

Multi-Residue Analysis of Certain Lanolin Nipple Care Products for Trace Contaminants

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Background

Topical lanolin is commonly used on nipples to increase comfort and aid breastfeeding success. USP and Ph. Eur. compliant lanolin is non-toxic, has neutral taste and smell, and low allergenicity¹. It is derived from sheep wool and undergoes refinement to remove contaminants such as detergents, salts and pesticides. The level of processing will influence the purity of the final product.¹ The objective of this study was to investigate whether samples of lanolin products intended for use to support breastfeeding contained any residual pesticides.

Methods

Three lanolin nipple care products (HPA^a, MED^b, ARD^c) intended for use when breastfeeding were analysed to detect and quantify 178 residual organochloropesticides (OCP), pyrethroids and organophosphopesticides (OPP) pesticide contaminants. The screening panel included all pesticides listed as reference pesticides in the USP and Ph. Eur. Lanolin monographs, and the limit of detection ranged from 0.01-0.05 ppm depending on the residue. The method for determination of pesticide residues was based on DIN EN 12393.^{2,3} Determination of free lanolin alcohols was performed using the gel permeation chromatographic clean up system followed by chromatographic analysis as described in the USP. Acid value, Anisidine value and peroxide value were determined as per the methods described in the European Pharmacopoeia wool fat monograph (Ph. Eur. 9.0., 2019). Antioxidant detection was via previously published methods.⁴

Contaminant	Description	Monograph requirements for compliance	
		Lanolin USP	Wool Fat Ph. Eur.
Free Lanolin Alcohols (FLA)	Wool alcohols are the principal component of lanolin in which allergens are found	6% max	n/a
Pesticides	Pesticides are toxic substances designed to kill weeds, fungi or pests. They are used in agriculture but can persist in the environment and accumulate as contaminants in food and natural materials	Total 3 mg/kg	Total 1 mg/kg
Oxidation Metabolites	Anisidine Value, Acid Value and Peroxide Value are measures of rancidity of lanolin. High levels of these oxidation metabolites can negatively impact the taste and smell of the product which may be distasteful to the infant	Acid Value max 0.90	Acid Value max 1.00, Peroxide Value max 20.00
Antioxidant	An antioxidant may be added to lanolin to improve stability, this is not required in super refined grades	Suitable antioxidant	Max 0.02% suitable antioxidant

a:HPA – Lansinoh HPA Lanolin, b:MED- Medela Purelan, c:ARD- Ardo Care Lanolin

Results:

HPA contained >3 times less FLA than MED and ARD

No antioxidants were detected in HPA or MED

HPA contained No Pesticide Residues
None of the 178 pesticides screened for were detected

Product	HPA			MED			ARD
LOT:	13099	17303	14355	011161-5	006222-6	004231-1	009421
Free Lanolin Alcohols (%)	0.49	0.56	0.79	2.80	2.50	3.00	2.10
Oxidation Metabolites (value)							
Peroxide Value	6.10	5.70	8.00	14.00	11.00	12.90	13.90
Acid Value	0.84	0.67	0.67	0.39	0.38	0.43	0.34
Anisidine Value	2.20	1.00	5.30	5.70	6.90	12.90	4.80
Antioxidants (mg/kg)							
Vitamin E	<10	<10	<10	<10	<10	<10	<10
BHT	<1	<1	<1	<1	<1	<1	<1
Benzophenone	<1	<1	<1	<1	<1	<1	3.2
Pyrethroids (mg/kg)							
Cypermethrin	<0.05	<0.05	<0.05	<0.05	<0.05	0.09	0.09
Organophosphoropesticides (mg/kg)							
Diazinon	<0.02	<0.02	<0.01	0.27	0.04	0.07	0.06
Diflubenzuron	<0.01	<0.01	<0.01	<0.01	0.02	<0.01	<0.01
PBO	<0.05	<0.05	<0.05	<0.05	0.10	0.27	<0.05
Triflumuron	<0.01	<0.01	<0.01	0.02	<0.01	<0.01	<0.01
Total Pesticides (mg/kg)	n/a	n/a	n/a	0.29	0.16	0.34	0.15

HPA and MED were tested in triplicate (3 different batches). None of the 178 pesticides included in the screening were detected in the HPA samples however 4 different OPP (Diazinon, Diflubenzuron, PBO & Triflumuron) were detected in the MED samples, albeit at extremely low trace levels. Cypermethrin, a pyrethroid insecticide, was also detected in a single sample of MED. It was only possible to test a single batch of ARD, however it was also found to contain a trace of Cypermethrin, as well as the OPP Diazinon. The total pesticides detected in all samples were still well below the permitted maximum of 1 mg/kg specified in the Ph. Eur. Monograph indicating all samples were extremely pure and suitable for their intended use on the nipples. FLA levels were notably lower for HPA lanolin compared to the other test products, indicating a superior purity consistent with the absence of pesticides. It was interesting that benzophenone was detected in the ARD sample as this lanolin does not list any preservative on its ingredients.

CONCLUSIONS

Compliance with Ph. Eur and USP has historically been considered the benchmark for purity, and all of the lanolin nipple care products evaluated in this study exceeded the requirements of these standards, giving confidence of a pure material suitable for its intended use. However, those benchmarks do not guarantee that lanolin products will be free of residual pesticides and antioxidants. Indeed, the data show that at least trace amounts of certain pesticides were measured in the ARD and MED lanolin products. By comparison, no such substances were detected in Lansinoh HPA Lanolin.

All products were compliant with USP and Ph. Eur. published monographs

Benzophenone was detected in ARD

Trace Pesticide Residues
Were detected in MED and ARD, however levels were within permitted limits

1. Clark, E. W. (1999). The History and Evolution of Lanolin. In The Lanolin Book (pp. 17–49). 2. Cetinkaya, M., & Leupold, D. I. (2013). Determination of Selected Pesticide Residues of Wool Fat by LC-MS/MS. *SOFW*, 139, 51–55. 3. Deutsches Institut für Normung E.V. (2014). *Foods of plant origin - Multiresidue methods for the determination of pesticide residues by GC or LC-MS/MS - Part 1: General considerations*. (DIN EN 12393-1). 4. Cetinkaya: Gas-Chromatographic Determination of BHT Residues in Wool Fat, *SÖFW-Journal* 133, 11-2007