Phenol, 2,6-bis(1,1-dimethylethyl)-4-methyl-: Environment tier II assessment

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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

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Acronyms & Abbreviations

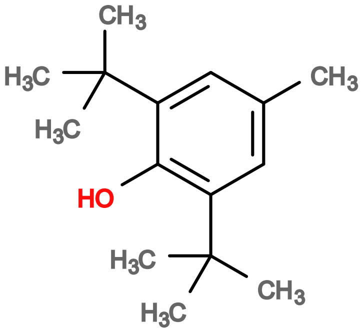
Rationale

This Tier II assessment considers the environmental risks associated with industrial uses of phenol, 2,6-bis(1,1-dimethylethyl)-4-methyl-, which is more commonly known as butylated hydroxytoluene (BHT). This chemical is a widely used phenolic antioxidant. It is used as an ingredient in personal care products and cosmetics, as an additive to petroleum products such as fuels and lubricating oils, in the production of plastics and synthetic rubbers, and as a preservative in food and animal feed. BHT is used in significant volumes worldwide, and is released to the environment from both industrial and non-industrial uses.

The Tier I assessment of BHT found that it is potentially of concern to the environment based on an unacceptably high risk quotient for emissions to surface waters in the treated effluent discharged from sewage treatment plants (STP), and possible PBT characteristics of the chemical. A more in-depth assessment at Tier II level was recommended under the IMAP framework.

Chemical Identity

Synonyms	butylated hydroxytoluene (BHT) 2,6-di-*tert*-butyl-4-methylphenol 2,6-di-*tert*-butyl-*p*-cresol

Structural Formula	
Molecular Formula	$C_{15}H_{24}O$
Molecular Weight (g/mol)	220.35
SMILES	C(C)(C)(C)c1c(O)c(C(C)(C)C)cc(C)c1

Physical and Chemical Properties

The physical and chemical property data for BHT were retrieved from the databases included in the OECD QSAR Toolbox (LMC, 2013):

Physical Form	solid
Melting Point	71°C (exp.)
Boiling Point	265°C (exp.)
Vapour Pressure	0.69 Pa (exp.)
Water Solubility	0.60 mg/L (exp.)
Ionisable in the Environment?	no

log K_{ow}	5.1 (exp.)

Import, Manufacture and Use

Australia

The volume of BHT introduced annually for use as an industrial chemical is in the range of 100 to 1000 tonnes based on information reported to NICNAS.

BHT has reported use as an antioxidant in commercial printing inks and industrial cleaners and adhesives. It is also used in automotive aftermarket products such as sealants and coatings, and in consumer cleaners and polishes.

The chemical is listed under schedule 15 of the *Australia New Zealand Food Standards Code* for use as a food additive (Commonwealth of Australia, 2017). The use of BHT as a food additive is outside of the scope of this assessment.

International

The global annual production capacity of BHT in the year 2000 was approximately 62 000 tonnes (OECD, 2002). The majority of this production volume was used in plastics and synthetic rubber. The chemical has other significant uses as an additive in mineral oil and fuel, in foodstuffs, pharmaceuticals, cosmetics, animal feed and printing inks (OECD, 2002). The main function of BHT in these products and articles is as an antioxidant, which protects organic materials from oxidation during storage. It also serves as an antiskinning agent in paints and inks, and is used in food packaging materials such as waxed paper, paper board, and polyethylene.

In the European Union (EU), the chemical is registered for use at a volume between 10 000 and 100 000 tonnes per annum (ECHA, 2014a). In the United States of America (USA), 7178 tonnes of the chemical was produced in 2012 (US EPA, 2013a), and in Japan, 5730 tonnes of the chemical was produced or imported in 2015 (NITE, 2017a).

Environmental Regulatory Status

Australia

The use of BHT is not subject to any specific national environmental regulations.

United Nations

The chemical is not currently identified as a Persistent Organic Pollutant (UNEP, 2001), ozone depleting substance (UNEP, 1985), or hazardous substance for the purpose of international trade (UNEP & FAO, 1998).

OECD

The chemical was sponsored by Germany for assessment under the 14th Screening Information Dataset (SIDS) Initial Assessment Meeting (SIAM 14). The SIDS Initial Assessment Report concluded that BHT was a candidate for further work and an environmental risk assessment is recommended. The report indicated the specific areas that required clarification are exposure, bioaccumulation and the toxicity of the metabolites (OECD, 2002).

The chemical is considered a High Production Volume (HPV) chemical by the OECD, which indicates that more than 1000 tonnes of the chemical are used per year in at least one member country (OECD, 2013).

