Hindered phenolic benzotriazoles: Human health tier II assessment

08 March 2019

Chemicals in this assessment

Chemical Name in the Inventory	CAS Number
Phenol, 2-(2H-benzotriazol-2-yl)-4,6-bis(1,1-dimethylethyl)-	3846-71-7
Phenol, 2-(2H-benzotriazol-2-yl)-4,6-bis(2,2-dimethylpropyl)-	15769-44-5
Phenol, 2-(2H-benzotriazol-2-yl)-4,6-bis(1,1-dimethylpropyl)-	25973-55-1
Phenol, 2-(2H-benzotriazol-2-yl)-4-(1,1-dimethylethyl)-6-(1-methylpropyl)-	36437-37-3

Preface

This assessment was carried out by staff of the National Industrial Chemicals Notification and Assessment Scheme (NICNAS) using the Inventory Multi-tiered Assessment and Prioritisation (IMAP) framework.

The IMAP framework addresses the human health and environmental impacts of previously unassessed industrial chemicals listed on the Australian Inventory of Chemical Substances (the Inventory).

The framework was developed with significant input from stakeholders and provides a more rapid, flexible and transparent approach for the assessment of chemicals listed on the Inventory.

Stage One of the implementation of this framework, which lasted four years from 1 July 2012, examined 3000 chemicals meeting characteristics identified by stakeholders as needing priority assessment. This included chemicals for which NICNAS already held exposure information, chemicals identified as a concern or for which regulatory action had been taken overseas, and chemicals detected in international studies analysing chemicals present in babies' umbilical cord blood.

Stage Two of IMAP began in July 2016. We are continuing to assess chemicals on the Inventory, including chemicals identified as a concern for which action has been taken overseas and chemicals that can be rapidly identified and assessed by using Stage One information. We are also continuing to publish information for chemicals on the Inventory that pose a low risk to human health or the environment or both. This work provides efficiencies and enables us to identify higher risk chemicals requiring assessment.

The IMAP framework is a science and risk-based model designed to align the assessment effort with the human health and environmental impacts of chemicals. It has three tiers of assessment, with the assessment effort increasing with each tier. The Tier I assessment is a high throughput approach using tabulated electronic data. The Tier II assessment is an evaluation of risk on a substance-by-substance or chemical category-by-category basis. Tier III assessments are conducted to address specific concerns that could not be resolved during the Tier II assessment.

These assessments are carried out by staff employed by the Australian Government Department of Health and the Australian Government Department of the Environment and Energy. The human health and environment risk assessments are conducted and published separately, using information available at the time, and may be undertaken at different tiers.

This chemical or group of chemicals are being assessed at Tier II because the Tier I assessment indicated that it needed further investigation.

For more detail on this program please visit:**www.nicnas.gov.au**

Disclaimer

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ACRONYMS & ABBREVIATIONS

Grouping Rationale

The chemicals are members of the group known as phenolic benzotriazoles. These chemicals are phenols which contains a benzotriazole (BZT) group in the ortho-position and at least two bulky and/or branched alkyl substituents at the ortho- and para-positions. These chemicals are similar in terms of their molecular structures (sterically-hindered benzotriazoles), uses (as ultraviolet (UV) absorbers), and hazard profiles (particularly repeated dose oral toxicity) (NTP, 2011; ECHA RAC, 2013; OECD, 2017; NICNAS). Based on these similarities, the chemicals are qualified to be assessed as a group. The available data for any of the chemicals will be applicable to the group where data are incomplete or unavailable .

The following abbreviations and their corresponding CAS numbers will be used in this assessment:

- UV-320 (CAS No. 3846-71-7)
- UV-328 (CAS No. 25973-55-1)
- UV-350 (CAS No. 36437-37-3)
- diNp-BZT (CAS No. 15769-44-5)

Import, Manufacture and Use

Australian

According to industry information, the chemical, UV-328, has domestic use in automotive aftermarket products including sealants. The chemical has also commercial use in automotive refinish paints (top coats and base coats) at a maximum concentration of 2.5%.

The chemical UV-328 has reported site-limited uses in the manufacture of other substances (NICNAS; Sigma-Aldrich SDS).

