

Scientific Documentation

Petrolatum, Yellow, USP

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





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Specification for Petrolatum, Yellow, USP (PE130)

Item Number	PE130
Item	Petrolatum, Yellow, USP
CAS Number	8009-03-8
Molecular Formula	
Molecular Weight	
MDL Number	
Synonyms	Petroleum Jelly ; Soft Paraffin

Test	Specific	ation
	Min	Max
APPEARANCE		
SPECIFIC GRAVITY @60 C	0.815	0.880
MELTING RANGE	38°	60°C
CONSISTENCY		TO PASS TEST
STABILIZER (BUTYLHYDROXYTOLUENE)		20 ppm
COLOR		TO PASS TEST
ACIDITY		TO PASS TEST
ALKALINITY		TO PASS TEST
RESIDUE ON IGNITION		0.1 %
ORGANIC ACIDS		TO PASS TEST
FIXED OILS, FATS AND ROSIN		TO PASS TEST
ELEMENTAL IMPURITIES:		
MOLYBDENUM (Mo)	AS REPORTED	
IDENTIFICATION		TO PASS TEST
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	PE130	Lot Number	2LH0357
Item	Petrolatum, Yellow, USP	CAS Number	8009-03-8

TECT	SPECIFICATION		
TEST	MIN	MAX	RESULT
APPEARANCE			YELLOW JELLY
SPECIFIC GRAVITY @60 C	0.815	0.880	0.8389
MELTING RANGE	38°	60°C	56.1°C
CONSISTENCY		TO PASS TEST	PASSES TEST
STABILIZER (BUTYLHYDROXYTOLUENE)		20 ppm	<20 ppm
COLOR		TO PASS TEST	PASSES TEST
ACIDITY		TO PASS TEST	PASSES TEST
ALKALINITY		TO PASS TEST	PASSES TEST
RESIDUE ON IGNITION		0.1 %	0.0 %
ORGANIC ACIDS		TO PASS TEST	PASSES TEST
FIXED OILS, FATS AND ROSIN		TO PASS TEST	PASSES TEST
ELEMENTAL IMPURITIES:			COMPLIES WITH STANDARD
MOLYBDENUM (Mo)	AS REPORTED		0.293 ppm
IDENTIFICATION		TO PASS TEST	PASSES TEST
EXPIRATION DATE			13-MAY-2025
DATE OF MANUFACTURE			13-MAY-2022
MONOGRAPH EDITION			USP 2023
RESIDUAL SOLVENTS:	AS REPORTED		
CLASS 2 (solvent) / TOLUENE			<890 ppm
CLASS 3 (solvent) / METHYLETHYLKETONE			<5000 ppm
CLASS 3 (solvent) / 2-PROPANOL			<5000 ppm

Certificate of Analysis Results Entered By:

GHERRERA Genaro Herrera 20-FEB-24 06:40:54

Spectrum Chemical Mfg Corp 755 Jersey Avenue New Brunswick 08901 NJ



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:

AWILLIAMS Allison Williams 20-FEB-24 07:19:00

SAFETY DATA SHEET

Revision date 09-September-2020

1. Identification	
Product identifier	
Product Name	PETROLATUM, YELLOW, USP
Other means of identification	
Product Code(s)	PE130
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

This chemical is not considered hazardous by the 2012 OSHA Hazard Communication Standard (29 CFR 1910.1200)

Hazards not otherwise classified (HNOC)

Not applicable

Label elements

Hazard statements

This chemical is not considered hazardous by the 2012 OSHA Hazard Communication Standard (29 CFR 1910.1200)

The product contains no substances which at their given concentration, are considered to be hazardous to health.

Appearance Semi-Solid

Physical state Solid

Odor Odorless



Revision Number 2

Other information

No information available.

3. Composition/information on ingredients

Substance

Chemical name	CAS No	Weight-%	Trade secret
Petrolatum, yellow	8009-03-8	100	*

*The exact percentage (concentration) of composition has been withheld as a trade secret.

4. First-aid measures

Description of first aid measures

Inhalation	Remove to fresh air.
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	Clean mouth with water and drink afterwards plenty of water.
Most important symptoms and effect	ts, both acute and delayed

Indication of any immediate medical attention and special treatment needed

Note to physicians Treat symptomatically.

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 No information available. chemical	
Explosion data Sensitivity to mechanical impact 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.

Methods and material for containment 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 container tightly closed in a dry and well-ventilated place.	

8. Exposure controls/personal protection

Control parameters

Exposure Limits	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	No special protective equipment required.	
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	Solid
Appearance	Semi-Solid
Color	Yellowish; amber

Odor Odor threshold	Odorless No information available	
Property pH Melting point / freezing point Boiling point / boiling range Flash point Evaporation rate Flammability (solid, gas) Flammability Limit in Air Upper flammability or explosive	Values no data available 36 - 60 °C / 96.8 - 140 °F no data available 185 °C / 365 °F no data available no data available No data available	Remarks • Method None known None known None known None known None known None known
limits Lower flammability or explosive limits	No data available	
Vapor pressure Vapor density Relative density Water solubility Solubility(ies)	No data available no data available 0.815 - 0.880 Insoluble in water Practically insoluble in alcohol Practically insoluble in Glycerol Soluble in Benzene Soluble in diethyl ether Soluble in Petroleum Ether Soluble in Chloroform Soluble in Chloroform	None known None known None known None known
Partition coefficient Autoignition temperature Decomposition temperature Kinematic viscosity Dynamic viscosity	No data available no data available No data available No data available	None known None known None known None known None known
Other information Explosive properties Oxidizing properties Softening point Molecular weight VOC Content (%) Liquid Density Bulk density	No information available No information available No information available No information available No information available No information available 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.

