AL –BIOSERVICES

# COSMETIC PRODUCT SAFETY REPORT

in compliance with Annex 1, EC Regulation 1223/2009

| | |
|---|---|
| Company | REPORT NUMBER **AL011071A** |
| **IMAN PRODUCT TRADING** | Batch |
| Contact Person | Product Name |
| KHURRAM MOHAMMED | **VIRGIN BLACK SEED OIL** |
| Company Address | Category of product |
| UNIT 8 STANLEY WORKS,STANLEY AVE, LONDON.HA0 4JB | **NIGELLA SATIVA SEED VIRGIN COLD PRESSED OIL** |
| Contact e-mail | Intended consumer group |
| info@imanproducts.com | **ADULTS** |
| Manufacturing company | Date of report |
| | **02.05.2017** |

Contents





**TECHNICAL CENTRE: TOPLEY HOUSE, OFFICE SUITE 7, 52 WASH LANE BURY, LANCS. BL9 6AS. Tel: 07760760346 /0161 764 9221**

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## Cross-reference to sub-headings of Annex 1 of EC1223/2009

This section is added as an aid to inspecting authorities. All sub headings listed in Annex 1 and detailed further in the Commission Implementing Decision 2013/674/EU are covered in this safety report as follows.

| Annex 1 sub-heading Section in this report<br>PART A | Section in this report<br><br>PART A |
|---|---|
| 1. Quantitative and qualitative composition of cosmetic product. | Quantitative product composition is given in Section 1. Correct INCI names as given on the EU "cosing" database are used in this report and EINECS/CAS numbers and ingredient functions are exactly as listed on the respective cosing entry. Purity and analytical specifications of raw materials are referred to in Section 3 Relevant physical/chemical characteristics on raw materials are referred to in Section 3. Relevant physical/chemical characteristics of the finished product are given in Section 2. The overall stability and stability testing of the finished product are summarised in Section 4.<br>The results of the preservative challenge test, where relevant for overall stability, is summarised in Section 5.<br>Raw material impurities are given in the certificates of analysis referred to in Section 3. Where unavoidable traces of prohibited substances are generally present in a particular raw material, this is detailed and commented on in the reference for that specific ingredient in Section 10 and Section 12. Relevant information on the packaging is given in Section 7.<br>Summarised in section 6 endpoints of relevance are summarised in Table 9.<br>Local toxicity endpoints are summarised in Table 11.<br>Suppliers' toxicity classifications, which are also taken into account in this report, are given in the CPL classifications on their safety data sheets which are referred to in Section 2. Specific exposure doses (SEDs), NOAEL values and margins of safety (MOS) are all given in Table 9. All justifications, other considerations, and sources of information for each ingredient are given in Section 10.<br>Section 14<br>Human studies of relevance are summarised in Section 13<br>Part B<br>Section 1<br>Section 2<br>Section 3<br>Assessor's credentials and confirmation of approval of this document are given in Section 6. The date of approval is the date on the first page of the whole report |
| 2. Physical/chemical characteristics and stability of the cosmetic product. | |
| 3. Microbiological quality. | |
| 4. Impurities, traces, information about the packaging material. | |
| 5. Normal and reasonable foreseeable use. | |
| 6. Exposure to the cosmetic product. | |
| 7. Exposure to the substances. | |
| 8. Toxicological profile of the substances. | |
| 9. Undesirable effects and serious undesirable effects. | |
| 10. Information on the cosmetic product | |
| PART B<br>1. Assessment conclusion<br>2. Labelled warning and instructions of use.<br>3. Reasoning. | |


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**PART A- Cosmetic Product Safety Information**

1. **Quantitative composition of the product.**

| Trade name of raw material | Supplier | INCI name | % raw material in final product | % name of daily application |
|---|---|---|---|---|
| **NIGELLA SATIVA SEED VIRGIN COLD PRESSED OIL** | | **NIGELLA SATIVA SEED VIRGIN COLD PRESSED OIL** | 100.00% | |
| | | | | |

2. **Physical/chemical characteristics of the product.**
   Appearance: oil
   Ph: 7
3. **Raw material specifications, impurities and hazard classifications**

