



Government
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Consultation Document
on the Proposed Risk Management for
Phenol, 2,6-bis(1,1-dimethylethyl)-4-(1-methylpropyl)-
(DTBSBP)

Chemical Abstracts Service Registry Number (CAS RN):
17540-75-9

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SUMMARY

This consultation document outlines the proposed risk management actions for Phenol, 2,6-bis(1,1-dimethylethyl)-4-(1-methylpropyl)- (referred to as DTBSBP). Stakeholders are invited to submit comments on the content of this consultation document or provide other information that would help to inform decision making.

SUMMARY OF PROPOSED RISK MANAGEMENT

The Government of Canada is proposing the application of Significant New Activity provisions under the *Canadian Environmental Protection Act, 1999* to DTBSBP.

Note: This summary is an abridged list of the instruments and tools proposed to risk manage this substance. Please see section 6 of this document for a complete explanation of risk management.

1. INTRODUCTION

In December 2006, the Government of Canada launched the Chemicals Management Plan to take action on chemicals that are harmful to human health or the environment. A key element in the Chemicals Management Plan is the initiative known as the “Challenge”. The Challenge identified 193 chemical substances through categorization which became high priorities for assessment due to their hazardous properties and their potential to pose risks to human health and the environment. In February 2007, the Ministers began publishing, for stakeholder comments, profiles of batches containing 12 to 19 high-priority substances. New batches were released for comments every three months.

The substance Phenol, 2,6-bis(1,1-dimethylethyl)-4-(1-methylpropyl)-, Chemical Abstracts Service Registry Number (CAS RN)¹ 17540-75-9, also known as 2,6-Di-tert-Butyl-4-Sec-Butylphenol and referred to throughout this document as “DTBSBP”, was included in Batch 8 of the Challenge under the Chemicals Management Plan (Canada 2009).

2. BACKGROUND

2.1 Final Screening Assessment Report

A notice summarizing the scientific considerations of a final screening assessment report was published by Environment Canada and Health Canada in the *Canada Gazette, Part I*, for DTBSBP on July 31st, 2010, under subsection 77(6) of the *Canadian Environmental Protection Act, 1999* (CEPA 1999) (Canada 1999). The final screening assessment report concluded that DTBSBP is entering or may be entering the environment in a quantity or a concentration or

¹ CAS RN: Chemical Abstracts Service Registry Number. The Chemical Abstracts Service information is the property of the American Chemical Society, and any use or redistribution, except as required in supporting regulatory requirements and/or for reports to the Government of Canada when the information and the reports are required by law or administrative policy, is not permitted without the prior written permission of the American Chemical Society.

under conditions that have or may have an immediate or long-term harmful effect on the environment or its biological diversity.

The final screening assessment report also concluded that DTBSBP meets the criteria for persistence and meets the criteria for bioaccumulation, as defined in the *Persistence and Bioaccumulation Regulations* made under CEPA 1999. The presence of DTBSBP in the environment results primarily from human activity.

For further information on the final screening assessment report conclusion for DTBSBP, refer to the final screening assessment report, available at <http://www.chemicalsubstanceschimiques.gc.ca/challenge-defi/batch-lot-8/index-eng.php>.

2.2 Proposed Risk Management Approach

The Proposed Risk Management Approach for DTBSBP published on July 31st, 2010, describes the proposed risk management at the time of its publication and is available at <http://www.ec.gc.ca/ese-ees/default.asp?lang=En&n=DA4EE57E-1>. The proposed risk management for DTBSBP was the implementation of regulatory controls toward virtually eliminating releases of DTBSBP to the environment. A regulation to prohibit and/or limit the conditions under which the substance may be imported, manufactured or used was being considered. In addition, the proposed Risk Management Approach indicated that the Government would also assess the potential for DTBSBP to meet the criteria set out in section 200 of CEPA 1999 in the event that it was to enter the environment as a result of an environmental emergency.