Canada

The chemical is listed on the Canadian Domestic Substances List (DSL). During the Categorization of the DSL, the chemical was categorised as not Persistent (not P), not Bioaccumulative (not B) and not Inherently Toxic to the Environment (not iT_E) (Environment Canada, 2013). The chemical is currently prioritised for further assessment based on human health considerations.

European Union

The chemical is not listed on the Candidate List for Eventual Inclusion in Annex XIV, Annex XIV (authorisation) or Annex XVII (restriction) of the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH) legislation. Therefore, the chemical is not subject to authorisation or restriction, and is not currently identified by the EU as a Substance of Very High Concern for the environment (SVHC) (ECHA, 2013, 2014b, 2017a).

BHT is currently subject to informal hazard assessment and risk management option analysis under the SVHC Roadmap (ECHA, 2016a). If these processes indicate that further action is needed, actions such as proposal for identification as a SVHC can be considered (ECHA, 2016b).

The chemical is currently undergoing evaluation under the Community Rolling Action Plan (CoRAP) (ECHA, 2017b). The chemical qualifies for CoRAP evaluation based on its wide dispersive release, high aggregated tonnage, exposure to workers and sensitive populations, and potential endocrine activity (ECHA, 2016c).

United States of America

This chemical does not belong to any of the chemical classes covered by an Existing Chemical Action Plan and has not been selected for action plan development (US EPA, 2013b).

Japan

The chemical is a Priority Assessment Chemical Substance (PACS) (NITE, 2017b).

Environmental Exposure

The major industrial use for BHT is as an antioxidant in synthetic rubbers and plastics. Release of BHT into the environment is expected from the migration of this chemical onto the surface of rubber and plastic articles, including imported articles, as well as from abrasion and wear of these articles during their normal use.

Available domestic and international use data also indicate that BHT is used as an antioxidant in a wide variety of consumer products, including cleaners, cosmetics and personal care products. Chemicals used in some cosmetic and personal care products are released to waste water as a normal part of their use in domestic situations and release of BHT to sewage treatment systems in Australia is, therefore, assumed.

International industrial use data also indicate that BHT is widely used in petroleum products, including ground vehicle and aviation gasolines, as well as lubricating, turbine, and insulation oils. The use of BHT as a fuel additive is expected to result in destruction of this organic compound through combustion in engines; however, emissions to the environment from other sources such as spills and inappropriate disposal are possible. The use of BHT in industrial lubricants has the potential to lead to environmental releases of this chemical based on standard exposure scenarios for lubricants (OECD, 2004).

A number of studies in the past decade have identified biological sources of BHT, with biosynthesis of this compound occurring in several species of cyanobacteria and plant (Ait-kaci Aourahoun, et al., 2014, Babu and Wu, 2008, Usman, et al., 2016). However, it does not appear to be a common natural chemical, and thus biological sources of BHT are not expected to significantly contribute to the total load of the chemical found in the environment.

Environmental Fate

Partitioning

BHT is expected to remain in soil, or partition to water and sediment, when released as a result of industrial uses.

The chemical is a very weak acid ($pK_a = 12.20$) (LMC, 2013), which is slightly soluble in water and moderately volatile. The estimated Henry's Law constant for the chemical (252.7 Pa m^3/mol) indicates that it is highly volatile from water and moist soil (US EPA, 2008).

The high pK_a of the chemical indicates that it is not expected to be ionised in the environment. The measured octanol-water partitioning constant ($\log K_{ow} = 5.1$) and the estimated soil absorption coefficient ($\log K_{oc} = 3.9$) (US EPA, 2008) are therefore likely to be reliable indicators of partitioning behaviour in the environment. On the basis of the values for these partitioning constants, this chemical can be characterised as a highly lipophilic neutral organic substance that will be immobile in soil.

Calculations with a standard multimedia partitioning (fugacity) model assuming equal and continuous emission of the chemical to the air, water and soil compartments (Level III approach) predict that, under steady-state conditions, the majority of the chemical will partition to soil (72.3%) with lower amounts predicted to partition to water (14.7%), sediment (12.5%) and air (0.463%) (US EPA, 2008). BHT is expected to remain in the soil compartment if released solely to soil. With sole release to the water compartment, it is predicted that BHT will mainly partition between the water (53%) and sediment compartments (44.9%), with minor partitioning to air (1.97%).

Degradation

The chemical is not expected to be persistent in the environment.

In an aquatic model ecosystem study when the radiolabelled BHT test substance was added as an aqueous emulsion, recovery of ^{14}C was 40–50% after 28 days suggesting over 50% had partitioned into the atmosphere (OECD, 2002). In air, the chemical is predicted to have a half-life of 7.0 hours due to oxidation by hydroxyl radicals (US EPA, 2008).

