



Government
of Canada

Gouvernement
du Canada

PROPOSED RISK MANAGEMENT APPROACH

for

Naphthalene

Chemical Abstract Service (CAS) Registry Number:
91-20-3

Environment Canada
Health Canada

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Canada

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This proposed risk management approach document builds on the previously released risk management scope document for naphthalene, and outlines the proposed control actions for this substance. Stakeholders are invited to submit comments on the content of this proposed risk management approach or provide other information that would help to inform decision making. Following this consultation period, the Government of Canada will initiate the development of the specific risk management instrument(s) where necessary. Comments received on the proposed risk management approach will be taken into consideration in developing the instrument(s). Consultation will also take place as instrument(s) are developed.

1. ISSUE

1.1 Categorization and the Challenge to Industry and Other Stakeholders

The *Canadian Environmental Protection Act, 1999* (CEPA 1999) (Canada 1999) requires the Minister of the Environment and the Minister of Health (the Ministers) to categorize all substances on the *Domestic Substances List* (DSL). Categorization involves identifying those substances on the DSL that a) are considered to be persistent (P) and/or bioaccumulative (B), based on the criteria set out in the *Persistence and Bioaccumulation Regulations*, and “inherently toxic” (iT) to humans or other organisms, or b) present, to individuals in Canada, the greatest potential for exposure (GPE). In addition, the Act requires the Ministers to conduct screening assessments of substances that meet the categorization criteria. The assessment further determines whether the substance meets the definition of “toxic” set out in section 64 of CEPA 1999.

In December 2006, the Challenge identified 193 chemical substances through categorization which became high priorities for assessment due to their hazardous properties and their potential to pose risks to human health and the environment. In February 2007, the Ministers began publishing, for industry and stakeholder comment, profiles of batches containing 15 to 30 high-priority substances. New batches are released for comment every three months.

In addition, the mandatory information-gathering provisions under section 71 of CEPA 1999 are being used under the Challenge to gather specific information where it is required. The information that is collected through the Challenge will be used to make informed decisions and appropriately manage any risks that may be associated with these substances.

The substance naphthalene, Chemical Abstract Service (CAS) Registry Number 91-20-3, referred to throughout this document by “naphthalene”, was included in Batch 1 of the Challenge under the Chemicals Management Plan.

1.2 Final Screening Assessment Report Conclusion for Naphthalene

A Notice summarizing the scientific considerations of a final screening assessment report was published by Environment Canada and Health Canada in the *Canada Gazette*, Part I, for naphthalene on July 5, 2008, under subsection 77(6) of CEPA 1999. The final screening assessment report (Canada 2008) concludes that naphthalene is entering or may be entering the

environment in a quantity or a concentration or under conditions that constitute or may constitute a danger in Canada to human life or health.

Assessments conducted by several international and national agencies indicate that a critical effect for the characterization of risk to human health for naphthalene is carcinogenicity, based on the observation of respiratory tract tumours in rodents. Naphthalene was also found to be genotoxic in some assays. Therefore, although the mode of induction of tumours has not been fully elucidated, it cannot be precluded that the tumours observed in experimental animals resulted from direct interaction with genetic material. In addition, the upper-bounding concentration of naphthalene in indoor air may approach the critical effect level for non-cancer effects of the respiratory system. On the basis of the carcinogenicity of naphthalene, for which there may be a probability of harm at any level of exposure, as well as the potential inadequacy of the margin between the upper-bounding concentration of naphthalene in indoor air and the critical effect level for non-cancer effects, it is concluded that naphthalene is a substance that may be entering the environment in a quantity or concentration or under conditions that constitute or may constitute a danger in Canada to human life or health.

The final screening assessment report also concluded that naphthalene is not entering the environment in a quantity or concentration or under conditions that have or may have an immediate or long-term harmful effect on the environment or its biological diversity, or that constitute or may constitute a danger to the environment on which life depends. Additionally, naphthalene does not meet the criteria for persistence and does not meet the criteria for bioaccumulation as defined by the *Persistence and Bioaccumulation Regulations* (Canada 2000) made under CEPA 1999. The presence of naphthalene in the environment results primarily from human activity.

For further information on the final screening assessment report conclusion for naphthalene, refer to the final screening assessment report, available at http://www.chemicalsubstanceschimiques.gc.ca/challenge-defi/batch-lot_1_e.html.