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 the European Union (EU) Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH) dossier (UV-328 only); the United States (US) National Library of Medicine's Household Products Database; and international assessments by the US Environmental Protection Agency (US EPA, 2009); National Toxicology Program (NTP, 2011); European Chemicals Agency Committee for Risk Assessment (ECHA RAC, 2013), and the Organisation for Economic Co-operation and Development (OECD, 2017).

By acting as UV absorbers to provide light stabilisation and protection against UV degradation, the chemicals have reported:

- cosmetic uses in secondary sunscreens, personal care products, and fragrances;
- domestic uses in adhesives and binding agents, printing inks, cleaning/washing detergents, interior/exterior vanishes (<5 % concentration), air care products (e.g. candles, air freshener aerosols) and automotive care products (e.g. polishes, waxes);
- commercial uses in adhesives, sealants, paints, coatings, construction and building materials, lubricants and greases;
- site-limited uses in adhesives, light-stabilised coatings, electrical and electronic products, rubber and plastic products, as plastic additives in food contact/packaging and in long-life articles.

Articles which contain the chemicals as stabilisers also have household use and mostly serve as domestic exposure sources (including via indoor dust).

The chemicals have also reported non-industrial uses as components of pesticides and sunscreens.

Restrictions

Australian

No known restrictions have been identified.

International

The chemicals UV-320, UV-328 and UV-350 are listed on the candidate list of substances of very high concern (SVHC) for eventual inclusion in Annex XIV (ECHA, 2014-15). In the European Union (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. Germany has submitted an Annex XV report proposing to restrict manufacturing and using the chemicals (ECHA, 2014-15).

Existing Worker Health and Safety Controls

Hazard Classification

The chemicals are not listed on the Hazardous Chemical Information System (HCIS) (Safe Work Australia).

Exposure Standards

Australian

No specific exposure standards are available.

International

No specific exposure standards are available.

Health Hazard Information

The chemicals UV-320, UV-328 and UV-350 have been identified as (very) persistent and (very) bio-accumulative (PB/vPvB) substances; and UV-320 and UV-328 also as toxic (T) substances (NICNAS; REACH).

Toxicokinetics

Based on the available data, the chemicals in this group are expected to be readily absorbed after oral exposure, then distributed mainly to the liver, and excreted mainly in the urine. Metabolites of UV-320 were not detected in plasma of either sex of the rat at doses up to 12.5 mg/kg bw/day for 28 days, suggesting that the chemicals in this group are unlikely to be metabolised, probably due to low reactivity of the bulky substituents on the phenolic ring (NTP, 2011; OECD, 2017).

Acute Toxicity

Oral

Based on the available data, the chemicals are expected to have low acute toxicity.

In rats, a median lethal dose (LD50) >2000 mg/kg bw was reported for UV-320, and LD50 >2325 mg/kg bw for UV-328 (US EPA, 2009; NTP, 2011).

Dermal

Limited data are available.

No mortality occurred in albino rabbits (2/sex) after 24-hour application of UV-328 at 1100 mg/kg bw to intact and abraded skin under occlusive conditions (REACH).

Inhalation

Limited data are available.

No mortality occurred in rats either following 1-hour whole body or 4-hour nose-only exposure to UV-328 at 0.129 mg/L (dust) or 0.4 mg/L (aerosol), respectively (REACH).

Corrosion / Irritation

Skin Irritation

Limited data are available. The chemicals are expected to be only slightly irritating to the skin.

Four-hour application of UV-328 (purity not specified) to the shaved (intact) skin of New Zealand White rabbits (3 males) under semi-occlusive conditions resulted in maximum scores of 2 for both erythema and oedema after 1 hour. The reactions were reversible after 48 hours. Mean 24–72 hour scores were 0.33 for erythema in 2/3 rabbits (REACH).

Twenty four-hour occlusive application of UV-328 (purity not specified) to the intact and abraded skin of albino rabbits (2/sex) caused minimal irritation which were reversible after 72 hours. The 48-hour scores were not reported (REACH).

Eye Irritation

Limited data are available. The chemicals are expected to be only slightly irritating to the eyes.

