

The Safety of Regulated Consumer Products and MOAH

Tim Yaskia
Regulatory Manager
Sonneborn, LLC
Petroia, PA

sonneborn[™]

AN HF SINCLAIR BRAND

Contents

- The Article
- History of Refined Petroleum Products
- Natural Products Used in Personal Care Formulations
- Safety Considerations
- PAH Levels in Refined Petroleum and Natural Products
- Conclusion



The Article

- On May 26, 2015, the German consumer organization, Stiftung Warentest, published an article on its web site test.de called “Mineralöle in Kosmetika: Kritische Stoffe in Cremes, Lippenpflegeprodukten und Vaseline”.
- Analyzed 25 personal care products including creams, baby care and lip care products, body oils, hair waxes and vaselines
- Found up to 9% Mineral Oil Aromatic Hydrocarbon (MOAH)
 - A C24 molecule with one aromatic ring is 25% aromatic carbon content but it considered 100% MOAH in this article
- Also reported finding Mineral Oil Saturated Hydrocarbon (MOSH) in C16 – C35 range in lip care products.

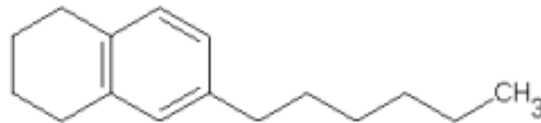
What is MOAH?

- A hydrocarbon compound with a single, substituted aromatic ring in a much larger molecule is considered 100% MOAH
 - Base oils (any molecule with Ca is classified as MOAH)
 - Linear Alkylbenzenes that are precursors for many detergents (20-25% of a typical laundry detergent)
- Other common single-ring, substituted aromatic compounds
 - Vanillin – the compound that makes vanilla taste the way it does
 - Aromatic Amino Acids (essential for human nutrition)
 - Phenylalanine
 - Tryptophan
 - Vitamins B12, E and K (essential for human health)
 - Melanin – the pigmentation in human skin

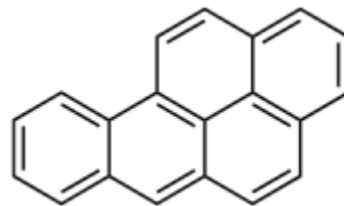


Two very different structures of “MOAH”

- Single Ring – Isolated, highly substituted, sterically hindered and unreactive mono-aromatic compounds having carbon numbers ranging from ~C16 to C100+

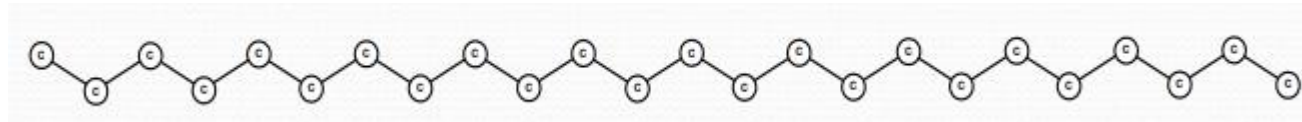


- Conjugated Rings – also known as Polycyclic Aromatic Hydrocarbons (PAH's) or two or more conjugated (fused) aromatic rings

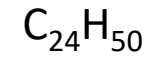


What is MOSH?

