Phosphine oxide, diphenyl(2,4,6-trimethylbenzoyl)-: Human health tier II assessment

08 March 2019

CAS Number: 75980-60-8

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.

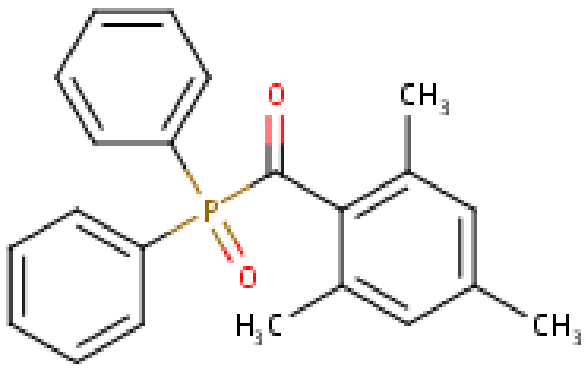
This chemical or group of chemicals are being assessed at Tier II because the Tier I assessment indicated that it needed further investigation.

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

Disclaimer

Acronyms & Abbreviations

Chemical Identity

Synonyms	TPO 2,4,5-trimethylbenzoyl diphenylphosphine oxide diphenyl(2,4,6-trimethylbenzoyl)phosphine oxide
Structural Formula	
Molecular Formula	C22H21O2P
Molecular Weight (g/mol)	348.38
SMILES	C(=O)(c1c(C)cc(C)cc1C)P(=O)(c1ccccc1)c1ccccc1

Import, Manufacture and Use

Australian

The following Australian uses have been identified through websites and safety data sheets (SDSs) available in Australia:

- cosmetic use in nail products at concentrations up to 2 %; and
- domestic use in printing inks and bonding agents; and

International

The following international uses have been identified through the European Union (EU) Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH) dossiers; the Substances and Preparations in Nordic countries (SPIN) database; the European Commission Cosmetic Ingredients and Substances (CosIng) database; Personal Care Products Council Ingredients Database; and the United States Environmental Protection Agency Chemical and Product Categories (US EPA CPCat).

The chemical has reported uses in nail polish and enamel products (Personal Care Products Council). The chemical is used as a chemical photo-initiator for polymerisation in artificial nail systems at concentrations between 0.5–5 %. In the system the chemical splits into two free radical fragments, which subsequently become incorporated into the polymer. Hence the chemical will be rapidly consumed during the polymerisation process and minor residual amounts are likely to be trapped in the hardened polymer matrix of the nail coating (SCCS, 2014).

The chemical is listed in the Compilation of Ingredients Used in Cosmetics in the United States (CIUCUS, 2011), indicating its use in three cosmetic products.

The chemical has reported domestic uses in:

- printing inks;
- paints, coatings, lacquers and varnishes;
- adhesives and sealants; and
- fillers, putties and plasters.

The chemical is a photoinitiator to cure pigmented ultraviolet (UV) curable coatings, as well as UV stabilised coatings, and typically used in concentrations of 0.5-6 % by weight. The photoinitiator is expected to undergo photoreaction on absorption of light leading to polymerisation reactions, and therefore, chemically and physically resistant coatings. The photo-initiator is mostly consumed during the curing step (BASF).

The chemical has reported commercial uses in photo chemicals and in 3-dimensional printing (Pawar et al., 2016).

The chemical has site-limited uses in manufacture of resins, rubbers, polymers, matrices, furniture, upholstery and electronic products.

The chemical has reported non-industrial uses as an auxiliary for dental technology.

Restrictions

Australian

No known restrictions have been identified.

International

No known restrictions have been identified.

Existing Work Health and Safety Controls

Hazard Classification

The chemical is classified as hazardous, with the following risk phrase for human health in the Hazardous Chemicals Information System (HCIS) (Safe Work Australia): Reproductive toxicity – Category 2; H361f (Suspected of damaging fertility).

Exposure Standards

Australian

No specific exposure standards are available for this chemical.

International

No specific exposure standards are available for this chemical.

