

Scientific Documentation

Light Mineral Oil, NF

Not appropriate for regulatory submission. Please visit www.spectrumchemical.com or contact Tech Services for the most up-to-date information contained in this information package.

Spectrum Chemical Mfg Corp 769 Jersey Avenue New Brunswick, NJ 08901 Phone 732.214.1300





Table of Contents

Product Specification Certificate of Analysis Safety Data Sheet (SDS) Certification of Current Good Manufacturing Practices (cGMP) Manufacturing Process Flowchart Technical Statements Elemental Impurities Statement Residual Solvents Statement General Label Information – Sample Label



Specification for Light Mineral Oil, NF (MI501)

Item Number	MI501
Item	Light Mineral Oil, NF
CAS Number	8042-47-5
Molecular Formula	
Molecular Weight	
MDL Number	
Synonyms	

Test	Specification		
	Min	Max	
APPEARANCE			
SPECIFIC GRAVITY @ 25°C	0.818	0.880	
VISCOSITY @40.0°C	3.0	34.4 mm²/s	
ACIDITY		1.0 ml	
READILY CARBONIZABLE SUBSTANCES	LESS COLOR THEN STANDARD		
POLYCYCLIC AROMATIC HYDROCARBONS	LESS ? STANDARD		
SOLID PARAFFIN	BLACK LINE IS CLEARLY VISIBLE		
SULFUR COMPOUNDS	NO DARK BROWN DEVELOPS		
ELEMENTAL IMPURITIES	AS REPORTED		
IDENTIFICATION (A)	SPECTRUM MATCHES REFERENCE		
IDENTIFICATION (B)	3.0 -34.4 mm²/s		
EXPIRATION DATE			
DATE OF MANUFACTURE			
MONOGRAPH EDITION			
RESIDUAL SOLVENTS	AS REPORTED		

Spectrum Chemical Mfg Corp

Corporate Headquarters:	West Coast Facility:
769 Jersey Ave.	14422 S. San Pedro St.

Spectrum Chemical Mfg Corp

 Corporate Headquarters:
 West Coast Facility:

 New Brunswick, NJ 08901
 Gardena, CA 90248

 732.214.1300
 310.516.8000



Certificate Of Analysis

Item Number	MI501	Lot Number	1NA0181
Item	Light Mineral Oil, NF	CAS Number	8042-47-5

TFCT	SPECIFICATION		
TEST	MIN	MAX	RESULT
APPEARANCE			CLEAR, COLORLESS LIQUID
SPECIFIC GRAVITY @ 25°C	0.818	0.880	0.8420
VISCOSITY @40.0°C	3.0	34.4 mm²/s	12.72 mm²/s
ACIDITY		1.0 ml	<1.0 ml
READILY CARBONIZABLE SUBSTANCES	LESS COLOR THEN STANDARD		LESS COLOR THAN STANDARD
POLYCYCLIC AROMATIC HYDROCARBONS	LESS ⅓ STANDARD		LESS ⅓ STANDARD
SOLID PARAFFIN	BLACK LINE IS CLEARLY VISIBLE		BLACK LINE IS CLEARLY VISIBLE
SULFUR COMPOUNDS	NO DARK BROWN DEVELOPS		NO DARK BROWN DEVELOPS
ELEMENTAL IMPURITIES	AS REPORTED		NO ELEMENTAL IMPURITIES PRESENT
IDENTIFICATION (A)	SPECTRUM MATCHES REFERENCE		SPECTRUM MATCHES REFERENCE
IDENTIFICATION (B)	3.0 -34.4 mm ² /s		12.72 mm²/s
EXPIRATION DATE			30-NOV-2026
DATE OF MANUFACTURE			30-NOV-2023
MONOGRAPH EDITION			(USP-NF) 2023
RESIDUAL SOLVENTS	AS REPORTED		NO RESIDUAL SOLVENTS PRESENT

Certificate of Analysis Results Entered By:

HBERMUDEZ Hernan Bermudez 31-JAN-24 17:05:18

Spectrum Chemical Mfg Corp 14422 South San Pedro Street Gardena 90248 CA



All pharmaceutical ingredients are tested using current edition of applicable pharmacopeia.

