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**NATIONAL INDUSTRIAL CHEMICALS NOTIFICATION AND ASSESSMENT SCHEME
(NICNAS)**

PUBLIC REPORT

Polymer in Lupasol PN 60

This Assessment has been compiled in accordance with the provisions of the *Industrial Chemicals (Notification and Assessment) Act 1989* (the Act) and Regulations. This legislation is an Act of the Commonwealth of Australia. The National Industrial Chemicals Notification and Assessment Scheme (NICNAS) is administered by the Department of Health, and conducts the risk assessment for public health and occupational health and safety. The assessment of environmental risk is conducted by the Department of the Environment and Energy.

This Public Report is available for viewing and downloading from the NICNAS website or available on request, free of charge, by contacting NICNAS. For requests and enquiries please contact the NICNAS Administration Coordinator at:

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**Director
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SUMMARY

The following details will be published in the NICNAS *Chemical Gazette*:

ASSESSMENT REFERENCE	APPLICANT(S)	CHEMICAL OR TRADE NAME	HAZARDOUS CHEMICAL	INTRODUCTION VOLUME	USE
LTD/1973	BASF Australia Ltd	Polymer in Lupasol PN 60	ND*	≤ 3 tonnes per annum	A component of printing press cleaners

*ND = not determined

CONCLUSIONS AND REGULATORY OBLIGATIONS

Hazard classification

Based on the available information, the notified polymer is not recommended for classification according to the *Globally Harmonised System of Classification and Labelling of Chemicals* (GHS), as adopted for industrial chemicals in Australia.

The environmental hazard classification according to the *Globally Harmonised System of Classification and Labelling of Chemicals* (GHS) is presented below. Environmental classification under the GHS is not mandated in Australia and carries no legal status but is presented for information purposes.

<i>Hazard classification</i>	<i>Hazard statement</i>
Acute Category 3	H402 - Harmful to aquatic life
Chronic Category 3	H412 - Harmful to aquatic life with long lasting effects

Human health risk assessment

Under the conditions of the occupational settings described, the notified polymer is not considered to pose an unreasonable risk to the health of workers.

When used in the proposed manner, the notified polymer is not considered to pose an unreasonable risk to public health.

Environmental risk assessment

On the basis of the PEC/PNEC ratio and the reported use pattern, the notified polymer is not considered to pose an unreasonable risk to the environment.

Recommendations

CONTROL MEASURES

Occupational Health and Safety

- No specific engineering controls, work practices or personal protective equipment are required for the safe use of the notified polymer itself. However, these should be selected on the basis of all ingredients in the formulation.

Guidance in selection of personal protective equipment can be obtained from Australian, Australian/New Zealand or other approved standards.

- A copy of the SDS should be easily accessible to employees.
- If products and mixtures containing the notified polymer are classified as hazardous to health in accordance with the *Globally Harmonised System of Classification and Labelling of Chemicals* (GHS) as adopted for industrial chemicals in Australia, workplace practices and control procedures consistent with provisions of State and Territory hazardous substances legislation should be in operation.

Disposal

- Where reuse or recycling are not appropriate, dispose of the notified polymer in an environmentally sound manner in accordance with relevant Commonwealth, state, territory and local government legislation.

Emergency procedures

- Spills or accidental release of the notified polymer should be handled by containment, physical collection and subsequent safe disposal.

Regulatory Obligations

Secondary Notification

This risk assessment is based on the information available at the time of notification. The Director may call for the reassessment of the chemical under secondary notification provisions based on changes in certain circumstances. Under Section 64 of the *Industrial Chemicals (Notification and Assessment) Act (1989)* the notifier, as well as any other importer or manufacturer of the notified chemical, have post-assessment regulatory obligations to notify NICNAS when any of these circumstances change. These obligations apply even when the notified polymer is listed on the Australian Inventory of Chemical Substances (AICS).

Therefore, the Director of NICNAS must be notified in writing within 28 days by the notifier, other importer or manufacturer:

- (1) Under Section 64(1) of the Act; if
 - the polymer has a number-average molecular weight of less than 1000;or
- (2) Under Section 64(2) of the Act; if
 - the function or use of the polymer has changed from a component of printing press cleaners, or is likely to change significantly;
 - the amount of polymer being introduced has increased, or is likely to increase, significantly;
 - the polymer has begun to be manufactured in Australia;
 - additional information has become available to the person as to an adverse effect of the polymer on occupational health and safety, public health, or the environment.

