



1-Propanol: Human health tier II assessment

22 March 2013

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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.

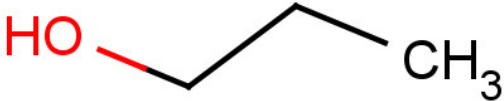
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Acronyms & Abbreviations

Chemical Identity

Synonyms	n-Propyl alcohol 1-Hydroxypropane Albacol Ethylcarbinol Propylic alcohol
Structural Formula	
Molecular Formula	C3H8O
Molecular Weight (g/mol)	60.095
Appearance and Odour (where available)	A clear, colourless liquid with a mild alcoholic odour.
SMILES	C(O)CC

Import, Manufacture and Use

Australian

The following Australian industrial uses were reported under previous mandatory and/or voluntary calls for information.

The chemical has reported use as a cosmetic ingredient.

The chemical has reported commercial use as a solvent.

The chemical is listed on the 2006 High Volume Industrial Chemicals List (HVICL) with a total reported volume between 1000 and 10,000 tonnes.

International

The following international uses have been identified through the 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 & eChemPortal—OECD High Production Volume chemical program (OECD HPV), the US Environmental Protection Agency's (EPA) Aggregated Computer Toxicology Resource (ACToR) and the 2012 Chemical Data Reporting (US EPA) database, and the US National Library of Medicine's Hazardous Substances Data Bank (HSDB):

The chemical has reported cosmetic use as:

- solvent for perfume substrates;
- anti-foaming;
- antiseptic properties; and
- soaps and nail polish.

The chemical has reported domestic use including:

- arts, craft and hobby material;
- disinfectants;
- washing/cleaning agents;
- paints;
- coating materials;
- enamel; and
- lacquer paints.

The chemical has reported commercial use including:

- carrier and extraction solvent for natural products such as flavourings, vegetable oils, resins, waxes, and gums;
- solvent for synthetic polymers such as polyvinyl butyral, cellulose esters, lacquers, and polyvinyl chloride (PVC) adhesives; and
- used in the flexographic inks and dyeing wool.

The chemical has reported site-limited use including:

- chemically processed to produce intermediates such as propyl amines, carboxylic acid, esters and halogenated products, which in turn are used in the synthesis of herbicides and pharmaceuticals.

The following non-industrial uses have been identified:

- pharmaceutical products.

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 phrases for human health in the Hazardous Substances Information System (HSIS) (Safe Work Australia):

Xi; R41 (Risk of serious damage to eyes)

Xi; R36 (Irritating to eyes)

R67 (Vapours may cause drowsiness and dizziness)

Exposure Standards

Australian

Time weighted average (TWA): 492 mg/m³ (200 ppm)

Short term exposure limit (STEL): 614 mg/m³ (250 ppm)

International

TWA: 500 mg/m³ (200 ppm), STEL: 625 mg/m³ (250 ppm) [Canada, Denmark, Egypt, France, Greece, Mexico, Phillipines, South Africa, Spain, Switzerland, United Kingdom and USA]

TWA: 350 mg/m³ (150 ppm), STEL: 600 mg/m³ (250 ppm) [Estonia and Sweden].

Health Hazard Information

Toxicokinetics

The chemical is rapidly absorbed and excreted.

In a study reported in the European Union Risk Assessment Report (ECB, 2008) a single oral dose of 174 mg of the radioactively labelled chemical was administered via gavage to Wistar rats. Total recovery of 80% in 72 hours after dosage was observed. The chemical was eliminated via expired air (74%), urine (5%) and faeces (0.4%). The radioactivity in tissues after 6 hours after from dosing, was found in: blood (0.4), brain (0.2), heart (0.3), kidney (0.7) and liver (1.3) in $\mu\text{mol/g}$ tissue.

In another study also reported in the ECB (2008), after oral doses with 1000, 2000 and 4000 mg/kg to mice, the chemical was below detection limits in blood after 40 minutes for the lowest dose and 80 minutes for the two higher doses. An estimated half life of 57 minutes was determined.

