

Revision Date: June 1, 2021

**TECHNICAL REGULATORY STATEMENT – SONNEBORN REFINED PRODUCTS B.V.**

Products:

INCI	CAS no.	EINECS No.	HS Code	REACH No.
Petrolatum	8009-03-8	232-373-2	2712-1090.00	01-2119490412-42-0007
Mineral Oil	8042-47-5	232-455-8	2710-1985-00	01-2119487078-27-0013
Microcrystalline Wax	63231-60-7	264-038-1	2712-9099-90	01-2119495561-32-0013

**Manufacturer/Supplier (physical location)**

Sonneborn Refined Products B.V.  
Mainhavenweg 6  
1043 AL Amsterdam  
The Netherlands

**Aflatoxins / Mycotoxins / Genotoxins:** Our products are free of aflatoxins, mycotoxins, genotoxins

**Allergens:** Our products are derived entirely from petroleum hydrocarbons and do not contain Allergens according to the Regulation (EU) No. 1169/2011 and 26 allergens according to EU Regulation (EC) No. 1223/2009 including melamine, gluten, shellfish, wheat, dairy, corn starch, lactose, nuts, gelatins, sulfites or any protein-based ingredients.

**Animal Testing:** Sonneborn B.V. does not conduct animal testing or has commissioned any testing of our products.

**Animal Derived Materials:** Based on our knowledge of the products and the manufacturing process, these products do not contain animal/animal by-products.

**Antibiotics:** Our products do not contain antibiotics or viral ingredients

**Asbestos:** Asbestos is not used in or intentionally added to our products. Therefore, our products are Asbestos free.

**Bioengineered products:** Our products do not contain bioengineered ingredients

**BPA:** BPA is not used or intentionally added to our products. Therefore, our products are BPA-free

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**BSE/TSE:** Our products are derived entirely from petroleum hydrocarbons and do not contain animal or animal by-products so they are BSE/TSE free.

**California Prop 65:** None of the substances in the CA PROP 65 list (current revision) are intentionally added or present in our products.

**CMR:** Our products are not classified as carcinogen, mutagenic, cytotoxic or toxic for reproduction (CMR) of category 1A, 1B and 2 under the requirements of Regulation (EC) No. 1272/2008 and its amendments.

**Conflict minerals:** None of the Conflict Minerals (Dodd-Frank Act) are intentionally added or present in our products.

**Ethylene oxide/Dioxin:** Ethylene oxide / Dioxin is not used in our products.

**Glycerol:** Our products do not contain glycerol or derivatives of glycerol.

**GMP:** Sonneborn BV achieved EXCiPACT Certification Standards for Pharmaceutical Excipient Suppliers: Good Manufacturing Practices and Good Distribution Practices (GMP-GDP)

**GMO:** Our products are derived entirely from petroleum hydrocarbons and do not contain Plant-based products so they are GMO free.

**HACCP:** Sonneborn BV plant is certified to FSSC 22000 (Food safety system certification).

**Heavy Metals:** Our products comply with USP <232> and EMEA, Elemental Impurities, for Metal catalysts and metal residues

**Ingredients:** Sonneborn BV products are derived entirely from petroleum hydrocarbons.

**Iron / Iron oxides:** These compounds and their derivatives are not present in our products

**Irradiation:** Sonneborn BV products are not irradiated.

**ISO 9001:** Sonneborn BV plant is certified to ISO 9001:2015.

**Latex:** Our products do not contain Latex.

**Lot code:** Sonneborn BV uses batch numbers that are assigned through SAP in sequential manner (6 digits)

**Microbeads / Microplastics:** These compounds are not present in our products

**Microbiological:** Due to the nature of our production process it is extremely unlikely that any micro biological organisms will be present in our end products, confirmed by limited testing, according to ISO 4833-1

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**Nano materials:** Our products do not contain nanoparticles or nano materials.

**Nitrosamine and/or nitroso impurities:** These compounds are not present in our products

**Nutritional statement:** Nutritional data is not tested or reported for our products.

**Organic statement:** Sonneborn BV products are not organic certified.

**Ozone, Hazardous Air Pollutants:** Our products are free of Ozone and Hazardous Air Pollutants (HAP).

**Paraben:** Our products are free of paraben.

**Pesticides:** Sonneborn BV products do not contain pesticides including PCB.

**Phthalates (BPA):** Our products are free of phthalates.

**Plant Hormones:** Our products do not contain hormones or growth promoters

**REACH:** Sonneborn BV products (substances) are REACH registered and do not contain SVHC (current list)

**Residual Solvents:** Our products fulfil the requirements following the "Guideline CPMP/ICH/1940/00" on Residual Solvents. None of the solvents classified "Residual Solvents" in the Current USP<467> and the ICH Q3C are likely to be present.

**RoHS:** Sonneborn BV products do not contain RoHS.

**Shelf-life Statement:** Limited testing has indicated that the product is stable for up to 3 years if kept in the dark and between 15°C and 30°C in factory sealed drums.

**Volatile Organic Compounds:** Our products are in compliance with the Directive 2004/42/EC on the limitation of emissions of Volatile Organic Compounds. Our products do not contain any V.O.C.

**Vegetarian / Vegan status:** Sonneborn B.V. products are not derived or sourced from animal / animal by-products.

The information provided in this document is correct to the best of our knowledge

Sincerely



Mr. H.F. van Tent Beeking  
Manager QA & EHS