The Director will then decide whether a reassessment (i.e. a secondary notification and assessment) is required.

Safety Data Sheet

The SDS of product containing the notified polymer provided by the notifier was reviewed by NICNAS. The accuracy of the information on the SDS remains the responsibility of the applicant.

ASSESSMENT DETAILS

1. APPLICANT AND NOTIFICATION DETAILS

APPLICANT(S)

BASF Australia Ltd (ABN: 62 008 437 867)
Level 12, 28 Freshwater Place
SOUTHBANK VIC 3006

NOTIFICATION CATEGORY

Limited: Synthetic polymer with $M_n \geq 1,000$ Da.

EXEMPT INFORMATION (SECTION 75 OF THE ACT)

Data items and details claimed exempt from publication: chemical name, other names, CAS number, molecular and structural formulae, molecular weight, analytical data, degree of purity, polymer constituents, residual monomers, impurities, additives/adjuvants, use details, and import volume.

VARIATION OF DATA REQUIREMENTS (SECTION 24 OF THE ACT)

Variation to the schedule of data requirements is claimed as follows: Boiling point, Density, Vapour pressure, Hydrolysis as a Function of pH, Adsorption/Desorption, Dissociation constant, Particle size, Flash point, Flammability, Autoignition temperature, and Explosive and Oxidising properties.

PREVIOUS NOTIFICATION IN AUSTRALIA BY APPLICANT(S)

None

NOTIFICATION IN OTHER COUNTRIES

Canada, Korea, Taiwan and USA

2. IDENTITY OF CHEMICAL

MARKETING NAME(S)

Lupasol PN 60 (containing notified polymer at < 50%)

MOLECULAR WEIGHT

Number Average Molecular Weight (M_n) is > 1,000 Da

ANALYTICAL DATA

Reference IR, and GPC spectra were provided.

3. COMPOSITION

DEGREE OF PURITY

> 95%

LOSS OF MONOMERS, OTHER REACTANTS, ADDITIVES, IMPURITIES

No losses of monomers by volatilisation, exudation or leaching are expected from the notified polymer under normal conditions of use.

DEGRADATION PRODUCTS

No degradation, decomposition or depolymerisation of the notified polymer is expected to occur under normal conditions of use.

4. PHYSICAL AND CHEMICAL PROPERTIES

APPEARANCE AT 20 °C AND 101.3 kPa: Colourless to yellowish liquid

Property	Value	Data Source/Justification
Melting Point/Freezing Point	75 °C	Measured
Boiling Point	Not determined	Decomposition of the notified polymer is expected before it reaches a boiling point

Density	1140 kg/m ³ at 23 °C	SDS*
Vapour Pressure	2.4 kPa at 20 °C	SDS*
Water Solubility	800-900 g/L at 23 °C	Measured [§]
Partition Coefficient (n-octanol/water)	log Pow < -4.9	Measured
Adsorption/Desorption	Not determined	60-70% of the notified polymer was removed via adsorption or other elimination mechanism in the batch test containing the activated sludge The notified polymer contains dissociable functional groups which are expected to dissociate under environmental pH of 4-9. Imported as an aqueous solution. Imported as an aqueous solution. Imported as an aqueous solution. Imported as an aqueous solution. The notified polymer does not contain functional groups that would imply explosive properties. The notified polymer does not contain functional groups that would imply oxidising properties.
Dissociation Constant	Not determined	
Particle Size	Not determined	
Flash Point	Not determined	
Flammability	Not determined	
Autoignition Temperature	Not determined	
Explosive Properties	Not determined	
Oxidising Properties	Not determined	

* Product containing < 50% notified polymer.

§ In-house method

DISCUSSION OF PROPERTIES

For full details of tests on physical and chemical properties, refer to Appendix A.

Reactivity

The notified polymer is expected to be stable under normal conditions of use.

