

## RAW MATERIAL INFORMATION FORM

### **Section 1: General Form:**

*Guidance for Section 1: see page 2*

**Please provide:**

**Date Completed:**

This questionnaire is intended to help in the technical approval and qualification of potential suppliers.

As such, the prompt and accurate completion of all sections will facilitate this process and the data on the form is treated as critical base data for safety and regulatory work.

All information will be treated as confidential.

If the information being requested is either unavailable or not applicable, please indicate and explain.

#### **A. Material /Supplier Identification:**

**Trade Name/Product #:**

**Harmonized Tariff Code:**

**Color Index Number (if applicable):**

**Manufacturer Name** (if different from Supplier):

**Supplier Name:**

**Contact Name:**

**Title:**

**E-mail Address:**

**Phone:**

**FAX:**

**Manufacturer's Plant Address**

(Address where material is manufactured):

**Country of Origin:**

#### **B. Required Supporting Documentation:**

Material Safety Data Sheet

☐

SDS

☐

Microbiological Specification

☐

Specification Sheet

☐

Certificate of Analysis (COA)

☐

GMP Certificate

☐

BSE Certificate

☐

Manufacturing Flow Chart

☐

#### **C. Applicable Sections:** **Please note if any data is restricted under confidentiality agreement (Mandatory in red).**

**General Form**

☐

**Restricted Data**

☐

**Regulatory Status**

☐

**Restricted Data**

☐

**Physical Chemical Properties**

☐

**Restricted Data**

☐

**Safety**

☐

**Restricted Data**

☐

**Environmental Impact**

☐

**Restricted Data**

☐

**Plant Derived Material**

☐

**Restricted Data**

☐

**TSE Certification**

☐

**Restricted Data**

☐

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#### D. Composition & Material Identification:

Total target contents of the components should sum up to 100%. **List all intentionally-added constituents in this table.** Please be noted the data here is critical base data for safety and regulatory work.

#### Definition of Function:

**Key Ingredients** - defined as chemicals intended to function in finished products.

**Additive Ingredients** – defined as chemicals intentionally added to material to maintain its quality or stability, such as preservative, anti-oxidant, UV filter, that does not function in finished product formula.

#	Constituent name (Assigned INCI name)	CAS#	EINECS# / ELINCS#	Min (W %)	Target (W %)	Max (W %)	Constituent Function	Feedstock Origin
1								
2								
3								
5								
6								
7								
8								
9								
10								

#### General Comments:

If you selected the Feedstock Origin “Bovine” or "Animal-other", please attach TSE certification.

If you select the Feedstock Origin "Other", please explain:

**Is the material a polymer according to the definition (ECHA)**

**Please note if the material is a polymer a detailed impurity profile should be provided in following table G.**

#### E. Certifications: Please supply as applicable.

Kosher Certification ☐ Yes ☐ No

Is the material Food Grade? ☐ Yes ☐ No

USP? ☐ Yes ☐ No

Other? (Please describe and/or attach)

Halal Certification

GRAS (Generally Recognized as Safe)?

EU Pharmacopeia?

☐ Yes ☐ No

☐ Yes ☐ No

☐ Yes ☐ No

#### LOI Declaration:

Do you certify that all the lots you supply will comply with all the answers until further notice from you? ☐ Yes ☐ No

#### Comments/Notes:

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**F. Global Inventory Status:** In the table below, please describe the inventory status of each constituent. Please choose the Inventory Status in each field below:

#	Constituent name (Assigned INCI name)	US	Canada	Australia	China	Japan		Korea	Philippines
		TSCA	Inventory	AICS	IECSC	ENCS	CLS	ECL	PICCS
1									
2									
3									
4									
5									
6									
7									
8									
9									
10									

**General Comments/Notes:**

**G. Impurity Profile:** Please refer to Guidance for explanation.

Impurities/Residues/Catalysts/Monomers/By-Products An impurity is any chemical substance that is unintentionally present. List all impurities (regardless of amount).	CAS #	Max Level in RM	% or ppm or ppb	Comments

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### Section 2: Regulatory Status: *Guidance for Section 2: see page 5*

**Instructions:** Provide any known restrictions on this material for use in cosmetic products: **For example, restrictions relating to UV Filters, colorants or preservatives or other restrictions noted in Annex III of the Cosmetic Directive, CIR, or Canadian Hot List**