Health Hazard Information

Toxicokinetics

Limited information is available for the chemical. However, very low levels of the chemical are expected to be bioavailable when used in nail products.

The bioavailability of the chemical from the nail products was evaluated by applying base coat nail gel containing 3 % of the chemical as well as intermediate colour coat gel and a top coat gel to a plastic nail tip. Each step was followed by curing. To extract any soluble chemicals from the cured polish the nail was soaked in an aqueous 0.1% sodium chloride solution for 16 hours at room temperature (22 °C) and at 50 °C. The levels of the chemical were not measurable using HPLC. Considering the detection limit of the instrument the concentration of the extracted chemical was considered to be less than 0.2 % of the applied amount (SCCS, 2014).

Acute Toxicity

Oral

The chemical has low acute toxicity based on animal tests following oral exposure. The median lethal dose (LD50) in rats is >5000 mg/kg bw.

In a study conducted according to the Organisation of Economic Cooperation and Development (OECD) Test Guideline (TG) 401 (Acute Oral Toxicity), Sprague-Dawley (SD) rats (5/sex) were orally administered a single dose of the chemical in arachis oil by oral gavage at 5000 mg/kg bw and observed for 14 days. No mortality was observed. Clinical signs of hunched posture,

lethargy, piloerection and decreased respiratory rate were noted in all treated animals one hour after dosing. All animals appeared normal one day after treatment. No abnormalities were noted at necropsy (REACH; SCCS, 2014).

In another OECD TG 401 acute oral toxicity study, SD rats (5/sex/dose) were administered a single dose of the chemical by oral gavage at 1000 and 5000 mg/kg bw and observed for 14 days. No mortality, clinical signs, or abnormalities at necropsy were observed. The LD50 was reported as > 5000 mg/kg bw (REACH; SCCS, 2014).

Dermal

The chemical has low acute toxicity based on results from animal tests following dermal exposure. The LD50 in rats is >2000 mg/kg bw.

In an OECD TG 402 acute dermal toxicity study, Wistar rats (5/sex/dose) were treated with a single dermal application of the chemical at 2000 mg/kg bw for 24 hours and observed for 14 days. No mortality, systemic toxicity, or abnormalities at necropsy were reported. The LD50 for dermal exposure was >2000 mg/kg bw (REACH).

Inhalation

No data are available for this chemical.

Corrosion / Irritation

Skin Irritation

The chemical may be slightly irritating to the skin. The effects are not sufficient to warrant hazard classification.

In a study conducted according to United States (US) Federal Register 38, No 187, §1500.41, the chemical (0.5 g as a 50 % aqueous solution) was applied occlusively to intact and abraded skin of Vienna white rabbits (2 males, 4 females) for 24 hours. The skin was observed after 24, 48, and 72 hours and on day 8 after treatment. Animals that received the chemical on intact sites showed signs of oedema (mean score, 0.3) and erythema (mean score, 0.6), which were fully reversible. At abraded sites the mean scores were 0.4 and 0.9 for oedema and erythema, respectively (REACH). No further information is available.

Eye Irritation

The chemicals may be slightly irritating to eyes. The effects are not sufficient to warrant hazard classification.

In a study conducted according to US Federal Register 38, No 187, §1500.42, 0.56 g of the chemical (neat) was applied to the conjunctival sac of the right eye of Vienna white rabbits (4 females, 2 males) without washing. Animals were observed for 5 days, with observations after 24, 48, and 72 hours. No effects were noted in the iris. Conjunctival redness (score 0.3–1) and discharge were observed in all animals but was fully reversible within 72 hours. Some corneal opacity was observed in 2 animals at 72 hours (score not reported) (REACH; SCCS, 2014). No further information is available.

Observation in humans

No irritation was produced from repeated applications of a nail gel containing 2.6 % of the chemical to nails in repeated insult patch test (refer to ***Sensitisation: Observations in humans***) (SCCS, 2014).

Sensitisation

Skin Sensitisation

Based on the available data the chemical is a weak sensitiser and warrants hazard classification (refer to ***Recommendation*** section).