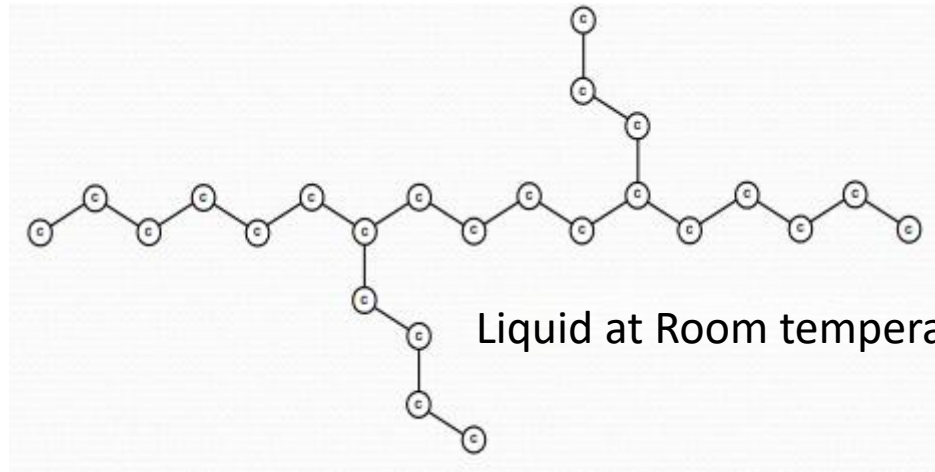
**Normal Paraffin
or n-alkane**



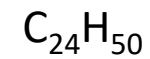
M.P =54°C (crystalline, solid at room temperature)



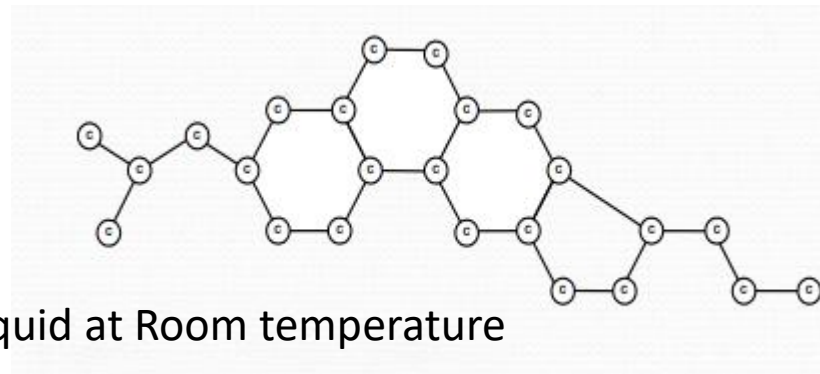
**Iso-Paraffin
or isoalkane**



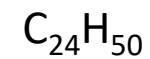
Liquid at Room temperature



**Cyclo-Paraffin
Cycloalkane**



Liquid at Room temperature



Petroleum Refining

- Physical separation
 - Fractional distillation
 - Atmospheric
 - Vacuum
- Deasphalting
 - PDA or propane deasphalting
- Deoiling or dewaxing (fractional crystallization)
 - MEK
 - Propane
 - Wax sweating



Petroleum Refining cont'd.

- Chemical transformation and separation
 - Liquid:Liquid separation, aka solvent extraction
 - Furfural or nMP
- Hydrogenation
 - Hydrofinishing – lower pressure; S and N removal
 - High pressure hydrogenation – saturation of aromatics
- Catalytic Dewaxing (isomerization) – turning wax into oil
- SO₃ or Oleum sulfonation (acid treatment)
- Adsorption – bauxite or clay filtration
- 21 CFR Compliance - chemical processes, positive controls, testing, and procedures in the case of high purity, food and pharmaceutical compliant oils, waxes and petrolatum
- **Confirmed by FDA audits for 21 CFR compliance**

White Mineral Oil USP

- FDA - **21 CFR 172.878** and **178.3620 (a)** for food
 - Release agent
 - Grain de-dusting
 - Plasticizer in food packaging
- Global standards..... Similar regulations worldwide
- Personal Care - **USP/NF**
 - Emollient
- Pharmaceutical - **USP/NF**
 - Active Ingredient
 - Excipient
- **No test or epidemiological evidence of mutagenicity or carcinogenicity in over a century of widespread use**

Petrolatum USP

- FDA - **21 CFR 172.880** for food
- FDA - **21 CFR 347.10 (m)** skin protectant monograph for OTC drugs
- **USP Grade** excipient in drug products
 - USP established chemical purity standards in 1920's
- Global standards..... Similar regulations worldwide
- Petrolatum was patented in 1872 by Robert Chesebrough ("Improvement in Products from Petroleum," US Patent 127,568 June 4, 1872)
- Petrolatum is known by several additional names including Petroleum Jelly and Vaseline® (a registered trademark of Unilever Corporation)
- **Over 150 years of demonstrated safe use...no laboratory or epidemiological evidence of mutagenicity or carcinogenicity**

