Octylphenols: Human health tier II assessment

02 March 2018

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Chemicals in this assessment

Chemical Name in the Inventory	CAS Number
Phenol, 4-(1,1,3,3-tetramethylbutyl)-	140-66-9
Phenol, 4-octyl-	1806-26-4
Phenol, 2-(1,1,3,3-tetramethylbutyl)-	3884-95-5
Phenol, 2,4-bis(1,1,3,3-tetramethylbutyl)-	5806-72-4
Phenol, (1,1,3,3-tetramethylbutyl)-	27193-28-8
Phenol, dioctyl-	29988-16-7
Phenol, tert-butyl 1,1,3,3-tetramethylbutyl derivatives	68610-50-4
Phenol, tert-butyl 1-phenylethyl 1,1,3,3-tetramethylbutyl derivatives	93455-61-9

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

Grouping Rationale

The chemicals in this group are various isomers of octylphenol with a general formula $C_6H_4(OH)(C_8H_{17})_x$. The chemicals vary by the degree of branching of the octyl group and the substitution position on the phenol ring.

There is a lack of information on dialkylphenols. In the absence of information to indicate lower toxicity for this group, they will be assumed to be represented by data for monoalkylphenols. It is also probable that dioctylphenols are not pure substances and; therefore, contain significant levels of octylphenols. Dioctylphenols have; therefore, been included in this assessment.

The majority of data are available for 4-tert-octylphenol (CAS No. 140-66-9). This is assumed to be the most commercially used of the chemicals in this group. Data are assumed to be representative of all isomers of octylphenol and dioctylphenols.

Import, Manufacture and Use

Australian

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

International

The following international uses have been identified through the European Union (EU) Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH) dossiers; the Organisation for Economic Co-operation and Development Screening information data set International Assessment Report (OECD SIAR); Galleria Chemica; the Substances and Preparations in Nordic countries (SPIN) database; and various international assessments (OECD, 2005; ECHA, 2011a).

Based on the available information, 4-tert-octylphenol (CAS No. 140-66-9) appears to be the most commercialy used of the chemicals in this group.

This chemical is mostly used as an intermediate in the manuacture of:

- ethoxylates, which are then used in a variety of products (industrial detergents, surfactants, cleaners, degreasers, adhesives, paints and coatings and emulsifiers);
- phenolic resins used in the formulation of adhesives;
- polymers;
- antioxidants; and
- rubber and plastic products.

At least 95–98 % of octylphenol in the United States is reported to be chemically altered prior to reaching consumer market. The remaining 2–5 % is reported to be used in fuel for aeroplanes (OECD, 2005). In the United Kingdom, 98 % is reported to be used in the manufacture of phenolic resins (ECHA, 2011a).

Restrictions

Australian

No known restrictions have been identified.

International

Phenol, 4-(1,1,3,3-tetramethylbutyl)- (CAS No. 140-66-9) is on the candidate list of substances of very high concern (SVHC) for eventual inclusion in Annex XIV (ECHA, 2011b). In the EU, companies could have legal obligations if the chemical that they produce, supply, or use is included on the candidate list whether on its own, in mixtures, or present in articles. The reason for inclusion is 'equivalent level of concern having probable serious effects to environment'.

Existing Worker Health and Safety Controls

Hazard Classification

The chemical, phenol, 4-(1,1,3,3-tetramethylbutyl)- (CAS No. 140-66-9), is classified as hazardous, with the following hazard categories and hazard statements for human health in the Hazardous Chemical Information System (HCIS) (Safe Work Australia):

- Skin irritation – category 2; H315 (Causes skin irritation)
- Eye damage – category 1; H318 (Causes serious eye damage)

The other chemicals are not listed on the HCIS (Safe Work Australia).

Exposure Standards

Australian

No specific exposure standards are available.

International

No specific exposure standards are available.

Health Hazard Information

The test substance used in the majortity of tests was identified as 4-tert-octylphenol (CAS No. 140-66-9). Data are assumed to be representative of all isomers of octylphenol and dioctylphenols.

Toxicokinetics

Following oral exposure, 4-tert-octylphenol is rapidly absorbed and quickly released into the blood. Bioavailability was reported to vary between strains. In Sprague Dawley (SD) rats bioavailabilities up to 55 % were reported whilst in Wistar rats bioavailability was determined to be 10 %. In an oral study in SD rats, there were no significant differences in tissue concentrations following single and repeated treatment indicating no bioaccumulation of 4-tert-octylphenol (ECHA, 2011a).