The chemical UV-328 was interpreted as causing minimal and reversible eye irritation in three rabbit studies reported in a REACH dossier. None of the studies were considered to be good laboratory practice (GLP) compliant and limited details are available, including no irritation scores at each 24, 48, or 72-hour observation time.

Sensitisation

Skin Sensitisation

Limited data are available. The chemicals are not expected to have sensitisation potential.

The chemical UV-328 was interpreted as 'not sensitising' following induction (intradermal at 1 % and epidermal at 30 %) then challenge (epidermal at 10 and 30 %) in two guinea pig maximisation tests reported in a REACH dossier. None of the studies were considered to be GLP compliant and limited details are available.

Repeated Dose Toxicity

Oral

Based on the available data and close structural similarity, the chemicals in this group are considered to be harmful to human health following repeated exposure by the oral route. Histopathological changes (such as hypertrophy, degeneration and necrosis of hepatocytes and renal tubular nephrosis) accompanied by changes in organ weights and alterations of biochemical parameters in both sexes of animals have provided sufficient evidence to warrant hazard classification (see **Recommendation** section).

Liver and kidneys are likely to be target organs of the phenolic benzotriazoles, including those under this assessment. According to OECD (2017), hepatotoxicity is considered a more critical effect of phenolic benzotriazoles, since nephrotoxicity generally occurred at higher doses than those required for hepatotoxicity in GLP studies (ECHA RAC, 2013). Regarding hepatotoxicity, the ECHA RAC was of the opinion that the reported effects of UV-320 and UV-328 at doses >10 mg/kg bw/day in 90-day studies (or >30 mg/kg bw/day in 28-day studies) meet the criteria for category 2 classification (GHS, 2009; ECHA RAC, 2013). Effects observed below these guidance values were insufficient to warrant category 1 classification, when considering their severity, relevance to human health and toxicological significance. NICNAS concurs with these conclusions.

UV-320:

In a GLP compliant 28-day repeated dose study, CD(SD)IGS rats (5/sex/dose) were administered UV-320 by gavage at 0, 0.5, 2.5, 12.5 or 62.5 mg/kg bw/day. Changes in blood biochemistry (males at ≥0.5 and females at 62.5 mg/kg bw/day) and haematology (males only at ≥2.5 mg/kg bw/day) were noted. Histopathological changes (hypertrophy and degeneration) were observed in the heart and particularly in the liver, including bile duct proliferation (males at ≥0.5 and females at ≥12.5 mg/kg bw/day). At the higher doses, kidney hypertrophy and thyroid hyperplasia (both sexes), and increased severity of kidney basophilic tubules and spleen extramedullary haematopoiesis (males only) were reported. Recovery was observed in females but not in males after 14 days (Hirata-Koizumi et al., 2007).

In a GLP compliant 52-week study (OECD TG 452 – Chronic toxicity), CD(SD)IGS rats (10/sex/dose) were administered UV-320 by gavage at 0, 0.1, 0.5 or 2.5 mg/kg bw/day (males), and 0, 0.5, 2.5 or 12.5 mg/kg bw/day (females), for either 13 or 52 weeks. The results were considered similar following the two exposure periods. Male body weight was decreased at 2.5 mg/kg bw/day from day 36 to week 52. Changes in blood biochemistry, haematology (anaemia-like) and histopathology of the liver (males at ≥0.5 and females at 12.5 mg/kg bw/day) were also found. At necropsy, absolute and relative liver weight were increased (males at ≥0.5 and females at 12.5 mg/kg bw/day). The no observed adverse effect level (NOAEL) was reported to be 0.1 and 2.5 mg/kg/day in male and female rats, respectively (Hirata-Koizumi et al., 2008).

UV-328:

In a 90-day study in rats (10/sex/dose), UV-328 was administered in diet at 0, 100, 200, 400, 800 or 1600 ppm. Effects were seen in several organs (blood, liver and kidney) at ≥200 ppm with the lowest observed adverse effect level (LOAEL) determined to be at ≥800 ppm (~52 mg/kg bw/day) (ECHA RAC, 2013). Gross and histopathological findings included greenish-drab discoloration and focal necrosis of the liver, enlarged parenchymal cells, renal tubular nephrosis, and bile duct proliferation (US EPA, 2009; NTP, 2011; OECD, 2017).

