

sonneborn

REFINED PRODUCTS

February 20, 2013

SUBJECT: Phthalate compounds in USP/NF products manufactured by Sonneborn, LLC.

To Whom It May Concern,

Sonneborn, LLC manufacture USP/NF white mineral oils, USP Petrolatums and NF Microcrystalline wax to meet the purity of USP/NF (current revision) and FDA 21 CFR 172.878, 172.880 and 172.886 respectively.

Phthalate compounds are not used in our process nor are they introduced into these products before, during, or after manufacture. Based upon our knowledge of our raw materials and of our refining process, we can state that none of the above mentioned compounds are present in the products we supply to you.

Regards,



Charles Sheppard
Technical Services
724-756-9598

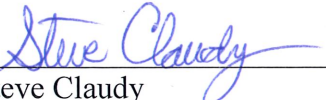
April 27, 2017

To Whom It May Concern:

Notice of Compliance to Current Good Manufacturing Practice

The Sonneborn, LLC - Petrolia Plant is a manufacturer of USP/NF White Mineral Oils, USP Petrolatums, and NF Microcrystalline Waxes that are used in various food, personal care, and pharmaceutical applications. These products are produced to meet strict requirements of purity and quality, within a system complying with the requirements of the Food and Drug Administration's Current Good Manufacturing Practice (cGMP) as described in the Q7A Good Manufacturing Practice Guidance for Active Pharmaceutical Ingredients.

The Petrolia Plant is also certified to the Food Safety System Certification FSSC 22000 that includes the GMPs associated with the Prerequisite Programs of the ISO 22000:2005 and the ISO/TS 22002-1:2009.



Steve Claudy
Manager of Quality Systems



QUALITY SYSTEMS
REGISTRARS, INC.

CERTIFICATE OF REGISTRATION

This is to certify that the management system of

Sonneborn, LLC

100 Sonneborn Lane
Petrolia, PA 16050

has been assessed and certified as meeting the requirements of

ISO 9001:2008

This certificate of registration remains valid subject to satisfactory surveillance audits for the following activities:

Manufacture of white oils, sulfonates, petrolatum, waxes and cable fillers and products produced under trade names agreed upon with distributors.

Certificate Number:	QSR-057
Certified since	December 15, 1992
Date issued	October 21, 2015
Date of certification	October 26, 2015
Valid until	September 15, 2018

Carol L. Tillman
Vice President



Manufacturing Date, Testing Date and Expiration Date of Products Shipped from the Petrolia Plant

Products Involved: All NF, USP, FDA, and Technical Grade White Oils
All USP, FDA Petrolatums
All NF, FDA Microcrystalline Waxes
All Sulfonates, All Cable Filler Compounds, Visconorust 2090P-4
All Ink Oils

The Petrolia Plant's quality system is ISO 9001:2008 registered with Quality Systems Registrars, Certificate number QSR-57.

As per ISO clause 7.5.3, Identification and traceability, and 7.5.5 Preservation of product, the Petrolia Plant has established documented procedures to identify and preserve the product during all stages of production and delivery. Within the plant, there are established procedures for storage and handling that prevent damage or deterioration of the product. In addition, a unique identification of individual batches of product is recorded and maintained. Shipments from production batches at the Petrolia Plant are given unique numbers based on the following criteria:

1. Bulk Shipments - each loading of a tank trailer or rail car is assigned a unique Sonneborn Delivery / item number and also carries a production Batch number. Both these numbers appear on the Certificate of Analysis.
2. Drum Shipments - each drum run of product is assigned an individual Batch number, i.e. drums filled from the same production batch are assigned the same drumming Batch number. This Batch number may be associated with different quantities of drums, based on the quantity needed for orders or stock.
3. Caked Waxes - each order or caking run is assigned an individual Batch number.

The Batch number is assigned for shipment or filling on a particular day. For products shipped from the Petrolia Plant, the Shipping date and Batch number entered on the Certificate of Analysis is traceable to its production batch and can be used as the Date of Testing.

Products shipped from the Petrolia Plant may show a Manufacturing Date and an expiration date on the COA. However, the longevity of products shipped from the Petrolia Plant is primarily based on the storage and handling conditions used after the product leaves the control of the Petrolia operation. Limited laboratory testing indicates that all of our products will last more than three years from date of shipment, if they are stored in darkness and at temperatures of 60°- 85°F (15°-30°C). It is up to the individual customer to evaluate the longevity of the product based on their particular storage and handling conditions.