Based on the water solubility, the partition coefficient of 4.12 and the molecular weight of 4-tert-octylphenol of 206 g/mol, a high dermal bioavailability can be assumed (ECHA, 2011a). There is evidence of dermal absorption from urine monitoring data for workers in Japan involved in the manufacture of octylphenols (OECD, 2005).

Similar to nonylphenol (NICNAS), octylphenol undergoes rapid first pass metabolism by phase I and phase II enzymes in the liver. Detoxification pathways include hydroxylation, glucuronidation and sulphation. In SD rats slower degradation of 4-tert-octylphenol by liver microsomes was observed in females compared to males. Metabolic saturation can occur (ECHA, 2011a).

Studies in rats have shown that 4-tert-octylphenol may have a direct inhibitory effect on cytochrome P450 activities, and can decrease protein levels of testosterone-hydroxylating CYP activities in the liver (ECHA, 2011a).

Acute Toxicity

Oral

The chemicals are expected to have low acute toxicity based on results from animal tests following oral exposure. In two studies conducted according to OECD Test Guideline (TG) 401, the median lethal dose (LD50) in rats is >2000 mg/kg bw. Observed sub-lethal effects included diuresis in both studies and ruffled fur, crouched posture, slight sedation and ataxia, diarrhoea, prone position, hypothermia, cyanosis, laboured breathing, staggering, trembling and small deep-red eyes in one study (OECD, 2005; REACH).

Dermal

The chemicals are expected to have low acute toxicity based on results from animal tests following dermal exposure.

In two studies conducted similar to OECD TG 402, the LD50 in rabbits is >2000 mg/kg bw. There were no signs of systemic effects but irritation effects were observed. The test substances were described as p-octylphenol (purity 89 %) and an alkylphenol with an alkylchain C_8H_{17} which might be either straight-chain or branched (purity 95 %) (REACH). An LD50 of 1880 mg/kg bw/day in rabbits has been reported but no study details were available (OECD, 2005).

Inhalation

Limited data are available. An LD100 (dose having 100 % probability of causing death) of ≤116 mg/L was reported in rats, following 24 hour exposure. No study details were available (OECD, 2005).

Corrosion / Irritation

Respiratory Irritation

No data are available for the chemicals. Based on information for the structurally related chemical nonylphenol, the chemicals could cause mild irritation to the respiratory tract at high exposure (NICNAS).

Skin Irritation

The chemical 4-tert-octylphenol (CAS No. 140-66-9) is classified as hazardous with hazard category ‘Skin irritation – category 2’ and hazard statement ‘Causes skin irritation’ (H315) in the HCIS (Safe Work Australia). The evidence of necrosis in animals supports a change to this classification with hazard category 'Skin corrosion - category 1B' (see **Recommendation** section).

In a study performed in accordance with OECD TG 404, 4-tert-octylphenol (99 % purity) produced only very slight erythema and oedema. All treated skin sites appeared normal seven days after treatment (OECD, 2005; REACH).

However in another study performed in accordance with OECD TG 404, 4-tert-octylphenol (96 % purity) produced severe erythema in all animals after 24 h. Necrosis was seen after 4 h. In two out of six animals this effect was not fully reversible, yielding scars at day 14 (REACH).

In acute dermal toxicity studies in rabbits, necrosis and persistent oedema were observed following 24 h exposure.

Animal data for the related chemical nonylphenol indicate that the chemical is corrosive to skin. Classification with hazard category 'Skin corrosion - category 1B' was supported (NICNAS).

Eye Irritation

The chemical 4-tert-octylphenol (CAS No. 140-66-9) is classified as hazardous with hazard category ‘ Eye damage – category 1’ and hazard statement ‘Causes serious eye damage’ (H318) in the Hazardous Chemical Information System (HCIS) (Safe Work Australia). Whilst the available data support this classification, this hazard will be covered by the proposed new classification for corrosivity (see **Recommendation** section).

Octylphenol (mixture of isomers) was reported to severly irritate the eyes when tested according to OECD TG 405. The average scores for cornea/iris conjunctivae (redness) and conjunctivae (chemosis) were given as 1.44, 1.0, 2.50 and 2.17, respectively. The effects were not reversible within 21 days after application.

A single application of 4-tert-octylphenol (purity 99 %) to the eye of a single rabbit produced corneal opacity, iridial inflammation and severe conjunctival irritation. The score by the method of Kay and Calandra was 63/110 (severely irritating) (OECD, 2005; REACH).