Read and understand label and SDS before handling any chemicals. All Spectrum's chemicals are for manufacturing, processing, repacking or research purposes by experienced personnel only. It is the customer's responsibility to provide adequate hazardous material training and ensure that appropriate Personal Protective Equipment (PPE) is used before handling any chemical.

The Elemental Impurities standards implemented by USP and other Pharmaceutical Compendia reflect a growing understanding of the toxicology of trace levels of elemental impurities that can remain in drug substances originating from either raw materials or manufacturing processes. Identifying and quantifying impurities can be critical to predicting the best possible patient outcomes. Elemental Impurities has been a requirement of all products meeting USP/NF, EP and BP monographs since January 1, 2018. More information can be found in USP sections <232> Elemental Impurities – Limits and <233> Elemental Impurities – Procedures. Data for drug substances furnished by Spectrum Chemical Mfg. Corp can be used to ensure that patient daily exposures by oral administration to the selected elements are not exceeded in the formulation of pharmaceutical products.

Certificate of Analysis Results Approved By:

AMENDEZ Ana Mendez 01-FEB-24 13:35:20

SAFETY DATA SHEET

Revision date 25-October-2022

1. Identification	
Product identifier	
Product Name	LIGHT MINERAL OIL, NF
Other means of identification	
Product Code(s)	MI501
Synonyms	None
Recommended use of the chemical and restrictions on use	
Recommended use	No information available
Restrictions on use	No information available
Details of the supplier of the safety data sheet	
Supplier Address Spectrum Chemical Mfg. Corp. 14422 South San Pedro St. Gardena, CA 90248 (310) 516-8000	
Emergency telephone number	

Emergency Telephone

Chemtrec 1-800-424-9300

2. Hazard(s) identification

Classification

Aspiration hazard

Category 1

Hazards not otherwise classified (HNOC) Not applicable

Label elements

Danger

Hazard statements

May be fatal if swallowed and enters airways



Revision Number 2



Appearance Clear

Physical state Oily liquid

Odor No information available

Precautionary Statements - Response

IF SWALLOWED: Immediately call a POISON CENTER or doctor Do NOT induce vomiting

Precautionary Statements - Storage Store locked up.

Precautionary Statements - Disposal

Dispose of contents/container to an approved waste disposal plant

Other information

May be harmful if swallowed.

3. Composition/information on ingredients

Substance

Chemical name	CAS No	Weight-%
Light Mineral Oil	8042-47-5	100

4. First-aid measures	
Description of first aid measures	
General advice	Immediate medical attention is required. Show this safety data sheet to the doctor in attendance.
Inhalation	Aspiration into lungs can produce severe lung damage. If breathing has stopped, give artificial respiration. Get medical attention immediately. Remove to fresh air. Avoid direct contact with skin. Use barrier to give mouth-to-mouth resuscitation. If breathing is difficult, (trained personnel should) give oxygen. Get immediate medical advice/attention. Delayed

 Eye contact
 Rinse thoroughly with plenty of water for at least 15 minutes, lifting lower and upper eyelids. Consult a physician.

Skin contact Wash skin with soap and water.

Ingestion	ASPIRATION HAZARD IF SWALLOWED - CAN ENTER LUNGS AND CAUSE DAMAGE. Do NOT induce vomiting. If vomiting occurs spontaneously, keep head below hips to prevent aspiration. Clean mouth with water and drink afterwards plenty of water. Never give anything by mouth to an unconscious person. Get immediate medical advice/attention.
Self-protection of the first aider	Ensure that medical personnel are aware of the material(s) involved, take precautions to protect themselves and prevent spread of contamination. Avoid direct contact with skin. Use barrier to give mouth-to-mouth resuscitation. Use personal protective equipment as required.

Most important symptoms and effects, both acute and delayed

Symptoms	Difficulty in breathing. Coughing and/ or wheezing. Dizziness.
Indication of any immediate medical	attention and special treatment needed
Note to physicians	Because of the danger of aspiration, emesis or gastric lavage should not be employed unless the risk is justified by the presence of additional toxic substances.