1.3 Proposed Measure

Following a screening assessment of a substance under section 74 of CEPA 1999, a substance may be found to meet the criteria under section 64 of CEPA 1999. The Ministers can propose to take no further action with respect to the substance, add the substance to the Priority Substances List (PSL) for further assessment, or recommend the addition of the substance to the List of Toxic Substances in Schedule 1 of CEPA 1999. Under certain circumstances, the Ministers must make a specific proposal either to recommend addition to the List of Toxic Substances or to recommend the implementation of virtual elimination (or both). In this case, the Ministers proposed to recommend the addition of naphthalene to the List of Toxic Substances in Schedule 1 of CEPA 1999. As a result, the Ministers will develop a regulation or instrument respecting preventive or control actions to protect the health of Canadians and the environment from the potential effects of exposure to this substance.

The final screening assessment report did not conclude that naphthalene meets the conditions set out in subsection 77(4) of CEPA 1999. As a result, naphthalene will not be subject to the virtual elimination provisions under CEPA 1999 and will be managed using a life-cycle approach, to prevent or minimize its release into the environment.

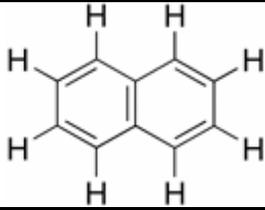
2. BACKGROUND

2.1 Substance Information

Naphthalene is part of the chemical grouping, discrete organics, and the chemical sub grouping, aromatic.

Table 1 presents other names, trade names, chemical groupings, the chemical formula, the chemical structure, and the molecular mass for naphthalene.

Table 1. Identity of naphthalene

CAS Registry Number	91-20-3
DSL name	Naphthalene
Inventory names	Naphthalene (TSCA, EINECS, ENCS, AICS, ECL, SWISS, PICCS, ASIA-PAC, NZIoC) NAPHTHALENE SCALES (PICCS)
Other names	Albocarbon; Camphor Tar; Dezodorator; Mighty 150; Mighty RD1; Moth Balls; Moth flakes; Naftalen; Naphtalene; Naphthalin; Naphthaline; Naphthene; Tar Camphor; White tar
Chemical group	Discrete organics
Chemical sub-group	Aromatic
Chemical formula	$C_{10}H_8$
Chemical structure	
SMILES	<chem>c(c(ccc1)ccc2)(c1)c2</chem>
Molecular mass	128.18 g/mol

¹ From NCI 2007: AICS (Australian Inventory of Chemical Substances); ECL (Korean Existing Chemicals List); EINECS (European Inventory of Existing Chemical Substances); ELINCS (European List of Notified Chemical Substances); ENCS (Japanese Existing and New Chemical Substances); PICCS (Philippine Inventory of Chemicals and Chemical Substances); TSCA (Toxic Substances Control Act Chemical Substance Inventory); ASIA-PAC (Combined Inventories from the Asia-Pacific Region); NZIoC (The New Zealand Inventory of Chemicals).

3. WHY WE NEED ACTION

3.1 Characterization of Risk

Based principally on the weight-of-evidence based assessments of several international and national agencies (IARC 2002; EURAR 2003; US EPA 1998; NTP 2004), a critical effect for

characterization of risk to human health is carcinogenicity. Although a mode of action for induction of tumours has not been fully elucidated, it cannot be precluded that the tumours observed involved direct interaction with genetic material.

With respect to non-cancer effects, the lowest identified concentrations at which effects were observed in animals were 5 mg/m³, in a 4-week inhalation study with rats (Huntingdon Research Centre 1993b) and 10 mg/m³, in a 13-week inhalation study with rats (Huntingdon Research Centre 1993a). These effect concentrations are 32 to 63 times higher, respectively, than the upper-bounding concentration of naphthalene in indoor air (158.05 µg/m³) in Canada (Health Canada 2008). Comparison of the same effect levels to the 90th percentile concentrations measured in indoor air (9.405 µg/m³ – Health Canada 2008) result in margins between critical effect levels for non-cancer effects and exposure to the general population via inhalation of 532 to 1063. These margins may not be adequate to account for uncertainties in the database on exposure and effects. For example, the indoor air survey (Health Canada 2008) was conducted in non-smoking homes; smoking households may potentially have higher indoor air concentrations of naphthalene. Additionally, dermal exposure from use of consumer products could contribute to exposure to the general population.