Microcrystalline Wax

- **FDA 21 CFR 172.886** – Petroleum Wax ...Microcrystalline Wax NF
- Higher carbon numbers form micro as opposed to macro crystals
- Developed circa 1926 by separating wax from petrolatum
- Need for protective coatings during WWII drove demand
- Today's uses
 - Viscosity Modifier for hot melt adhesive
 - Chewing Gum Base – **FDA 21 CFR 172.615**
 - Crystal modifier in candle formulations
 - Forms occlusive moisturizing barrier, water wash-off resistance and adds body in skin lotions and creams
- **No laboratory or epidemiological evidence of mutagenicity or carcinogenicity in nearly a century of widespread use**



Natural Fats, Oils, Fatty Acids and derivatives

- Triglycerides – animal and vegetable
 - Palm
 - Coconut
 - Soy
 - Olive
 - Canola
 - Tallow
 - Sunflower
 - Lard
- Grade Range
 - Extra Virgin (meaning no refining)
 - Refined, Bleached and Deodorized (RBD)
- Regulated? For insects, microbes, rodent hair and feces, but not for chemical composition....
- **No US regulatory limits or controls for PAH's**

The logo graphic consists of three overlapping triangles pointing towards the top right. The top triangle is light blue, the middle one is a medium blue, and the bottom one is a dark blue. The brand name 'sonneborn' is written in white lowercase letters across the dark blue triangle.

sonnebornTM

AN HF SINCLAIR BRAND

Natural Products Processing

- Separations
 - Pressing
 - Expelling
 - Solvent extraction
- Chemical refining and processing.....parallel to treatment of petroleum
- Hydrolysis
- Dewaxing
- Hydrogenation
- Amidization
- Ethoxylation
- Sulfonation
- Reduction to alcohols
- Bleaching
- Deodorizing

A graphic element in the bottom right corner consisting of several overlapping triangles in shades of blue, creating a dynamic, geometric shape.

sonnebornTM

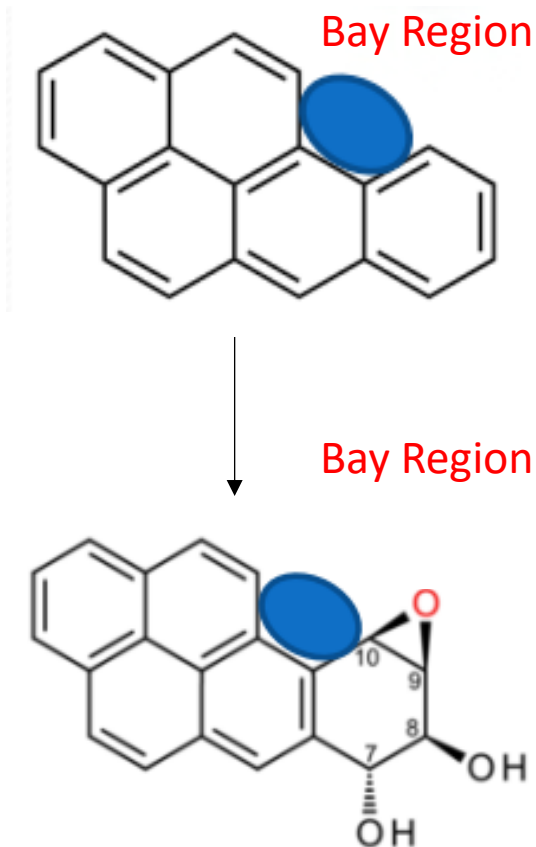
AN HF SINCLAIR BRAND

Natural Products Processing cont'd

- Extra virgin is the least rigorous grade from a chemical standpoint
- No refining other than simple filtration
- **No regulatory control for PAH's in natural products in the United States**

Petroleum Refining

- Why is limiting exposure to PAH important?
- Cancer in Climbing Boys (chimney sweeps)....Potts...1775
- Polycyclic Aromatic Hydrocarbons
- Bay region theory – PAH metabolizes to diol epoxides in turn react with DNA to form mutagens
- Bay region exists exclusively within fused rings
- Potentially created anytime you burn a hydrocarbon
 - Product of incomplete combustion
- Wood, coal, oils, peat and most famously, tobacco