Sensitisation

Skin Sensitisation

Based on the available data the chemicals are not considered to be skin sensitisers and do not warrant classification.

In a guinea pig maximisation test, 4-tert-ocylphenol (purity 96 %) was considered not sensitising (OECD, 2005; REACH). Due to local effects only results of sites without Freunds Complete Adjuvant (FCA) were considered in the evaluation of the sensitising potential. All induction sites of test and control animals treated with FCA showed intense erythema, swelling and necrosis. Treatment with 1% test substance in corn oil induced distinct erythema and swelling. Distinct local effects were considered to be caused by the irritating properties of the substance.

The structurally related chemical is not considered to be a sensitiser (NICNAS).

Repeated Dose Toxicity

Oral

Based on the available data, the chemicals are not considered to cause serious damage to health following repeated exposure in rats. Whilst adverse systemic effects were observed at high doses, effects observed at doses considered relevant for classification were not significant enough to warrant classification.

Several repeated dose toxicity studies in rats are available. The exposure period ranged from 28 to 60 days. At daily dosages of 125–450 mg 4-tert-octylphenol/kg bw/day observed systemic effects included reductions in body weight gain and changes in liver and kidney organ weights. Histopathological changes were not consistently observed. This is consistent with effects observed in repeated dose oral toxicity studies with nonylphenol (NICNAS). Significant mortality was observed at doses 500 mg/kg bw/day (ECHA, 2011a).

Effects on the male and female reproductive system were observed in some studies (see **Reproductive and Developmental toxicity** section).

Dermal

No data are available.

Inhalation

No data are available.

Genotoxicity

Based on the available data, the chemicals are not considered genotoxic.

The chemical p-tert-octylphenol was negative with and without activation in:

- several bacterial mutation assays with *Salmonella typhimurium;*

- a mammalian cell HPRT gene mutation assay in Chinese hamster ovary cells; and
- two chromosome aberration assays with Chinese hamster lung cells (OECD, 2005; REACH).

In vivo test data are not available for the chemicals. The structurally related chemical, nonylphenol, had negative results in two in vivo micronucleus tests (NICNAS).

Carcinogenicity

No data are available for octylphenols and limited data are available for nonylphenols (NICNAS). Based on the available data for genotoxicity for the chemicals in this group, carcinogenicity via a genotoxic mechanism is not expected.

Reproductive and Developmental Toxicity

Several studies are available that investigate the reproductive and developmental effects of 4-tert-octylphenol. While effects on the reproductive and developmental systems including interference with the oestrous cycle and damage to male reproductive organs were reported, these were often from non-guideline studies, at doses at which systemic toxicity was observed or were not consistently observed across studies. Overall, based on the weight of evidence, classification is not considered warranted.

A guideline two-generation study is considered to be the key study, based on route of exposure (oral compared with subcutaneous injection) and the fact that reproductive and developmental effects observed in studies with nonylphenol were largely observed in offspring (NICNAS).

In a two generation study conducted according to OECD TG 416, SD rats were fed with dietary concentrations of 0, 0.2, 20 and 2000 ppm (equivalent to 0, 0.011–0.034, 1.05–3.3, 10.9–32.6, and 111–369 mg/kg bw/day). Animals were dosed for 10 weeks pre-breeding and through the mating and gestation periods. Treatment related systemic effects were limited to reductions in bodyweight in some animals and weight gains in the remainder of the animals in all generations at the top dose. There were no treatment related effects in reproductive organs, measurements or extensive evaluation of sperm measurements in three generations of males. There were also no effects in F0 and F1 females. Effects in offspring occurred only at the top dose and were limited to reduced bodyweights and delayed vaginal opening and preputial separation. The latter is considered due to the lower bodyweights. No oestrogen-like or anti-androgenic effects on males or females were evident. The NOAEL for reproductive toxicity was established as the highest dose tested 2000 ppm (111–369 mg/kg bw/day) (ECHA, 2001a).

In an single generation screening guideline study (OECD TG 421) in rats, effects on reproduction including impaired mating performance, reduced implantation rate and minor histopathological changes in the testes were observed at the highest dose tested (500 mg/kg bw/day). These effects were only observed in the presence of severe toxicity, including mortality. The NOAEL for reproductive effects was 250 mg/kg bw/day (OECD, 2005; ECHA, 2011a).

