



AN HF SINCLAIR BRAND

Regulatory Document for CARNATION

Plant name and location:	Sonneborn, LLC 100 Sonneborn Lane Petrolia, PA 16050 USA Ph.: 724-756-2210 Fax: 724-756-9346 (not monitored)
Corporate Offices:	HF Sinclair 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:	8/30/2024

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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-27	10/20 & 10/23- 10/24/2023	Certificate No. 63396
FSSC 22000	Bureau Veritas	Initial: 8 Jan 2020 Reissuing date: 2/28/22	25-Jan-25	12/27 - 12/28/2023	Certificate of Registration Number: US017770/11
Kosher	Orthodox Union (OU)	10/5/2023	31-Oct-24	N/A	
Halal	IFANCA	8/2/2023	31-Aug-25	2/2/2022	1132.13093.II210021
Vegan	American Vegetarian Association	1/20/2022	31-Jan-25	N/A	#122121HF
NSF	NSF	N/A	31-Jan-25	N/A	
EPA Inert	EPA	N/A		N/A	
PA Dept of Agriculture	PA Dept of Agriculture	6/4/2019	15-Apr-25	10/18/2023	179872
PA Dept of Health	PA Dept of Health	5/26/2005	30-Jun-25	N/A	2000002684
FDA Drug Establishment	FDA - CDER	12/2/2020	31-Dec-24	7/9 & 7/10/2019	2515782
FDA Food Facility Reg.	FDA - CFSAN	10/15/2020	31-Dec-24	11/1/2021	12719311620
REACH Reg. No.	ECHA	N/A	N/A	N/A	01-2119487078-27-0030
DUNS No.	D&B	N/A	N/A	N/A	613030811
Tax ID No.	IRS	N/A	N/A	N/A	20-2545879
Tariff Code	USITC	N/A	N/A	N/A	2710.19
CAS No. / EC No.	CAS/EC	N/A	N/A	N/A	8042-47-5 / 232-455-8

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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 CARNATION .

Allergens

Based on our knowledge of the product and the manufacturing process, CARNATION 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. CARNATION does not contain any of the allergens listed in Regulation (EU) No. 1169/2011 or fragrance allergens listed in Regulation (EC) No. 1223/2009 as amended by Commission Regulation (EU) 2023/1545.

Animal Components

Based on our knowledge of the product and the manufacturing process, CARNATION 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 CARNATION

Anti-Oxidant

See "Tocopherol"

Asbestos

Based on our knowledge of the product and the manufacturing process, CARNATION does not contain asbestos.

Batch Code

For all Mineral Oils produced at Petrolia, PA site, the batch number is a 6 digit number, assigned sequentially in SAP.

Biodegradability

CARNATION is inherently biodegradable.

Bioengineered products

Based on our knowledge of the product and the manufacturing process, CARNATION does not contain bioengineered ingredients.

Bisphenol A, B and S

Based on our knowledge of the product and the manufacturing process, CARNATION does not contain Bisphenol A, B or S.

BSE/TSE

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

CA Prop 65

CARNATION 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.

Canadian F&D Regs, Division 23

Based on our knowledge of the product and the manufacturing process, CARNATION meets the requirements for Food Packaging Materials according to the Canadian Food and Drug Regulations, Part B - Foods, Division 23.

CAS No. / EC No.

White Mineral Oil

CAS No. 8042-47-5

EC No. 232-455-8

China GB 9685-2016

CARNATION does not comply with China GB-9685-2016

CMR

CARNATION is manufactured to meet the purity of USP/NF and FDA 21 CFR 172.878 and 178.3620(a) and are not categorized as Carcinogenic, Mutagenic or Toxic for Reproduction.

Composition

CARNATION is mineral oil, which may contain up to 10ppm of tocopherol.

Component	CAS#	%
Mineral oil	8042-47-5	100 %
Tocopherol	10191-41-0	1-10 ppm

CONEG (Heavy Metals)

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

Conflict Minerals

Based on our knowledge of the product and the manufacturing process, CARNATION 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

CARNATION complies with USP <232> and EMEA, Elemental Impurities, for Metal catalysts and metal residues.

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Ethanol

Based on our knowledge of the product and the manufacturing process, ethanol is not present in CARNATION .

Ethylene oxide / Dioxin

Based on our knowledge of the product and the manufacturing process, CARNATION does not contain Ethylene Oxide or Dioxin.

EU 10/2011

CARNATION 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

CARNATION meets the requirements for U.S. FDA 21 CFR 172.878 and 21 CFR 178.3620(a).

