Dichlorophene and its sodium salts: Human health tier II assessment

02 March 2018

Chemicals in this assessment

Chemical Name in the Inventory	CAS Number
Phenol, 2,2'-methylenebis[4-chloro-	97-23-4
Phenol, 2,2'-methylenebis[4-chloro-, disodium salt	22232-25-3
Phenol, 2,2'-methylenebis[4-chloro-, monosodium salt	10187-52-7

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

This group consists of dichlorophene (CAS No. 97-23-4) and the monosodium (CAS No. 10187-52-7) and disodium (CAS No. 22232-25-3) salts. These chemicals are considered together in this assessment report. The speciation of these chemicals in biological fluids will be dependent on the pH of the fluid, but independent of the original form. The toxicity profile of these chemicals are expected to be driven by the hazards of the parent chemical.

Import, Manufacture and Use

Australian

The following non-industrial uses have been identified for dichlorophene in Australia:

- as a parasiticide, herbicide, fungicide and antimicrobial product; and
- as an anthelminthic (worm treatment) for human and animal use.

No specific Australian use, import, or manufacturing information has been identified for the other chemicals in this group.

International

The following international uses have been identified through Galleria Chemica; the Substances and Preparations in Nordic countries (SPIN) database; the European Commission Cosmetic Ingredients and Substances (CosIng) database; the United States (US) Personal Care Products Council International Nomenclature of Cosmetic Ingredients (INCI) Dictionary; the US National Library of Medicine's Hazardous Substances Data Bank (HSDB); Compilation of Ingredients used in Cosmetics in the United States (CIUCUS, 2011); and a Cosmetic Ingredient Review (CIR).

Dichlorophene has reported cosmetic use as an antifungal and deodorant in tonics, foot powders and sprays, dressings and hair grooming aids. Current concentration and use data are not available. Historical data (reported by industry to the US Food and Drug Administration in 1984) indicated that dichlorophene was typically used at concentrations in two ranges: 0–0.1 % and 0.1–1.0 %, and in more types of products than reported more recently (CIR, 2004). The chemical is used in two cosmetic products in the US (CIUCUS, 2011).

Dichlorophene has reported domestic use in cleaning and washing agents.

Dichlorophene has reported commercial uses, including:

- as a fungicide and bactericide treatment for cotton and woollen textiles (for example, in beach furniture, canvas lawns, rug backings), leather and paper;
- in articles used as food packaging; and
- as a cement additive in the construction industry.

Dichlorophene has reported site-limited use, including as a biocide in oilfield operations.

Dichlorophene has excluded uses including:

- as an anthelminthic for human and animal use; and
- an antiseptic for animals.

The disodium salt has reported commercial use as an industrial biocide (to prevent fungal and bacterial growth) and excluded uses to prevent infection.

Restrictions

Australian

Dichlorophene is listed in the *Poisons Standard—the Standard for the Uniform Scheduling of Medicines and Poisons* (SUSMP) in Schedules 4, 5 and 6 (SUSMP, 2018).

Schedule 4:

'Dichlorophen for human therapeutic use'

Schedule 5:

'Dichlorophen for the treatment of animals'

Schedule 6:

'Dichlorophen except:

(a) when included in Schedule 4 or 5; or

(b) in fabrics other than when:

i) for human therapeutic use; or

ii) as part of a registered pesticidal product.

Schedule 4 chemicals are described as 'Substances, the use or supply of which should be by or on the order of persons permitted by State or Territory legislation to prescribe and should be available from a pharmacist on prescription.'

Schedule 5 chemicals are described as 'Substances with a low potential for causing harm, the extent of which can be reduced through the use of appropriate packaging with simple warnings and safety directions on the label.' Schedule 5 chemicals are labelled with 'Caution' (SUSMP, 2018).

Schedule 6 chemicals are described as 'Substances with a moderate potential for causing harm, the extent of which can be reduced through the use of distinctive packaging with strong warnings and safety directions on the label'. Schedule 6 chemicals are labelled with 'Poison' (SUSMP, 2018).