Since the publication of the Proposed Risk Management Approach for DTBSBP, further investigations have brought forth new information regarding the use profile and potential releases of DTBSBP. In light of this information, the Government of Canada is proposing to use another more appropriate regulatory control, the application of the Significant New Activity provisions under section 81(3) of CEPA 1999, to support virtually eliminating releases of DTBSBP to the environment than what was considered in July 2010. These changes are summarized in section 6 of this document.

2.3 Proposed Order to Add DTBSBP to Schedule 1

The Proposed Order to add DTBSBP to Schedule 1 of the CEPA 1999 was published in the *Canada Gazette* Part I on October 2nd, 2010 and is available at <http://www.gazette.gc.ca/rp-pr/p1/2010/2010-10-02/html/reg2-eng.html>. (Canada 2010b).

3. USES AND RELEASES OF DTBSBP

3.1 Current Uses

Information was collected through surveys conducted for the years 2005 and 2006 under *Canada Gazette* notices issued pursuant to section 71 of CEPA 1999 (Canada 2006, Canada 2009). These notices requested data on the Canadian manufacture, import and use of DTBSBP. Three companies reported total importations of between 1000 kg and 100 000 kg of the substance into Canada in 2005 (Environment Canada 2006). In Canada in 2006, no company reported manufacturing DTBSBP (above the reporting threshold of 100 kg). In 2006, 16 686 kg of DTBSBP was imported into Canada by five companies, including one below the reporting threshold of 100 kg/year. Six companies identified a stakeholder interest (Canada 2009).

In response to the CEPA section 71 notices, DTBSBP was identified as used in plastics product manufacturing (primarily urethane and other foam products, except polystyrene) and as an antioxidant/corrosion inhibitor used in brake fluid. Other uses were noted to be confidential business information (CBI). Although not described here, this CBI information was considered in estimating environmental releases and in risk management development.

Since 2006, new information obtained by Environment Canada through follow up with industry indicates that one of the confidential uses has been discontinued. In addition, DTBSBP quantities used in plastics product manufacturing have decreased significantly since 2006 due to the plastics industry reducing and replacing DTBSBP in certain chemical formulations.

Other Potential Uses and Industrial Sectors

The additional information below on potential uses of DTBSBP was found through searches of the available scientific and technical literature, although potential uses in Canada were not specifically confirmed.

DTBSBP is listed by the U.S. Food and Drug Administration as a food contact substance, which is any substance that is intended for use as a component of materials used in manufacturing, packing, packaging, transporting, or holding food (US FDA 2008).

It is specifically used as an antioxidant in plasticized vinyl chloride homo- and co-polymers (PVC) (SII 2001). For example, it may be used in PVC films for wrapping meat and produce, and in plastic hoses employed to transfer food during processing and packaging (2009 email from Food Directorate, Health Canada, to Risk Management Bureau, Health Canada; unreferenced).

According to the North American manufacturer of DTBSBP, worldwide it is used in the following industries (SI Group 2009):

- PVC, both rigid and flexible grades – polymerization chain terminator and PVC stabilizer;
- thermoplastics, such as low-density polyethylene (LDPE);
- polyols/flexible foams – stabilizer/antioxidant;

- brake fluids - stabilizer/antioxidant/corrosion inhibitor;
- ink resins - stabilizer/antioxidant;
- peroxide inhibitor for petrochemical and refinery streams - stabilizer/antioxidant; and
- mineral/vegetable oils, such as turbine oil, hydraulic oil, chainsaw oil - stabilizer/antioxidant.

The purity of commercially available DTBSBP is typically 98.6%. When used as an antioxidant, the concentration of DTBSBP ranges from 0.03-0.10 %wt (SI Group 2009). This substance may also be used as an antioxidant in mineral oils such as turbine oil, hydraulic oil and chain saw oil, in vegetable oils that have replaced mineral oils in some applications due to biodegradability issues, and is being tested for potential needs in bio-diesel (SI Group 2009), though there were no reported uses in these products in the recent section 71 surveys.