In a 90-day study in beagle dogs (3–5/sex/dose), UV-328 was administered in diet at 0, 15, 30, 60, 120 or 240 mg/kg bw/day. One male dog at the highest dose died on week 8. Anaemia-like effects and increased liver weights associated with severe liver damage (jaundice), Kupffer cell hyperplasia and centrilobular choleostasis were observed at ≥120 m/kg bw/day. Microscopic changes in the liver (fatty degeneration of hepatocytes and fibrosis) and kidney toxicity were reported at ≥60 m/kg bw/day. Significant changes in serum enzymes and protein pattern at ≥15 mg/kg bw/day were also reported (ECHA RAC, 2013; NTP, 2011; OECD, 2017).

UV-350:

In a combined repeated dose and reproductive and developmental toxicity screening study in rats, UV-350 was administered by gavage at 0, 0.5, 2.5 or 12.5 mg/kg bw/day for 42 days (males) or for 41–55 days (females through pre-mating, mating, pregnancy until lactation day 4). At the highest dose, increased liver and kidney weights (but without any histopathological findings) and changes in blood chemistry parameters were observed in both sexes. The NOAEL was reported to be 12.5 mg/kg bw/day (OECD, 2017).

In another rat study with similar dosing regimen, UV-350 was administered at 0, 0.8, 4, 20 or 100 mg/kg bw/day for 42 days (males) or for 42–56 days. Increased liver enzymes and relative liver weights, together with centrilobular hypertrophy of liver cells, were observed in males at ≥20 mg/kg bw/day and females at 100 mg/kg bw/day. Haematological effects were seen in both sexes at 100 mg/kg bw/day. The NOAEL values were reported to be 4 and 20 mg/kg bw/day for male and female rats, respectively (OECD, 2017).

Dermal

One limited study is available. Systemic toxicity was not reported at 140 mg/kg bw/d for 14 days.

Rabbits with intact or abraded skin (3/group) were treated with ten applications, five/week, of UV-328 (Tinuvin 328) at140 mg/kg bw. Local irritation and orange staining of the fur and skin were noted. The urine was brown. No further study results were reported (REACH).

Inhalation

No data are available.

Genotoxicity

No in vivo genotoxicity data are available. The in vitro data do not suggest that the chemicals in the group are likely to have genotoxic potential.

UV-320 was negative in (NTP, 2011):

- Point mutation tests in *Salmonella typhimurium* (TA1538, TA98) with metabolic activation, and *Escherichia coli* with or without metabolic activation;
- Chromosomal aberration test in Chinese hamster lung cells, with or without metabolic activation.

UV-328 was negative in (US EPA, 2009; NTP, 2011; REACH):

- Point mutation tests in *S. typhimurium* (TA1535, TA1537, TA97, TA98, TA100, TA102) and *E. coli* (WP2/pKM101); no information is available on the use of metabolic activation;
- Gene mutation assay in Chinese hamster lung fibroblasts (V79), with and without metabolic activation;
- Chromosome aberration test in Chinese hamster lung fibroblasts (CHL/IU), with and without metabolic activation.

Carcinogenicity

No data are available.

Reproductive and Developmental Toxicity

Limited data are available. Some findings in animal studies indicate potential for effects on the male and female reproductive systems.

UV-320:

After 13- and 52-week repeated oral exposure, increased weights of testes and/or epididymides were reported in rats at 2.5 mg/kg bw/day (Hirata-Koizumi et al., 2008; NTP, 2011).

UV-328:

After 90-day repeated oral exposure, histopathological and reproductive organ weight changes were observed in rats (increased relative testes weight at ≥25 mg/kg bw/day) and in dogs (abnormal spermogenesis and atrophy of the prostate at ≥30 mg/kg bw/day, and atrophy of the uterus at ≥60 mg/kg bw/day) (US EPA, 2009; NTP, 2011; ECHA RAC, 2013; OECD, 2017).

Risk Characterisation

Critical Health Effects

The chemicals can cause harmful systemic effects following repeated oral exposure, with the liver and kidney as the main target organs.

