

RAW MATERIAL INFORMATION FORM

Section 1: General Form:

Instructions for Section 1: see page 2

Please provide:

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 #: Allantoin

Harmonized Tariff Code: 2933.21.0000

Color Index Number (if applicable):

Manufacturer Name (if different from Supplier): ISP Chemicals LLC (Legal entity of Ashland Specialty Ingredients)

Supplier Name: Ashland Specialty Ingredients

Contact Name: Dale Brigandi

Title: Customer Support

E-mail Address: dbrigandi@ashland.com

Phone: (908) 243-3508

FAX: (908) 243-3580

Manufacturer's Plant Address

(Address where material is manufactured): **116 Summit Avenue, Chatham, NJ 07928**

Country of Origin: U.S.A.

B. Required Supporting Documentation:

Material Safety Data Sheet

SDS

Microbiological Specification

Specification Sheet

Certificate of Analysis (COA)

GMP Certificate

BSE Certificate

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

Environmental Impact statement (if available) with this completed questionnaire.

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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.

Carryover 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 (Approved INCI name)	CAS#	EINECS# / ELINCS#	Min (W %)	Target (W %)	Max (W %)	Constituent Function	Feedstock Origin
1	Allantoin	97-59-6	202-592-8		100		Key Ingredient	Synthetic
2							Select	Select
3							Select	Select
4							Select	Select
5							Select	Select
6							Select	Select
7							Select	Select
8							Select	Select
9							Select	Select
10							Select	Select

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 (Cefic) Select

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

E. Certifications:

Kosher Certification

Yes No

Halal Certification

Yes No

Is the material Food Grade?

Yes No

GRAS (Generally Recognized as Safe)?

Yes No

USP?

Yes No

EU Pharmacopeia?

Yes No

Other? (Please describe and/or attach) Depending on version of Allantoin can be USP and EP.

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 add in the Inventory Number or choose the Inventory Status in each field below:

#	Constituent name (Approved INCI name)	US		Canada		Australia		China		Japan		Korea		Philippines	
		TSCA	Listed	Inventory	AICS	IECSC	ENCS	JCIA	ECL	PICCS					
1	Allantoin	Listed	DSL	Listed	Listed	Listed	Listed	Listed	Listed	Listed	Listed	Listed	Listed	Listed	Listed
2		Select	Select	Select	Select	Select	Select	Select	Select	Select	Select	Select	Select	Select	Select
3		Select	Select	Select	Select	Select	Select	Select	Select	Select	Select	Select	Select	Select	Select
4		Select	Select	Select	Select	Select	Select	Select	Select	Select	Select	Select	Select	Select	Select
5		Select	Select	Select	Select	Select	Select	Select	Select	Select	Select	Select	Select	Select	Select
6		Select	Select	Select	Select	Select	Select	Select	Select	Select	Select	Select	Select	Select	Select
7		Select	Select	Select	Select	Select	Select	Select	Select	Select	Select	Select	Select	Select	Select
8		Select	Select	Select	Select	Select	Select	Select	Select	Select	Select	Select	Select	Select	Select
9		Select	Select	Select	Select	Select	Select	Select	Select	Select	Select	Select	Select	Select	Select
10		Select	Select	Select	Select	Select	Select	Select	Select	Select	Select	Select	Select	Select	Select

General Comments/Notes:

G. Impurity Profile: Please refer to General Form Instructions 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: *Instructions for Section 2: see page 4*

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	Use Level/Restriction: 0.5% - 2%
EU	
Australia	
China	Allantoin - MEP/CFDA Compliant
Japan	Use Level/Restriction: 0.50% for rinse off products not used on mucous membranes. 0.3% for leave-on products not used on mucous membranes. 0.20% for products used on mucous membranes.
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?	No	based on 12/72/2008/EC
Does the raw material as supplied contain any ingredients or impurities identified on the Substances of Very High Concern List under the REACH (NUMBER)	No	
Are all of the ingredients compliant with the European Dangerous Substance Directive (67/548/EEC: 79/831/EEC)?	Yes	based on 12/72/2008/EC
Are all of the ingredients in compliance with the European Cosmetic Directive (76/768/EEC)?	Yes	based on 1223/2009/EC
Are any of the ingredients or impurities listed by California Proposition 65?	No	
Are any of the ingredients declarable by California's SB 484?	No	
Are any of the ingredients or impurities found to be Carcinogenic by NTP?	No	
Are any of the ingredients or impurities found to be Carcinogenic by IARC?	No	

****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 th Amendment of the European Cosmetic Directive 74/768/EEC prohibiting animal testing after a certain date?	Yes	based on 1223/2009/EC
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.	No	
If testing was conducted post September 11, 2004, please specify date; describe purpose and endpoints for the test(s).		

