Ethylphenols: Human health tier II assessment

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Chemicals in this assessment

Chemical Name in the Inventory	CAS Number
Phenol, 2-ethyl-	90-00-6
Phenol, 4-ethyl-	123-07-9
Phenol, 3-ethyl-	620-17-7

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

Three members of the group: o-ethylphenol (CAS No: 90-00-6), p-ethylphenol (CAS No: 123-07-9), and m-ethylphenol (CAS No: 620-17-7) are chemical isomers, differing only in the position of the ethyl group relative to the hydroxyl group on the phenol ring.

As members of this group have similar molecular formula, molecular weight, physicochemical properties and hazardous classification, a similar hazard profile for human health is also expected. This conclusion is also supported by the similar toxicities exhibited by the methylphenol isomers (NICNASa). These chemicals have also been grouped together as all the chemicals have a boiling point below 220°C and are listed together in the Poisons Standard (Standard for the Uniform Scheduling of Medicines and Poisons (SUSMP, 2013)) for regulatory control.

The members of the group have similar reported uses.

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 European Union Registration, Evaluation and Authorisation of Chemicals (EU REACH) dossiers; the Organisation for Economic Cooperation and Development Screening information data set International Assessment Report (OECD SIAR); Galleria Chemica; Substances and Preparations in the Nordic countries (SPIN)

database; the European Commission Cosmetic Ingredients and Substances (CosIng) database; United States (US) Personal Care Product Council International Nomenclature of Cosmetic Ingredients (INCI) Dictionary; and eChemPortal: OECD High Production Volume chemical program (OECD HPV), the US Environmental Protection Agency's Aggregated Computer Toxicology Resource (ACToR), and the US National Library of Medicine's Hazardous Substances Data Bank (HSDB).

All the chemicals in this group are included in the list of fragrance ingredients used in consumer goods published by the International Fragrance Association (IFRA).

The chemicals p-ethylphenol (CAS No: 123-07-9) and m-ethylphenol (CAS No: 620-17-7) have reported cosmetic use in perfume. There is currently no documented use of the chemicals in this group in cosmetic products in the United States (Personal Care Products Council, 2011), although individual chemicals used at low concentrations in compound fragrances are not reported in this compilation. The US Household Products Database also did not indicate any cosmetic or domestic use of the chemicals in this group.

The chemicals o-ethylphenol (CAS No: 90-00-6) has reported commercial use including as a laboratory reagent, and p-ethylphenol (CAS No: 123-07-9) has reported commercial use as a synthetic flavour.

The majority of the chemicals in this group have reported site-limited use including:

- as a starting material for photochemicals;
- as a starting material for producing 4-vinylphenol and various antioxidants, which are used in rubber and polymers;
- as an intermediate for pharmaceuticals and dyes;
- in producing phenolic resins following the presence of these chemicals in xylenol fraction, boiling between approximately 205°C and 225°C obtained from tar phenols; and
- in the varnish industry following the presence of these chemicals in xylenol fraction.

Restrictions

Australian

As the chemicals in this group are all homologues of phenol with a boiling point below 220°C, the chemicals in this group are listed in the Poisons Standard (SUSMP, 2013) in Schedule 6 as follows:

'PHENOL, including cresols and xylenols and any other homologue of phenol boiling below 220°C, **except**:

(a) when separately specified in these Schedules;

(b) when included in Schedule 5; or

(c) in preparations containing 3 per cent or less of such substances'.

Schedule 6 chemicals are labelled with 'Poison'. These are substances with a moderate potential for causing harm, the extent of which can be reduced by using distinctive packaging with strong warnings and safety directions on the label.

The chemicals are also listed in Schedules 2 and 5 for non-industrial uses. The Schedule 5 entry relates to use in animal feed.

International

No known restrictions have been identified.

Existing Worker Health and Safety Controls

Hazard Classification

The chemicals in this group are 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 are available.