Other Health Effects

Endocrine Disruption

In vitro and in vivo studies provide evidence that 4-tert-octylphenol has some but low oestrogenic potential in comparison to reference oestrogens. Effects on cycle irregularities and male reproductive organs observed in some studies could have an endocrine mode of action. However, it is noted that these effects were induced at relatively high dosages with concurrent systemic toxicity. Therefore, other modes of action may be more sensitive to the chemical. The chemical, 4-tert-octyl phenol is not considered to be a substance with endocrine disruptor properties of strong potency for mammalian systems; however, effects on aquatic organisms have been reported (ECHA, 2011a).

Risk Characterisation

Critical Health Effects

The critical health effects for risk characterisation include local effects (skin and eye damage). Adverse systemic long-term effects including reproductive and developmental effects were only observed at relatively high doses. The chemicals have been shown to have weak oestrogenic activity, but there are currently no established adverse outcome pathways for weak oestrogenic activity.

Public Risk Characterisation

Given the uses identified for the chemicals, it is unlikely that the public will be directly exposed to the chemicals. Although the public could come into contact with articles and/or coated surfaces containing the unreacted chemicals, it is expected that the residual levels would be very low.

Given the breakdown of octylphenol ethoxylates to octylphenols there may be potential for human exposure via the environment. Octylphenol has been measured in indoor air, house dust and human blood, breast milk and urine (ECHA, 2011c). However, the available information indicates that adverse systemic effects are only observed at relatively high doses. Therefore, the chemicals are not considered to pose an unreasonable risk to public health.

Occupational Risk Characterisation

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

Given the critical local health effects, the chemicals could pose an unreasonable risk to workers unless adequate control measures to minimise dermal and ocular exposure are implemented. The chemicals 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 data available support an amendment to the hazard classification in the HCIS (Safe Work Australia) (see **Recommendation** section).

NICNAS Recommendation

Assessment of these chemicals 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.

Further controls may be determined necessary as part of any environmental assessment of the chemicals.

Regulatory Control

Work Health and Safety

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

From 1 January 2017, under the model Work Health and Safety Regulations, chemicals are no longer to be classified under the Approved Criteria for Classifying Hazardous Substances system.

Hazard	Approved Criteria (HSIS)[a]	GHS Classification (HCIS)[b]
Irritation / Corrosivity	Not Applicable	Causes severe skin burns and eye damage - Cat. 1 (H314)

[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 industry

Control measures

Control measures to minimise the risk from dermal and ocular exposure to the chemicals 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 chemicals are used. Examples of control measures that could minimise the risk include, but are not limited to:

- using local exhaust ventilation to prevent the chemicals from entering the breathing zone of any worker;
- 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 chemicals.

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 chemicals 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 these chemicals has not been undertaken as part of this assessment.

References

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OECD 2005. SIDS Initial Assessment Report (SIAR), for Phenol, 4-(1,1,3,3-tetramethylbutyl)- (140-66-9). OECD, Paris. Accessed May 2017 at **http://webnet.oecd.org/HPV/UI/SIDS_Details.aspx?key=ae0f6581-7cb1-462a-9589-f1f6647c4d09&idx=0**

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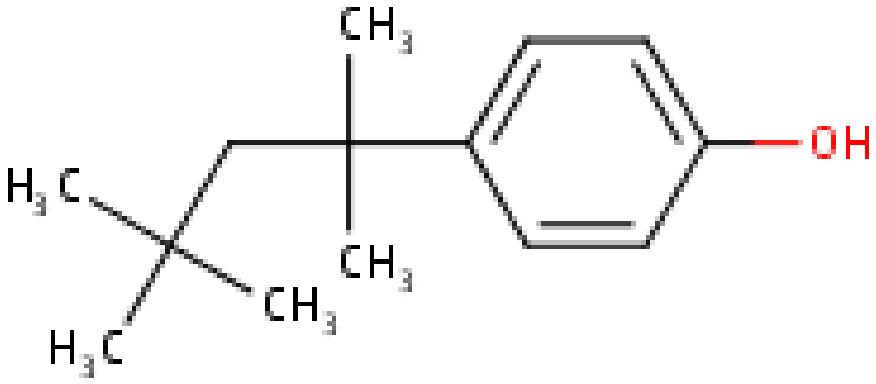
Safe Work Australia. Hazardous Chemicals Information System (HCIS). Accessed June 2017 at **http://hcis.safeworkaustralia.gov.au/HazardousChemical**

Substances in Preparations in Nordic Countries (SPIN) Database. Accessed May 2017 at **http://spin2000.net/**