The stability of BHT in dry soil was determined with three different soil types (light clay, sandy clay loam and sandy loam) under sterilised and non-sterilised conditions. Within one day of incubation 63–82% of BHT was decomposed in non-sterilised and 25–35% in sterilised soils. After 24 days of incubation, mineralisation up to 29% was observed under non-sterilised conditions. It was concluded that BHT is altered to non-volatile products mainly by biological processes. In soil more than 10 degradation products were found (OECD, 2002).

A photolysis study was conducted on ^{14}C-BHT in water. After 8 days exposure to natural sunlight, 25% of BHT remained unchanged with several oxidised products detected. A large proportion of degradants (corresponding to 48% of applied radioactivity) were unidentified polar compounds. In a dark control, 60% of BHT remained unchanged. It was concluded that BHT is unstable in water, with accelerated degradation when irradiated (OECD, 2002).

In a modified MITI test according to OECD Test Guideline (TG) 301C, an unadapted mixed microbial inoculum mineralised 4.5% of BHT within 28 days of incubation. Therefore, BHT is not expected to be readily biodegradable in surface waters or sewage treatment plants (OECD, 2002). Furthermore, as BHT has been shown to degrade abiotically in water, this study indicates that the BHT degradation products are also unlikely to undergo rapid biodegradation.

In one study, the susceptibility of BHT and several of its major transformation products to degradation under water chlorination conditions was investigated (Rodil, et al., 2012). BHT-CHO (3,5-di-*tert*-butyl-4-hydroxy-benzaldehyde, CAS RN 1620-98-0) and BHT-quinone, or BHT-Q (2,6-di-*tert*-butyl-*p*-benzoquinone, CAS RN 719-22-2) were found to be stable under strong chlorination conditions (< 20% removal, 10 mg L^{-1} chlorine, 24 h). This stability, in combination with their likely recalcitrance towards biodegradation, suggests that BHT-CHO and BHT-Q will resist degradation during STP processes and may persist in the environment once released.

Bioaccumulation

The chemical is expected to have a moderate to high bioaccumulation potential in aquatic organisms.

Bioconcentration tests according to OECD TG 305C were conducted using BHT (LMC, 2013, OECD, 2002). The tests were conducted using flow-through conditions, in vessels modified for volatile test substances. Bioconcentration factors in the range of 230–2500 L/kg wet weight were determined for *Cyprinus carpio* (common carp) after 56 days, at 50 nanograms per litre (ng/L) and 5 ng/L nominal BHT concentrations. A test with a nominal BHT concentration of 500 ng/L was also conducted for 42 days in total, giving bioconcentration factors in the range of 220–2800 L/kg. The high variation of measured BCF values has not been explained, as noted by Germany in the OECD SIAR for this chemical (OECD, 2002).

Based on the observed range of experimental BCF values and a measured log K_{ow} of 5.1 (LMC, 2013, OECD, 2002), it is concluded that BHT has a moderate to high bioaccumulation potential in aquatic species.

BHT-Q has a measured log K_{ow} of 4.43 and BHT-CHO has a calculated log K_{ow} of 4.2, indicating a high bioaccumulation potential for both of these BHT degradation products (LMC, 2013, US EPA, 2008).

Transport

Based on its predicted rapid degradation in the troposphere by indirect photo-oxidation, the chemical is not expected to undergo long-range transport.

Predicted Environmental Concentration (PEC)

A reasonable worst case environmental concentration for BHT in Australian inland surface waters is predicted to be 791 ng/L, based on international monitoring data.

As a first approximation, standard exposure modelling for the release of chemicals to surface water from STPs is used to estimate the concentration of BHT in river water receiving treated effluents (EPHC, 2009, Struijs, 1996). The chemical has many industrial and non-industrial uses, but the relative proportions of each use in Australia are unknown. Therefore, a worst case assumption is made that 100% of the quantity of chemical introduced for industrial uses is released to STPs nationwide. Based on this standard approach, 81% of the chemical in waste water entering an STP is predicted to be removed as a result of volatilisation (28%) and partitioning to sludge (53%). Based on an introduction volume of 1000 tonnes the PEC for the riverine compartment is calculated to be 115.1 micrograms per litre (µg/L).

