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HACCP Plan for Petrolatum Sonneborn, LLC Petrolia Plant

VERSION: 10		REVISION DATE: March 6, 2023	
DATE	REVIEWED	DATE	APPROVED
	Jing Humphreys Preventive Controls Qualified Individual		Dustin Simmonds V.P. of Manufacturing Americas
AMENDMENT RECORD			
Various updates. Updated Process flowchart. Changes are in bold print.			

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HACCP Team

16 The HACCP Team is made up of the individuals with responsibilities listed below. They are
17 responsible for ensuring the Sonneborn’s food grade products, production facilities and
18 employees comply with cGMP according to 21 CFR Parts 110 and 117, FSSC 22000 and the
19 HACCP program that they have developed. The team will meet at least annually to review and
20 revise the plan, if necessary.

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22 HACCP Team Member

Responsibilities

23 Dave Collwell

Superintendent of Compounding and Shipping

24 Scott Deal

Maintenance Supervisor

25 Timothy Dietrich

Compounding Supervisor

26 Brian Fuhrer

Purchasing Manager

27 Jing Humphreys

Quality Assurance Coordinator

28 Ashley McNany

Quality Management Coordinator

29 Kenton McNany

Quality Control Supervisor

30 Ken Mittereder

Superintendent of Engineering/Plant Services

31 Craig Steiner

Hydrogenation Plant Superintendent

32 Tim Yasika

Regulatory Manager

33 Lance Zielinski

Safety Manager

34 **Evan Bernard**

Wax Supervisor

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Scope

37 The HACCP plan covers the following products.

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39 Petrolatum meeting 21 CFR 172.880

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Product Characteristics

42 Raw Materials for Petrolatum certified to 21 CFR 172.880

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- Raw materials, ingredients and product contact materials

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- Base oils, Waxy Base Oils, Bright stock, Bright stock Slack Wax (BSSW), Waxy Bright stock, Slack Wax, Scale Wax, Micro Foots Oil, Microcrystalline Wax, Fully Refined Paraffin Wax, White Mineral Oil (Petroleum Feedstocks)

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- Transported, transferred and stored in mild steel lines and vessels

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- Food Grade dl alpha-Tocopherol (Vitamin E)

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- Food Grade Butylated Hydroxy Toluene (BHT)

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- Biological, chemical and physical properties

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- Biologically unreactive

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- Not a food source

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- Very low moisture content, < 50 ppm

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- Chemically composed of:

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- Aromatic hydrocarbons

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- Saturated aliphatic and cyclic hydrocarbons