According to the ECB (2008), it may be assumed that human absorption of the chemical would be similar to measured tissue/gas partition coefficients of aliphatic C1-C4 alcohols (ethanol and butanol) being 40 - 50%. In a topical antiseptic containing 9-15 g of the chemical, 0.2 to 0.4 mg/L of the chemical was found in the blood, indicating absorption through the skin. When ingested, blood levels peaked 30 - 60 minutes after drinking, indicating rapid absorption from the gastrointestinal tract.

The chemical is readily metabolised to propionic acid; metabolism may be inhibited by already present ethanol in the system.

Acute Toxicity

Oral

The chemical was reported to have low acute toxicity via the oral route (LD50 in rats > 2000 mg/kg bw).

In a reliable study (REACH, 2012), five male albino rats per dose were administered 2520, 5000, 10000 and 20000 mg/kg bw of the chemical by oral gavage and observed for 14 days. No animals died in the low dose group. Deaths were observed in the 5000, 10000 and 20000 mg/kg bw groups (two died after two days, all died after one day, and all animals died after four hours respectively). Hyperaemia and distension of the stomach and intestines were observed in all rats which died during the observation period, whereas none of the surviving rats exhibited any gross lesions upon pathological examination. A LD50 of 5400 mg/kg bw was determined.

The ECB (2008) reports a LD50 value for mice of 5467 mg/kg bw and for rabbits of 2823 mg/kg bw.

Dermal

The chemical was reported to have low acute toxicity via the dermal route (LD50 in rabbits 4032 mg/kg bw).

In a study (REACH, 2012), that was equivalent to the OECD Guideline 402 (Acute Dermal Toxicity) four males NZ giant albino rabbits/dose, were exposed to up to 20 mL/kg bw of the chemical via 24 hour occlusive patch, with a 14 day observation period. There were no data on clinical signs or gross pathology. A dermal LD50 value of 4032 mg/kg bw was reported.

Inhalation

The chemical is currently classified with the risk phrase 'Vapours may cause drowsiness and dizziness (R67)' in Australia (Safe Work Australia – HSIS). The data available support this classification.

In an acute toxicity study (REACH, 2012) via the inhalation route, equivalent to OECD Guideline 403 (Acute Inhalation Toxicity), five animals/sex/dose Sprague Dawley rats were whole body vapour exposed to 5185, 9741 and 13548 ppm of the chemical for four hours with a 14 day observation period. Clinical signs included nasal, respiratory and eye irritation, hypoactivity, as well as reduced pain reflex. Central nervous system depression was clearly seen at 9741 ppm with narcosis within two hours of exposure. No mortality or gross pathological lesions were observed. An LC50 value of >13548 ppm was reported.

An inhalation toxicity study was performed on six animals/sex/dose of Wistar rats, using whole body aerosol inhalation for three (62.48 mg/L) or eight hour (51.91 mg/L) exposures and one week observation period, following the dose. No deaths occurred at the three hour exposure, and one occurred at the eight hour exposure. Clinical signs were irritation of mucous membranes,

decrease of pain reflex and by end of exposure, all animals were in deep narcosis for both exposure times. All signs of toxicity had disappeared after 24 hours. No gross pathological findings were observed after animals were sacrificed at the end of the study, although from the animal that died, acute dilation and congestion was seen in the heart and the lungs were filled with blood and slight oedema was observed (REACH, 2012).

In a poorly described study (REACH, 2012), six animals /sex/dose rats were exposed to 4000 ppm of the chemical vapour for four hours with a 14 day observation period. Two animals out of six died within 14 days although no clinical or gross pathological data were available. An LC50 of 4000 ppm was reported.

On a weight of evidence basis, the data available support the current classification.

Observation in humans

One woman died within five hours after drinking 500 mL (401g) of the substance that was a solvent in hair lotion (ECB, 2008). It was mentioned that ingestion of this solution occurred more than once in the past. An autopsy revealed lung oedema and a swollen brain. Death could have been contributed by other unknown components in the hair lotion. From this study, the lethal dose of the chemical was estimated to be between 4600 - 5770 mg/kg bw.

Corrosion / Irritation

Respiratory Irritation

There were several reports for the RD50 from mice reported in the ECB (2008) and the chemical was considered a very weak sensory irritant. As a result classification for respiratory irritation is not considered appropriate.