3.2 Alternative Chemicals or Substitutes

DTBSBP is considered part of a broader category of substances known as alkylphenols (US EPA 2009) that are commonly used as anti-oxidants and chemical intermediates. Some substances in this same broad category of hindered phenolic substances could be substitutes for DTBSBP. However, they will all possess to a slightly greater or lesser extent the same environmental characteristics of DTBSBP. In addition, some of these substances may also be subject to assessment in an upcoming phase of the Chemicals Management Plan.

DTBSBP may be used as an alternative to BHT in several applications as it is solid at room temperature and can be heated slightly to a liquid state, facilitating industrial processing and providing a benefit in lower overall capital cost for control technologies, and reduces the exposure potential of workers to dust invariably created in solids handling activities (SI Group 2009).

3.3 Releases and Exposure Sources to the Environment

DTBSBP is not reported to be naturally produced in the environment and has not been measured in any environmental media or industrial discharge (Canada 2010). The estimate of release to the environment, and subsequent environmental concentrations, are based on estimates of release applied throughout the lifecycle of this substance.

Since the July 2010 publication of the Proposed Risk Management Approach for DTBSBP, new information obtained from a recent contract study conducted for Environment Canada has led to revised release estimates in the life cycle analysis for DTBSBP.

Container Handling and Industrial Releases

In the plastics sector it is estimated that there are negligible releases from used container handling and disposal (totaling less than 1 kg/year).

Foam Use and Disposal

Based on information obtained from a recent contract study conducted for Environment Canada, it is estimated that there are no releases from polyurethane foam manufacturing.

Confidential Product Use and Disposal

In light of the new information obtained on the discontinued confidential use, releases are no longer expected.

Brake Fluid Use and Disposal

Brake fluids are manufactured in the US and imported into Canada by bulk tanker trucks or trailers. The brake fluid may then be repackaged into 350-ml to 20-L bottles at sites which are equipped with dedicated feeding lines and collection tanks for the management of residual brake fluids. As a result no or very low releases from brake fluid transport and repackaging are expected.

Based on the losses estimated for DTBSBP over its life-cycle for worst-case scenario applications outlined in the Final Screening Assessment Report, the only remaining potential releases of DTBSBP to the environment are assumed to be coming from the presence of DTBSBP in brake fluids (Canada 2010). Specifically, an estimated 1% of the DTBSBP contained in brake fluids in Canada could be released to paved/unpaved land surfaces (i.e., roads, driveways, parking lots) as a result of spills/leaks during use or from car accidents; where half of this amount would remain on the road surfaces or soil where the spill or leak occurred, and the other 0.5% could be washed into public or private wastewater systems. These infrequent and widely dispersive consumer releases would contain very small amounts of DTBSBP (less than 100 kg/year).

Releases from the disposal of brake fluids containing DTBSBP are not expected to be of concern in light of existing controls in place to manage the end of life of used oils and hazardous and non-hazardous wastes, as described in Section 4.1. The vast majority of brake fluid operations are performed in commercial maintenance and service centers which ensure that brake fluids are captured for proper treatment/disposal. These centers may either capture spent brake fluids indirectly with used oils or as hazardous waste sent to licensed facilities. In general, used oils are highly recovered in Canada (UOMA 2009) and empty containers from garages and the general public are either sent to hazardous waste depots/facilities or disposed of in landfills in light of the increased awareness of best management practices used in automotive recycling (Canada's Vehicle Recycling Program, 2011). There may be occasional small releases of brake fluids containing DTBSBP to the environment from do-it-yourself (DIY) jobs or from operating vehicles and from the improper disposal of empty containers.

4. EXISTING RISK MANAGEMENT ACTIONS

4.1 Existing Canadian Risk Management

Currently, there are no known risk management measures related specifically to DTBSBP in Canada. However, there are existing controls in place in Canada for the management of hazardous and non-hazardous wastes and recyclable materials, including used oils, where DTBSBP may be found. Furthermore, as described in section 3.3, releases from disposal of brake fluid are not expected to be of concern in light of these existing controls. This is consistent with Environment Canada's approach, outlined in its report entitled *Follow Up on the Final Decision on the Assessment of Releases of Used Crankcase Oils (UCOs)² to the Environment*, published in April 2011, where provincial and territorial preventative and control actions were specifically re-evaluated against several criteria on used oil management and were concluded as effective, without any further action needed, with respect to the management of releases of UCOs to the environment (Environment Canada 2011b).