Public Risk Characterisation

Although the general public could be exposed to the chemicals through potential cosmetic and domestic uses, the chemicals are not considered to pose an unreasonable risk to public health given the low concentration used (<5 %), the low probability of

repeated ingestion or inhalation of the cosmetic or domestic products containing the chemicals to toxic levels, and the comparatively low repeated dose dermal toxicity of the chemicals.

Three chemicals in this group (UV-320, UV-328 and UV-350) have been categorised as persistent and bioaccumulative substances (NICNAS). Chemicals which are persistent and bioaccumulative remain in the environment and accumulate in biota over an extended period of time. Therefore secondary exposure to the chemicals in environmental media could occur. Limited monitoring data are available for the chemicals to estimate the risk. In Canada, general population exposure to UV-328 was considered to be negligible as exposure via environmental media was estimated to be in the order of nanograms (10^{-9} g) per kg bw (kilogram of body weight) per day across all age groups (Government of Canada, 2018). Further assessment of these chemicals may be required if information becomes available to indicate that significant concentrations of these chemicals are identified either in humans or environmental media in Australia.

Occupational Risk Characterisation

Given the critical systemic long-term effects, the chemicals could pose an unreasonable risk to workers unless adequate control measures to minimise oral and inhalation 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 available data support an amendment to the hazard classification in the HCIS (Safe Work Australia) (see **Recommendation** section).

NICNAS Recommendation

Further risk management is required. Sufficient information is available to recommend that risks for workplace health and safety be managed through changes to classification and labelling.

If any information becomes available to indicate significant consumer exposure to the chemicals in Australia (i.e. higher concentrations or quantities in cosmetics or domestic products or in any environmental media), risks to public health and safety may have to be managed by changes to the Poisons Standard.

Assessment of these chemicals is considered sufficient, provided that risk management recommendations are implemented, and all labelling and other requirements are met under workplace health and safety and poisons legislation as adopted by the relevant state or territory.

Regulatory Control

Public Health

Products containing the chemicals should be labelled in accordance with state and territory legislation.

Work Health and Safety

The chemicals are recommended for classification and labelling in alignment with the Globally Harmonized System of Classification and Labelling of Chemicals (GHS) as below.

This assessment 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]
Repeat Dose Toxicity	Not Applicable	May cause damage to the liver and kidneys through prolonged or repeated exposure - Cat. 2 (H373)