Physical hazard classification

Based on the submitted physico-chemical data depicted in the above table, the notified polymer is not recommended for hazard classification according to the *Globally Harmonised System of Classification and Labelling of Chemicals (GHS)*, as adopted for industrial chemicals in Australia.

5. INTRODUCTION AND USE INFORMATION

MODE OF INTRODUCTION OF NOTIFIED CHEMICAL (100%) OVER NEXT 5 YEARS

The notified polymer will not be manufactured in Australia. It will be imported into Australia as a component of an aqueous solution at < 50% concentration for reformulation into end use products at < 1%.

MAXIMUM INTRODUCTION VOLUME OF NOTIFIED CHEMICAL (100%) OVER NEXT 5 YEARS

Year	1	2	3	4	5
Tonnes	< 1	< 1.5	< 2	< 2.5	< 3

PORT OF ENTRY
Melbourne

TRANSPORTATION AND PACKAGING

The notified polymer will be imported into Australia in 120 kg open head plastic drums or in 1000 litre intermediate bulk containers (IBC) by sea in a shipping container and transported by road to distribution warehouses around the country. The plastic drums are expected to be packed on wooden pallets and bound with plastic shrink wrap. The reformulated products containing the notified polymer at < 1% in 20 L steel pails and 200 L steel drums will be transported by road to the end use customers.

USE

The notified polymer will be imported into Australia as a component of an aqueous solution at < 50% concentration for reformulation as a component in printing press cleaners at < 1% concentration.

OPERATION DESCRIPTION

The imported products containing the notified polymer at < 50% concentration will be blended (at < 1% concentration) with other components to produce printing press cleaning products. The printing press cleaning products will be sold to major printing companies for the washing and cleaning of printing press plates.

6. HUMAN HEALTH IMPLICATIONS

6.1. Exposure Assessment

6.1.1. Occupational Exposure

CATEGORY OF WORKERS

<i>Category of Worker</i>	<i>Exposure Duration (hours/day)</i>	<i>Exposure Frequency (days/year)</i>
Transport and warehouse	4 – 8	40
Reformulation and Repackaging Workers	Not known	Not Known
Service technicians	0.5 – 2	20
Printer operators	2 – 4	200 – 240

EXPOSURE DETAILS

Transport and Storage

Transport and storage workers are not expected to be exposed to the notified polymer except in the event of accidental rupture of the containers (120 kg plastic drums, 20 L steel pails, 200 L steel drums or IBCs).

Reformulation/Repackaging

Reformulation and repackaging workers may be exposed to the notified polymer, at < 50% concentration, during reformulation processes, which include transfer, and blending of the notified polymer with other components. Workers may also be exposed to the notified chemical at < 1% concentration during repackaging.

Dermal, ocular and inhalation exposures are expected to be reduced through the use of personal protective equipment (PPE) including gloves, glasses, coveralls and respiratory protection and the use of local exhaust ventilation.

Printer operation

Dermal, ocular and inhalation exposure of printer operators and service technicians to printing press cleaner containing the notified polymer at < 1% may occur during cleaning, maintenance, removal and replacement of the printing plates. However, exposure is expected to be minimised by the use of PPE such as gloves, glasses, coveralls and respirator. The use of local exhaust ventilation in areas surrounding the printing machines is expected to further minimise the inhalation exposure.

6.1.2. Public Exposure

The notified polymer will be for industrial use only and will not be sold to the general public. Printed articles are not expected to contain the notified polymer, and therefore exposure of the general public is expected to be negligible.

6.2. Human Health Effects Assessment

The results from toxicological investigations conducted on the notified polymer are summarised in the following table. For full details of the studies, refer to Appendix B.

<i>Endpoint</i>	<i>Result and Assessment Conclusion</i>
Rat, acute oral toxicity	LD50 > 2000 mg/kg bw; low toxicity
Mutagenicity – bacterial reverse mutation	non mutagenic

Toxicokinetics, metabolism and distribution

Based on the high molecular weight ($M_n > 1000$ Da) and the small percentage of low molecular weight species (< 1000 Da and < 500 Da), dermal absorption is expected to be low, limiting the potential for systemic exposure.

Acute toxicity

The notified polymer is expected to be of low acute toxicity via the oral route based on a study in rats. No acute dermal or inhalation toxicity data were provided.