4. CURRENT USES AND INDUSTRIAL SECTORS

Naphthalene is found in eroded geologic deposits of lignite, anthracite, bituminous and sub-bituminous coal. Responses to a section 71 survey of CEPA 1999 conducted in 2000, indicated there were 13 manufacturers and 18 importers of naphthalene in Canada, a total of 25 companies from both sets of respondents that specified their products which contain naphthalene and associated uses of these products. In all, Canadian companies reported manufacturing more than 52 000 000 kg of naphthalene and importing more than 150 000 000 kg into the country (Environment Canada, 2006).

According to submissions made under section 71 of CEPA 1999, from the Challenge questionnaire submission and other data voluntarily submitted (Environment Canada 2006), naphthalene is reported to be used in the petroleum sector as an oilfield chemical, solvent, refinery cleaner, fuel additive and feedstock. Other non-petroleum stream uses that were reported included its use as a solvent and intermediate in automotive paint manufacturing and driveway sealants, in pest control products such as moth repellants, as a chemical intermediate in the manufacture of pharmaceutical, agricultural and construction products, and as a feedstock for the production of naphthalene sulfonate plasticizers and surfactants. Consumer product uses of naphthalene may include some commercially available paints, stains and coatings (NIH 2007).

In Canada, four end-use products containing naphthalene are registered for use as moth repellents under the *Pest Control Products Act* (PMRA 2007). Naphthalene was reported in two notifications of cosmetic products (wig glue removers) filed with Health Canada under the *Cosmetic Regulations* of the *Food and Drug Act* (Health Canada, Product Safety Programme; personal communication, September 2007; unreferenced). Naphthalene is also a component of tobacco combustion products

5. PRESENCE IN THE CANADIAN ENVIRONMENT AND EXPOSURE SOURCES

5.1 Releases to the Environment

The National Pollutant Release Inventory (NPRI) reports that 120 tonnes of naphthalene were released by Canadian industries in 2005, with 34 out of 73 facilities reporting releases. The top four releasing facilities were located in Ontario (NPRI 2007).

5.2 Exposure Sources

The final screening assessment report indicates that Canadians may be exposed to naphthalene through air, water, soil, food and consumer products. The major source of exposure is indoor air, accounting for up to 99.0% of the total daily intake across all age groups. A Health Canada survey of homes in Windsor, Canada in 2005 and 2006 (Health Canada 2008) identified maximum indoor air concentrations of $158.05 \mu\text{g}/\text{m}^3$. The corresponding mean and 90th percentile values from this study were significantly lower (6.778 and $9.405 \mu\text{g}/\text{m}^3$ respectively). Another Health Canada study conducted in Ottawa, Canada (Zhu et al. 2005) reported maximum indoor air concentrations of $144.44 \mu\text{g}/\text{m}^3$. The corresponding arithmetic mean and 90th percentile values from this study were also significantly lower (3.87 and $4.75 \mu\text{g}/\text{m}^3$ respectively). The maximum value from the Windsor survey was considered to be more appropriate for use in deriving upper-bounding estimates of intake than the maximum value of $398.70 \mu\text{g}/\text{m}^3$ as reported in an earlier Canadian survey (Fellin et al. 1992), as it is considered to be more representative of current exposures. However, the Windsor survey was conducted on non-smoking homes and since cigarette smoke is a source of naphthalene, smoking households may potentially have higher indoor air concentrations than those reported above for non-smoking homes. Therefore it is considered appropriate to use the maximum values in deriving upper-bounding estimates of exposure.

Measured values of indoor air and ambient air are believed to generally capture emissions from consumer products and other sources such as migration of volatile organic compounds from attached garages (Batterman et al. 2007). It is notable that air concentrations of $520\text{--}820 \mu\text{g}/\text{m}^3$ were reported in a limited study which simulated moth ball use in 3 homes (ECB 2003). Relevance of this data to the Canadian use pattern for moth balls is uncertain. Dermal exposure to naphthalene from use of consumer products containing naphthalene can contribute to general population exposure.