Health Hazard Information

Although limited human health hazard data are available for three individual isomers of this group, data are available for a mixture of ethylphenol isomers (CAS No: 25429-37-2), comprising o-ethylphenol (CAS No: 90-00-6) (25.9 %), p-ethylphenol (CAS No: 123-07-9) (33.0 %), and m-ethylphenol (CAS No: 620-17-7) (41.1 %). This mixture was formulated in the USA to match the ratios of three individual isomers in a commercial product containing the highest percentage of all three individual isomers. Considering that this mixture comprised three individual isomers, human health hazards associated with this mixture are expected to take account of the properties of each of the three individual isomers, as indicated in this report. Furthermore, as ethylphenols and methylphenols are structurally similar, data from methyphenols have also been used in this report for certain end points (NICNAS a).

Toxicokinetics

No data are available for the chemicals in this group. The analogue chemicals, methylphenols, are absorbed across the respiratory and gastrointestinal tracts and also through the intact skin in animals and humans. Methylphenols are mainly excreted in the urine following metabolism in the liver (NICNAS a).

Acute Toxicity

Oral

The chemicals in this group are expected to be of moderate acute toxicity in animal tests following oral exposure. The median lethal dose (LD50) in rats is 981 mg/kg bw for a mixture of ethylphenol isomers, comprising o-ethylphenol (CAS No: 90-00-6) (25.9 %), p-ethylphenol (CAS No: 123-07-9) (33.0 %), and m-ethylphenol (CAS No: 620-17-7) (41.1 %). While data were not available for individual isomers, the available data for the mixture comprising individual isomers at lower concentrations support classification of the individual isomers (refer to **Recommendation** section). Reported signs of toxicity include decreased motor activity, twitching behaviour, prostration, ptosis, ataxia, impaired righting reflexes and limb use, and tachypnoea (US EPA, 2008).

Dermal

No data are available.

Inhalation

No data are available.

Corrosion / Irritation

Skin Irritation

Although one member of this group (p-ethylphenol—CAS No: 123-07-9) is reported, in an animal study, to slightly irritate skin, the effects were not sufficient to warrant a hazard classification. Even though data are not available, similar results could be expected for other members of this group.

In a skin irritation study, mild dermal irritation was noted following exposure of rabbits to p-ethylphenol (CAS No: 123-07-9) at 0.5 ml/kg. The lesions consisted of very slight erythema without oedema, and slight erythema with oedema (US EPA, 2008).

Eye Irritation

The chemical p-ethylphenol (CAS No: 123-07-9) has been reported to induce severe irritation to rabbit eyes in an eye irritation study. Although scores for individual animals were not available, ulceration and the persistence of severe irritation at day seven following application of the chemical, support the need for classification (refer to **Recommendation** section). Even though data are not available, similar results could be expected for other chemicals in this group.

In an eye irritation study, 0.1 mL/kg of p-ethylphenol (CAS No: 123-07-9) was applied to the conjunctival sac of one rabbit eye (sex, strain, and numbers not specified). Although scores for individual animals were not available, severe ocular irritation was noted at 24 hours following application of the chemical and the lesions consisted of moderate to severe conjunctival irritation, iritis, corneal opacity, stippling and ulceration. Severe irritation persisted at day seven after application of the chemical and the chemical was therefore classified as severely irritating to rabbit eyes in this study (US EPA, 2008).

Note: The irritation data for the ethylphenols contrast with those for the analogue phenol and the cresols. A clear trend from higher to lower irritancy is observed in the following order: phenol >cresols >ethylphenols.

Sensitisation

Skin Sensitisation

Data are not available regarding the skin sensitisation potential of chemicals in this group. The chemicals do not contain a structural alert for skin sensitisation (OECD Toolbox). In addition, as methylphenols group of chemicals were considered not likely to be skin sensitisers, chemicals in this group are also not likely to be skin sensitisers (NICNASa).

Repeated Dose Toxicity

Oral

Although limited information is available on the effects of repeated oral exposure, the chemicals in this group are not considered to cause serious damage to health from repeated oral exposure.