Testing of Petroleum Products for PAH levels

- FDA Method - Haenni / Hall UV Absorbance
- DMSO Extractions to isolate all PAH compounds
- UV Spectroscopy for PAH's is very specific and quantitatively precise
 - Elegant, robust, low-cost test that is globally recognized
- No complicated million dollar instruments needed



Product Testing in Humans and Surrogates

- Skin Painting
 - Absorption Studies
 - For C16 and C22 - No absorption of beyond the epidermis
 - Carcinogenicity of petroleum products correlated to IP 346 limit of 3% DMSO extractables
 - IP 346 values compared to mouse skin painting results and Modified Ames Test results
- Feeding
 - Accumulation C16 - C35 in F344 Rats at 5% and 10% of diet (no inflammation)
 - Evidence of reversibility



PAH Levels in Refined Petroleum and Natural Products

- Concentration of 28 PAH's measured in Refined Petroleum and Natural Products (Grimmer GC/MS)
- Samples tested
 - Carnation® White Mineral Oil
 - Kaydol® White Mineral Oil
 - Super White Protopet® Petrolatum
 - Multiwax® W-445 Microcrystalline Wax
 - SonneNatural® (100% vegetable-based emollient)
 - Canola Oil
 - Certified Organic Coconut Oil

IARC Groups

	Supporting Evidence			
		HUMAN	EXPERIMENTAL ANIMALS	RELEVANT MECHANISMS
Group 1	Carcinogenic to humans	Sufficient	Sufficient	Sufficient
Group 2A	Probably carcinogenic to humans	Limited	Sufficient	Sufficient
Group 2B	Possibly carcinogenic to humans	Limited	Limited	Limited
Group 3	Not classifiable as to its carcinogenicity to humans	None	Limited	Limited
Group 4	Probably not carcinogenic to humans	Sufficient	Sufficient	Sufficient

Results

Units = µg/kg or parts per billion (ppb)

BUI Report Number	SON 1506	SON 1511	SON 1514	SON 1003D	SON 1519	SON 1512	SON 1513
	Carnation S/N 29350	Kaydol S/N 29355	SonneNatural (100% Vegetable S/N 29358)	Multiwax W-445 S/N 15682	Superwhite Protopet S/N 29363	Canola Oil S/N 29356	Certified Organic Coconut Oil S/N 29357
Group 1	0.000	0.093	0.053	0.000	0.127	0.000	1.692
Group 2A	0.000	0.011	0.000	0.000	0.218	0.000	3.986
Group 2B	1.459	4.406	0.280	0.280	2.218	13.377	41.361
Group 3	1.116	3.099	1.291	1.700	31.792	70.133	77.361
Total PAH	2.575	7.609	1.624	1.731	34.355	83.510	124.213

Conclusions

- MOAH is a generic, non-specific classification of aromatic hydrocarbons that provides no information regarding mutagenicity or carcinogenicity
- There is no evidence to suggest that single-ring, highly substituted, sterically hindered, aromatic structures that exist in food and pharmaceutical grade refined petroleum products are problematic.
 - Supported by CONCAWE studies in establishing limits for IP-346
 - Safety factor on the order of at least 30,000 ($3\% \div 1 \text{ ppm}$)
- Topically applied, hydrocarbons $>C_{16}$ will not penetrate the epidermisrather they form an occlusive barrier promoting retention of moisture in the skin (moisturization)
- Hydrocarbons $>C_{35}$ show little to no accumulation

More Conclusions

- Current FDA standards for PAH levels in compliant white oils, petrolatum and waxes provides a wide margin of safety for the positive control to avoid dangerous levels of known carcinogens
- There are no US standards for control of PAH's in “natural” products



Contributors

- Paul Raymond
- Luther Jones
- Tony Banaszewski
- Clay Rozic
- Jing Humphreys
- Nicole Bozzell



THANK YOU!

sonnebornTM

AN HF SINCLAIR BRAND