This calculated PEC is likely to be a significant overestimate of the maximum environmental concentration of BHT in Australian rivers. The mean, median and highest concentrations of BHT found in several major German rivers were 176, 96 and 791 ng/L, respectively (Fries and Püttmann, 2002). A further study of contaminants in river water and sewage treatment works effluent in the Oderbruch area of Germany detected BHT in river samples at a maximum concentration of 365 ng/L, and in STP effluent samples at a maximum concentration of 258 ng/L (Fries and Püttmann, 2004). Assuming that the use patterns for BHT are similar in Australia and in Germany, a reasonable worst case environmental concentration for BHT in domestic rivers is predicted to be 791 ng/L. While STP effluent monitoring data are available in these studies, the river water data are considered to be more relevant for determination of the PEC in this case.

One available domestic monitoring study determined BHT to be present at a concentration of 200 ng/L in a single sample taken from the Herbert River in Queensland (O'Brien, et al., 2015), confirming that the chemical is present in Australian rivers.

In a study conducted at a sewage treatment plant located in Beijing, China, BHT concentrations in effluent waters were found to be 237–287 ng/L (Liu, et al., 2015). Influent water concentrations were from 2010–2839 ng/L, showing roughly 90% removal of BHT, which is consistent with the SimpleTreat calculated removal rate (81%).

In the same study, STP effluent waters also contained identifiable degradants of BHT, which were all detected in effluent at greater concentrations than found in influent waters (Liu, et al., 2015). These degradants include the previously mentioned BHT-CHO and BHT-Q, as well as BHT-quinol (2,6-di-*tert*-butyl-4-hydroxy-4-methyl-2,5-cyclohexadienone, CAS RN 10396-80-2). Moreover, the concentrations of these degradants were frequently greater than the concentration of BHT in effluent waters, with measured concentrations of BHT-CHO up to 704 ng/L, BHT-quinol up to 747 ng/L and BHT-Q up to 125.7 ng/L (Liu, et al., 2015). BHT-CHO was also detected in the German river water studies, up to 223 ng/L in river water and up to 101 ng/L in STP effluent (Fries and Püttmann, 2002, 2004). These degradants are potentially of concern to the environment as both BHT-CHO and BHT-Q are possibly persistent and bioaccumulative chemicals.

Studies have confirmed that BHT partitions to sludge during STP processes (Liu, et al., 2015). The mean and maximum concentrations of BHT found in sludge from wastewater treatment plants in China were 4140 and 30 300 ng/g dry weight respectively. BHT-Q was the BHT degradant found in highest concentrations in sludge in this study, with mean and maximum concentrations of 562 and 5130 ng/g dry weight respectively.

In a study of phenolic antioxidants in indoor dust in 12 different countries, BHT and its degradation products accounted for up to 58% of the sum of synthetic phenolic antioxidants and metabolites present in dust (Wang, et al., 2016).

Environmental Effects

Effects on Aquatic Life

BHT causes toxic effects in aquatic organisms across multiple trophic levels.

Acute toxicity

There are measured aquatic ecotoxicological data available for this chemical. The following median lethal concentration (LC50) and median effective concentrations (EC50s) for model organisms across three trophic levels were obtained from databases in the OECD QSAR Toolbox (LMC, 2013):

Taxon	Endpoint	Method
Fish	96 h LC50 = 1.1 mg/L	Experimental *Oryzias latipes* (Medaka) OECD TG 203
Invertebrates	48 h EC50 = 0.48 mg/L	Experimental *Daphnia magna* (Water flea) OECD TG 202
Algae	72 h EC50 > 0.24 mg/L	Experimental *Pseudokirchneriella subcapitata* (Green algae) OECD TG 201

No measured aquatic toxicity data for the BHT degradation products BHT-CHO and BHT-Q were identified. The acute aquatic toxicities of BHT-CHO and BHT-Q were estimated using standard QSARs (US EPA, 2012). BHT-Q was predicted to be the most acutely toxic, with LC50 and EC50 values ranging from 0.03 to 0.061 mg/L across three trophic levels. BHT-CHO had predicted acute toxicity similar to the measured toxicity of BHT, with LC50 and EC50 values ranging from 0.51 to 1.28 mg/L across three trophic levels.

Chronic toxicity

The following no-observed-effect concentration (NOEC) values for model organisms from three aquatic trophic levels were obtained from databases included in the OECD QSAR Toolbox (LMC, 2013):

Taxon	Endpoint	Method
Fish	30 d NOEC = 0.053 mg/L	Experimental *Oryzias latipes* (Medaka) OECD TG 210 (Early Life Stage Test)
Invertebrates	21 d NOEC = 0.069 mg/L	Experimental *Daphnia magna* (Water flea)OECD TG 211
Algae	72 h NOEC = 0.24 mg/L	Experimental *Pseudokirchneriella subcapitata* (Green algae) OECD TG 201

No measured chronic toxicity data for BHT-CHO or BHT-Q were identified. One study investigating the ability of BHT degradants to induce oxidative DNA damage (Oikawa, et al., 1998) found that BHT-Q could cause damage in the presence of Cu(II) and NADH (nicotinamide adenine dinucleotide, a ubiquitous biological cofactor). This implies potential genotoxic effects for BHT-Q.