International

Dichlorophene is listed on the following (Galleria Chemica):

- EU Cosmetics Regulation 1223/2009 Annex III—List of substances which cosmetic products must not contain except subject to the restrictions laid down;
- New Zealand Cosmetic Products Group Standard—Schedule 5 - Table 1: Components Cosmetic Products Must Not Contain Except Subject to the Restrictions and Conditions Laid Down; and
- ASEAN Cosmetic Directive Annex III - Part 1 List of substances which cosmetic products must not contain except subject to restrictions and conditions laid down.

European Union (EU): Using dichlorophene in cosmetics in the European Union is subject to the restrictions described in EU Regulation Annex III/V (Cosing). This chemical may be used in cosmetics and personal care products at a maximum concentration of 0.5% (CosIng).

Dichlorophene has been prohibited for use in Japan since 1973 based on concerns about potential photosensitisation (CIR, 2004).

Existing Worker Health and Safety Controls

Hazard Classification

Dichlorophene (CAS No. 97-23-4) 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):

Acute toxicity – Category 4; H302 (Harmful if swallowed)

Eye irritation – Category 2; H319 (Causes serious eye irritation)

The salts are not listed on the HCIS.

Exposure Standards

Australian

No specific exposure standards are available.

International

No specific exposure standards are available.

Health Hazard Information

Toxicokinetics

Following oral administration in rats, dichlorophene is well absorbed and rapidly excreted, primarily through the urine following metabolism in the liver and intestinal wall. Evidence suggests that some of the metabolites undergo enterohepatic circulation prior to being metabolised further and eliminated in the urine.

In one study using rats, 95 % of ^{14}C labelled dichlorophene was excreted in the urine and faeces two days after dosing. Most of the chemical (78 %) was recovered in the urine with 17 % in the faeces. Only 4 % of the radiolabel found in the urine was unmetabolised dichlorophene. The urinary metabolites consisted of dichlorophene monoglucuronide (25 %), dichlorophene diglucuronide (19 %) and dichorophene sulfate (17 %) (CIR, 2004).

Acute Toxicity

Oral

Dichlorophene is classified as hazardous with hazard category 'Acute Toxicity Category 4' and hazard statement 'Harmful if swallowed' (H302) in the HCIS (Safe Work Australia). The available data support this classification.

The median lethal dose (LD50) in rats is between 1000 and 3000 mg/kg bw (CIR, 2004).

The acute oral LD50 for dichlorophene in guinea pigs was 1240 mg/kg and 2000 mg/kg for dogs. Dosing guinea pigs with 1000 mg/kg bw of dichlorophene caused 60–80 % mortality in both sexes (CIR, 2004).

Dermal

No data are available.

Inhalation

No data are available.

Corrosion / Irritation

Skin Irritation

Dichlorophene is not classified as a skin irritant and the available data supports this.

No more than mild to moderate irritation was observed in rabbits exposed to dichlorophene in irritation studies. Reported test conditions were as follows:

- three rabbits were treated with 5 % dichlorophene in petroleum jelly twice per day for ten days;
- one group of rabbits (number unspecified) was treated with 1 % in butyl carbitol acetate and a second group was treated with 10 % dichlorophene (same vehicle) for a total of 20 applications over 28 days;

- the pure chemical (0.5 mL) was appled to the shaved, abraded skin of six albino rabbits (sex and exposure period unspecified); and
- six male albino rabbits were treated with wet and dry samples of dichlorophene on cotton cloth (equivalent to 1–12 % dichlorophene that could be leached from the material by water or saline solution) on separate intact and abraded skin test sites on each rabbit for 24 hours (CIR, 2004).

Eye Irritation

Dichlorophene is classified as hazardous with hazard category ‘Eye irritation –Category 2’ and hazard statement ‘Causes serious eye irritation’ (H319) in the HCIS (Safe Work Australia). Limited information indicates that eye effects can be severe. However, the data are not sufficient to amend the classification.