In a repeated dose toxicity study, Sprague Dawley (SD) rats were administered (by gavage) p-ethylphenol (CAS No: 123-07-9) or m-ethylphenol (CAS No: 620-17-7) at doses of 0, 100, 300 or 1000 mg/kg bw/day for 28 days. While half the animals in each group were euthanised on the day following the last treatment, the remaining animals had a two-week recovery period before being euthanised. Clinical signs in the animals treated with 1000 mg/kg bw/day with both chemicals were noted immediately following dosing. Only 2/14 males and 5/14 females exposed to m-ethylphenol (CAS No: 620-17-7) showed clinical signs compared with 11/14 males and 9/14 females exposed to p-ethylphenol (CAS No: 123-07-9). While body weights were significantly reduced in the males on days two and seven in the high-dose group exposed to m-ethylphenol (CAS No: 620-17-7), significant reductions in mean body weight were observed from days 7–28 in males and days 14–28 in females in the high-dose group exposed to p-ethylphenol (CAS No: 123-07-9). Relative liver weights were significantly increased in both sexes in the high-dose groups for both chemicals and also in the males of the mid-dose group administered p-ethylphenol (CAS No: 123-07-9). Hyperplasia of the squamous cells in the forestomach was noted in all high-dose animals exposed to m-ethylphenol (CAS No: 620-17-7) and was noted only in 1/7 animals administered the mid-dose of p-ethylphenol (CAS No: 123-07-9). Lesions of the forestomach were observed in the high-dose males (5/7) and females (2/7) given m-ethylphenol (CAS No: 620-17-7) and also in high-dose males (7/7) and females (6/7) given p-ethylphenol (CAS No: 123-07-9). There were no treatment-related effects for the animals at the end of the two-week recovery period for either of the chemicals; suggesting that the observed effects were transient. The NOAELs were determined to be 300 mg/kg bw/day and 100 mg/kg bw/day for m-ethylphenol (CAS No: 620-17-7) and p-ethylphenol (CAS No: 123-07-9), respectively, based on increased relative liver weights and lesions in the forestomach at the next higher dose of 1000 mg/kg bw/day for m-ethylphenol (CAS No: 620-17-7) and 300 mg/kg bw/day for p-ethylphenol (CAS No: 123-07-9).

In a combined repeated dose/reproductive/developmental toxicity study (see **Reproductive & developmental toxicity**), SD rats were administered (by gavage) the mixture of ethylphenol isomers at 0, 30, 100 or 245 mg/kg bw/day for 28 days in males or 54 days in females. The mixture comprised o-ethylphenol (CAS No: 90-00-6) (25.9 %), p-ethylphenol (CAS No: 123-07-9) (33.0 %), and m-ethylphenol (CAS No: 620-17-7) (41.1 %). Immediately following dosing, urine-stained fur in males and salivation in females were noted at all doses. Although body weight gain and food consumption were reduced at all dose levels in males (significance is not stated), body weight gain and food consumption were unaffected by treatment in females. There was no mortality. There were no other clinical signs of toxicity and haematology, clinical chemistry, and gross pathology or histopathology in male or female rats were also unaffected. The no observed adverse effect level (NOAEL) was established as 245 mg/kg bw/day, based on no treatment-related effects being observed at the highest tested dose for the rats (US EPA, 2008).

Dermal

No data are available.

Inhalation

No data are available.

Genotoxicity

Overall, the limited available data reveal that the chemicals in this group have no potential for genotoxic activity in vivo.

The chemical o-ethylphenol (CAS No. 90-00-6) was reported to be negative in Ames tests at up to 1000 µg/plate concentrations (*Salmonella typhimurium* TA97, TA98, TA100, and TA1535), in the presence and absence of metabolic activation. The mixture of ethylphenol isomers was also reported to be negative in Ames tests at up to 5000 µg/plate concentrations (*Salmonella typhimurium* TA98, TA100, TA1535, and TA1537; and *Escherichia coli* strain WP2 uvrA), in the presence and absence of metabolic activation (US EPA, 2008).

In a chromosomal aberration test, Chinese hamster ovary (CHO) cells were exposed to the mixture of ethylphenol isomers at concentrations ranging from 50–1200 µg/mL for four hours in the presence and absence of metabolic activation, or 5–120 µg/mL for 20 hours in the absence of metabolic activation. The percentage of cells with structural aberrations was markedly increased by 4- and 20-hour treatments without metabolic activation, and by a 4-hour treatment with activation. No treatment-related increases in numeric aberrations were observed. It was concluded that the mixture of ethylphenol isomers induced increases in chromosome aberrations in this assay (US EPA, 2008).