All raw materials are from European cosmetic, food or pharmaceutical ingredient suppliers. Purity and analytical specifications of raw materials are contained on the Certificates of Analysis / Sales Specifications, which are held by the manufacturer / Responsible Person.
Specific impurities, where relevant to the safety assessment, will be detailed also in Section 1. Traces of prohibited substances, where possible for the ingredient in question, are described in Section 10 and

Section 12. Raw material physical characteristics and suppliers' hazard classifications under CPL are given in the safety data sheets.

| 4 RESULTS ON STABILITY, SHELF LIFE, BACTERIA ANALYSIS | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|
| **Date** | **28.3.17** | **04.04.17** | **11.04.17** | **18.04.17** | **25.04.17** | | | | |
| **TESTS EC1223/2009** | | | | | | | | | |
| **pH** | 7 | 7 | 7 | 7 | 7 | | | | |
| **Centrifugal Test @50** | No separation | No separation | No separation | No separation | No separation | | | | |
| | | | | | | | | | |
| **Date** | **28.3.17** | **04.04.17** | **11.04.17** | **18.04.17** | **25.04.17** | | | | |
| **Stability Tests EC1223/2009** | | | | | | | | | |
| **Odour** | normal | normal | normal | normal | normal | | | | |
| **Appearance** | Normal | normal | normal | normal | normal | | | | |


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| | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|
| | lotion | | | | | | | | |
| **Room Temp 24 - 25** | normal | normal | normal | normal | normal | | | | |
| **Accelerated 45 o C** | normal | normal | normal | normal | normal | | | | |
| **Date** | **28.3.17** | **04.04.17** | **11.04.17** | **18.04.17** | **25.04.17** | | | | |
| 5. Microbiological Testing | | | | | | | | | |
| **Bacteria** | No growth | No growth | No growth | No growth | No growth | | | | |
| **Mould** | No growth | No growth | No growth | No growth | No growth | | | | |
| **Fungus** | No growth | No growth | No growth | No growth | No growth | | | | |
| **Pseudomonas Aeruginosa** | No growth | No growth | No growth | No growth | No growth | | | | |
| **Staphylococcus** | No growth | No growth | No growth | No growth | No growth | | | | |


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# COSMETIC PRODUCT SAFETY REPORT

in compliance with Annex 1, EC Regulation 1223/2009

| Date of Receipt | Date of Report. | **Report No AL011071** |
|---|---|---|
| Customer: | | **Sample Date:** |
| **Customer Address** | | |
| | | |

| **Date** | **28.3.17** | **04.04.17** | **11.04.17** | **18.04.17** | **25.04.17** | | | | |
|---|---|---|---|---|---|---|---|---|---|
| **TESTS EC1223/2009** | | | | | | | | | |
| **pH** | 7 | 7 | 7 | 7 | 7 | | | | |

Tests performed :

**Challenge Test** – Test Method Cosmetic Regulation EC 1223/2009

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**Stability Tes**t – Test Method Cosmetic Regulation EC 1223/2009

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**Microbiological Tests** Cosmetic Regulation EC 1223/2009

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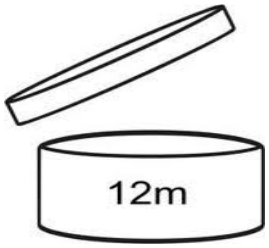
On the information gained over the 4 weeks, showed over 12 months shelf life achieved




**6. Normal and reasonable foreseeable use.**
Use as a typical oil, apply to required area

**7. Primary Packaging Information**
Packaging Supplier
**----------**
Primary packaging style and sizes
Test packaging is a 50 ml dark amber plastic bottle with plastic lid.

