



AN HF SINCLAIR BRAND

Regulatory Document for WHITE PROTOPET® 1S Petrolatum

Plant name and location:	Sonneborn, LLC 100 Sonneborn Lane Petrolia, PA 16050 Ph.: 724-756-2210 Fax: 724-756-9346 (not monitored)
Corporate Offices:	HollyFrontier Corporation 2828 N. Harwood, Suite 1300 Dallas, TX 75201 (214) 871-3555
Plant history:	W. H. Daugherty started processing petrolatum in the late 1800's. The Sonneborn family bought the plant in 1904. The Witco Corporation bought the Sonneborn Chemical and Refining Company in 1960. Crompton and Knowles merged with Witco on September 1, 1999 to form CK Witco. The name was changed to Crompton Corporation in April of 2000. Crompton divested the Refined Products division and the Petrolia plant in June 2005 to Sun Capital Partners, Inc. and formed Sonneborn, Inc. The name was changed in 2012 to Sonneborn, LLC when One Equity Partners purchased the company. February 1, 2019 Sonneborn LLC was purchased by HollyFrontier Lubricants & Specialties Products. March 15, 2022, HF Sinclair became the new parent entity of HollyFrontier.
Major Products:	White Mineral Oils - USP/NF, Petrolatums - USP, Microcrystalline waxes - NF, Cable Fillers, Sodium and Barium Sulfonates, Natural Emollients, and Specialty Alkanes
Customer Care 24 hr. phone number:	1-877-948-2688
Acreage:	400 acres total, ~ 50 acres involved with production
Number of employees:	Total = 173, Hourly, Bargaining Unit = 90, Salaried = 83, Laboratory Quality Control = 13, Quality Assurance = 4
Shifts:	The Hydrogenation plant runs 24 hours/7 days a week, with three eight-hour shifts. The rest of the plant has an eight-hour shift, five days a week.
Prepared by:	Amanda Isaacson
Title:	Regulatory Advisor
Date:	8/24/2023

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Certification/ Registration	Certifying Agency	Certification Date	Expiration Date	Last Audit Date	Reg. No.
ISO 9001:2015	ABS Quality Evaluations	Initial: 15 Dec 1992 Effective date: 12-20-2021	7-Apr-24	10/04 -10/05/2021	Certificate No. 63396
FSSC 22000	Bureau Veritas	Initial: 8 Jan 2020 Reissuing date: 2/28/22	25-Jan-25	1/25 - 1/28/2022	Certificate of Registration Number: US017770/11
Kosher	Orthodox Union (OU)	10/18/2022	31-Oct-23	N/A	
Halal	IFANCA	8/2/2023	31-Aug-24	2/2/2022	1132.13093.II210021
Vegan	American Vegetarian Association	1/20/2022	31-Jan-24	N/A	#122121HF
PA Dept of Agriculture	PA Dept of Agriculture	6/4/2019	15-Apr-24	9/21/2021	179872
PA Dept of Health	PA Dept of Health	5/26/2005	30-Jun-24	N/A	2000002684
FDA Drug Establishment	FDA	10/19/2021	31-Dec-23	7/9 & 7/10/2019	2515782
FDA Food Facility Reg.	FDA	10/2/2020	31-Dec-24	11/1/2021	12719311620
REACH Reg. No. Petrolatum Microcrystalline Wax	ECHA	N/A	N/A	N/A	01-2119490412-42-0012 01-2119495561-32-0013
DUNS No.	D&B	N/A	N/A	N/A	613030811
Fed Tax ID No.	N/A	N/A	N/A	N/A	20-2545879
Tariff Code Petrolatum Microcrystalline Wax	USITC	N/A	N/A	N/A	2712.10 2712.90
CAS No. / EC No. Petrolatum Microcrystalline Wax	CAS/EC	N/A	N/A	N/A	8009-03-8 / 232-373-2 63231-60-7 / 264-038-1

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Aflatoxin Mycotoxin Genotoxin

Based on our knowledge of the product and the manufacturing process, Aflatoxins, Mycotoxins and Genotoxins are not present in WHITE PROTOPET® 1S Petrolatum.

