUCUS, 2011). In which case, the chemical is not expected to be widely used in cosmetics. If it is used as a minor ingredient (as an antioxidant), the concentration of the chemical is expected to be very low.

The chemical may also be present in polymer/rubber articles. However, the leaching or migration of the substance from such articles is not expected to occur, and the consumer exposure from the polymer/rubber is expected to be negligible (OECD, 2001).

Therefore, the public risk to the chemical is not expected to be unreasonable.

Occupational Risk Characterisation

Given the critical systemic long-term health effects, the chemical could pose an unreasonable risk to workers unless adequate control measures to minimise oral exposure are implemented. The chemical should be appropriately classified and labelled to ensure that a person conducting a business or undertaking (PCBU) at a workplace (such as an employer) has adequate information to determine the appropriate controls.

The available data support hazard classification of the chemical (refer to **Recommendation** section).

NICNAS Recommendation

Assessment of the chemical is considered to be sufficient, provided that the recommended amendment to the classification is adopted, and labelling and all other requirements are met under workplace health and safety and poisons legislation as adopted by the relevant state or territory.

Regulatory Control

Public Health

Products containing the chemical should be labelled in accordance with state and territory legislation.

Work Health and Safety

The chemical is recommended for classification and labelling under the current approved criteria and adopted GHS as below. This assessment does not consider classification of physical and environmental hazards.

Hazard	Approved Criteria (HSIS)[a]	GHS Classification (HCIS)[b]

Hazard	Approved Criteria (HSIS)[a]	GHS Classification (HCIS)[b]
Reproductive and Developmental Toxicity	Repro. Cat 2 - May impair fertility (T; R60)	May damage fertility or the unborn child - Cat. 1B (H360F)

[a] Approved Criteria for Classifying Hazardous Substances [NOHSC:1008(2004)].

[b] Globally Harmonized System of Classification and Labelling of Chemicals (GHS) United Nations, 2009. Third Edition.

[*] Existing Hazard Classification. No change recommended to this classification

Advice for consumers

Products containing the chemical should be used according to label instructions.

Advice for industry

Control measures

Control measures to minimise the risk from oral exposure to the chemical should be implemented in accordance with the hierarchy of controls. Approaches to minimise risk include substitution, isolation and engineering controls. Measures required to eliminate, or minimise risk arising from storing, handling and using a hazardous chemical depend on the physical form and the manner in which the chemical is used. Examples of control measures that could minimise the risk include, but are not limited to:

- using closed systems or isolating operations;
- health monitoring for any worker who is at risk of exposure to the chemical, if valid techniques are available to monitor the effect on the worker's health;
- minimising manual processes and work tasks through automating processes;
- work procedures that minimise splashes and spills;
- regularly cleaning equipment and work areas; and
- using protective equipment that is designed, constructed, and operated to ensure that the worker does not come into contact with the chemical.

Guidance on managing risks from hazardous chemicals are provided in the *Managing risks of hazardous chemicals in the workplace—Code of practice* available on the Safe Work Australia website.

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. Guidance in selecting personal protective equipment can be obtained from Australian, Australian/New Zealand or other approved standards.

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 are 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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