

RAW MATERIAL QUESTIONNAIRE

Instructions: Please type response to the raw material questionnaire into the fields.

Submit completed forms to amwaytechreg@amway.com

If any changes are made to the information provide in this form, updated supporting documents must be provided.

Note: Blank spaces are not permitted. If any item is not applicable the space must be so marked to indicate that.

SUPPLIER / MANUFACTURER DETAILS	
Supplier / Manufacturer:	
Trade Name of Product:	
Common or Usual Name of Product:	
Supplier's Product Code:	
Supplier Name:	
Corporate Office Address:	
City, State, Zip Code:	
Country:	
Company Website:	
Supplier Contact Information	
Supplier Primary Contact Name:	
Title for Supplier Primary Contact :	
Supplier Email Address:	
Supplier Phone Number:	
Manufacturer Contact Information (if different than supplier)	
Name of Manufacturer:	
Address of Manufacturing Site:	
Address of Manufacturer:	
Country of Manufacture:	
<small>If China, provide production license of the manufacturer.</small>	
Technical Support Contact Information	
Technical/R&D Contact Name:	
Title of Technical Contact:	
Technical Contact Email Address:	
Technical Contact Phone Number:	
Quality Assurance Contact Information (optional, if different than Technical Support)	
QA Contact Name:	
Title of QA Contact:	
QA Contact Email Address:	
QA Contact Phone Number:	

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Regulatory Status	
<p>US Dietary Ingredient Regulatory Status under DSHEA 1994: Please check the appropriate classification and provide substantiation indicated.</p> <p>Link to US FDA: New Dietary Ingredients in Dietary Supplements- Background for the Industry</p> <p>Link to: Draft Guidance for Industry: Dietary Supplements Ingredient Notifications and Related Issues (Issued August 2016)</p> <p>Link to: CRN List of Dietary Ingredients "Grandfathered" Under DSHEA</p>	<p><input type="checkbox"/> Old/Grandfathered Dietary Ingredient (ODI) = Dietary ingredient marketed in the United States before October 15, 1994. <i>Provide supporting documentation to show marketed before Oct 15, 1994.</i></p> <p><input type="checkbox"/> New Dietary Ingredient (NDI) = Dietary ingredient not marketed in the US before Oct 15, 1994 requiring Notification. <i>Provide usage levels and conditions of use included in the NDI Notification, safety substantiation data may also be required.</i></p> <p><input type="checkbox"/> New Dietary Ingredient Exempt from Notification (NDI exempt) = New dietary ingredient present in the food supply as an article used for food in a form which the food has not been chemically altered <i>Provide rational for use in the food supply and not chemically altered.</i></p>
Additional Regulatory Information	
<p>Is this material Generally Recognized as Safe (GRAS) affirmed?</p> <p>Link to FDA Reference: Generally Recognized as Safe</p>	<p><input type="checkbox"/> Yes <input type="checkbox"/> No</p> <p>If yes, please attach <i>GRAS Notice reference and/or attach GRAS documentation.</i></p>
<p>Monograph/Pharmacopeial /Compendia/ Regulatory Grade Reference: Please specify</p> <p><i>Attached current version of supporting reference.</i></p>	<p><input type="checkbox"/> USP <input type="checkbox"/> NF <input type="checkbox"/> EP <input type="checkbox"/> JP <input type="checkbox"/> FCC <input type="checkbox"/> Food Grade <input type="checkbox"/> Commission E <input type="checkbox"/> Other _____</p>
<p>Conforms to established European Purity criteria for this material : Per Directive (EC) 231/2012</p> <p>Link to (EC) 231/2012</p>	<p><input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Not applicable</p> <p>If yes, please state the specific purity criteria and attach <i>European Purity Support Documentation and E-number.</i></p>
<p>Approved for use in the following countries:</p>	
<p>Tariff Code for Import/Export:</p>	