Last Update 02 March 2018

Chemical Identities

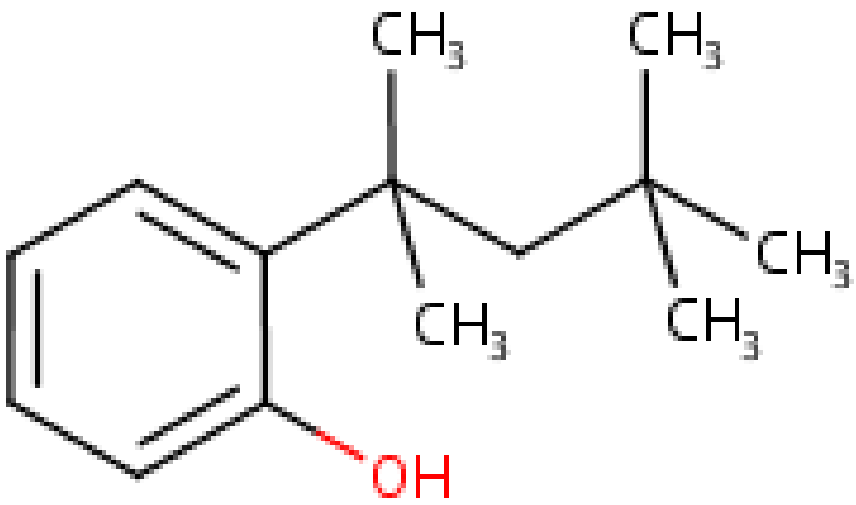
Chemical Name in the Inventory and Synonyms	**Phenol, 4-(1,1,3,3-tetramethylbutyl)-** p-octylphenol p-tert-octylphenol 4-tert-octylphenol
CAS Number	140-66-9
Structural Formula	

	
Molecular Formula	C14H22O
Molecular Weight	206.32

Chemical Name in the Inventory and Synonyms	**Phenol, 4-octyl-** p-octylphenol
CAS Number	1806-26-4
Structural Formula	

	
Molecular Formula	C14H22O
Molecular Weight	206.32

Chemical Name in the Inventory and Synonyms	**Phenol, 2-(1,1,3,3-tetramethylbutyl)-** 2-(1,1,3,3-tetramethylbutyl)phenol
CAS Number	3884-95-5
Structural Formula	