The analogue chemicals, methylcresols, also induced chromosome aberrations in CHO cells in vitro but there was no evidence for genotoxic activity in vivo (NICNASa).

Carcinogenicity

No data are available for the chemicals in this group. Although there is some evidence of carcinogenicity in animals for the analogue chemicals, methylphenols, the relevance of this to humans is considered questionable (NICNASa).

Reproductive and Developmental Toxicity

The chemicals in this group do not show specific reproductive or developmental toxicity. Any reproductive and developmental effects were only observed secondary to maternal toxicity.

In a combined repeated dose/reproductive/developmental toxicity study (see **Repeat dose toxicity: oral**), SD rats were administered (by gavage) the mixture of ethylphenol isomers at 0, 30, 100 or 245 mg/kg bw/day for 28 days in males or 54 days in females. The treatment had no effects on mating, fertility, pup viability, developmental parameters or reproductive performance. The reproductive and developmental NOAEL was determined as 245 mg/kg bw/day, based on no treatment-related effects observed at the highest tested dose (US EPA, 2008).

In another study, newborn SD rats were administered (by gavage) p-ethylphenol (CAS No: 123-07-9) or m-ethylphenol (CAS No: 620-17-7) at 0, 30, 100 or 300 mg/kg bw/day on postnatal days (PND) 4–21. While half the animals were euthanised on PND 22, the remaining pups had a nine-week recovery period (euthanised on PND 86). The body weights were significantly reduced in rats treated with m-ethylphenol (CAS No: 620-17-7) as well as p-ethylphenol (CAS No: 123-07-9) at 300 mg/kg bw/day. In addition, rats treated with p-ethylphenol (CAS No: 123-07-9) at 300 mg/kg bw/day also showed mortality, hypoactivity, Straub tail, deep respiration, and/or a delayed righting reflex. Treatment-related effects were not noted after the end of the recovery period, suggesting that the effects observed were transient. The NOAEL was established as 100 mg/kg bw/day for both chemicals, based on reduced body weights for m-ethylphenol (CAS No: 620-17-7) and on mortality as well as reduced body weights, and clinical signs for p-ethylphenol (CAS No: 123-07-9) (US EPA, 2008).

Other Health Effects

Neurotoxicity

In a combined repeated dose/neurotoxicity study (see **Repeat dose toxicity: oral**), SD rats were administered (by gavage) the mixture of ethylphenol isomers at 0, 30, 100 or 245 mg/kg bw/day for 28 days in males or 54 days in females. There were no clinical signs of toxicity from a functional observational battery of tests, and motor activity in male or female rats was also unaffected. The NOAEL was established as 245 mg/kg bw/day, based on no treatment-related effects observed at the highest tested dose (US EPA, 2008).

Risk Characterisation

Critical Health Effects

The critical health effects for risk characterisation include a systemic acute effect (acute toxicity from oral exposure) and a local effect (severe eye irritation).

Public Risk Characterisation

The use of chemicals in this group in cosmetic and domestic products in Australia is not known. The chemicals are reported to be used as fragrance ingredients in consumer products overseas (see **Import, manufacture and use**). The available North American and European databases do not supply evidence for other uses of the chemical in consumer products. Therefore, the use of the chemicals in this group in cosmetic and consumer products is not anticipated in Australia. Hence, the public risk from chemicals in this group is not considered to be unreasonable.

However, as the current schedule entry for these chemicals is part of the entry for phenol (see **Restrictions: Australia),** NICNAS has recommended that an amendment to the current entry for phenol in the SUSMP be considered (NICNASb), given that necrosis of human skin has been reported at concentrations as low as 1 %. The possibility of a higher degree of local damage from phenol was also raised as it may diminish the sensation of pain and it was also noted that Canada, New Zealand and the European Union have prohibited the use of phenol in cosmetics. Therefore, a consideration of the schedule entry for the present group of chemicals will be necessary.