Responses to the 2007 Challenge questionnaires and requests for other information indicated concentration ranges for naphthalene in various consumer and industrial use products, excluding moth repellents, up to 13%. Additional information from Health Canada's Cosmetics Division, notes its presence in cosmetic products (wig glue removers) within a concentration range of 30–100%.

6. OVERVIEW OF EXISTING ACTIONS

6.1 Existing Canadian Risk Management

Naphthalene is subject to:

- the *Export and Import of Hazardous Waste and Hazardous Recyclable Waste Regulations*;
- the *Feeds Regulations*;
- the *Controlled Products Regulations* established under the *Hazardous Products Act*, requiring that any ingredient on the Ingredient Disclosure List be disclosed on the Material Safety Data Sheet;
- the *Consumer Chemicals and Containers Regulations, 2001* established under the *Hazardous Products Act*, requiring that products be classified against criteria based on short-term exposure situations, with the results determining the appropriate product labeling and packaging requirements;
- the *Canada Shipping Act*;
- regulations under the *Food and Drugs Act*;
- the *Pest Control Products Act*, under which it is currently listed as an active ingredient as well as a formulant (a component of petroleum distillates) in pesticides, and is scheduled for reassessment, completion target, late 2008; and
- CEPA 1999's *Environmental Emergency Regulations*, proposed addition.

In addition, the Ontario Ministry of the Environment has established a half-hour point of impingement standard of $36 \mu\text{g}/\text{m}^3$, based on odour, and a 24-hour ambient air quality guideline of $22.5 \mu\text{g}/\text{m}^3$, based on health.

6.2 Existing International Risk Management

The United States, most European countries, and many other countries have various guidelines in place for naphthalene in occupational settings, environmental media and consumer products. A cursory review indicates guidelines for drinking water ranging from 6.8 to $500 \mu\text{g}/\text{L}$, and for soils, 0.05 to $1300 \mu\text{g}/\text{g}$. Use rates specified for moth repellents have been cited at levels of 165 to $330 \text{ g}/\text{m}^3$ (ECB 2003). The European Union (European Commission 2005) has set a health-based long-term exposure limit of $10 \mu\text{g}/\text{m}^3$ for air, and the Netherlands (Dusseldorp et al 2007), a health-based guideline value of $25 \mu\text{g}/\text{m}^3$ for the indoor environment.

7. CONSIDERATIONS

7.1 Alternative Chemicals or Substitutes

No information on alternative chemicals or substitutes is available.

7.2 Alternative Technologies and/or Techniques

Several U.S. companies now manufacture naphthalene-free paint formulations and solvents for both industrial and consumer applications. Various other processes have been highlighted which minimize releases of naphthalene from coke production, wastewater treatment, wood-treating processes and treated wood products, and motor boat engines.

7.3 Socio-economic Considerations

Where information was available, socio-economic factors have been considered, at least in a qualitative manner, in the selection process for an instrument respecting preventive or control

actions, and in the development of the risk management objective(s). Socio-economic factors will also be considered in the development of regulations, instrument(s) and/or tool(s) as identified in the *Cabinet Directive on Streamlining Regulation* (Treasury Board of Canada Secretariat 2007) and the guidance provided in the Treasury Board document *Assessing, Selecting, and Implementing Instruments for Government Action*.

7.4 Children's Exposure

In screening assessments, potential exposure of the general population, including infants and children, is estimated. To the extent possible, based on available data, exposure to naphthalene from multiple routes (i.e., inhalation, ingestion and contact on the skin) and possible sources (ambient air, indoor air, drinking water, food, beverages - including breast milk and formula for infants - soil, and in some instances consumer products) is estimated. Infants and children's exposure is characterized by their unique physiology (e.g., intake of air, food and water relative to body size) and generally known behaviour characteristics (e.g. crawling versus walking, mouthing activity).

As part of the Challenge, the Government asked industry and interested stakeholders to submit any information on the substance that may be used to inform risk assessment, risk management and product stewardship. In particular, stakeholders were asked through a questionnaire if any of the products containing the substance were intended for use by children. Given the information received, and other data considered, it is proposed that no additional risk management actions to specifically protect children are required for this substance at this time.