5. Fire-fighting measures

Suitable Extinguishing Media	Use extinguishing measures that are appropriate to local circumstances and the surrounding environment.
Large Fire	CAUTION: Use of water spray when fighting fire may be inefficient.
Unsuitable extinguishing media	Do not scatter spilled material with high pressure water streams.
Specific hazards arising from the chemical	No information available.
Hazardous combustion products	Carbon Monoxide, Carbon Dioxide.
Explosion data Sensitivity to mechanical impac	:t none.
Sensitivity to static discharge	none.
Special protective equipment for fire-fighters	Firefighters should wear self-contained breathing apparatus and full firefighting turnout gear. Use personal protection equipment.

6. Accidental release measures

Personal precautions, protective equipment and emergency procedures		
Personal precautions	Ensure adequate ventilation. Use personal protective equipment as required.	
Other information	Refer to protective measures listed in Sections 7 and 8.	
Methods and material for containme	ent and cleaning up	
Methods for containment	Prevent further leakage or spillage if safe to do so.	

Methods for cleaning up Pick up and transfer to properly labeled containers.

7. Handling and storage		
Precautions for safe handling		
Advice on safe handling	Handle in accordance with good industrial hygiene and safety practice.	
Conditions for safe storage, including any incompatibilities		
Storage Conditions	Keep containers tightly closed in a dry, cool and well-ventilated place. Store locked up. Keep out of the reach of children. Store away from other materials. Protect from light.	

8. Exposure controls/personal protection

Control parameters

Exposure Limits Appropriate engineering controls	The following ingredients are the only ingredients of the product above the cut-off level (or level that contributes to the hazard classification of the mixture) which have an exposure limit applicable in the region for which this safety data sheet is intended or other recommended limit. At this time, the other relevant constituents have no known exposure limits from the sources listed here.	
Appropriate engineering controls		
Engineering controls	Showers Eyewash stations Ventilation systems.	
Individual protection measures, such as personal protective equipment		
Eye/face protection	If splashes are likely to occur, wear safety glasses with side-shields.	
Skin and body protection	No special protective equipment required.	
Respiratory protection	No protective equipment is needed under normal use conditions. If exposure limits are exceeded or irritation is experienced, ventilation and evacuation may be required.	
General hygiene considerations	Handle in accordance with good industrial hygiene and safety practice.	

9. Physical and chemical properties

Information on basic physical and	chemical properties	
Physical state	Oily liquid	
Appearance	Clear	
Color	Colorless	
Odor	No information available	
Odor threshold	No information available	
Property	Values	Remarks • Method
pH	no data available	None known
Melting point / freezing point	no data available	None known
Boiling point / boiling range	> 220 °C / 428 °F	None known
Flash point	no data available	None known
Evaporation rate	no data available	None known
Flammability (solid, gas)	no data available	None known
Flammability Limit in Air		None known
Upper flammability or explosive	No data available	
limits		
Lower flammability or explosive	No data available	
limits		
Vapor pressure	No data available	None known
Vapor density	no data available	None known
Relative density	0.85	None known
Water solubility	Insoluble in water	None known
Solubility(ies)	Soluble in most organic solvents	None known
Partition coefficient	No data available	None known
Autoignition temperature	no data available	None known
Decomposition temperature		None known
Kinematic viscosity	no data available	None known
Dynamic viscosity	No data available	None known
Other information		
Explosive properties	No information available	
Oxidizing properties	No information available	
Softening point	No information available	
Molecular weight	No information available	
VOC Content (%)	No information available	

10. Stability and reactivity

Reactivity	No information available.
Chemical stability	Stable under normal conditions.
Possibility of hazardous reactions	None under normal processing.
Conditions to avoid	None known based on information supplied.
Incompatible materials	None known based on information supplied.
Hazardous decomposition products None known based on information supplied.	

11. Toxicological information

Information on likely routes of exposure

Inhalation	Specific test data for the substance or mixture is not available. Aspiration into lungs can produce severe lung damage. May cause pulmonary edema. Pulmonary edema can be fatal. May cause irritation of respiratory tract.
Eye contact	Specific test data for the substance or mixture is not available. May cause irritation.
Skin contact	Repeated exposure may cause skin dryness or cracking.
Ingestion	Specific test data for the substance or mixture is not available. Potential for aspiration if swallowed. May cause lung damage if swallowed. Aspiration may cause pulmonary edema and pneumonitis. May be fatal if swallowed and enters airways.
Symptoms related to the physical, chemical and toxicological characteristics	
Symptoms	Difficulty in breathing. Coughing and/ or wheezing. Dizziness.