Effects on Terrestrial Life

A feeding study on Wistar rats focusing on possible hepatotoxic effects of BHT was conducted. Progressive hepatocyte necrosis was observed at the highest dose level of 500 mg/kg bodyweight/day, while only slight cell damage was seen at the next highest dose level of 250 mg/kg bodyweight/day. A NOAEL (no-observed adverse effect level) of 25 mg/kg bodyweight/day was concluded (OECD, 2002).

Predicted No-Effect Concentration (PNEC)

The PNEC for the chemical is calculated to be 5.3 µg/L, based on the measured chronic toxicity to fish (30 d NOEC = 0.053 mg/L) and an assessment factor of 10. An assessment factor of 10 was selected because reliable measured chronic ecotoxicity data are available for species from three aquatic trophic levels (EPHC, 2009).

Categorisation of Environmental Hazard

The categorisation of the environmental hazards of phenol, 2,6-bis(1,1-dimethylethyl)-4-methyl- according to domestic environmental hazard thresholds is presented below (EPHC, 2009, NICNAS, 2013):

Persistence

Not Persistent (Not P). Based on the 40% abiotic primary degradation of BHT in water with no irradiation after 8 days, the chemical is categorised as Not Persistent.

Bioaccumulation

Bioaccumulative (B). Based on some measured bioconcentration factors above 2000 L/kg and a log $K_{ow} > 4.2$, the chemical is conservatively categorised as Bioaccumulative.

Toxicity

Toxic (T). Based on a chronic aquatic ecotoxicity value below 0.1 mg/L, BHT is categorised as Toxic.

Summary

Phenol, 2,6-bis(1,1-dimethylethyl)-4-methyl- is categorised as:

- Not P
- B
- T

Risk Characterisation

Based on the PEC and PNEC values determined above, the following Risk Quotient (RQ = PEC ÷ PNEC) has been calculated for release of BHT into rivers:

PEC (µg/L)	PNEC (µg/L)	RQ
0.791	5.3	0.15

An RQ value less than 1 indicates that the environmental concentrations of this chemical are unlikely to exceed levels which cause ecotoxic effects in exposed organisms. Hence, BHT is unlikely to be present in the aquatic environment at concentrations that would be of significant concern.

Insufficient ecotoxicity data are available to characterise the risks posed by release of this chemical to the sediment and soil compartments. However, BHT is not expected to be persistent in soil.

Several monitoring studies have detected and quantified a range of BHT degradants with environmental concentrations approaching that of BHT itself. Notable among these are BHT-CHO and BHT-Q, which may have significant environmental hazards. There is currently insufficient data available to further characterise the risks posed by release of these degradants of BHT.

Key Findings

BHT is a high volume chemical used both domestically and internationally as an antioxidant in a wide range of products and industries.

BHT is degradable, has moderate to high bioaccumulation potential, and has high aquatic toxicity. However, the concentrations of this chemical likely to be present in surface waters in Australia are not expected to pose a significant risk to the environment. BHT is not a PBT substance according to domestic environmental hazard criteria.

Several studies demonstrate that the chemical is unstable in water and soil. In these compartments, BHT would be expected to rapidly degrade abiotically into several degradants. Some of these degradants have been detected in surface waters internationally, and may be of high environmental concern based on possible PBT characteristics.

Further assessment may be required if information becomes available to indicate that BHT is present in the Australian environment at concentrations exceeding the level of concern, or that the degradation products of BHT possess properties that may pose a risk to the environment.

Recommendations

No further assessment is currently required.

Environmental Hazard Classification

In addition to the categorisation of environmental hazards according to domestic environmental thresholds presented above, the classification of the environmental hazards of phenol, 2,6-bis(1,1-dimethylethyl)-4-methyl- according to the third edition of the United Nations’ Globally Harmonised System of Classification and Labelling of Chemicals (GHS) is presented below (UNECE, 2009):

Hazard	GHS Classification (Code)	Hazard Statement
Acute Aquatic	Category 1 (H400)	Very toxic to aquatic life
Chronic Aquatic	Category 2 (H411)	Toxic to aquatic life with long lasting effects

The classification of the aquatic hazards of BHT was performed based on the measured ecotoxicity data presented in this assessment (UNECE, 2009).

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