In a study conducted according to OECD TG 429 (Skin Sensitisation: Local Lymph Node Assay), 5 female CBA/CaOlaHsd mice received topical applications the chemical in acetone/olive oil (4:1 v/v) at concentrations of 10 %, 25 %, and 50 % (w/w). The reported stimulated indices (SI) were 2.22, 2.96, and 3.46 for concentrations of 10 %, 25 %, and 50 %, respectively. The reported concentration producing a 3-fold increase in lymphocyte proliferation (EC3 value) was 27 %, indicating weak sensitisation potential (REACH; SCCS, 2014).

Observation in humans

A nail gel containing the chemical at 2.6 % was tested for its potential to induce allergic contact sensitisation in a repeated insult patch test. The chemical was applied to the nails of healthy human volunteers (51 females, 18–65 years of age) for 10 minutes. During the induction phase, this procedure was repeated 3 times per week for a total of 9 applications. After a 2-week rest period, a challenge application was applied to the nail. During the whole induction period and also after challenge, no visible nail cuticle reactions were observed (scored as grade 0). There was no indication of sensitising potential under these conditions of exposure (SCCS, 2014).

Repeated Dose Toxicity

Oral

Based on the available information, the chemical may cause adverse effects at high doses (NOAEL of 50 mg/kg bw/day). The available data for repeated dose toxicity are not sufficient to conclude on specific target organ toxicity other than reproductive system (refer to ***Reproductive and Developmental Toxicity*** section).

In a 28-day study conducted according to Japanese Ministry of Health and Welfare guidelines (1986), SD rats (5/sex/dose) were administered the chemical by oral gavage, at dose levels of 50, 250, or 750 mg/kg bw/day. Satellite groups (5/sex/dose) were treated with vehicle (control) or 750 mg/kg bw/day throughout the 28 day study period and maintained without treatment for a further 14 days. Two females died in the satellite group (1 control and 1 treated with the chemical). No signs of toxicity were seen at low dose (50 mg/kg bw/day). A dose-related impairment in health status was observed in animals in the mid- (250 mg/kg bw/day) and high-dose (750 mg/kg bw/day) groups. Clinical signs included increased salivation, red-brown staining around the snout and mouth, wet fur, red-brown staining of the fur, hair loss, piloerection, hunched posture, lethargy, ptosis and diuresis. The high-dose animals also displayed diarrhoea, abdominal distension, and vocalisation. All effects were reversible in the satellite high-dose animals after cessation of dosing. In the mid-dose (250 mg/kg day) and high-dose (750 mg/kg day) groups, reduced bodyweight gains were observed during the last week of treatment. Weight gains recovered quickly in the 750 mg/kg bw/day satellite males during the treatment free period. Food consumption was similar in all groups.

High-dose animals displayed consistent changes in blood and urine chemistry indicative of hepatic and renal abnormalities. Some effects were also reported at mid-dose. The blood and urinalysis parameter changes were reversible in the satellite animals. Relative liver weights were increased in the high- and mid-dose animals of both sexes. Relative kidney weights were increased in high-dose animals of both sexes and mid-dose males. The liver weight increase was not reversible in the high-dose satellite group while kidney weights returned to normal. Treatment-related changes in the liver and kidney histopathology were reported in the high-dose group, but not in the satellite group. The reported NOAEL was 50 mg/kg bw/day, based on liver effects, reduced body weight gain and impaired general state of health observed at 250 mg/kg bw/day (RAC, 2010c; REACH; SCCS, 2014).

In a 90-day study conducted in accordance with the Environmental Protection Agency Toxic Substances Control Act (EPA-TSCA guideline including functional observational battery and neuropathology, Wistar rats (20/sex/dose) were administered the chemical by oral gavage at doses of 0, 100, 300 or 1000 mg/kg bw/day in carboxymethyl cellulose (0.5 % aqueous solution). Two females died in the high-dose group (1000 mg/kg bw/day). Females in this group showed a reduced general state of health.