8week stability test done in packaging, no deterioration to product or packaging were observed.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**8. Exposure estimates used in this safety report**.
A. Dermal Exposures

| | |
|---|---|
| Target Consumer | ADULTS |
| Leave On | yes |
| Site of application | body |
| Amount of substance applied per use. | 7.82g |
| Frequency of use | Daily |
| Retention factor | 1.0 |
| Calculated daily exposure | 7.82 |
| Relative daily exposure per kg of body weight | 123.20 |

Note: Exposure estimates are taken directly from Tables 2 and 3 of SCCS Notes of Guidance (SCCS/1501/12) where the particular product category is listed, or are otherwise estimated using the Guidance and our experience. Relative daily exposure figures are not intended to be the absolute maximum that a user may experience but represent 90th
percentile exposures in the population. More detailed arguments for the figures we use are available on request. Data for adults refers to adults and teenagers aged 12 and over. Where different consumer categories are given the highest relative daily exposure figure is used for margin of safety calculations.

b. Oral Exposure: Unlikely with this product.

c. Inhalation Exposure: Unlikely with this product.

**9. Systemic Toxicity Data and Calculations of Margins of safety**

**.**

| **INCI name** | **% weight** | **Daily Exposure Mg/kg/day** | **Critical Toxicity Effect** | **Margin of Safety** | **Critical Toxicity Effect** |
|---|---|---|---|---|---|
| **NIGELLA SATIVA SEED VIRGIN COLD PRESSED OIL** | **100.00%** | | | | |

**Notes to Table 9**
(i) Relative daily exposure to product (from Section 8) x % in product
(ii) Dermal absorption usually assumed conservatively to be 100%. Reasons and references for figures lower than 100% are given in Section 10
(iii) SED=Systemic Exposure Dose = Relative daily exposure x Dermal Absorption
(iv) No Observed Adverse Effect Level in mg/kg/day in an animal model, unless otherwise stated. See reference in Table 10 for further information
(v) Margin of Safety = NOAEL divided by the SED. A figure of >100 is generally considered to be safe if the NOAEL is based on animal studies. MOE = Margin of Exposure based on known safe levels in humans; a figure of less than 100 may be acceptable – see comment in Table 10. <TTC means systemic exposure is less than “Threshold for Toxicological Concern” of 0.0015mg/kg/day, which is the threshold for toxicity for chemicals of unknown systemic toxicity with no structural alerts for genotoxicity and not suspected to be neurotoxic via anti-cholinesterase activity, according to the EFSA


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2011 Draft Opinion on the Concept of Threshold of Toxicological Concern. We have first made the judgement that the ingredient does not contain, or is unlikely to contain, any structural alerts for genotoxicity. Our TTC calculation also assumes a conservative dermal absorption of 25%.

**10. References and Reasoning for Toxicity Effects on each Ingredient:-**

**NIGELLA SATIVA SEED VIRGIN COLD PRESSED OIL**

Nigella sativa, commonly known as black seed or black cumin, is a plant which has been extensively used for centuries in folk medicines by the Asians, the Africans and the Middle East people. The popularity of this plant was highly enhanced by the popular belief in herbs as a panacea. The oil extracted from the seeds was a precious remedy for the Egyptians who named it "Pharaoh's oil" for its healthy properties. Nowadays, Nigella oil finds topical application in the supportive treatment of different skin inflammatory conditions, for its antimicrobial and antioxidant properties.

INCI NAME: Nigella sativa seed oil

Nigella oil is an amber oil which is a natural antioxidants source thanks to the presence of thymoquinone and several phytosterols, responsible also for the lenitive and emollient effects. It has been reported that cold pressed black cumin oil has a higher radical scavenger activity than extra virgin olive oil, when they are compared using stable DPPH and galvinoxyl radicals. Nigella oil is able to inhibit the production of 5-lipoxygenase, reducing the inflammation. Consequently, it can find topical application for the cosmeceutical treatment of skin inflammatory conditions such as psoriasis and eczema. It is also active against several bacteria and yeast.Nigella oil has a good amount of linoleic acid which is involved in the skin barrier function and skin permeability. These features make the oil ideal for cosmetic products aimed for sensitive skin.

APPEARANCE AND SENSORIALITY: Nigella oil has an amber yellow color and a spicy smell. It is highly nourishing/emollient and leaves the skin smooth and silky.