Occupational Risk Characterisation

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

Given the critical health effects, the chemical may pose an unreasonable risk to workers unless adequate control measures to minimise dermal, ocular and inhalation exposure to the chemical 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 appropriate controls.

The data available support an amendment to the hazard classification in HSIS (refer to the **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.

NICNAS has also recommended a change to the Scheduling of phenol (NICNASb). The current entry for phenol is complex and includes additional chemicals, including the cresols and ethylphenols. Any change to the scheduling of phenol will have flow on effects to these other chemicals (see **Restrictions: Australia)** and these changes are discussed in the report for cresols (NICNASa). If scheduling entry for phenol is separated into phenol and cresols, the present group of chemicals should stay with cresols as limited data are available on these chemicals to warrant a separate entry.

Regulatory Control

Public Health

It is recommended that the present group of chemicals should stay with cresols in the event that a separate entry for cresols is established in the SUSMP (currently cresols and ethylphenols are included as part of the entry for phenol). Matters to be considered in the recommended separate entry in the SUSMP for these chemicals include that they do not pose a risk to the public for identified domestic and cosmetic uses.

Work Health and Safety

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

Hazard	Approved Criteria (HSIS)[a]	GHS Classification (HCIS)[b]
Acute Toxicity	Harmful if swallowed (Xn; R22)	Harmful if swallowed - Cat. 4 (H302)
Irritation / Corrosivity	Risk of serious eye damage (Xi; R41)	Causes serious eye damage - Cat. 1 (H318)

[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 the instructions on the label.

Advice for industry

Control measures

Control measures to minimise the risk from oral 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 chemical is used. Examples of control measures which may minimise the risk include, but are not limited to:

- 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 assist with meeting 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.

References

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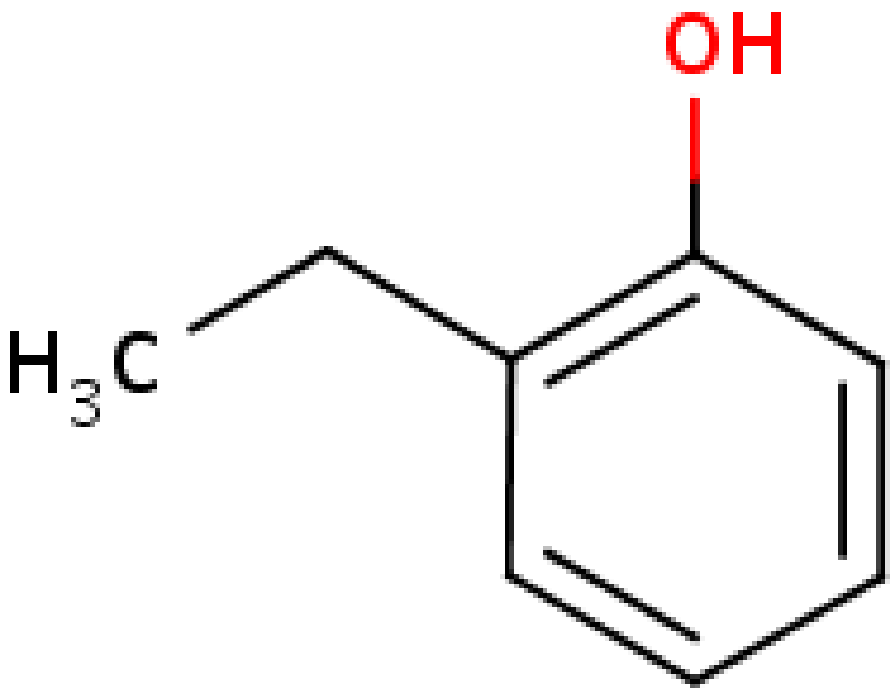
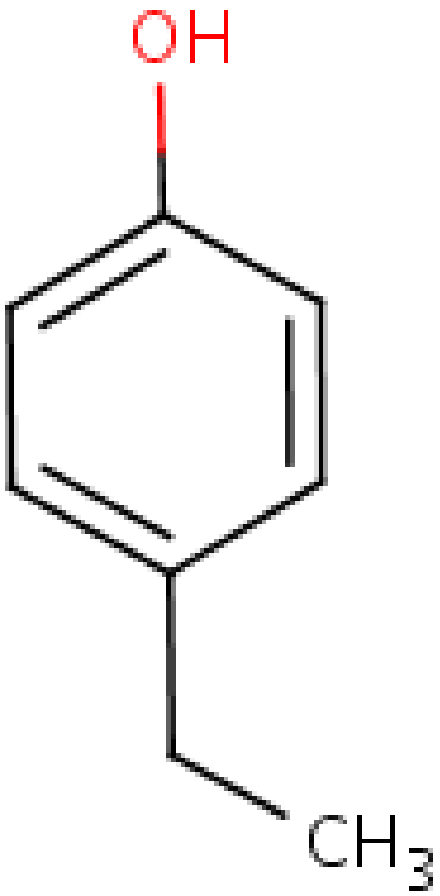
US Household Products Database. Accessed March 2014 at http://householdproducts.nlm.nih.gov/advancedsearch.htm Last Update 11 April 2014