Allergens

Based on our knowledge of the product and the manufacturing process, WHITE PROTOPET® 1S Petrolatum is not derived from the following allergens or its derivatives: Peanuts, Tree Nuts, Sesame, Milk (Diary), Eggs, Fish, Crustaceans, Soy, Wheat, Mustard, Gluten, Sulphites, Molluscs (Shellfish), Celery, Lupin.

Animal Components

Based on our knowledge of the product and the manufacturing process, WHITE PROTOPET® 1S Petrolatum does not contain animal/animal by-products.

Animal Testing

Sonneborn (Petrolia, PA) does not conduct animal testing or have commissioned any animal testing since 2009.

Antibiotics

Based on our knowledge of the product and the manufacturing process, antibiotics or viral ingredients are not present in WHITE PROTOPET® 1S Petrolatum

Anti-Oxidant

See "Tocopherol"

Asbestos

Based on our knowledge of the product and the manufacturing process, WHITE PROTOPET® 1S Petrolatum does not contain asbestos.

Batch Code

The batch number is a unique 6 digit number, assigned sequentially in SAP system.

Biodegradability

WHITE PROTOPET® 1S Petrolatum is inherently biodegradable.

Bioengineered products

Based on our knowledge of the product and the manufacturing process, WHITE PROTOPET® 1S Petrolatum does not contain bioengineered ingredients.

BSE/TSE

Based on our knowledge of the product and the manufacturing process, WHITE PROTOPET® 1S Petrolatum does not contain animal/animal by-products and therefore there is no risk of BSE/TSE transmission.

CA Prop 65

WHITE PROTOPET® 1S Petrolatum does not contain any chemicals which are known to the State of California to cause cancer, birth defects or other reproductive harm at concentrations that trigger the warning requirements of California Proposition 65. For more information go to www.P65Warnings.ca.gov.

CAS No. / EC No.

Petrolatum

CAS No. 8009-03-8

EC No. 232-373-2

China GB 9685-2016

WHITE PROTOPET® 1S Petrolatum does not comply with China GB-9685-2016

CMR

WHITE PROTOPET® 1S Petrolatum is not categorized as Carcinogenic, Mutagenic or Toxic for Reproduction.

Composition

WHITE PROTOPET® 1S Petrolatum is derived from petroleum hydrocarbons and may contain up to 25 ppm BHT and 10 ppm Tocopherol added as stabilizer.

Component	CAS No.	%
Petrolatum	8009-03-8	100 %
BHT	128-37-0	< 25 ppm
Tocopherol	10191-41-0	< 10 ppm

CONEG (Heavy Metals)

Based on our knowledge of the product and the manufacturing process, WHITE PROTOPET® 1S Petrolatum does not contain lead, mercury, cadmium and hexavalent chromium at concentration levels exceeding 100 parts per million.

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Conflict Minerals

Based on our knowledge of the product and the manufacturing process, WHITE PROTOPET® 1S Petrolatum does not contain the Conflict Minerals identified in the Dodd-Frank Act (gold, cassiterite, columbite-tantalite and wolframite and their derivatives (ie. tin, tantalum and tungsten)).

Country of Origin

Country of Origin is U.S.A.

Elemental Impurities

WHITE PROTOPET® 1S Petrolatum complies with USP <232> and EMEA, Elemental Impurities, for Metal catalysts and metal residues.

Ethanol

Based on our knowledge of the product and the manufacturing process, ethanol is not present in WHITE PROTOPET® 1S Petrolatum.

Ethylene oxide / Dioxin

Based on our knowledge of the product and the manufacturing process, WHITE PROTOPET® 1S Petrolatum does not contain Ethylene Oxide or Dioxin.

EU 10/2011

WHITE PROTOPET® 1S Petrolatum does not comply with EU 10/2011.