APPLICATIONS

- Cosmeceutical treatment of skin inflammatory conditions
- Products for sensitive and dry skin
- Hair care
- Massage oil


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**11.** Local Toxicity Data on 100% active ingredient Skin/eye corrosion, skin irritation, eye irritation and skin sensitisation data in this table are based on GHS (Global Harmonised Standard) classifications. Our data is taken from the REACH register for that entry where test results are given for the specific substance in question. Failing that, we consult expert reports
from other government or inter-governmental bodies. Weight of evidence summaries in SCCS and CIR opinions are also used in preference to individual suppliers' data. In the absence of the above, we use suppliers' classifications where specific validated test methods are referenced on the safety data sheet.
Otherwise, we perform our own literature searches or we read across from similar substances. Skin photosensitivity is based on examination of the chemical structure, UV absorption data, suppliers' data if available, and broader literature searching. Mucous membrane irritation data is taken as the same as eye irritation.

| INCI Name | % wt | Corrosivity | Eye irritation | Skin irritation | Skin sensitisation | Photo-toxicity |
|---|---|---|---|---|---|---|
| **NIGELLA SATIVA SEED VIRGIN COLD PRESSED OIL** | **100.00** | | yes | | | |

**Note to table 11:** means no local toxicity issues known for the given end point

12. **Restrictions and compliance with the EU Annexes**

| **INCI name** | **% weight** | **EU Annex restriction details** |
|---|---|---|
| NIGELLA SATIVA SEED VIRGIN COLD PRESSED OIL | | **none** |
| ethylhexylglycerine | | **none** |

**Perfume compliance to IFRA regulation**

| **% Perfume in product** | **IFRA category** | **IFRA regulations edition on certificate** | **Maximum % allowed on IFRA certificate** |
|---|---|---|---|
| **Not applicable** | **--------** | **----------** | **----------** |

**13 Human and in vitro toxicity studies on the finished product.**
**No human studies and no vitro toxicity studies have been carried out on the finished product.**
**13A No animal testing have been carried out on the finished product**

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**14 Reported Adverse Events.**
**Product new to the market when safety report was written.**


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**PART B- Cosmetic Product Safety Assessment**

**1. Assessment Conclusion**

We confirm that the product is safe in the stated application when used under normal and reasonably foreseeable use, and the product composition complies with EC Regulation 1223/2009 and all its annexes.

| | |
|---|---|
| Systemic,toxicity,including reproductive/ developmental toxicity | No concerns |
| Carcinogenicity/Mutagenicity | No concerns |
| Skin sensitisation | No concerns |
| Skin Irritancy | No concerns |
| Eye irritancy | No concerns |
| Phototoxicity and photosensitisation | No concerns |
| Microbiological Safety | No concerns |
| Product stability | No concerns |
| Packaging safety | No concerns |
| Formation of toxic materials via chemical eaction | No concerns |

**2. Safety assessor's warnings and specific instructions required for safe use**

The following warnings are required on both the inner and outer packaging Warning: avoid getting into the eyes. If product gets into the eyes wash out thoroughly with water.
It is assumed that instructions or use of commonplace product type names (e.g. "serum") as described in section 6 of Part A are used. No particular extra instructions are required for the safe use of this product.

**3. Reasoning**

This type of oil has been in common use in cosmetics over many years without any particular concerns.

**(a) Potential systemic toxic effects**

Table 9 gives the margin of safety for each of the ingredients used. It takes into account all systemic toxicity end points including organ toxicity, reproductive and developmental toxicity, blood and metabolic effects, and carcinogenicity. The end point that drives the NOAEL or other repeat dose toxicity value is given in the critical toxicity effect column, and is usually derived from repeat dose animal studies. If none is written it means that no toxicity was seen at the highest dose tested. All the ingredients used are
considered safe because they have a margin of safety (MOS) of 100 or over or, for ingredients for which safe levels in the human diet have been calculated, have a margin of exposure (MOE) of 1.0 or greater.The lowest margin of safety in this product is for SLES with a MOS value of 1500.