Irritation and sensitisation

No information on skin and eye irritation effects of the notified polymer was provided.

Mutagenicity/Genotoxicity

The notified polymer was not mutagenic to bacteria in a bacterial reverse mutation assay.

Health hazard classification

Based on the available information, the notified polymer is not recommended for classification according to the *Globally Harmonised System of Classification and Labelling of Chemicals (GHS)*, as adopted for industrial chemicals in Australia.

6.3. Human Health Risk Characterisation**6.3.1. Occupational Health and Safety**

The notified polymer was of low acute toxicity and was not mutagenic. In addition systemic effects are unlikely due to the expected low dermal absorption.

During reformulation and printer operation workers may be exposed to the notified polymer at $< 50\%$ or $< 1\%$ concentration respectively. Occupational exposure to the notified polymer is expected to be minimised by the use of personal protective equipment (PPE) such as gloves, glasses, respirators and coveralls, in addition to the use of local exhaust ventilation. Due to the expected low hazard and the Overall, the risk to workers from use of the notified polymer is not considered to be unreasonable.

6.3.2. Public Health

The product containing the notified polymer will not be made available to the general public. Therefore, the risk to public health is not considered to be unreasonable.

7. ENVIRONMENTAL IMPLICATIONS**7.1. Environmental Exposure & Fate Assessment****7.1.1. Environmental Exposure****RELEASE OF CHEMICAL AT SITE**

The notified polymer will be imported as a component of an aqueous solution for reformulation as a component in printing press cleaners. The reformulation of the notified polymer into final products will occur in enclosed systems. The notified polymer will be blended with other components to produce a press cleaner to clean printing press plates and machines. It is estimated that up to 0.1% of the notified polymer may be released to the environment from cleaning of equipment. The release of the notified polymer to the environment during importation, storage, and transport is expected to be limited to accidental spills. These wastes are expected to be collected and recycled where possible or disposed of to landfill.

RELEASE OF CHEMICAL FROM USE

A press cleaner containing the notified polymer will be mixed with other solvents and applied to equipment cleaning at the completion of a printing run. Solvent used for equipment washing containing the notified polymer, is expected to be recycled for reuse on site or disposed of via waste disposal contractors. It is estimated by the notifier that up to 2% of the notified polymer may be disposed of to landfill from equipment cleaning processes. Spilled material (estimated to be 1%) will be collected and disposed of in accordance with local regulations. Therefore, no significant release of the notified polymer to the environment is expected during use.

RELEASE OF CHEMICAL FROM DISPOSAL

Solvent containing the notified polymer will be disposed of via waste disposal contractors for off-site solvent regeneration with any remaining solids from this process being disposed of to landfill. Residual products containing the notified polymer in empty containers will be disposed of to landfill.

7.1.2. Environmental Fate

No environmental fate data were submitted. The majority of the product containing the notified polymer will be recycled and reused to clean printing equipment. Therefore, the exposure of the notified polymer to the aquatic environment is anticipated to be very low. In the unlikely event of the notified polymer's release into the sewer, it is expected to be efficiently removed via partitioning to sludge material in sewage treatment plants (STPs) due to its high molecular weight and cationic functional groups. In addition, the submitted study by the notifier indicates that significant proportion of the notified polymer is removed via adsorption and/or other elimination mechanisms in the batch test containing the activated sludge (BASF 2005e).

The notified polymer disposed of to landfill as residues in empty containers, spilled material or sludge, is not expected to be mobile and bioavailable. Due to its high molecular weight, the notified polymer will not readily cross biological membrane and, therefore, bioaccumulation is not expected. In landfill or water, the notified polymer is expected to undergo biotic and abiotic degradation, eventually forming water and oxides of carbon and nitrogen.

7.1.3. Predicted Environmental Concentration (PEC)

The notified polymer is not expected to be present in significant concentrations in the aquatic environment because of the very low potential for direct release to surface waters. Therefore, a predicted environmental concentration (PEC) has not been calculated.

7.2. Environmental Effects Assessment

The results from ecotoxicological investigations conducted on the notified polymer are summarised in the table below. Details of these studies can be found in Appendix C.