Dichlorophene (0.1 mL) was instilled into the conjunctival sac of six albino rabbits which were examined every 24 h for 3 days. Corneal opacity, iris congestion, and severe conjunctival irritation were observed in all six treated eyes (CIR, 2004). No information regarding reversibility of these effects was reported.

In a study with limited information, a 40 % solution of dichlorophene was placed into the conjunctival sac (species, strain and number of animals unstated), producing severe irritation of the conjunctival membranes and necrosis of the entire cornea (CIR, 2004). No further information characterising corneal effects was available.

The corneal necrosis reported in one study was inconsistent with a more recent study that also contained limited study details.

Sensitisation

Skin Sensitisation

Based on the available data, dichlorophene is not a skin sensitiser.

In a guinea pig maximisation test (GPMT), guinea pigs (strain and sex unspecified) were induced intradermally with 5 % dichlorophene in polyethylene glycol and topically with 25 % dichlorophene in petrolatum. The induction site was pre-treated with 10 % sodium lauryl sulfate in petrolatum 24 h prior to the induction patch test. Positive dermal reactions were reported in 1/20 animals when treated with 1 % dichlorophene in petrolatum in a closed (occluded) challenge test (CIR, 2004).

Negative results were obtained for dichlorophene in two other studies in guinea pigs. One study with no study details reported no allergic reactions following administration of the chemical to 10 guinea pigs. In another study, negative results were reported following application of 1.1–1.9 % dichlorophene (vehicle unspecified) to 10 male albino guinea pigs for nine treatments over a 3-week period. The challenge patch was administered to all animals using the same method following a 2-week nontreatment period (CIR, 2004).

Observation in humans

Negative results were obtained in clinical dermal sensitisation studies following exposure to subjects with and without reported pre-existing skin conditions. However, evidence obtained from case studies indicates that some individuals are sensitive to dichlorophene and can experience severe reactions, particularly if they have a history of skin conditions such as stasis dermatitis and/or ulcers (CIR, 2004).

Positive reactions were observed in 3/194 men and women exposed to 4 % dichlorophene for 48 h. In a second study, dichlorophene was tested as a 1 % solution in propylene glycol and 1 % as an emulsion in a Human Repeat Insult Patch Test (HRIPT) with 50 subjects (25/sex); it was reported that 'dichlorophene was not considered a sensitiser' (further details were not available). In a third study, no dermal reactions occurred at challenge in 208 men tested with 5 % induction and 5 % challenge concentrations of dichlorophene; one out of 110 men had a reaction following treatment with dichlorophene at 20 % for induction and at 5 % for challenge (CIR, 2004).

Eight of 465 individuals (235 males and 230 females) with a history of eczema had positive patch test reactions to 1 % dichlorophene in petrolatum. In another study, positive patch test results were observed in 22/4320 patients with eczema treated using the A1 patch test technique and 1 % dichlorophene in petrolatum. It was reported that 'four of the positive tests were clinically explainable'. In another study, 25 subjects with leg ulcers present from 1 to ≥5 years were patch tested with dichlorophene. Only one subject had a positive response (CIR, 2004).

Dichlorophene was not found to be phototoxic in three photo patch studies where subjects were exposed to the chemical and UV light. However, evidence obtained from case studies indicates that some individuals are sensitive to dichlorophene (CIR, 2004).

Repeated Dose Toxicity

Oral

Based on the available data from 14–90 day studies in rats, guinea pigs and rabbits, the chemical is not considered to cause severe effects from repeated oral exposure. Although kidney effects were observed in two of the three 90 day studies, these were at high doses (CIR, 2004).

In a 90 day study, no adverse effects were found during microscopic examination of rats (strain and sex unspecified) fed 400 mg/kg/day dichlorophene. In another 90 day study with limited details, renal damage occurred in rats treated with dichlorophene at 1000 mg/kg/day. In a third 90 day dietary study, rats (20/sex/group) were fed 0.02 %, 0.2 % and 0.5 % dichlorophene. Data were not available for the group treated with the intermediate dose (0.2 %). Animals treated with the highest dose (0.5 %, approximately equal to 150–300 mg/kg bw/day) were reported to have focal interstitial nephritis with tubular necrosis and focal areas of tubular dilatation and eosinophilic casts 'that could be compound related. These lesions were present to some degree in all the animals of this group' (CIR, 2004).