	
Molecular Formula	C14H22O
Molecular Weight	206.32

Chemical Name in the Inventory and Synonyms	**Phenol, 2,4-bis(1,1,3,3-tetramethylbutyl)-** 2,4-bis(1,1,3,3-tetramethylbutyl)phenol
CAS Number	5806-72-4
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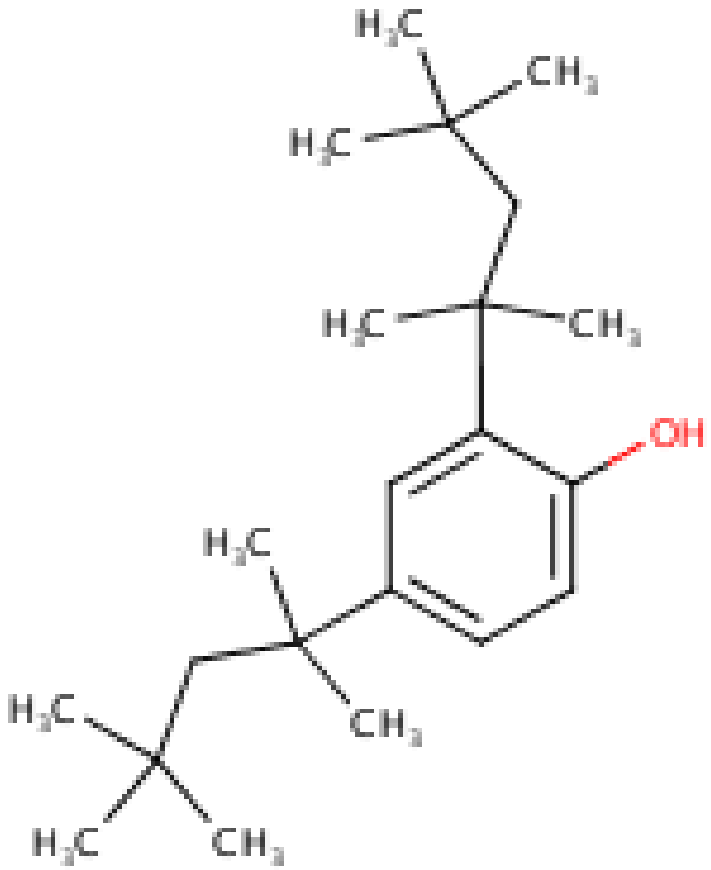
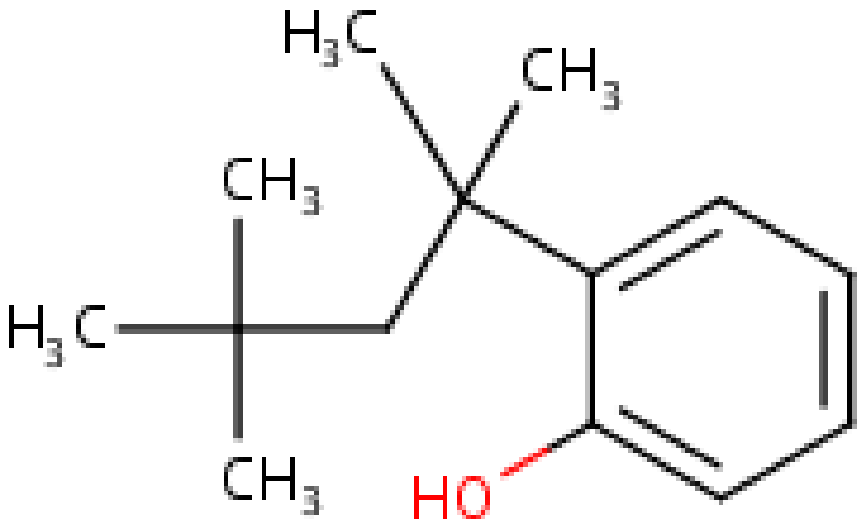
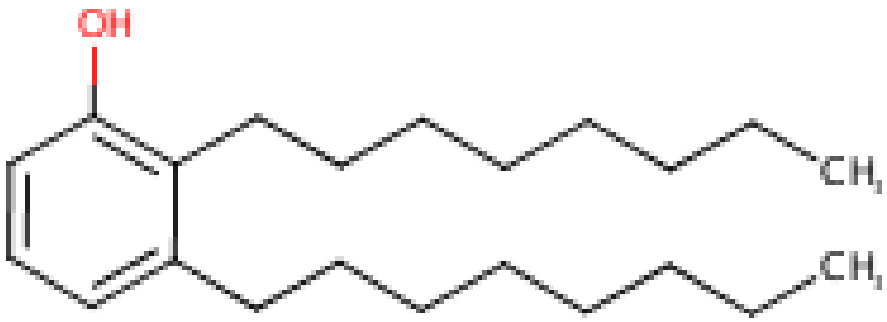
	
Molecular Formula	C22H38O
Molecular Weight	318.54

Chemical Name in the Inventory and Synonyms	**Phenol, (1,1,3,3-tetramethylbutyl)-** octylphenol
CAS Number	27193-28-8
Structural Formula	

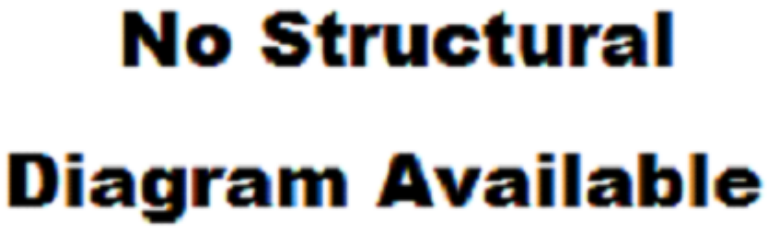
	
Molecular Formula	C14H22O
Molecular Weight	206.32

Chemical Name in the Inventory and Synonyms	**Phenol, dioctyl-** dioctylphenol
CAS Number	29988-16-7
Structural Formula	

	
Molecular Formula	C22H38O
Molecular Weight	318.54

Chemical Name in the Inventory and Synonyms	**Phenol, tert-butyl 1,1,3,3-tetramethylbutyl derivatives**
CAS Number	68610-50-4
Structural Formula	**No Structural Diagram Available**

Molecular Formula	Unspecified
Molecular Weight	Unspecified

Chemical Name in the Inventory and Synonyms	**Phenol, tert-butyl 1-phenylethyl 1,1,3,3-tetramethylbutyl derivatives**
CAS Number	93455-61-9
Structural Formula	
Molecular Formula	Unspecified
Molecular Weight	Unspecified

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