8. PROPOSED OBJECTIVES

8.1 Environmental or Human Health Objective

An environmental or human health objective is a quantitative or qualitative statement of what should be achieved to address environmental or human health concerns identified during a risk assessment. The proposed human health objective for naphthalene is to minimize, to the extent practicable, exposure to naphthalene and hence risk to human health associated with this substance.

8.2 Risk Management Objective

A risk management objective is a target expected to be achieved for a given substance by the implementation of risk management tool(s) and/or instrument(s). The risk management objective is to reduce exposure to naphthalene.

9. PROPOSED RISK MANAGEMENT

9.1 Proposed Risk Management Instrument(s) and/or Tool(s)

As required by the Government of Canada's *Cabinet Directive on Streamlining Regulation*², and criteria identified in the Treasury Board document entitled *Assessing, Selecting, and Implementing Instruments for Government Action*, the proposed risk management regulations, instrument(s) and/or tools(s) were selected using a consistent approach, and took into consideration the information that has been received through the Challenge and other information available at the time.

In order to achieve the risk management objective and to work towards achieving the human health objective, the risk management being considered for naphthalene pertains to minimization of naphthalene in indoor air, particularly potential contributions from consumer products. Additional actions are focused on moth repellents, foods, food packaging, therapeutic products, homeopathic preparations, and cosmetics.

9.1.1 Naphthalene Releases from Consumer Products

Health Canada will undertake investigations to better characterize controllable sources of naphthalene in indoor air in order to design effective risk management measures. This will include determination of potential exposure to naphthalene from products and activities. Under the Clean Air Regulatory Framework for Improvement of Indoor Air Quality, Health Canada will also use this information to determine whether an indoor air quality guideline for naphthalene is appropriate.

9.1.2 Naphthalene Release from Moth Repellents

Regulation of naphthalene in moth repellants falls under the program area of the Pest Management Regulatory Agency (PMRA). Naphthalene is an active ingredient in 5 products in addition to being a list 2 formulant. The registered application rates are 1589 to 1665 g/m³. The continued use of naphthalene as an active ingredient in pest control products in Canada is currently being re-evaluated under the PMRA re-evaluation program.

Under the re-evaluation program, active ingredients and their end-use products are reviewed to determine whether and under what conditions their uses continue to be acceptable under current standards for health and environmental protection. Conditions of acceptability include acceptable uses, rates, timing, methods of application, appropriate cautionary and first aid statements, and necessary limitations or risk reduction measures will be determined during the re-evaluation.

The Canadian re-evaluation of naphthalene will be based on information used in the screening assessments conducted for Challenge substances under the Chemicals Management Plan. The PMRA will also consider other sources of data/information such as the work generated in the European Union and the US EPA Re-Registration Decision (RED) document (scheduled for release July 2008).

² Section 4.4 of the *Cabinet Directive on Streamlining Regulation* states that "Departments and agencies are to: identify the appropriate instrument or mix of instruments, including regulatory and non-regulatory measures, and justify their application before submitting a regulatory proposal".

9.1.3 Naphthalene Contamination of Foods

Under Health Canada's *Food and Drugs Act* and *Food and Drugs Regulations*, naphthalene is not permitted as a food additive in Canada. Nonetheless, Health Canada will continue to investigate the levels of naphthalene in foods. Previous investigations have not indicated reason for concern regarding unacceptable exposure.

9.1.4 Naphthalene Releases from Food Packaging

Issues pertaining to naphthalene in food packaging fall under Health Canada's *Food and Drugs Act* and *Food and Drug Regulations*. Naphthalene is used as a solvent in food packaging coatings, and would volatilize and thus would not be expected to be present in the food product. Health Canada will review future submissions for the use of naphthalene as a solvent in coatings of food cans toward the objective that residual levels in finished materials are as low as possible and accordingly that potential migration of naphthalene into food is negligible.

9.1.5 Naphthalene Releases from Therapeutic Products

Issues pertaining to naphthalene in therapeutic products fall under Health Canada's *Food and Drugs Act* and *Food and Drugs Regulations*. This would encompass personal care, health, and nutrition products, including medicated toiletries such as coal-tar based shampoos.

Naphthalene as the pure substance meets the definition of a natural health product. However, it is also an unavoidable component in coal tar preparations used for the topical treatment of various skin disorders. Coal tar itself, however, is not a natural health product and is regulated by Health Canada.