[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 inhalation 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 closed systems or isolating operations;
- using local exhaust ventilation to prevent the chemicals from entering the breathing zone of any workers;
- health monitoring for any worker who is at risk of exposure to the chemicals, if valid techniques are available to monitor the effect on the worker's health;
- 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 safety data sheets (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 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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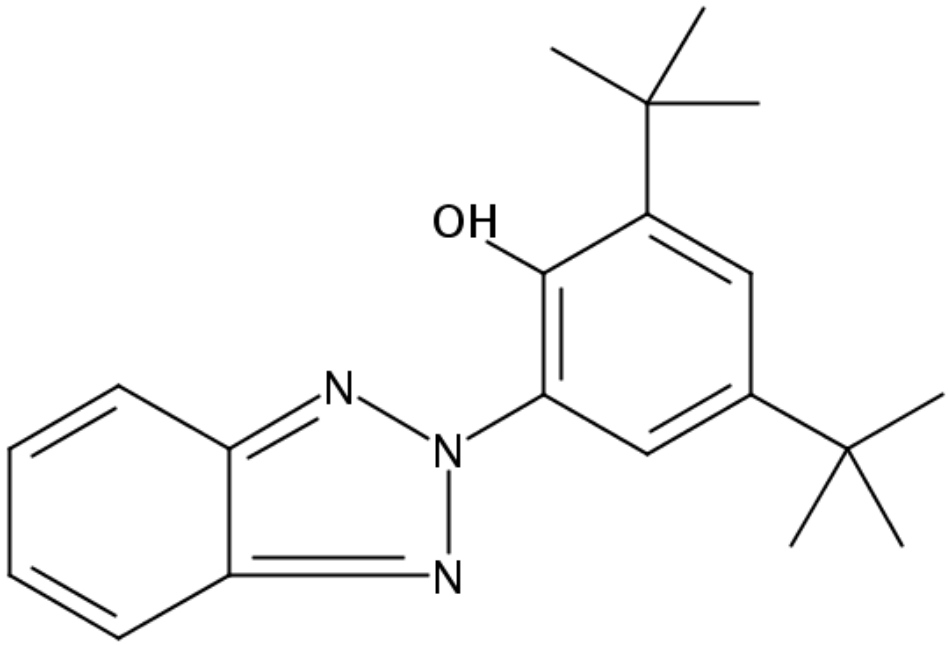
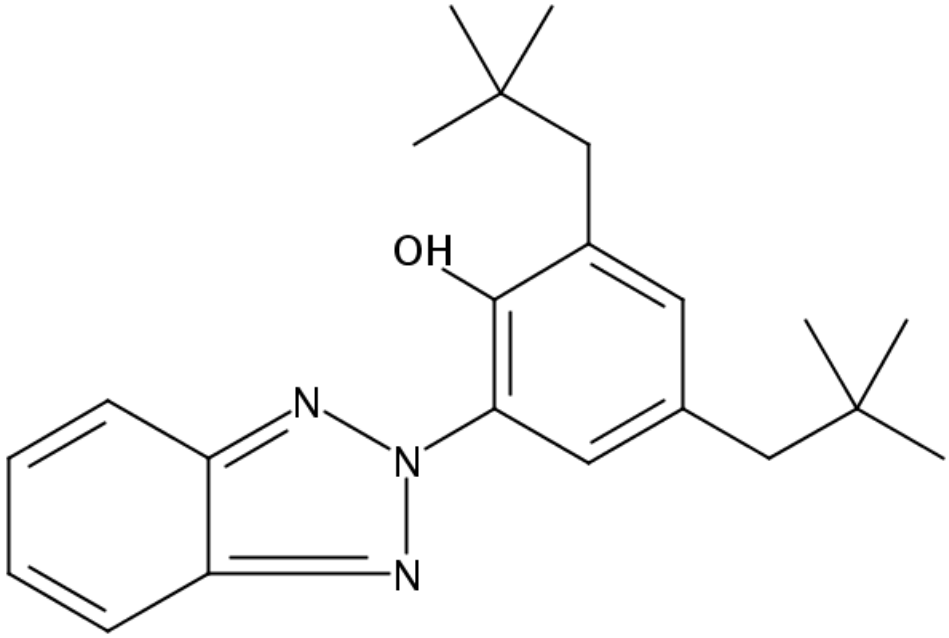
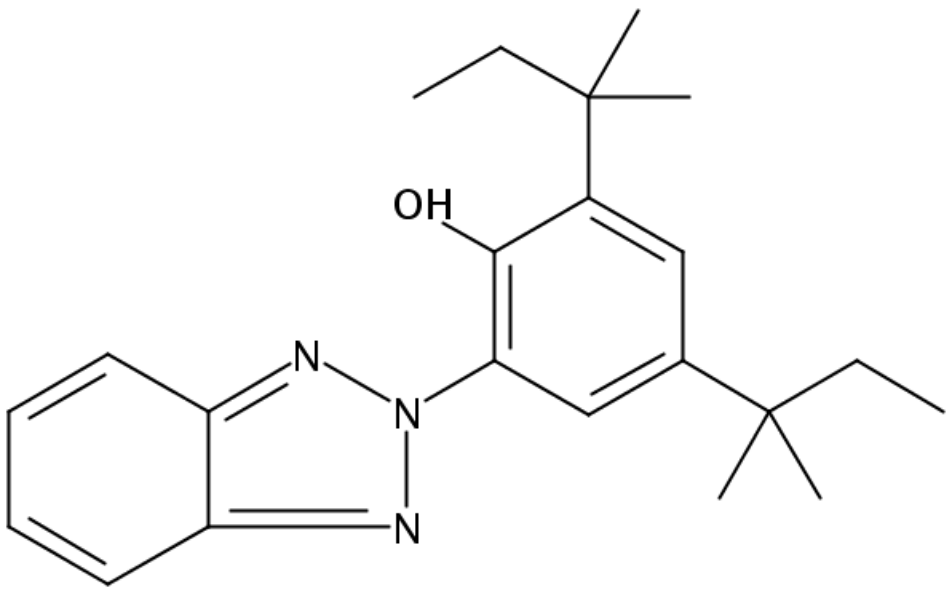
Last Update 08 March 2019