The RD50 was reported to have been calculated as 12704 ppm (31760 mg/m³) when a range of concentrations were tested for 10 minutes in one study. In another study the RD50 value was 17967 ppm (44230 mg/m³) for sensory irritation and 15593 ppm (38980 mg/m³) for pulmonary irritation during a 30 minute exposure study.

Skin Irritation

The chemical was reported to not cause skin irritation.

In a study (REACH, 2012) that was similar to OECD Guideline 404 (Acute Dermal Irritation / Corrosion), two male Vienna rabbits were exposed to 1 mL of the chemical using an occlusive patch for one, five or 15 minutes on the dorsal skin and 20 hours on the ear (no washing after exposure), with an eight day observation period. The reported oedema score was zero for both the 15 minute and 20 hour exposure and erythema score was 0.17 for the 15 minute exposure and 0.33 for the 20 hour exposure. Following the 20 hour exposure, which is beyond the four hour guideline recommended exposure period, flaky skin was observed in one of two animals. Mild desquamation developed in the same animal by day seven and was still present on day nine at termination of the study.

The study showed that the chemical is not irritating to the skin.

Eye Irritation

The chemical is currently classified with the risk phrase 'Risk of serious damage to eyes' (Xi; R41) in Australia (Safe Work Australia 2012). The only available data are sourced from animal studies with limitations, and do not support this classification. In the absence of more comprehensive information, the current HSIS classification is warranted based on the observations in humans.

In an eye irritation study (REACH, 2012), 0.05 mL of the chemical was applied to the conjunctival sac of one eye (not washed out) of two male Vienna rabbits which were observed up to ten days. Average scores for corneal opacity (1.7), iris lesion (1),

conjunctivae (1.5) and chemosis (1.5) were reported. Although the effects on the iris were fully reversible within the observation period, effects on the corneal opacity and redness of conjunctivae was present in both animals, and swelling was present in only one animal, by the end of the observation period. Given the observation period did not extend to 21 days, it is difficult to conclude any findings on the reversibility of the irritation.

In another study reported in the REACH (2012), eye irritation was only partially reversible within a 14 day observation period. Effects on the cornea persisted in four out of six rabbits.

Observation in humans

Notable erythema formation occurred in seven out of ten subjects when their forearms were immersed in water at 33 degrees Celsius for ten minutes and then exposed to a closed patch of 0.3 mL of the chemical for ten minutes. Non-hydrated forearms with the same exposure did not react.

Accidental exposure to the chemical caused the formation of vacuoles on the cornea but did not result in scar formation. This observation supports the hazard classification of R41 (Risk of serious damage to eyes) (ECB, 2008).

Sensitisation

Skin Sensitisation

The chemical was reported to not cause skin sensitisation.

In a guinea pig maximisation study (REACH, 2012) that was similar to OECD Guideline 406 (Skin Sensitisation), Hartley guinea pigs exposed to intradermal and topical induction and then challenged by an occlusive patch for 24 hours, showed zero reactions out of 15 test animals.

Observation in humans

In one study, all 50 volunteers showed negative responses when exposed by patch testing with 24 hour applications of 0.2 mL of the chemical (9 times over the period of 3 weeks) and then challenged 10 to 14 days later (ECB, 2008).

In another report, one female laboratory worker who was primarily exposed to the commercial chemical had a positive patch test reaction to 50% of both 1-propanol and 2-propanol, but not to primary alcohols with less than three carbon atoms and other substances (ECB, 2008).

Although one female worker demonstrated allergic skin reactions after patch testing to the chemical, based on the the weight of human and animal evidence, the chemical is a not considered a skin sensitiser.

Repeated Dose Toxicity

Oral

Available studies are of limited reliability and hence cannot be used to derive a reliable NOAEL. However, the test results indicate low repeated dose toxicity.

In a limited repeat dose oral toxicity study on male rats exposed to drinking water containing a nominal dose of 3000 mg/kg bw/day of the chemical for 4 months, no relevant toxic effects were observed (ECB, 2008). The limited parameters investigated included: body weight, food and water consumption, liver weight and histology. No inflammation or cirrhosis were observed in the liver and a NOAEL of 3000 mg/kg bw/day was reported.

Dermal

There are no data available.

Inhalation

No adverse systemic effects were reported in the available repeat dose studies via the inhalation route.