#### A. Restrictions:

Country	Restriction ( % and approved use if any)
US	
Canada	
EU	
Australia	
China	
Japan	
Korea	
Other:	

#### B. Compliance:

Compliance with Regulations:	Yes or No?	Description
Are <u>any</u> of the ingredients a known Carcinogen, Mutagen or Reproductive Toxicant as defined in Annex I Directive 67/548 / EEC?		
Does the raw material as supplied contain any ingredients or impurities identified on the Substances of Very High Concern List under REACH?		
Are all of the ingredients compliant with the European Dangerous Substance Directive (67/548/EEC: 79/831/EEC)?		
Are all of the ingredients in compliance with the European Cosmetic Directive (76/768/EEC)?		
Are any of the ingredients or impurities listed by California Proposition 65?		
Are any of the ingredients declarable by California's SB 484?		
Are any of the ingredients or impurities found to be Carcinogenic by NTP?		
Are any of the ingredients or impurities found to be Carcinogenic by IARC?		

**\*\*Please attach the REACH status and summary (including any components that may require authorization) for the material.**

Animal Testing:	Yes or No?	Description
Are you in compliance with the 7 <sup>th</sup> Amendment of the European Cosmetic Directive 76/768/EEC prohibiting animal testing after a certain date?		
Has your company conducted or commissioned any animal testing on this raw material, or are you aware of any such animal testing conducted by a third party? Please specify most recent testing date.		
If testing was conducted post September 11, 2004, please specify date; describe purpose and endpoints for the test(s).		

Volatile Organic Content	Description
Are any of this material's ingredients classified as a VOC?	
Total Raw Material VOC content in % (wt/wt) <b>HVOC</b>	
<b>MVOC</b>	
<b>LVOC</b>	
<b>VOC Exempt?</b>	

## RAW MATERIAL INFORMATION FORM

### **Section 3: Physical Chemical Properties**

*Guidance for Section 3: see page 6*

#### **A. Physical Form:**

The material is supplied as

If material is a **powder** please supply Particle Size Distribution data

The physical parameters reported here are applicable to the material as it is supplied.

If no is chosen, explain:

#### **B. Physical Constants:**

Physical Parameter	Value	Additional Information
Molecular Weight*		
Specific Gravity		
Partition Coefficient (K <sub>ow</sub> )		
Melting Point	°C	
Boiling Point	°C	
Freezing Point	°C	
Flash Point	°C	
Minimum Ignition Temperature	°C	
<b>Spectral Data (As applicable)</b>		
UV/Visible		
IR		
Mass		
Fluorescence		
NMR		
<b>Separation/ Analysis Data</b>		
GC		
HPLC		
HPTLC		

\*Average molecular weight for key component.

**Please indicate SMILES notation for the key component:**

**Note: If physical property data is included in the attached MSDS, check here:** ☐

**If Particle Size distribution data is on the agglomerate please check this box:**

**Please also specify percentage of material that is less than 100 nm.**

## RAW MATERIAL INFORMATION FORM

### **Section 4. Human Safety**

*Guidance for Section 4: see page 6*

**Please supply robust summaries of the tests performed as an attachment.**

The testing identified here was completed on the material as it is supplied.

If the answer is “no,” please explain.

Please specify when *in vitro* models are used.

#### **A. Testing Summary:**

<i>Test</i>	<i>Protocol</i>	<i>Date</i>	<i>Result</i>
Acute Oral Toxicity			
Sub chronic Toxicity (28 / 90 day test)			
Dermal Irritation			
Dermal Sensitization			
Dermal Absorption			
Mucous Membrane Irritation (Eye)			
Mutagenicity (Ames)			
Genotoxicity			
Carcinogenicity			
Inhalation Toxicity			
Reproductive Toxicity			
Comedogenicity			
Photo-irritation			
Photo-toxicity			
Photosensitization			
Other:			
Other:			
Other:			
Other:			
Other:			

**General Comments/Notes:**

## RAW MATERIAL INFORMATION FORM

**B. Materials of Concern:** *Guidance for a list of Materials of Concern, see page 7*

Material(s) of Concern	CAS#	<i>ALL SOURCES:</i> Total Inclusion Level %	<i>Added Ingredient Contribution</i> Inclusion Level %	<i>Natural Source Contribution</i> Inclusion Level %