**(b) Carcinogenicity / mutagenicity / reproductive toxicity**

None of the ingredients are confirmed or suspected to be carcinogens, mutagens or reproductive toxins (class IA, 1B or 2 under GHS). Based on weight of evidence of in vitro studies, and in vivo studies where appropriate, none of the ingredients are considered to be mutagenic.

**(c) Potential skin sensitisation effects**

The main causes of skin sensitisation in cosmetics are perfume ingredients, essential oils and perfuming
absolutes, certain other non-perfuming plant extracts containing high concentrations of terpenes, some preservatives, some hair dyes, and some UV filters.

**(c1) Potential skin sensitisation from perfumes, synthetic aromas, essential oils and absolutes:** The International Fragrance Research Association (IFRA) has a series of regulations designed to prevent


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sensitisation to perfumes, essential oils and absolutes. The maximum concentrations of various ingredients for different types of cosmetic products (in %) are based on a NESIL value (No Expected Sensitisation Induction Level) in µg/cm2 from weight of evidence of both human (e.g. RIPT) and animal (e.g. mouse LLNA) studies. The calculations include a safety factor (SAF) of between 30 and 300
including a factor of 10 for inter-individual variability, as summarised in "Dermal Sensitization Quantitative Risk Assessment (QRA) for Fragrance Ingredients, IFRA Technical Dossier 2006". For a few perfuming actives such as Hydroxyisohexyl 3-Cyclohexene Carboxaldehyde (Lyral) this QRA method has not been undertaken due to lack of data, but provisional limits have been derived by IFRA based on other, e.g epidemiological, evidence. For perfumes, we have checked the relevant IFRA certificate and confirmed that the concentration of perfume complies in this product. For essential oils, absolutes and hydrosols, we have checked the maximum likely level of any IFRA regulated components and sensitisers and we confirm that the product complies with the regulations.

**(c2) Potential skin sensitisation from other ingredients**: The use of preservatives, UV filters and hair dyes is controlled by the EU on Annexes VI and VII and all toxicity endpoints, including skin sensitisation, are taken into account before an ingredient is listed. This product complies with any maximum concentration
restrictions imposed by the Annexes. For most other skin sensitisers (i.e. excluding essential oils and perfumes), the final product would not be considered a risk if the final concentration is less than 0.01%, which is the limit for classification under the CPL regulations. These levels are not exceeded in the product.

**(d) Potential skin / eye irritation effects**
Total concentration of irritant ingredients = <0.1%.
A general rule of thumb used in the classification of mixtures of chemicals under the EU REACH / CPL regulations is that skin or eye irritation is not significant if the total concentration of individual ingredients classified as irritant is less than 20% by weight. For leave-on skin-care products we would look for a total
of less than 10%. Additionally, the concentration of chemicals classified as corrosive or as capable of causing serious damage to the eye must be very low, and the pH should be between 3 and 10.
Based on the total concentrations of such ingredients as summarised in Table 11 and how the product is used skin irritation is not considered significant but the product will have a tendency to irritate the eye if left in.

**(e) Potential phototoxicity / photosensitisation**
This is a leave on product, phototoxicity is not an issue.

**(f) Microbiological safety**
A preservative challenge test has been carried out and has passed, and every batch is tested for microbial contamination v. EU industry standards.It is assumed that the manufacturer is following Good Manufacturing Practice and that microbiological contamination of the final product is being minimised.

**(g) Impact of product stability on safety**
Given the observations / testing on the product to date, and experience with this type of product, stability
is considered satisfactory and is not detrimental in terms of safety.
**(h) Impact of packaging on safety**
No chemical incompatibilities are expected between the primary packaging material (PE/PP) and the product, and this material(s) is regularly used to package similar cosmetic products in the EU. No deterioration has been seen in 8-week compatibility tests in the final packaging. Since this packaging is specifically stated as compliant with food contact packaging legislation in the EU it
is considered unlikely that toxic substances will migrate from the packaging to the product.


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**(i) Consideration of possible chemical reactions**
Our examination of possible reactive groups and chemical types of ingredients in this product indicates that there are unlikely to be any chemical reactions taking place that will affect the overall safety conclusions. Formation of nitrosamines in this product is not possible. The concentration of nitrate is very small and it needs to be reduced to nitrite before it can potentially form nitrosamines with residual diethanolamine from the Cocamide DEA. Chemical reducing conditions don't exist in the product in this packaging so there is no risk of formation of nitrosamines.