The chemical was not reported to cause signs of repeat dose toxicity via the inhalation route for Wistar rats exposed by nose only, to vapour at 8000 mg/m³ of the chemical, following the OECD Guideline 413 (Sub chronic Inhalation Toxicity: 90-Day) 1981 (REACH, 2012). A NOAEC of >8000 mg/m³ was calculated based on the highest dose tested.

In another repeat dose toxicity study via the inhalation route (ECB, 2008), Sprague Dawley rats were exposed to 100, 500 and 1000 ppm for six hours/day, four days/week, up to two weeks (nine exposure days). No mortalities occurred during the study, although clinical observations such as lightly swollen periocular tissue, minimal perinasal and periocular encrustations in the 1000 ppm exposure group were noted. A NOAEC of 500 ppm was reported based on local irritation.

Observation in humans

In a study reported in the ECB (2008), after twenty volunteers rubbed 5 ml of 50% of the chemical into their hands, 15 times a day, five days a week for two weeks, a slight, yet significant effect on appearance, intactness and turgor of the skin was produced. In addition, taking into account the defatting solvent character of this chemical the ECB (2008) proposed classification with R66 (Repeated exposure may cause skin dryness or cracking).

Genotoxicity

The chemical was negative in several in vitro genotoxicity studies (ECB, 2008). There are no reliable in vivo studies.

An Ames test in *Salmonella typhimurium* (TA 98, 100, 1535 & 1537) and *Escherichia coli* (WP2 uvr A), with and without S9 mix, following the OECD Guideline 471 (Bacterial Reverse Mutation Assay) was negative. In vitro studies in mammalian Chinese hamster ovary (CHO) cells with and without S9 mix, following the OECD Guideline 476 (In vitro Mammalian Cell Gene Mutation Test), was negative. Another in vitro study in mammalian Chinese hamster lung fibroblasts (V79) cells with and without S9 mix, following the OECD Guideline 473 (In vitro Mammalian Chromosome Aberration Test), was also negative.

Carcinogenicity

There is no valid carcinogenicity study available (REACH, 2012), (ECB, 2008).

Reproductive and Developmental Toxicity

Reproductive and developmental effects were observed secondary to maternal toxicity and at high doses that do not warrant classification. Therefore, the chemical is not a specific reproductive or developmental toxin.

In a whole body exposure study reported in the ECB (2008), female rats for seven hours/day on gestation days 1 – 20 and male rats for seven hours/day for six weeks to 0, 3500 ppm (8730 mg/m³) and 7000 ppm (17460 mg/m³) of the chemical. While the highest dose caused reduced maternal weight gain and feed intake, no maternal toxicity was seen at 3500 ppm. Exposure of males rats to 7000 ppm of the chemical caused reversible infertility with only two litters resulting from 16 sperm positive female rats. Thirteen weeks following exposure, fertility reversed in the retained male rats. A NOAEC of 3500 ppm (8730 mg/m³) was reported based on fertility effects. However, given the high dose of exposure (calculated to be equivalent to an oral uptake of 5800 mg/kg bw/day at 7000 ppm) no classification is warranted for this endpoint.

A developmental toxicity study reported in the ECB (2008) used pregnant Sprague-Dawley rats exposed whole body to 0, 3500, 7000, and 10000 ppm (0, 8730, 17460 and 24940 mg/m³, respectively) of the chemical for seven hours per day on gestation days 1 – 19. No clinical effects were observed in dams. At 7000 ppm feed intake was reduced during the last two weeks of gestation and at the highest dose feed intake was reduced throughout gestation. Maternal body weight was significantly affected at the end of gestation (details not available).

No developmental effects were observed at 3500 ppm. At 7000 ppm, fetuses were observed with significantly lower body weights than controls and a higher incidence of skeletal malformations. At the 10000 ppm exposure level, higher incidence of external malformation (missing tail or ectrodactyly in one third of fetuses), an increase in the incidence of skeletal malformation, cardiovascular or urinary defects and the incidence of resorptions (57% reabsorbed compared to 6% in controls) were observed. A NOAEC of 3500 ppm was derived based on foetal body weight reduction and higher incidence of skeletal malformations.