Volatile Organic Content	Description

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Are any of this material's ingredients classified as a VOC?	
Total Raw Material VOC content in % (wt/wt) HVOC	
MVOC	
LVOC	
VOC Exempt?	

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Section 3: Physical Chemical Properties

Instructions for Section 3: see page 4

A. Physical Form:

The material is supplied as Powder

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

If no is chosen, explain:

B. Physical Constants:

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

*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:

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Section 4. Human Safety

Instructions for Section 4: see page 5

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

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

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:

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B. Materials of Concern:

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:

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 checked="" type="checkbox"/>			
Amyl cinnamal	122-40-7	<input checked="" type="checkbox"/>			
Amyl cinnamyl alcohol	101-85-9	<input checked="" type="checkbox"/>			
Anise alcohol	105-13-5	<input checked="" type="checkbox"/>			
Benzyl alcohol	100-51-6	<input checked="" type="checkbox"/>			
Benzyl benzoate	120-51-4	<input checked="" type="checkbox"/>			
Benzyl cinnamate	103-41-3	<input checked="" type="checkbox"/>			
Benzyl salicylate	118-58-1	<input checked="" type="checkbox"/>			
Butylphenyl methylpropional	80-54-6	<input checked="" type="checkbox"/>			
Cinnamal	104-55-2	<input checked="" type="checkbox"/>			
Cinnamyl alcohol	104-54-1	<input checked="" type="checkbox"/>			
Citral	5392-40-5	<input checked="" type="checkbox"/>			
Citronellol	106-22-9	<input checked="" type="checkbox"/>			
Coumarin	91-64-5	<input checked="" type="checkbox"/>			
Eugenol	97-53-0	<input checked="" type="checkbox"/>			
Isoeugenol	97-54-1	<input checked="" type="checkbox"/>			
Evernia Furfuracea (Treemoss) Extract	90028-67-4	<input checked="" type="checkbox"/>			
Evernia Prunastri (Oakmoss) Extract	90028-68-5	<input checked="" type="checkbox"/>			
Farnesol	4602-84-0	<input checked="" type="checkbox"/>			
Geraniol	106-24-1	<input checked="" type="checkbox"/>			
Hexyl cinnamal	101-86-0	<input checked="" type="checkbox"/>			
Hydroxycitronellal	107-75-5	<input checked="" type="checkbox"/>			
Hydroxyisihexyl 3-cyclohexene carboxaldehyde (Lyral)	31906-04-4	<input checked="" type="checkbox"/>			
Limonene	5989-27-5	<input checked="" type="checkbox"/>			
Linalool	78-70-6	<input checked="" type="checkbox"/>			
Methyl 2-octynoate	111-12-6	<input checked="" type="checkbox"/>			

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Section 5. Environmental Impact. *Instructions for Section 5: 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. **Select** If the answer is “no,” please explain.

<i>Endpoint</i>	<i>Protocol</i>	<i>Date</i>	<i>Result</i>
<i>Aquatic Toxicity</i>			
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			
<i>Degradation</i>			
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			
<i>Fate & Behavior in the Environment</i>			
Life cycle analysis (LCA)			
Adsorption/desorption screening study			
Bioconcentration in an aquatic species			
<i>Effects on Organisms</i>			
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			

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Section 6: Plant Derived: *Instructions for Section 6: see page 7.*

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 Not Applicable

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 %
Tree Nuts --	<input checked="" type="checkbox"/>			
Almonds	<input checked="" type="checkbox"/>			
Brazil nuts	<input checked="" type="checkbox"/>			
Cashews	<input checked="" type="checkbox"/>			
Chestnuts	<input checked="" type="checkbox"/>			
Cobnuts	<input checked="" type="checkbox"/>			
Hazelnuts (Filberts)	<input checked="" type="checkbox"/>			
Macadamia nuts	<input checked="" type="checkbox"/>			
Pecans	<input checked="" type="checkbox"/>			
Pistachio nuts	<input checked="" type="checkbox"/>			
Shea nuts	<input checked="" type="checkbox"/>			
Seed products, oils or derivatives --	<input checked="" type="checkbox"/>			
Peanuts	<input checked="" type="checkbox"/>			
Sesame seed	<input checked="" type="checkbox"/>			
Sunflower seed	<input checked="" type="checkbox"/>			
Cotton seed	<input checked="" type="checkbox"/>			
Canola (Rapeseed)	<input checked="" type="checkbox"/>			
Other (please specify and describe)	<input checked="" type="checkbox"/>			

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Section 7: TSE Certification: *Instructions for Section 7: see page 7*

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	Not Applicable	Select				
2		Select				
3		Select				
4		Select				
5		Select				
6		Select				
7		Select				
8		Select				
9		Select				
10		Select				

** 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 1774/2002**. 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.

Dale Brigandi

Dale Brigandi
Name of Certifying Person

Customer Support

Title

July 28, 2015
Date