**4. Purity conditions**
This assessment assumes that only cosmetic, pharmaceutical or food grade ingredients are used. Certain
ingredients may have particular purity restrictions imposed on them under the annexes to the EU regulation and this Safety Report is only valid if these requirements are met. Such ingredients are indicated in Table 12 of Part A. Assuming any such restrictions are met, there are unlikely to be significant traces of heavy metals or any other prohibited or Annex III – restricted impurities in the final product.

**5. General notes and conditions of this safety report**
a. This safety report has been generated in edit-protected pdf format. It is not valid if any details are manually changed or the report is electronically scanned or altered in any way.
b. This safety report applies to products manufactured, sold or marketed by the company named above.
It cannot be transferred or sold to third parties, except with the agreement of EF Chemical Consulting Ltd.
c. This safety report only fully complies with Annex 1 of EC1223/2009 if it is filed in conjunction with the certificates of analysis, IFRA certificates, and safety data sheets for each ingredient. These are documentation and the Responsible Person should ensure they are filed together – or provide an electronic link to them.
d. Original versions of challenge test reports, stability testing reports and dermatological testing must also be filed alongside the safety report in the PIF file.
e. The assessment assumes that all other aspects of EC regulation 1223/2009 is being complied with, especially adherence to Good Manufacturing Practices (GMP).
f. Although this document is entitled "Cosmetic Product Safety Report" we do not make any reassurances that the product is considered to be a cosmetic under the EU Cosmetics Regulation. For borderline products we recommend you consult the relevant EU guidance documents and take independent advice.
g. This document does not confirm that we agree with any claims made about the product or implied in the product name. AL-BIOSERVICES are not involved in cosmetic claims support.
h. This assessment applies only to the ingredients listed and the specific application state. A new assessment will be required if a raw material is substituted with a different INCI name, a different colour, or a different perfume or essential oil, or if the same formula is used for a product with a different application.
i. If new undesirable events or "Serious Undesirable Events" are reported then this safety report will require updating.
j. We try to use the European INCI names as listed in the EU's cosing database in the assessments, but we do not guarantee it.
k. Except for the main preservatives and ingredients where the margin of safety is less than 110, this assessment is valid for concentration variations of +/- 10% of the declared percentage, to allow for manufacturing variations. For products containing water, this assessment is also valid for dilutions of the above formula with up to 5% water, as long as the preservative level is maintained at the same concentration in the finished product.


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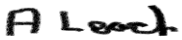
l. In supplying this safety assessment AL-BIOSERVICES makes no assurances that the individual substances or ingredients are registered or exempt under REACH. This is not usually an issue if the ingredient is sourced within the EU, but importers into the EU are warned that REACH notification rules apply once the annual imported quantity of a particular substance aggregated over all their products exceeds 1 TPA. Even if the substance has been registered it is possible that the registration doesn't cover its use a cosmetic ingredient. Importers into the EU of products containing botanical ingredients derived from endangered species should also make themselves aware of any CITES restrictions. We do not make these checks.

5 Name of assessor

A.Leach Technical Director AL-BIOSERVERICES BSc



Assessor Career

**Internal Auditors Course.**
**R.S.A. Health and Safety Management for Small Business Part 1**
**BSc Technology - University of Bolton**
**SDS Training using REACH software**
**Essentials Oil Training Course run by Aromahead Institute**
**Working knowledge on CosIng**

Angie has been working within in the cosmetic business for over 20 years. Starting off working at Northern Aromatics as a Q.C Chemist in their perfumery department. Working at Personal care manufacturers, with detail to CPSR on company products, a cosmetic chemist and safety assessor over the last 3 years. Angie makes her own products after visiting craft fairs, her interest in natural products came to a height when her son developed eczema, she developed her own products. Started up her own business 10 years ago, she is currently working with large cosmetic /perfume companies, down to small scale producers and has great understanding on a wide range of products.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