Developmental toxic effects were seen at high exposure levels that are maternally toxic and are considered to be secondary to the maternal toxicity. Given the high doses resulting in both maternal and developmental toxicity, no classification is warranted for this endpoint.

Risk Characterisation

Critical Health Effects

The main critical effects to human health are the potential for serious damage to eyes and intoxication symptoms following inhalation of high vapour concentrations. The chemical may also cause skin dryness or cracking on repeat dermal exposure.

Public Risk Characterisation

The chemical is not currently listed in the Poisons Standard (SUSMP) and there are no restrictions to use this chemical in Australia.

Exposure to the public could occur in the use of cosmetics containing this chemical. Overseas the chemical is used in domestic products such as arts, craft and hobby material, disinfectants, washing/cleaning agents and paint. A recent industry survey by the US Environmental Protection Agency (US EPA 2012) found that the chemical is being used at concentrations between 30% and 60% in arts, crafts and hobby materials.

An internet search for similar products in Australia confirm that some art and craft products contain concentrations of the chemical above 10%. While whiteboard markers containing the chemical may not deliver the chemical in a manner that could cause eye exposure, where the chemical is used in surface cleaning sprays, this would be of concern.

Concentrations of the chemical $\geq 10\%$ are considered to cause serious eye damage with eye exposure, while concentrations $\geq 5\%$ and $< 10\%$ are considered to cause eye irritation (Safe Work Australia).

Occupational Risk Characterisation

Occupational exposures occur primarily in the production and use of the chemical as a solvent in resins, lacquers, PVC adhesives and when chemically processed to produce intermediates for future synthesis of herbicides and pharmaceuticals.

Given the critical health effects, the risk to workers from this chemical is considered low if adequate control measures to minimise occupational exposure to the chemical are implemented. The chemical should be appropriately classified and labelled to ensure that a person conducting a business or an employee at a workplace has adequate information to determine appropriate controls. The existing hazard classification for worker health and safety should be amended as recommended.

NICNAS Recommendation

Further risk management is required. Sufficient information is available to recommend that risks to public health and safety from the potential use of the chemical in cosmetics and/or domestic products be managed through changes to poisons scheduling, and risks for workplace health and safety be managed through changes to classification and labelling.

Assessment of the chemical is considered to be sufficient provided that risk management recommendations are implemented and all requirements are met under workplace health and safety and poisons legislation as adopted by the relevant state or territory.

Regulatory Control

Public Health

It is recommended that the use of this chemical in cosmetics and domestic products such as arts, craft and hobby material be controlled through scheduling. Matters for consideration for scheduling are:

- use of the chemical in cosmetic products and potential use in domestic products (eg. art and craft products) in Australia. Concentration in cosmetic products is unknown;
- use of the chemical in a range of domestic products overseas. Use concentration in some products is up to 60%;
- risk of serious eye damage at high concentrations.

Work Health and Safety

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

Hazard	Approved Criteria (HSIS) ^a	GHS Classification (HCIS) ^b
Acute Toxicity	Vapours may cause drowsiness and dizziness (R67)*	May cause drowsiness or dizziness - Specific target organ tox, single exp Cat. 3 (H336)
Irritation / Corrosivity	Risk of serious eye damage (Xi; R41)*	Causes serious eye damage - Cat. 1 (H318)
Repeat Dose Toxicity	Repeated exposure may cause skin dryness or cracking (R66)	Repeated exposure may cause skin dryness and cracking (AUH066)

^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 label instructions.

Advice for industry

Control measures

Control measures to minimise the risk from dermal, ocular and inhalation 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 storage, handling and use of a hazardous chemical are dependent 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:

- use of local exhaust ventilation to prevent the chemical from entering the breathing zone of any worker;
- air monitoring to ensure control measures in place are working effectively and continue to do so;
- minimisation of manual processes and work tasks through automation of processes;
- work procedures that minimise splashes and spills;
- regular cleaning of equipment and work areas; and
- use of 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 be relied upon on its own to control risk and should only be used when all other reasonably practicable control measures do not eliminate or sufficiently minimise risk. Guidance in selection of 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 hazardous chemical are prepared; and
- management of risks arising from storage, handling and use of 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 physical hazards of the chemical has not been undertaken as part of this assessment.

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