Both sexes in this group had lesions on the hairless skin of the extremities, and reddening and scale formation on the ears. Body weights were reduced in the high-dose group in both sexes and in males of the mid-dose group. Increased food consumption was reported for high-dose females. Changes in several haematological parameters indicating hepatic abnormalities were reported in males and females receiving the high-dose, and in females receving the mid-dose. High-dose females had increased absolute liver and kidney weights. Histopathological findings were not reported. Neurotoxic effects were not observed. The reported NOAEL was 100 mg/kg bw/day, based on multiple systemic effects observed in the 300 mg/kg bw/day group (RAC, 2010c).

Dermal

No data are available for this chemical.

Inhalation

No data are available for this chemical.

Genotoxicity

Based on the limited available information, the chemical is not expected to be genotoxic.

The chemical tested negative for genotoxicity in the following studies:

- In a study similar to OECD TG 471 (Bacterial reverse mutation assay), where the chemical (0 –5000 µg/plate) was tested in *Salmonella typhimurium* (*S. typhimurium*) strains TA 1535, TA 1537, TA 98, TA 100 and *Escherichia coli* (*E. coli*) WP2, with and without metabolic activation (REACH; RAC, 2010c; SCCS, 2014).
- In a study similar to OECD TG 473 (In vitro mammalian chromosome aberration test), where the chemical was tested in Chinese hamster lung cell line (CHL), with S9 for 6 hours (0–30 µg/mL) and without S9 for 6 hours (0–25 µg/mL), 24 hours (0–20 µg/mL) and 48 hours (0–20 µg/mL) (REACH; RAC, 2010c).
- In a study conducted according to OECD TG 476 (In vitro mammalian cell gene mutation test), where the chemical was tested in Chinese hamster lung fibroblasts (V29), with S9 for 4 hours (3.4–54 µg/mL first exposure; 10.0–60.0 µg/mL second exposure) and without S9 for 4 hours (1.3–40.0 µg/mL) and 24 hours (5.0–40.0 µg/mL) (REACH; SCCS, 2014).

Carcinogenicity

No data are available for the chemical.

Reproductive and Developmental Toxicity

The chemical is classified for Reproductive toxicity – Category 2; H361f (Suspected of damaging fertility). The data supports this classification, as shown by studies showing testicular atrophy in male rats.

The chemical does not show specific developmental toxicity. The developmental effect of skeletal variations was only observed secondary to maternal toxicity.

Reproductive toxicity

In a 28-day systemic toxicity study, SD rats (5/sex/dose) were administered 50, 250, or 750 mg/kg bw/day of the chemical (refer to ***Repeated Dose Toxicity*** section). All males in the high-dose group (750 mg/kg bw/day) showed testicular atrophy that was not observed in control animals. These effects were also present in the satellite group following 14-day recovery (RAC, 2010a; REACH).

In a 90-day systemic toxicity study, Wistar rats were treated at 0, 100, 300 or 1000 mg/kg bw/day (refer to ***Repeated Dose Toxicity*** section). Males in the 300 and 1000 mg/kg bw/day groups showed decreased absolute and relative testes weights and marked diffuse atrophy of the testicular parenchyma. There was no clear dose-response relationship. One male rat receiving 100 mg/kg bw/day of the chemical exhibited moderately reduced spermiogenesis, which was considered a spontaneous event and not induced by the test substance (RAC, 2010b, 2010c).

Two confirmatory studies were conducted to reproduce the stated effects of the above 90-day study on the testes.

In a 28-day study, male Wistar rats (3/dose) were administered the chemical daily at doses of 0 or 1000 mg/kg bw/day in carboxymethyl cellulose (0.5% aqueous solution) by oral gavage. No substance-related effects were found on body weight or on absolute and relative mean testes weights. No gross or histopathologic lesions were observed.

In a 90-day study, male Wistar rats (10/dose) were administered the chemical daily at doses of 0 or 1000 mg/kg bw/day in carboxymethyl cellulose (0.5% aqueous solution) by oral gavage. Substance-related effects on body weight and on the absolute and relative testes weights were reported. The testes of 8/10 treated rats were reduced in size and showed a loss of turgor, compared to control. The size of epididymis was also reduced. In all animals, the seminiferous tubules of the testes exhibited a slight to severe diffuse atrophy (mostly bilateral). In 4 animals, oedemas and minimal to slight hyperplasia of the Leydig cells were also seen. In the epididymis with reduced size, there was oligo- and azoospermia (a reduction in or absence of mature sperm) (RAC, 2010c).