Chemical Identities

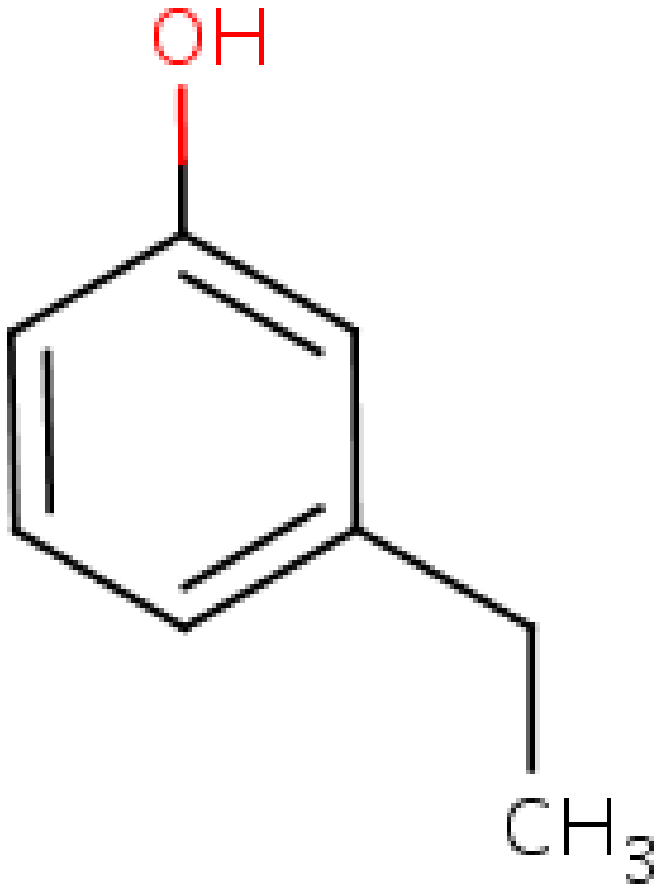
Chemical Name in the Inventory and Synonyms	**Phenol, 2-ethyl-** o-ethylphenol 2-ethylphenol 1-ethyl-2-hydroxybenzene o-hydroxyethylbenzene
CAS Number	90-00-6
Structural Formula	

	
Molecular Formula	C8H10O
Molecular Weight	122.17

Chemical Name in the Inventory and Synonyms	**Phenol, 4-ethyl-** p-ethylphenol 4-ethylphenol 1-ethyl-4-hydroxybenzene
CAS Number	123-07-9
Structural Formula	

	
Molecular Formula	C8H10O
Molecular Weight	122.17

Chemical Name in the Inventory and Synonyms	**Phenol, 3-ethyl-** m-ethylphenol 3-ethylphenol 1-Ethyl-3-hydroxybenzene 1-ethyl-3-hydroxybenzene
CAS Number	620-17-7
Structural Formula	

	
Molecular Formula	C8H10O
Molecular Weight	122.17

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