No specific action with respect to coal tar is being taken by Health Canada at this time. Coal tar remains an important therapeutic option for psoriasis, particularly for the chronic stable forms, and is the only therapeutic option for some patients. The amount of naphthalene expected to be emitted from coal tar is 70 µg/g, a concentration far less than exposure to naphthalene from natural sources (approximately 1% from the typical North American diet). Exposure per use is estimated to be between 63 and 354 mcg per application. The weight of the clinical evidence shows no increased risk of cancer when crude coal tar is applied topically over prolonged periods of time.

Health Canada issued a monograph on October 12, 2006, for antidandruff products that indicates that coal tar is safe for use at concentrations of 0.5 to 10%.

9.1.6 Naphthalene Releases from Homeopathic Preparations

Issues pertaining to naphthalene in homeopathic preparations fall under Health Canada's *Food and Drugs Act* and *Food and Drugs Regulations*. Concentrations of naphthalene in these products are in the range of 1 ppm, and that therefore exposure would be minimal. In addition, Health Canada has indicated that homeopathic preparations containing naphthalene that have a Drug Identification Number (DIN) will be given a Natural Product Number (NPN).

9.1.7 Naphthalene Releases from Cosmetics

Issues pertaining to naphthalene in cosmetics fall under the Health Canada's *Food and Drugs Act*. Section 16 of the Act states that no person shall sell a cosmetic product that has in it any substance that may injure the health of the user when the cosmetic is used according to its customary method. To help cosmetic manufacturers satisfy this requirement, Health Canada has developed the Cosmetic Ingredient Hotlist – a list of substances which are restricted and prohibited in cosmetics. Health Canada will propose that naphthalene be added to the Cosmetic Ingredient Hotlist toward the objective that these substances will not be used in cosmetic products in the future.

9.2 Implementation Plan

The proposed regulation or instrument will be published in the *Canada Gazette*, Part I, no later than July 2010, as per the timelines legislated in CEPA 1999.

Releases of naphthalene will continue to be monitored under the National Pollutant Release Inventory. Other monitoring will be considered in order to assess the performance of the risk management instrument and to determine whether further action needs to be taken with respect to naphthalene.

10. PROPOSED CONSULTATION APPROACH

The risk management scope for naphthalene, which summarized the proposed risk management under consideration at that time, was published on January 19, 2008, and is available at www.ec.gc.ca/TOXICS/EN/detail.cfm?par_substanceID=236&par_actn=s1.

Industry and other interested stakeholders were invited to submit comments on the risk management scope during a 60-day comment period. Comments received on the risk management scope document were taken into consideration in the development of the proposed risk management approach document.

Consultation for the risk management approach will involve publication on July 5, 2008, and a 60-day public comment period.

The primary stakeholders include:

- manufacturers of moth repellents, cosmetics, pharmaceuticals, paints, coatings, sealants, adhesives and solvents, and food packaging.
- Health Canada and Environment Canada

11. NEXT STEPS / PROPOSED TIMELINE

Actions	Date
Electronic consultation on Proposed Risk Management Approach	July 5, 2008 to September 3, 2008
Response to comments on the Risk Management Approach	At time of publication of proposed instrument
Consultation on the draft instrument	Winter 2008-2009
Publication of the proposed instrument	No later than July 2010
Formal public comment period on the proposed instrument	No later than summer 2010
Publication of the final instrument	No later than January 2012

Industry and other interested stakeholders are invited to submit comments on the content of this proposed risk management approach or provide other information that would help to inform decision making. Please submit comments prior to September 3, 2008, since the Government of Canada will be moving forward with the risk management of naphthalene after this date. Pursuant to section 313 of CEPA 1999, any person who provides information to the Minister under CEPA 1999 may submit with the information a request that it be treated as confidential. During the development of the risk management instrument(s) and/or tool(s), there will be opportunity for further consultation on the proposed instrument(s). Comments and information submissions on the proposed risk management approach should be submitted to the address provided below:

Existing Substances Division
 Place Vincent Massey, 20th Floor
 351 Saint Joseph Boulevard
 Gatineau QC K1A 0H3
 Tel: 1-888-228-0530 / 819-956-9313
 Fax: 1-800-410-4314 / 819-953-4936
 Email: Existing.Substances.Existantes@ec.gc.ca

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