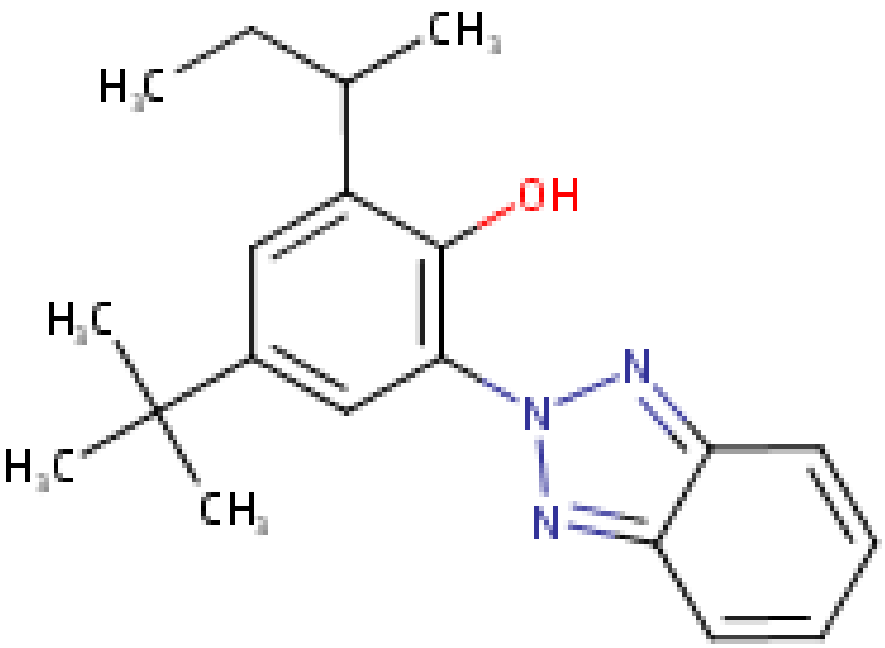
Chemical Identities

Chemical Name in the Inventory and Synonyms	**Phenol, 2-(2H-benzotriazol-2-yl)-4,6-bis(1,1-dimethylethyl)-** 2-benzotriazol-2-yl-4,6-di-tert-butylphenol (ditBu-BZT) 2-(benzotriazol-2-yl)-4,6-bis(2-methylbutan-2-yl)phenol 2-(2'-hydroxy-3',5'-di-tert-butylphenyl)benzotriazole UV-320
CAS Number	3846-71-7
Structural Formula	
Molecular Formula	C20H25N3O
Molecular Weight	323.43

Chemical Name in the Inventory and Synonyms	**Phenol, 2-(2H-benzotriazol-2-yl)-4,6-bis(2,2-dimethylpropyl)-** phenol, 2-(2H-benzotriazol-2-yl)-4,6-dineopentyl- (diNp-BZT)
CAS Number	15769-44-5
Structural Formula	

	
Molecular Formula	C22H29N3O
Molecular Weight	351.49

Chemical Name in the Inventory and Synonyms	**Phenol, 2-(2H-benzotriazol-2-yl)-4,6-bis(1,1-dimethylpropyl)-** 2-(2H-benzotriazol-2-yl)-4,6-ditertpentylphenol (ditPe-BZT) 2-(2'-hydroxy-3',5'-di-t-amylphenyl) benzotriazole UV-328
CAS Number	25973-55-1
Structural Formula	
Molecular Formula	C22H29N3O
Molecular Weight	351.49

Chemical Name in the Inventory and Synonyms	**Phenol, 2-(2H-benzotriazol-2-yl)-4-(1,1-dimethylethyl)-6-(1-methylpropyl)-** 2-(2H-benzotriazol-2-yl)-4-(tert-butyl)-6-(sec-butyl)phenol 2-(benzotriazol-2-yl)-6-butan-2-yl-4-tert-butylphenol UV-350
CAS Number	36437-37-3
Structural Formula	
Molecular Formula	C20H25N3O
Molecular Weight	323.43

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