<i>Endpoint</i>	<i>Result</i>	<i>Assessment Conclusion</i>
Daphnia Toxicity	48 h EC50 > 100 mg/L	Not harmful to aquatic invertebrates
Algal Toxicity	96 h EC50 = 51.8 mg/L NOEC = 12.5 mg/L	Harmful to algae

Based on the above ecotoxicological points the notified polymer is expected to be harmful to algae. Therefore, under the Globally Harmonised System of Classification and Labelling of Chemicals (GHS) (United Nations, 2009), the notified polymer is formally classified as "Acute Category 3; Harmful to aquatic life". Based on the acute toxicity and potential persistence, the notified polymer has been formally classified as "Chronic Category 3; Harmful to aquatic life with long lasting effects" under the GHS for chronic toxicity.

7.2.1. Predicted No-Effect Concentration

The predicted no-effect concentrations (PNEC) for the notified chemical have been derived and compared from both the most sensitive acute endpoint (EC50) and chronic endpoint (NOEC) for algae. An assessment factor of 500 has been used as measured acute endpoints for two trophic levels are available.

Predicted No-Effect Concentration (PNEC) for the Aquatic Compartment		
EC50 (Alga)	51.80	mg/L
Assessment Factor	500	
Mitigation Factor	1.00	
PNEC:	103.60	µg/L

7.3. Environmental Risk Assessment

The Risk Quotient ($Q = \text{PEC}/\text{PNEC}$) of the notified polymer has not been calculated since no significant release of the notified polymer to the aquatic environment is expected from the reported use pattern. On the basis of the maximum annual importation volume, low expected aquatic exposure and assessed use pattern, the notified polymer is not expected to pose an unreasonable risk to the environment.

APPENDIX A: PHYSICAL AND CHEMICAL PROPERTIES**Melting Point/Freezing Point** 75 °C

Method Guideline Annex Commission Directive 92/69/EEC, part A.1 Melting/Freezing Temperature.
Remarks Differential Scanning Calorimetry (DSC) method. The test item has an extrapolated onset temperature at about 75 °C.
Test Facility BASF (2005)

Water Solubility 800-900 g/L

Method In-house method. Standard Operation Procedure PCE/006 from GKA Competence Center Analytics, BASF AG
Remarks Test substance and water were mixed and shaken in different ratios at three different pH and room temperature and visual observations were made
Test Facility BASF (2005)

Partition Coefficient (n-octanol/water) log Pow < -4.9

Method Modified OECD TG 117 Partition Coefficient (n-octanol/water)
Remarks The Pow was estimated from the single solubility in octanol and water based on visual observations.
Test Facility BASF (2005)

APPENDIX B: TOXICOLOGICAL INVESTIGATIONS**B.1. Acute toxicity – oral**

TEST SUBSTANCE	Notified Polymer
METHOD	OECD TG 423 Acute Oral Toxicity – Acute Toxic Class Method.
Species/Strain	Rat/Wistar HanRec:WIST(SPF)
Vehicle	Distilled water
Remarks - Method	No significant protocol deviations.

RESULTS

<i>Group</i>	<i>Number and Sex of Animals</i>	<i>Dose mg/kg bw</i>	<i>Mortality</i>
1	3 F	2000	0/3
2	3 F	2000	0/3

LD50	> 2000 mg/kg bw
Signs of Toxicity	There were no unscheduled deaths, and no test substance related clinical signs.
Effects in Organs	There were no test substance related necropsy findings.
Remarks - Results	The mean body weights of the administration groups increased throughout the study period.

CONCLUSION	The notified polymer is of low toxicity via the oral route.
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TEST FACILITY	BASF (2005a)
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B.2. Genotoxicity – bacteria

TEST SUBSTANCE	Notified Polymer
METHOD	OECD TG 471 Bacterial Reverse Mutation Test. EC Directive 2000/32/EC B.13/14 Mutagenicity – Reverse Mutation Test using Bacteria. Plate incorporation procedure and Pre incubation procedure <i>S. typhimurium</i> : TA1535, TA1537, TA98, TA100, <i>E. coli</i> : WP2uvrA Aroclor-induced rat liver (S-9 mix)
Species/Strain	
Metabolic Activation System	
Concentration Range in Main Test	a) With metabolic activation: 20 – 5000 µg/plate b) Without metabolic activation: 20 – 5000 µg/plate
Vehicle	Water
Remarks - Method	No significant protocol deviations. No preliminary dose range finding study was conducted.