Expiry Date

Expiry date is 3 years from Date of Manufacture. Manufactured Date and Expiration Date are listed on product Certificate of Analysis.

FDA Compliance

WHITE PROTOPET® 1S Petrolatum meets the requirements for U.S. FDA 21 CFR 172.880.

FDA Food Facility

Petrolia, PA site is registered as U.S. FDA Food Facility, Registration number is 12719311620.

FDA GRAS

Petrolatum is Generally Recognized as Safe when used in accordance with US FDA 21 CFR 172.880, or as otherwise listed in the Code of Federal Regulations.

Food Defense

The Sonneborn Petrolia Plant has established a Food Defense Plan that is in line with the Global Food Safety Initiative (GFSI) and FSSC 22000 requirements for preventing food adulteration. The Food Defense Plan addresses security of the complete supply chain; specifically: visitor/employee access protocol, chemical, equipment, and ingredient/final product storage, and raw material/ final product transport.

Food Safety

Sonneborn (Petrolia, PA) Site is certified to FSSC 22000 v5 through 25 Jan 2025 by NSF ISR to ensure compliance to U.S. FDA 21 CFR Part 117 preventative control requirements.

FSMA Compliance

Sonneborn (Petrolia, PA) is certified to FSSC 22000 v5 through 25 Jan 2025 by NSF ISR. All materials and processes in the supply chain of WHITE PROTOPET® 1S Petrolatum are overseen and monitored in accordance with the U.S. Food Safety Modernization Act (FSMA), as applicable.

Gluten

Based on our knowledge of the product and the manufacturing process, gluten is not present in WHITE PROTOPET® 1S Petrolatum.

Glycerol

Based on our knowledge of the product and the manufacturing process, WHITE PROTOPET® 1S Petrolatum does not contain glycerol or derivatives of glycerol.

GMO

Based on our knowledge of the product and the manufacturing process, WHITE PROTOPET® 1S Petrolatum does not contain genetically modified organisms (GMO).

GMP

Sonneborn, LLC's plant is registered with the United States FDA as a cGMP facility meeting ICH Q7 guidelines as well as U.S. FDA 21 CFR Part 110 and 21 CFR Part 117.

HACCP

Sonneborn (Petrolia, PA) Site is certified to FSSC 22000 v5 through 25 Jan 2025 by NSF ISR that includes development of a HACCP Plan.

Heavy Metals

See "Elemental Impurities"

INCI

The INCI Name for WHITE PROTOPET® 1S Petrolatum is PETROLATUM.

Ingredients

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- see 'Composition' statement

Irradiation

Based on our knowledge of the product and the manufacturing process, WHITE PROTOPET® 1S Petrolatum is not irradiated.

Latex

Based on our knowledge of the product and the manufacturing process, WHITE PROTOPET® 1S Petrolatum does not contain latex.

Lot Code

-See "Batch Code"

Manufacturing Process

WHITE PROTOPET® 1S Petrolatum is purified using 2-stage high temperature, high pressure catalytic hydrogenation.

Melamine

Based on our knowledge of the product and the manufacturing process, WHITE PROTOPET® 1S Petrolatum does not contain melamine.

Microbeads / microplastics

Based on our knowledge of the product and the manufacturing process, WHITE PROTOPET® 1S Petrolatum does not contain microbeads/microplastics.

Microbiological

WHITE PROTOPET® 1S Petrolatum does not promote microbiological growth. The purification process, consisting of high temperature (>250°C) / high pressure hydrogenation, precludes the presence of microbial growth. Limited laboratory testing indicates that our products do not contain microbial growth as per USP <61>. We do not routinely test for microbial growth, therefore it is not reported on the Certificate of Analysis.

MOAH/MOSH

Sonneborn Petrolatums may contain <1.3% MOAH, and 98.7% MOSH.

Nano

Based on our knowledge of the product and the manufacturing process, WHITE PROTOPET® 1S Petrolatum does not contain nanoparticles or nano materials.

Nitrosamines

Based on our knowledge of the product and the manufacturing process, WHITE PROTOPET® 1S Petrolatum does not contain nitrosamines.