**C. Declarable Allergens:** Allergens other than those listed here may be disclosed in the Botanical Section.

Regulated Allergens	CAS#	Does not contain	<i>ALL SOURCES</i> Total Inclusion Level %	<i>Added Ingredient Contribution</i> Inclusion Level %	<i>Natural Source Contribution</i> Inclusion Level %
Alpha-Isomethyl Ionone	127-51-5	<input type="checkbox"/>			
Amyl cinnamal	122-40-7	<input type="checkbox"/>			
Amyl cinnamyl alcohol	101-85-9	<input type="checkbox"/>			
Anise alcohol	105-13-5	<input type="checkbox"/>			
Benzyl alcohol	100-51-6	<input type="checkbox"/>			
Benzyl benzoate	120-51-4	<input type="checkbox"/>			
Benzyl cinnamate	103-41-3	<input type="checkbox"/>			
Benzyl salicylate	118-58-1	<input type="checkbox"/>			
Butylphenyl methylpropional	80-54-6	<input type="checkbox"/>			
Cinnamal	104-55-2	<input type="checkbox"/>			
Cinnamyl alcohol	104-54-1	<input type="checkbox"/>			
Citral	5392-40-5	<input type="checkbox"/>			
Citronellol	106-22-9	<input type="checkbox"/>			
Coumarin	91-64-5	<input type="checkbox"/>			
Eugenol	97-53-0	<input type="checkbox"/>			
Isoeugenol	97-54-1	<input type="checkbox"/>			
Evernia Furfuracea (Treemoss) Extract	90028-67-4	<input type="checkbox"/>			
Evernia Prunastri (Oakmoss) Extract	90028-68-5	<input type="checkbox"/>			
Farnesol	4602-84-0	<input type="checkbox"/>			
Geraniol	106-24-1	<input type="checkbox"/>			
Hexyl cinnamal	101-86-0	<input type="checkbox"/>			
Hydroxycitronellal	107-75-5	<input type="checkbox"/>			
Hydroxyisihexyl 3- cyclohexene carboxaldehyde (Lylal)	31906-04-4	<input type="checkbox"/>			
Limonene	5989-27-5	<input type="checkbox"/>			
Linalool	78-70-6	<input type="checkbox"/>			
Methyl 2-octynoate	111-12-6	<input type="checkbox"/>			

**Please Note:** Allergens not included in this list may be disclosed under materials of concern section above or in the Plant Derived Section.

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### Section 5. Environmental Impact. *Guidance for Section 5: see page 8*

**Please supply robust summaries of the tests performed as an attachment.** The testing identified here was completed on the material as it is supplied. If the answer is “no,” please explain.

<i>Endpoint</i>	<i>Protocol</i>	<i>Date</i>	<i>Result</i>
<b><i>Aquatic Toxicity</i></b>			
Short-term toxicity testing on <i>Daphnia</i> *			
Long-term toxicity testing on <i>Daphnia</i>			
Growth inhibition study on algae			
Short-term toxicity testing on fish*			
Long-term toxicity testing on fish (OECD 210, OECD 212 or OECD 215)			
Activated sludge respiration inhibition testing			
Nitrification inhibition testing			
<b><i>Degradation</i></b>			
Biodegradability Study			
Simulation testing on ultimate degradation in surface water			
Soil simulation testing			
Sediment simulation testing			
Aerobic rate of biodegradation (please specify media)			
Anaerobic rate of biodegradation (please specify media)			
Hydrolysis as a function of pH			
Identification of degradation products			
<b><i>Fate &amp; Behavior in the Environment</i></b>			
Life cycle analysis (LCA)			
Adsorption/desorption screening study			
Bioconcentration in an aquatic species			
<b><i>Effects on Organisms</i></b>			
Short-term toxicity testing on earthworms*			
Long-term toxicity testing on earthworms			
Long-term toxicity testing on soil invertebrates other than earthworms			
Effects on soil microorganisms			
Short-term toxicity testing to plants*			
Long-term toxicity testing to plants			
Long-term toxicity testing to sediment organisms			
Long-term or reproductive toxicity testing to birds			



## RAW MATERIAL INFORMATION FORM

### **Section 6: Plant Derived:** *Guidance for Section 6: see page 9.*

**Please attach a manufacturing flow chart specifying mode of isolation or extraction.** For materials that have identified plant or combination feedstock origin, or contain more than one plant species please fill out one for each species identified.