Eye contact	Specific test data for the substance or mixture is not available.
Skin contact	Specific test data for the substance or mixture is not available.
Ingestion	Specific test data for the substance or mixture is not available.

Symptoms related to the physical, chemical and toxicological characteristics

Symptoms No information available.

Acute toxicity

Numerical measures of toxicity

Chemical name	Oral LD50	Dermal LD50	Inhalation LC50
Petrolatum, yellow 8009-03-8	-	> 3600 mg/kg (Rabbit)	-

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

Skin corrosion/irritation Serious eye damage/eye irritation Respiratory or skin sensitization Germ cell mutagenicity	No information available. No information available. No information available. No information available.
Reproductive toxicity	No information available.
STOT - single exposure STOT - repeated exposure Aspiration hazard	No information available. No information available. No information available.
Other adverse effects	No information available.
Interactive effects	No information available.

12.	Eco	logical	information

Ecotoxicity	The environmental impact of this product has not been fully investigated.
Persistence and degradability Bioaccumulation	No information available. Inherently biodegradable.
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

not regulated
not regulated

15. Regulatory information

International Inventories

TSCA	Complies	
DSL/NDSL	Complies	
EINECS/ELINCS	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

Revision Note

EPA Pesticide Registration Number Not applicable

16. Other information NFPA Health hazards 2 Flammability 1 Instability 0 Physical and chemical properties -HMIS Health hazards 2* Flammability 1 Physical hazards 0 Personal protection X Chronic Hazard Star Legend * = Chronic Health Hazard 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 date** 09-September-2020

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

No information available.

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

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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
PE130	Petrolatum, Yellow, USP

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>gualityassurance@spectrumchemical.com</u>

Sincerely,

Oulu Clamy

Oralia Chavez Quality Assurance Specialist

spectrum

PE130, Petrolatum, Yellow, USP

Source Statement

The above mentioned catalog item is manufactured from petrochemicals. 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 been tested on animals. Date of last testing was 1993.

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

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RE: Elemental Impurities - Petrolatum, Yellow, USP (Cat# PE130)

To Whom It May Concern:

Thank you for your interest in Spectrum high quality chemicals.

The above material complies with the USP<232>, <233> Elemental Impurities and the ICH Q3D Elemental Impurities Guideline. The following elemental impurities are likely to be present:

Elemental Impurity		Class	Expected Concentration
Cobalt	Co	2A	Not Detected
Nickel	Ni	2A	Not Detected
Molybdenum	Мо	3	< 0.293 ppm

Other elemental impurities considered by USP <232>, <233> and ICH Q3D which are not addressed in the above mentioned table are not 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 - Petrolatum, Yellow, USP (Cat# PE130)

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 USP <467> Residual Solvents and ICH Q3C Residual Solvents Guideline. The following solvents are likely to be present:

Residual Solvent	Class	Expected Concentration
Toluene	2	< 890 ppm
Methylethylketone	3	< 5000 ppm
2-Propanol	3	< 5000 ppm

No Class 1 or other solvents are used or produced in the manufacturing process of this material.

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

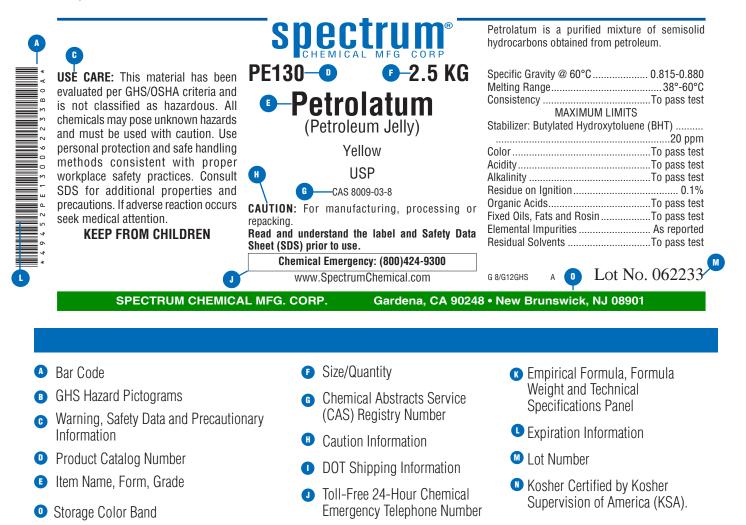
14422 South San Pedro Street Gardena, California 90248 PHONE 310.516.8000 FAX 310.516.9843

AN ISO 9001:2015 REGISTERED COMPANY

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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.





This color-coded band indicates the hazard most likely to be posed by that material under storage conditions. The criteria used to assign band colors have been established by the Storage Code working group of the Society for Chemical Hazard Communication (SCHC). It is recommended that like colors be stored together, unless otherwise stated, based on the color codes indicated to the right. However, it is the responsibility of the customer to check with their local fire department for possible conflicts with our recommendations when storing hazardous chemicals.

Spectrum Chemical Mfg Corp

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