Acute toxicity

Numerical measures of toxicity

Component Information

Chemical name	Oral LD50	Dermal LD50	Inhalation LC50
Light Mineral Oil	> 5000 mg/kg (Rat)	-	-
8042-47-5			

Delayed and immediate effects as well as chronic effects from short and long-term exposure

Skin corrosion/irritation	No information available.
Serious eye damage/eye irritation	No information available.
Respiratory or skin sensitization	No information available.
Germ cell mutagenicity	No information available.
Reproductive toxicity	No information available.
STOT - single exposure	No information available.
STOT - repeated exposure	No information available.
Aspiration hazard	May be fatal if swallowed and enters airways.

No information available.

Interactive effects

No information available.

12. Ecological information

Ecotoxicity

Chemical name	Algae/aquatic plants	Fish	Toxicity to	Crustacea
			microorganisms	
Light Mineral Oil	-	LC50: >10000mg/L (96h,	-	-
8042-47-5		Lepomis macrochirus)		

Persistence and degradabilityNo information available.BioaccumulationInherently biodegradable.

Component Information

Chemical name	Partition coefficient
Light Mineral Oil	>6
8042-47-5	

Other adverse effects

No information available.

13. Disposal considerations

Waste treatment methods

Waste from residues/unused products	Dispose of in accordance with local regulations. Dispose of waste in accordance with environmental legislation.
Contaminated packaging	Do not reuse empty containers.

14. Transport information

DOT	not regulated
TDG	not regulated
MEX	not regulated
ICAO (air)	not regulated
IATA	not regulated
IMDG_	not regulated
RID	not regulated
ADR	not regulated
ADN	not regulated

15. Regulatory information

International Inventories

TSCA

Complies

DSL/NDSL EINECS/ELINCS	Complies Complies
ENCS	This product complies with ENCS:
IECSC	This product complies with China:
KECL	Complies
PICCS	Complies
AICS	All the constituents of this material are listed on the Australian Inventory of Chemical Substances (AICS).

Legend:

TSCA - United States Toxic Substances Control Act Section 8(b) Inventory

DSL/NDSL - Canadian Domestic Substances List/Non-Domestic Substances List

EINECS/ELINCS - European Inventory of Existing Chemical Substances/European List of Notified Chemical Substances

ENCS - Japan Existing and New Chemical Substances

IECSC - China Inventory of Existing Chemical Substances

KECL - Korean Existing and Evaluated Chemical Substances

PICCS - Philippines Inventory of Chemicals and Chemical Substances

US Federal Regulations

SARA 313

Section 313 of Title III of the Superfund Amendments and Reauthorization Act of 1986 (SARA). This product does not contain any chemicals which are subject to the reporting requirements of the Act and Title 40 of the Code of Federal Regulations, Part 372.

SARA 311/312 Hazard Categories

Should this product meet EPCRA 311/312 Tier reporting criteria at 40 CFR 370, refer to Section 2 of this SDS for appropriate classifications.

CWA (Clean Water Act)

This product does not contain any substances regulated as pollutants pursuant to the Clean Water Act (40 CFR 122.21 and 40 CFR 122.42).

CERCLA

This material, as supplied, does not contain any substances regulated as hazardous substances under the Comprehensive Environmental Response Compensation and Liability Act (CERCLA) (40 CFR 302) or the Superfund Amendments and Reauthorization Act (SARA) (40 CFR 355). There may be specific reporting requirements at the local, regional, or state level pertaining to releases of this material.

US State Regulations

California Proposition 65

This product does not contain any Proposition 65 chemicals.