Please specify plant species

Please specify plant part(s) used to make this material

Extract %                      Solids %

If a marker compound is included, or available please identify and specify level.

Please specify Phylogenetic name:

Genetically modified? Yes ☐ No ☐ Unknown ☐

**If the INCI name includes the phylogenic name of the plant, please answer the following questions:**

1. Is your Raw Material included in the IFRA guidelines? Yes ☐ No ☐
2. If 'Yes', does the Raw Material meet the IFRA guidelines? Yes ☐ No ☐
3. If 'Yes', please specify the amendment:
4. Revision Date:
5. Was the plant / botanical / fragrance screened for pesticides? Yes ☐ No ☐
6. If 'Yes', what are the pesticide residue levels?
7. Do the pesticide residues present meet the European Pharmacoposia Guidelines? Yes ☐ No ☐
8. Does the Raw Material contain any denatured alcohol? Yes ☐ No ☐
9. If "Yes", please specify the denaturant(s):

**Does the botanical contain, by addition or as a processing aid, any of the following nut/seed products?**

Materials of Concern	Does Not Contain	All Sources Total Inclusion Level %	Added Ingredient Contribution Inclusion Level %	Natural Source Contribution Inclusion Level %
<b>Tree Nuts --</b>	<input type="checkbox"/>			
Almonds	<input type="checkbox"/>			
Brazil nuts	<input type="checkbox"/>			
Cashews	<input type="checkbox"/>			
Chestnuts	<input type="checkbox"/>			
Cobnuts	<input type="checkbox"/>			
Hazelnuts (Filberts)	<input type="checkbox"/>			
Macadamia nuts	<input type="checkbox"/>			
Pecans	<input type="checkbox"/>			
Pistachio nuts	<input type="checkbox"/>			
Shea nuts	<input type="checkbox"/>			
<b>Seed products, oils or derivatives --</b>	<input type="checkbox"/>			
Peanuts	<input type="checkbox"/>			
Sesame seed	<input type="checkbox"/>			
Sunflower seed	<input type="checkbox"/>			
Cotton seed	<input type="checkbox"/>			
Canola (Rapeseed)	<input type="checkbox"/>			
<b>Other (please specify and describe)</b>	<input type="checkbox"/>			

## RAW MATERIAL INFORMATION FORM

### **Section 7: TSE Certification:** *Guidance for Section 7: see page 9*

The information captured here is intended to collect details on components that are derived from internal organs or connective tissues of animals.

	Ingredient	Identify Animal Species	Identify Source Organs	Age of Animal	Country of Origin	BSE Country Status GBR#
1						
2						
3						
4						
5						
6						
7						
8						
9						
10						

\*\* Category rating based on the EU Commission scientific steering committee (SCC) Regulation 999/2001-Geographical Risk of Spongiform Encephalopathy (GBR) Adopted on January 11, 2002. Updated on October 31 2007. As noted on the [EFSA Website](#)

**NOTE:** Level I--Highly Unlikely, Level II--Unlikely but Not Excluded, Level III--Likely but Not Confirmed or Confirmed at a Lower Level, Level IV--Confirmed at a Higher Level

### **Certification of Isolation Method:**

The material described in the table above is certified to be classified as a Category 3 under **Regulation (EC) No. 1174/2002**. As such the material shall be compliant with Articles 6 & 7 including:

- (b) processed in a processing plant approved in accordance with Article 13 using any of processing methods 1 to 5, in which case the resulting material shall be permanently marked, where technically possible with smell, in accordance with Annex VI, Chapter I, and disposed of as waste either by incineration or by co-incineration in an incineration or co-incineration plant approved in accordance with Article 12 or in a landfill approved under Directive 1999/31/EC;
- (c) processed in a processing plant approved in accordance with Article 17;
- (d) transformed in a technical plant approved in accordance with Article 18;

and suitable for its intended use.

Name of Certifying Person

Title

Date