RESULTS

<i>Metabolic Activation</i>	<i>Test Substance Concentration (µg/plate) Resulting in:</i>			
	<i>Cytotoxicity in Preliminary Test</i>	<i>Cytotoxicity in Main Test</i>	<i>Precipitation</i>	<i>Genotoxic Effect</i>
<i>Absent</i>				
Test 1	-	> 5000	> 5000	negative
Test 2		≥ 5000	> 5000	negative
<i>Present</i>				
Test 1	-	> 5000	> 5000	negative
Test 2		≥ 5000	> 5000	negative

Remarks - Results	There was no significant increase in the number of revertants observed in any of the test strains, either in the presence or absence of metabolic
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activation. Cytotoxicity was observed at 5000 µg/plate in the pre-incubation test both with and without metabolic activation. No precipitation of the test substance was found.

Negative controls were within historical limits. Positive controls confirmed the sensitivity of the test system.

CONCLUSION

The notified polymer was not mutagenic to bacteria under the conditions of the test.

TEST FACILITY

BASF (2005b)

APPENDIX C: ENVIRONMENTAL FATE AND ECOTOXICOLOGICAL INVESTIGATIONS

C.1. Ecotoxicological Investigations

C.1.1. Acute toxicity to aquatic invertebrates

TEST SUBSTANCE	Notified polymer
METHOD	OECD TG 202 Daphnia sp. Acute Immobilisation Test and Reproduction Test – Static.
Species	<i>Daphnia magna</i>
Exposure Period	48 hours
Auxiliary Solvent	None
Water Hardness	2.43 mmol CaCO ₃ /L
Analytical Monitoring	Titration
Remarks - Method	The stock solution was prepared by stirring the test substance in the test medium at the concentration of 200.4 mg/L for about 7 days at approximately 20 °C. The nominal concentrations were prepared by diluting the stock solution.

RESULTS

Concentration mg/L		Number of <i>D. magna</i>	Number Immobilised	
Nominal	Actual*		24 h	48 h
Control	Control	20	0	0
12.5	10.5	20	0	0
25	23.0	20	0	0
50	48.5	20	0	0
100	99.0	20	0	0

*Mean values based on the measurements at 0 and 48 h.

EC50	> 100 mg/L at 48 hours
Remarks - Results	All validity criteria were satisfied. As the recovery rates of the test substance was in the range of ±20 % of the nominal concentrations, the test endpoints are based on nominal concentrations.
CONCLUSION	The notified polymer is not harmful to aquatic invertebrates
TEST FACILITY	BASF (2005c)

C.1.2. Algal growth inhibition test

TEST SUBSTANCE	Notified polymer
METHOD	OECD TG 201 Alga, Growth Inhibition Test.
Species	<i>Desmodesmus subspicatus</i>
Exposure Period	72 hours
Concentration Range	Nominal: 0.391, 0.781, 1.56, 3.13, 6.25, 12.5, 25, 50 and 100 mg/L Actual: 5, 11.5, 23.5, 48.5 and 100 mg/L
Auxiliary Solvent	None
Water Hardness	Unknown
Analytical Monitoring	Titration
Remarks - Method	The stock solution was prepared by stirring the test substance in the medium at the concentration of 222.4 mg/L for about 7 days at approximately 20 °C. The nominal concentrations were prepared by diluting the stock solution.

RESULTS

<i>Biomass</i>		<i>Growth</i>	
<i>EC50</i> <i>mg/L at 72 h</i>	<i>NOEC</i> <i>mg/L</i>	<i>EC50</i> <i>mg/L at 72 h</i>	<i>NOEC</i> <i>mg/L</i>
16.4	6.25*	51.8	12.5*

*The results were amended due to editorial fault

Remarks - Results	All validity criteria were satisfied. As the recovery rates of the test substance was in the range of ± 20 % of the nominal concentrations, the test endpoints are based on nominal concentrations.
CONCLUSION	The notified polymer is harmful to algae
TEST FACILITY	BASF (2005d and 2006)

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