Dermal

Available data are limited to one 14-day non-guideline study in dogs which reported no significant treatment-related effects (CIR, 2004).

Inhalation

No data are available.

Genotoxicity

Based on the data available, the chemical is not considered to be genotoxic. Several positive in vitro results were reported but in vivo test results were negative.

In vitro

Positive results were reported in the following bacterial reverse mutation tests in *Salmonella typhimurium* strains (CIR, 2004):

- TA1535A/B, TA100, TA1538, TA98, TA1537 exposed at 5 doses ≤3600 μg/plate, with and without S9 activation; and
- (strain unspecified) exposed at 50 nmol/plate without S9 activation.

Negative results were reported in the following bacterial reverse mutation tests in *S. typhimurium* strains (CIR, 2004):

- TA98 (dose unspecified) with and without S9 activation; and

- TA1535, TA1537, TA1538, TA98, TA100 exposed at concentrations 3.12, 6.25, 12.5, 25.0, 50.0 and 100.0 μg/plate with and without S9 activation; positive controls were used.

In vivo

Negative results were reported in two in vivo tests:

- a micronucleus test where Naval Medical Research Institute male and female mice and Sprague Dawley rats were treated intraperitoneally (i.p.) at 0 and 24 h, bone marrow smears were prepared at 30 h; and
- a sex-linked recessive test where Berlin K and Basc strains of *Drosophila melanogaster* fruit flies were treated with doses 'close to the LD50', 12.5 mM.

Carcinogenicity

No data are available.

Reproductive and Developmental Toxicity

No data are available.

Risk Characterisation

Critical Health Effects

The critical health effects for risk characterisation include acute effects from oral exposure to dichlorophene. The chemical can also cause eye irritation. Limited information indicates that eye effects can be severe; however, this is not likely to occur at the concentrations used in cosmetics during normal use.

Public Risk Characterisation

Public exposure is likely to be through skin from application of cosmetics containing low concentrations (0–1.0 %) or contact with fabric treated with the chemicals. Dichlorophene is currently listed on Schedule 6 of the SUSMP and is, therefore, unlikely to be used in cosmetics in Australia.

It is difficult to determine the residual public risk in relation to impregnated fabrics given the lack of hazard data in relation to long term exposures. The closest chemical analogue is chlorophene, which was recommended for classification as a potential reproductive toxicant and carcinogen (NICNAS). However, the structural similarity is not close enough to allow for reading across hazard properties. The structural similarity still indicates that dichlorophene may have systemic hazards similar to chlorophene. The extent to which this may be the case and, whether there are additional hazards, remains unclear.

Occupational Risk Characterisation

During product formulation, ocular exposure might 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.

Oral exposure is also possible but can be prevented by good hygiene practices.

Given the critical acute and local health effects, the chemicals could pose an unreasonable risk to workers unless adequate control measures to minimise 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) for the sodium salts (see **Recommendation** section).

NICNAS Recommendation

Assessment of these 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. However, should information regarding potential chronic systemic risks become available, potential risks would need to be reconsidered.

Regulatory Control

Public Health

Products containing the chemicals should be labelled in accordance with state and territory legislation (SUSMP, 2018).

Work Health and Safety

Dichlorophen monosodium (CAS No. 10187-52-7) and dichlorophen disodium salt (CAS No. 22232-25-3) are recommended for classification and labelling aligned with the Globally Harmonized System of Classification and Labelling of Chemicals (GHS) as below. This is the existing classification for dichlorophen (CAS No. 97-23-4). 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.

In the absence of specific data on all the chemicals, data have been read-across (OECD, 2014) from the chemicals in this group for which data was available. Should empirical data become available indicating that a lower (or higher) classification is appropriate for these chemicals, this may be used to amend the default classification.