As discussed in section 3.1, DTBSBP may also be used in PVC films that come in contact with food, although this use in Canada was not specifically confirmed. The safety of all materials used for packaging foods is controlled under Division 23 of the Food and Drugs Regulations, Section B.23.0001 of which prohibits the sale of foods in packages that may impart harmful substances to their contents. Because of the general nature of this requirement, and in the absence of positive lists delineating permitted ingredients, packaging materials intended for use with foods may be submitted voluntarily to the Food Directorate for a premarket assessment of their chemical safety in relation to Section B.23.001. This applies to any type of material, whether it is in the form of a finished product, such as a laminated film, a container (Canada 1985).

4.2 Existing International Risk Management

DTBSBP is included in the U.S. EPA's *Toxic Substances Control Act* inventory and has been identified as a High Production Volume (HPV) chemical under the United States Environmental Protection Agency's HPV Challenge Program. This program challenged companies to make health and environmental effects data publicly available for chemicals produced in high quantities (US EPA 2009).

DTBSBP is listed by the U.S. Food and Drug Administration (FDA) as a food contact substance subject to FDA Code of Federal Regulations Title 21, section 175.105 (US FDA 2009) as an antioxidant at a maximum concentration of 0.06% by weight of the finished polymer in PVC under certain conditions of use (US FDA 2008).

² UCOs are defined as used lubricating oil removed from the crankcase of internal combustion engines. Crankcase oils are altered during use because of the breakdown of the additives, contamination with the products of combustion, and the addition of metals from the wear and tear of the engine. Generally, UCOs are a complex mixture of substances (such as arsenic, benzene, cadmium, etc.), many of which are already declared toxic and on Schedule 1 of CEPA 1999.

DTBSBP is present on the European Inventory of Existing Commercial Chemical Substances. It is considered hazardous as per the Safety Data Sheets Directive (91/155/EC) as amended, with EU symbols Xi – Irritant and N – Dangerous for the environment.

DTBSBP is also included on the Oslo-Paris (OSPAR) Commission's list of substances of possible concern. Although OSPAR lists the functional use category of DTBSBP as a pesticide, it is further stated that there is no authorized use in the European Union in plant protection products (OSPAR 2006). It is not registered for use as a pesticide active ingredient (PMRA 2009) or formulant in Canada (PMRA 2007).

5. PROPOSED OBJECTIVES

5.1 Environmental Objective

As outlined in the Proposed Risk Management Approach, the ultimate environmental objective for DTBSBP remains its virtual elimination as defined under section 65 of CEPA 1999.

5.2 Risk Management Objective

As outlined in the Proposed Risk Management Approach, the risk management objective remains to be to minimize releases of DTBSBP to water and soil to the greatest extent practicable.

6. PROPOSED RISK MANAGEMENT ACTIONS FOR DTBSBP

6.1 Proposed Risk Management

The Proposed Risk Management Approach for DTBSBP, published in July 2010, outlined that the Government of Canada was at the time considering a regulation to prohibit and/or limit the conditions under which the substance may be imported, manufactured or used (Canada 2010c). However, in light of the pro-active and ongoing reduction/replacement or discontinued use of DTBSBP in certain applications by industry, the limited release potential of DTBSBP in the environment, and existing controls in place for the management of hazardous and non-hazardous wastes and recyclable materials, including used oils, where DTBSBP may be found, the Government of Canada is now considering the application of the Significant New Activity provisions under section 81(3) of CEPA 1999 to DTBSBP.

Measures that are complementary to SNAc provisions such as working with industry to encourage further substitution of DTBSBP are ongoing. In addition, it should be noted that the use of DTBSBP in polyurethane foams is being voluntarily phased out. The Government of Canada will continue to monitor progress towards a complete phase-out of DTBSBP in polyurethane foams.