U.S. State Right-to-Know Regulations

This product does not contain any substances regulated under applicable state right-to-know regulations

U.S. EPA Label Information

EPA Pesticide Registration Number Not applicable

16. Other information

NFPA_____ Health hazards 2 Flammability 0 Instability 0 Physical and chemical properties - HMIS Health hazards 2 Flammability 0 Physical hazards 0 Personal protection X

Key or legend to abbreviations and acronyms used in the safety data sheet Legend Section 8: EXPOSURE CONTROLS/PERSONAL PROTECTION TWA TWA (time-weighted average) STEL STEL (Short Term Exposure Limit) Ceiling Maximum limit value Key literature references and sources for data used to compile the SDS Agency for Toxic Substances and Disease Registry (ATSDR) U.S. Environmental Protection Agency ChemView Database European Food Safety Authority (EFSA) EPA (Environmental Protection Agency) Acute Exposure Guideline Level(s) (AEGL(s)) U.S. Environmental Protection Agency Federal Insecticide, Fungicide, and Rodenticide Act U.S. Environmental Protection Agency High Production Volume Chemicals Food Research Journal Hazardous Substance Database International Uniform Chemical Information Database (IUCLID) Japan GHS Classification Australia National Industrial Chemicals Notification and Assessment Scheme (NICNAS) NIOSH (National Institute for Occupational Safety and Health) National Library of Medicine's ChemID Plus (NLM CIP) National Library of Medicine's PubMed database (NLM PUBMED) National Toxicology Program (NTP) New Zealand's Chemical Classification and Information Database (CCID) Organization for Economic Co-operation and Development Environment, Health, and Safety Publications Organization for Economic Co-operation and Development High Production Volume Chemicals Program Organization for Economic Co-operation and Development Screening Information Data Set World Health Organization

Revision date25-October-2022Revision NoteNo information available.Disclaimer

The information provided in this Safety Data Sheet is correct to the best of our knowledge, information and belief at the date of its publication. The information given is designed only as a guidance for safe handling, use, processing, storage, transportation, disposal and release and is not to be considered a warranty or quality specification. The information relates only to the specific material designated and may not be valid for such material used in combination with any other materials or in any process, unless specified in the text.

End of Safety Data Sheet

spectrum

Certification of Compliance with current Good Manufacturing Practices

Dear Valued Customer:

Spectrum Chemical Mfg Corp certifies that the following product(s) is produced, processed, packaged and held in compliance with current Good Manufacturing Practices (cGMP) in accordance with the applicable parts of 21 CFR, parts 210 and 211 of the Code of Federal Regulations.

Catalog Number	Product Name
MI501	Light Mineral Oil, NF

Spectrum is an FDA registered and inspected Drug Establishment. Our United States Food and Drug Administration (USFDA) Registration numbers are as follows:

Spectrum-Gardena, CA: Spectrum-New Brunswick, NJ: 2020632 2246824

Thank you for your interest in Spectrum products. If we may be of further assistance, please feel free to contact the Quality Assurance department at 310-516-8000 or via email at <u>qualityassurance@spectrumchemical.com</u>

Sincerely,

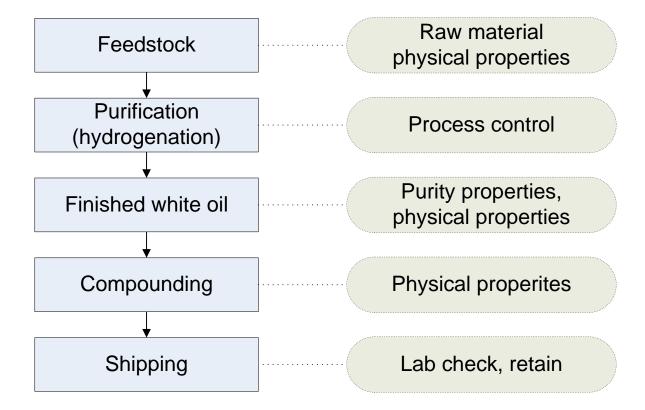
Oulu Umy

Oralia Chavez Quality Assurance Specialist



Manufacturing Process Flowchart

Light Mineral Oil, NF - MI501



Spectrum Chemical Mfg Corp

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West Coast Facility: 14422 S. San Pedro St. Gardena, CA 90248 310.516.8000

spectrum

MI501, Light Mineral Oil, NF

Source Statement

The above mentioned catalog item is manufactured by chemical synthesis. No animal or plant derived products are used in the manufacturing process.

BSE/TSE Statement

The above mentioned catalog item does not contain nor is manufactured using any animal derived products and is therefore, BSE/TSE free.