Hazard	Approved Criteria (HSIS)[a]	GHS Classification (HCIS)[b]
Acute Toxicity	Not Applicable	Harmful if swallowed - Cat. 4 (H302)
Irritation / Corrosivity	Not Applicable	Causes serious eye irritation - Cat. 2A (H319)

[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 chemicals 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 chemicals are used. Examples of control measures that could 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 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.

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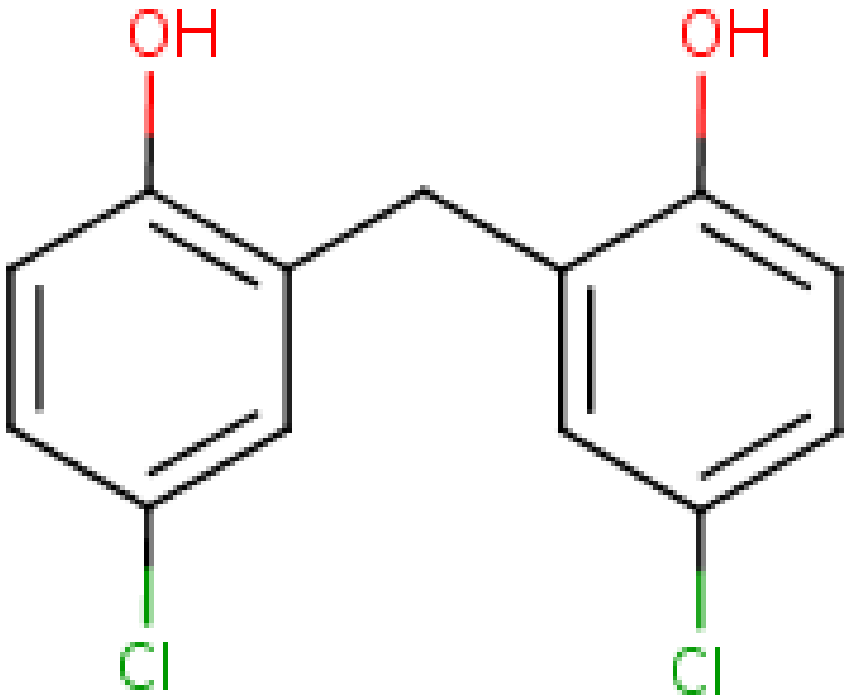
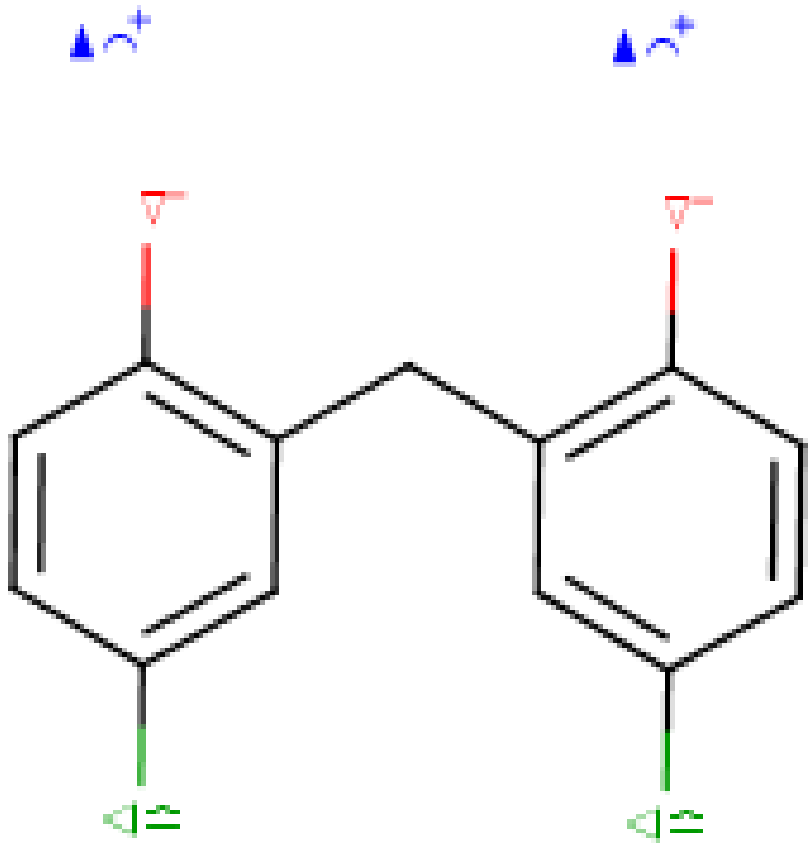
Last Update 02 March 2018