Developmental toxicity

In a study conducted according to OECD TG 414 (Prenatal developmental toxicity study), pregnant Wistar female rats (22/dose) were administered the chemical by oral gavage at concentrations of 50, 150 or 500 mg/kg bw/day on days 6 to 20 post-coitum. Females treated with 500 mg/kg bw/day showed reduced body weight gain associated with decreased food consumption. Five out of 6 females receiving the highest dose showed hunched posture, piloerection and/or salivation, and increased liver weights were observed at termination. No clear signs of toxicity were observed in pregnant female rats treated with 150 mg/kg bw/day or less (REACH). There were no effects on the number of pregnant females, corpora lutea, implantation site, pre- or post-implantation loss or litter size noted with treatment up to 500 mg/kg bw/day. Female foetal weights were slightly but significantly lower compared to the control group at 500 mg/kg bw/day. A similar reduction was observed in male foetal weights, but this was not statistically significant. There were no treatment related effects on visceral morphology. The incidence of foetuses with bent limb bones, skeletal variations, reduced ossification of the skull and unossified metatarsals and metacarpals were increased significantly compared to the control group in the highest dose group. These findings were considered to be related to the decreased maternal toxicity at the highest dose. The bent limb bones were considered temporary effects rather than malformations. The NOAEL for both maternal and developmental toxicity was 150 mg/kg bw/day (REACH).

Other Health Effects

Neurotoxicity

In a 90-day study conducted in accordance with the EPA-TSCA guideline (refer to ***Repeated Dose Toxicity*** section), Wistar rats were administered the chemical by oral gavage at doses of 0, 100, 300 or 1000 mg/kg bw/day in carboxymethyl cellulose (0.5% aqueous solution). Neither functional defects nor any other signs of neurotoxicity were observed (RAC, 2010c).

Risk Characterisation

Critical Health Effects

The critical health effects for risk characterisation include the systemic long-term effect of reproductive toxicity and the local effect of skin sensitisation.

Public Risk Characterisation

The chemical is used as a photoinitiator in cosmetic nail preparations, printing inks as well as various coatings that may be available for use by the public. Therefore, the public could be exposed to the chemical.

The chemical is used as polymerisation initiator and most of the chemical is incorporated into a polymer. Therefore, only small amounts (less than 4 % of the initial chemical concentration) are expected to be bioavailable. Based on a specific human study, the chemical is not expected to be a skin sensitiser at these low concentrations (refer to ***Skin sensitisation*** section).

Considering the potential reproductive effects, the European Commission Scientific Committee on Consumer Safety (SCCS) (2014) derived the margin of safety (MOS) for use of the chemical in nail products at concentrations up to 5 %. The MOS 1515 indicated that the chemical, when used in cosmetic products, does not pose a human health risk. Higher use concentrations are not expected to be efficacious. The exposure from the domestic products is not expected to be greater. Hence, the public risk from this chemical is not considered to be unreasonable.

Occupational Risk Characterisation

During product formulation, dermal 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 chemical at lower concentrations could 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 systemic long-term and local health effects, the chemical could pose an unreasonable risk to workers unless adequate control measures to minimise dermal, ocular and inhalation exposure 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 the appropriate controls.

The data available support an amendment to the hazard classification in the Hazardous Chemical Information System (HCIS) (Safe Work Australia) (refer to **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.

Regulatory Control

Work Health and Safety

The chemical is 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]
Sensitisation	Not Applicable	May cause an allergic skin reaction - Cat. 1B (H317)
Reproductive and Developmental Toxicity	Not Applicable	Suspected of damaging fertility - Cat. 2 (H361f)*

[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 dermal exposure to the chemical 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 that could minimise the risk include, but are not limited to:

- using closed systems or isolating operations;
- health monitoring for any worker who is at risk of exposure to the chemical, 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 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 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 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.

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