The SNAC provisions will enable the Government of Canada to assess any new use or activity that could result in a significantly greater quantity or concentration of DTBSBP in the environment; or a significantly different manner or circumstances of exposure to the substance to determine whether the activity would result in an exposure of concern.

The application of the SNAC provisions to a substance pursuant to subsection 87(3) of CEPA 1999 will result in the substance being listed on the *Domestic Substances List* with a “SNAC flag”. This “flag” means that for certain “significant new activities”, the substance will have to be notified under the New Substances provisions of CEPA 1999. A SNAC notice sets out the criteria under which a notification is required. Following the outcome of the assessment of a new use or activity for DTBSBP, the Government of Canada may consider further risk management, if necessary.

Socio-economic factors have been considered in the selection process for the application of the SNAC provisions and will continue to be in their development as identified in the *Cabinet Directive on Streamlining Regulation*³ (Treasury Board of Canada Secretariat 2007a) and the guidance provided in the Treasury Board document *Assessing, Selecting, and Implementing Instruments for Government Action* (Treasury Board of Canada Secretariat 2007b).

In July 2010, the Government of Canada also committed to assessing the potential for DTBSBP to meet the criteria set out in section 200 of CEPA 1999 in the event that it was to enter the environment as a result of an environmental emergency. DTBSBP has been assessed against this criteria and it has been determined that it does not meet the criteria set out in section 200 of CEPA 1999.

6.2 Other Information Gathering/Research

Surveillance for DTBSBP in the environment (e.g., along transportation corridors) is being considered under a comprehensive monitoring and surveillance strategy under the Chemicals Management Plan. Monitoring has been identified as a key pillar in the Chemicals Management Plan, and will serve the following functions: to collect and generate human health and environmental data to inform decision-making; to identify the need for any further risk management measures; and to measure the efficacy of preventive and mitigation actions for DTBSBP.

7. REQUEST FOR INPUT

Industry and other interested stakeholders are invited to submit comments on the content of this consultation document or provide other information that would help to inform decision making. Environment Canada is seeking comments from stakeholders on the following issues:

³ Section 4.4 of the *Cabinet Directive on Streamlining Regulation* states that “Departments and agencies are to: identify the appropriate instrument or mix of instruments, including regulatory and non-regulatory measures, and justify their application before submitting a regulatory proposal”.

1. Do you support the risk management actions proposed for DTBSBP?
2. Are there any existing uses of DTBSBP in Canada that have not previously been notified to Environment Canada?

Companies who have a business interest in DTBSBP are encouraged to identify themselves as stakeholders. Stakeholders will be informed of future decisions regarding DTBSBP and may be contacted for further information.

Please submit comments prior to February 19, 2012, since the risk management of DTBSBP will be moving forward after this date. Comments can be submitted as follows:

<p>By mail</p> <p>Executive Director Chemicals Management Division Environment Canada Fontaine, 2nd Floor 200 Sacré-Coeur Gatineau QC K1A 0H3</p>	<p>By e-mail</p> <p>E-mail: Substances@ec.gc.ca</p> <p>Please type “CONSULTATION ON DTBSBP RISK MANAGEMENT” in the subject line of your message.</p>
<p>By fax</p> <p>Executive Director Chemicals Management Division Environment Canada Fax: 819-997-7121</p>	<p>Please type “CONSULTATION ON DTBSBP RISK MANAGEMENT” in the subject line of your fax.</p>

Pursuant to section 313 of CEPA 1999, any person who provides information to the Minister of the Environment under CEPA 1999 may submit with the information a request that it be treated as confidential.

8. NEXT STEPS

Comments provided will be taken into consideration by the Government of Canada in the development of the proposed risk management instrument. Following this initial consultation, there will be the opportunity for stakeholders to provide comments on the proposed risk management instrument.

Action	Date
Response to comments on the consultation document on the proposed risk management	No later than the time of publication of the proposed instrument
Publication of the proposed instrument	No later than July 2012
Formal public comment period on the proposed instrument	60 day comment period following publication of proposed instrument
Publication of the final instrument	No later than January 2014

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