Allergen Statement

The above mentioned catalog item does not contain any of the following:

- Milk
- Egg
- Fish
- Shellfish
- Tree Nuts
- Wheat
- Peanuts
- Soy

- Cereals containing Gluten
- Celery
- Mustard
- Sesame Seed
- Corn
- Latex
- Sulfites > 10 ppm

EU Fragrance Allergen Statement

The above mentioned catalog item does not contain any of the 26 EU fragrance allergens listed in Annex III lines 67-92. These substances are not intentionally added to the following chemical and therefore are not expected to be present.

GMO Statement

The above mentioned catalog item is manufactured without the use of genetically modified organisms and is therefore GMO free.

Melamine Statement

The above mentioned catalog does not use or add melamine to the manufacturing process and is considered melamine-free.



Nitrosamine Statement

Based on knowledge of the manufacturing process, nitrosamine impurities are not known or suspected to be present in this material.

Animal Testing Statement

The above mentioned catalog item has not been tested on animals.

Organic Compliance Statement

The above mentioned catalog item has not been produced using GMOs, irradiation, ethylene oxide (EtO) or sewage sludge.

Shelf Life Statement

The above mentioned catalog item is typically assigned a shelf life of 36 months from the date of manufacture. The actual assigned shelf life for any specific lot should be referenced on the Certificate of Analysis.

Other Chemicals Statement

Spectrum does not have any reason to suspect the above mentioned catalog item contains any of the following chemicals. This product does not come into contact with these chemicals during packaging or storage:

- Aflatoxins
- Antibiotics
- Bisphenol A (BPA)
- CMR Substances

- Parabens
- Pesticides
- Phthalates
- Preservatives

spectrum

RE: Elemental Impurities - Light Mineral Oil, NF (Cat# MI501)

To Whom It May Concern:

Thank you for your interest in Spectrum high quality chemicals.

The above mentioned material complies with the USP<232>, <233> Elemental Impurities and the ICH Q3D Elemental Impurities Guideline. No Class 1, Class 2A, Class 2B or Class 3 elemental impurities are likely to be present. These substances are not used in the production process, are not intentionally added or known to be present in the above mentioned material.

This information is subject to change and is intended for risk assessment only. It is responsibility of the end user to evaluate suitability of any chemical for the intended use as well as to assess compound-specific limits of daily intake of metal impurities. For lot-specific information, please refer to the respective Certificate of Analysis.

If you have any further questions, please contact us by telephone at 1(800)772-8786 Option 2, or by email at <u>TechServices@spectrumchemical.com.</u>

Sincerely,

Technical Services Spectrum Chemical Mfg. Corp.

This document has been produced electronically and is valid without a signature.

CORPORATE HEADQUARTERS

769 Jersey Avenue New Brunswick, NJ 08901 PHONE 732.214.1300 FAX 732.246.7132

WEST COAST FACILITY

14422 South San Pedro Street Gardena, California 90248 PHONE 310.516.8000 FAX 310.516.9843

AN ISO 9001:2015 REGISTERED COMPANY

spectrum

RE: Residual Solvents - Light Mineral Oil, NF (Cat# MI501)

To Whom It May Concern:

Thank you for your interest in Spectrum high quality chemicals.

The above mentioned catalog item complies with the requirements of the USP <467> Residual Solvents and the ICH Q3C Residual Solvents Guideline. No Class 1, Class 2, Class 3 or other solvents are used or produced in the manufacture of this product.

For lot-specific information, please refer to the respective Certificate of Analysis.

If you have any further questions, please contact us by telephone at 1(800)772-8786 Option 2, or by email at <u>TechServices@spectrumchemical.com.</u>

Sincerely,

Technical Services Spectrum Chemical Mfg. Corp.

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CORPORATE HEADQUARTERS

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WEST COAST FACILITY

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AN ISO 9001:2015 REGISTERED COMPANY

www.spectrumchemical.com

spectrum®

Label Information

The Spectrum label presents technical and safety information in an easily understood format. Our technical specialists stay abreast of the latest requirements of the Globally Harmonized System for Classification and Labelling of Chemicals (GHS), as well as the Occupational Safety and Health Administration (OSHA), the Food and Drug Administration (FDA) and other government regulatory agencies in order to ensure compliance, accuracy and concise hazard communication. Below you will find a typical label example for this catalog item.



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