Chemical Identities

Chemical Name in the Inventory and Synonyms	**Phenol, 2,2'-methylenebis[4-chloro-** 2,2-dihydroxy-5,5-dichlorodiphenylmethane dichlorophen dichlorophene
CAS Number	97-23-4
Structural Formula	

	
Molecular Formula	C13H10Cl2O2
Molecular Weight	269.13

Chemical Name in the Inventory and Synonyms	**Phenol, 2,2'-methylenebis[4-chloro-, disodium salt** 2,2-methylenebis[4-chlorophenol dichlorophen disodium salt
CAS Number	22232-25-3
Structural Formula	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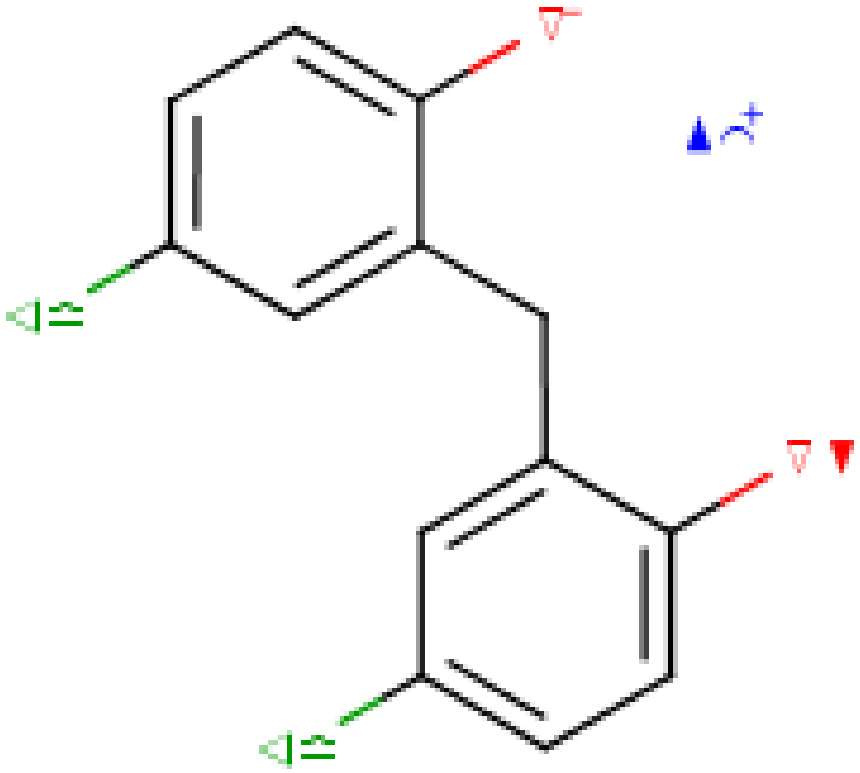
Molecular Weight	313.09

Chemical Name in the Inventory and Synonyms	**Phenol, 2,2'-methylenebis[4-chloro-, monosodium salt** 2,2-methylenebis[4-chlorophenol dichlorophen monosodium monosodium dichlorophene
CAS Number	10187-52-7
Structural Formula	

	
Molecular Formula	C13H10Cl2O2.Na
Molecular Weight	291.108

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