Nutritional

Nutritional data is not tested or reported for this product.

Organic

Organic designation is not applicable for WHITE PROTOPET® 1S Petrolatum.

Origin

WHITE PROTOPET® 1S Petrolatum is derived from petroleum hydrocarbons.

Ozone Depletion

Based on our knowledge of the product and the manufacturing process, WHITE PROTOPET® 1S Petrolatum does not contain Hazardous Air Pollutants.

PAHs

Sonneborn USP Petrolatum products comply with the UV Absorbance specifications of 21 CFR 172.880 which specifies the limits for the Poly Aromatic Hydrocarbon (PAH) content of the product and correspond to approximately 1.0 ppm PAH according to literature.

Palm

Based on our knowledge of the product and the manufacturing process, WHITE PROTOPET® 1S Petrolatum does not contain palm oil and/or palm derivatives.

Parabens

Based on our knowledge of the product and the manufacturing process, WHITE PROTOPET® 1S Petrolatum does not contain parabens.

Pesticides

Based on our knowledge of the product and the manufacturing process, WHITE PROTOPET® 1S Petrolatum does not contain pesticides.

Per- and Polyfluoroalkyl Substances (PFAS)

Based on our knowledge of the product and the manufacturing process, WHITE PROTOPET® 1S Petrolatum does not contain Per- and Polyfluoroalkyl Substances (PFAS).

Phthalates

Based on our knowledge of the product and the manufacturing process, WHITE PROTOPET® 1S Petrolatum does not contain phthalate compounds.

Preservatives

Based on our knowledge of the product and the manufacturing process, WHITE PROTOPET® 1S Petrolatum does not contain preservatives.

Radiological

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-Refer to "Irradiation"

REACH

WHITE PROTOPET® 1S Petrolatum conforms to the requirements of Regulation (EC) No. 1907/2006 (REACH).

EC Number: 232-373-2

Registration number is 01-2119490412-42-0012

REACH SVHC

WHITE PROTOPET® 1S Petrolatum does not contain Substances of Very High Concern (SVHC), as of current revision.

Residual Solvents

WHITE PROTOPET® 1S Petrolatum does not contain reportable quantities of residual solvents according to USP <467>.

ROHS

Based on our knowledge of the product and the manufacturing process, WHITE PROTOPET® 1S Petrolatum does not contain lead, mercury, cadmium, hexavalent chromium, polybrominated biphenyls or polybrominated diphenyl ethers and therefore meets the requirements of the Restriction of Hazardous Substances Directive.

Shelf Life

Limited testing has indicated that WHITE PROTOPET® 1S Petrolatum is stable for at least 3 years if kept in the dark and 15°C and 30°C in factory sealed containers.

Site

Manufacturing location:

Sonneborn, LLC - 100 Sonneborn Lane, Petrolia, PA 16050, USA

Source

WHITE PROTOPET® 1S Petrolatum is derived from petroleum hydrocarbons.

Stability

Limited testing has indicated that WHITE PROTOPET® 1S Petrolatum is stable for at least 3 years if kept in the dark and 15°C and 30°C in factory sealed containers.

Storage Conditions

WHITE PROTOPET® 1S Petrolatum should be stored under protected storage conditions, which includes: indoor or covered storage, protected from contamination including exposure to rain and snow, exposure to direct sunlight, exposure to extreme temperatures and high / low temperatures cycles.

Sulfites/Sulphites

Based on our knowledge of the product and the manufacturing process, WHITE PROTOPET® 1S Petrolatum does not contain sulfites.

Supplier Approval

All Third Party Suppliers are approved based on our Quality Management System prior to use and evaluated on a regular basis.

Tariff Code

Petrolatum HTS code is 2712.10

USP or NF Compliance

WHITE PROTOPET® 1S Petrolatum is a USP White Petrolatum

Vegan/Vegetarian

WHITE PROTOPET® 1S Petrolatum is certified VEGAN by the American Vegetarian Association.