FDA Food Facility

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

FDA GRAS

White mineral oil is Generally Recognized as Safe when used in accordance with US FDA 21 CFR 172.878, or as otherwise listed in the Code of Federal

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 v5.1 through 25 Jan 2025 by Bureau Veritas to ensure compliance to U.S. FDA 21 CFR Part 117 preventative control requirements.

FSMA Compliance

Sonneborn (Petrolia, PA) is certified to FSSC 22000 v5.1 through 25 Jan 2025 by Bureau Veritas. All materials and processes in the supply chain of CARNATION 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 CARNATION .

Glycerol

Based on our knowledge of the product and the manufacturing process, CARNATION does not contain glycerol or derivatives of glycerol.

GMO

Based on our knowledge of the product and the manufacturing process, CARNATION 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 v5.1 through 25 Jan 2025 by Bureau Veritas that includes development of a HACCP Plan.

Heavy Metals

See "Elemental Impurities"

INCI

The INCI Name for white mineral oil is MINERAL OIL.

Ingredients

- see 'Composition' statement

Irradiation

Based on our knowledge of the product and the manufacturing process, CARNATION is not irradiated.

Latex

Based on our knowledge of the product and the manufacturing process, CARNATION does not contain latex.

Lot Code

-See "Batch Code"

Manufacturing Process

CARNATION is purified using 2-stage high temperature, high pressure catalytic hydrogenation.

Melamine

Based on our knowledge of the product and the manufacturing process, CARNATION does not contain melamine.

Microbeads / microplastics

Based on our knowledge of the product and the manufacturing process, CARNATION does not contain microbeads/microplastics.

Microbiological

CARNATION 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 White Mineral Oils are expected to have less than 0.2% total aromatics.

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Nano

Based on our knowledge of the product and the manufacturing process, CARNATION does not contain nanoparticles or nano materials.

Nitrosamines

Based on our knowledge of the product and the manufacturing process, CARNATION does not contain nitrosamines.

Nutritional

Nutritional data is not tested or reported for our products, CARNATION may contain up to 10 ppm tocopherol (Vitamin E) as a stabilizer.

Organic

Organic designation is not applicable for CARNATION .

Origin

CARNATION is derived from petroleum.

Ozone Depletion

Based on our knowledge of the product and the manufacturing process, CARNATION does not contain Hazardous Air Pollutants.

PAHs

CARNATION meets the Limit of PAH criteria as defined in NF Monograph for Light Mineral Oil and 21 CFR 172.878 for White Mineral Oil.

Palm

Based on our knowledge of the product and the manufacturing process, CARNATION does not contain palm oil and/or palm derivatives.

Parabens

Based on our knowledge of the product and the manufacturing process, CARNATION does not contain parabens.

Pesticides

Based on our knowledge of the product and the manufacturing process, CARNATION does not contain pesticides.

Per- and Polyfluoroalkyl Substances (PFAS)

Based on our knowledge of the product and the manufacturing process, CARNATION does not contain per- and polyfluoroalkyl substances.

Phthalates

Based on our knowledge of the product and the manufacturing process, CARNATION does not contain phthalate compounds.

Preservatives

Based on our knowledge of the product and the manufacturing process, CARNATION does not contain preservatives.

Radiological

-Refer to "Irradiation"

REACH

CARNATION conforms to the requirements of Regulation (EC) No. 1907/2006 (REACH).

EC Number: 232-455-8

Registration number is 01-2119487078-27-0030

REACH SVHC

CARNATION does not contain Substances of Very High Concern (SVHC), as of current revision.

Residual Solvents

CARNATION does not contain reportable quantities of residual solvents according to USP <467>.

ROHS

Based on our knowledge of the product and the manufacturing process, CARNATION 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 CARNATION 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

CARNATION is derived from petroleum.

Stability

Limited testing has indicated that CARNATION is stable for at least 3 years if kept in the dark and 15°C and 30°C in factory sealed containers.

Storage Conditions

CARNATION 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, CARNATION 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

HS Tariff Classification No. 2710.19

Tocopherol

CARNATION may contain up to 10 ppm Tocopherol (Vitamin E) added as stabilizer.

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USP or NF Compliance

CARNATION meets the requirements of the Light Mineral Oil monograph in the National Formulary (NF).

Vegan/Vegetarian

CARNATION is certified VEGAN by the American Vegetarian Association.

Vitamin E

CARNATION may contain up to 10 ppm Tocopherol (Vitamin E) added as stabilizer.

Vitamin E - Source

Synthetic CAS No. 10191-41-0 Country of Origin: Switzerland