Genetically Modified Organism (GMO) Status	
<p><u>Select the GMO Status:</u> Product must be GMO Free, Identity Preserved (IP), or PCR Negative with the following exceptions:</p> <p><u>Please provide a "Statement of Certification" declaring GMO status, on signed corporate letterhead.</u></p> <p>EXAMPLE - <i>"This raw material (including all subcomponents such as additives or excipients, and the origin feedstock) has not been genetically modified or is IP of at least 99.1%. Provide PCR test results when applicable.</i></p> <p><i>Reference Regulation (EC) 1829/2003 and Regulation (EC) 1830/2003 with regard to labeling.</i></p> <p>Link to: Commercial GM Crop List</p>	<p><input type="checkbox"/> GMO Free Material derived from sources for which there is no existing commercial GM crops reported and would expect GMO Test results to be negative for GM DNA.</p> <p><input type="checkbox"/> IP (Identity Preserved) Materials derived from traditional, non-GMO seeds with a documented traceability process in place to assure that appropriate segregation of ingredient from seeds, through harvesting, transportation, storage and production of final product is maintained (with a recombinant DNA threshold of no more than 0.9%).</p> <p><input type="checkbox"/> PCR Negative Material from which GMO crops do exist commercially (for example: corn, soy, potato, tomato, cotton, sugar, beet, rapeseed, etc.), but the vendor is unable to provide traceability to support that material is not from a GM-crop or GM-microorganism. However, materials are highly refined/processed resulting in little to no DNA present so no GM DNA is detected when measured by the PCR test method.</p> <p><input type="checkbox"/> GMO Suspect If GMO is suspect, please explain: _____</p>

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Processing Information	
Manufacturing Process	
Brief Process description (ex. "single step alcohol extraction"):	
Source of starting material:	
Are processing aids used in the manufacturing process?	<input type="checkbox"/> Yes <input type="checkbox"/> No
	If yes, list: 1. _____ 2. _____ 3. _____
Please provide a <i>Manufacturing Process Flow Chart</i> to satisfy foreign market registration requirements.	Include parameters of processing, such as time, temperature, solvents (and residue levels), etc.
Solvents	
Are solvents used in the manufacturing process?	<input type="checkbox"/> Yes <input type="checkbox"/> No
	If yes, list percentage (strengths) of each solvent: 1. _____ 2. _____ 3. _____
Solvent residual level (ppm):	
Enzymes	
Are Enzymes used in Manufacturing?	Yes No
List Enzymes:	
Do the Enzyme(s) comply with EU: Reg (EC) 1332/2008?	Yes No

Sub-Ingredient Breakdown and Source of Raw Material (Physical Composition including excipients)									
INGREDIENT / SUB-INGREDIENT <small>(name as it should appear on product labeling)</small>	Percent (%) <small>(Range is acceptable, but please also provide target)</small>	Function <small>(e.g., Nutrient source, binder, carrier, solvent, sweetener, etc.)</small>	CAS Number <small>(if applicable)</small>	European E-number <small>(Conforms to European purity criteria) Per directive (EC) 231/2012</small>	(√) source				Please List Source. <small>If plant or animal source, also fill out sections below</small>
					Natural	Synthetic	Animal	Other? <small>(bio-fermentation)</small>	
					<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
					<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
					<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
					<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
					<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
					<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	

Active Marker		
Does this material contain an active marker?	<input type="checkbox"/> Yes <input type="checkbox"/> No	
If yes, complete this section		
Active Marker (BioActive) Name	% Range	Reference (example: HPLC)

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Modified Starch Status	
Is a subcomponent a modified food starch?	<input type="checkbox"/> Yes <input type="checkbox"/> No If yes, complete this section
Select the nature/treatment of the starch.	<input type="checkbox"/> Acid-modified Starch <input type="checkbox"/> Gelatinized Starch (Alkaline treated) <input type="checkbox"/> Hydroxypropyl Distarch Phosphate <input type="checkbox"/> Oxidized Hydroxypropyl Starch <input type="checkbox"/> Bleached Starch <input type="checkbox"/> Oxidized Starch <input type="checkbox"/> Starch Acetate <input type="checkbox"/> Acetylated Distarch Adipate <input type="checkbox"/> Starch Phosphate <input type="checkbox"/> Starch Sodium Octenyl Succinate <input type="checkbox"/> Distarch Phosphate <input type="checkbox"/> Phosphated Distarch Phosphate <input type="checkbox"/> Acetylated Distarch Phosphate <input type="checkbox"/> Hydroxypropyle Starch <input type="checkbox"/> Acetylated Distarch Glycerol <input type="checkbox"/> Succinyl Distarch Glycerol <input type="checkbox"/> Starch Aluminum Octenyl Succinate <input type="checkbox"/> Starch Sodium Succinate <input type="checkbox"/> Distarchoxy Propanol <input type="checkbox"/> Distarch Glycerol <input type="checkbox"/> Hydroxypropyl Distarch Glycol <input type="checkbox"/> Other _____

Flavor Status	
Is the product a flavor?	<input type="checkbox"/> Yes <input type="checkbox"/> No If yes, complete this section, and list all carriers and solvents under the sub ingredient breakdown section.
Is the flavor Natural or Artificial?	<input type="checkbox"/> Natural <input type="checkbox"/> Artificial
Reference to the regulation used to determine natural or artificial flavor status.	

Cultural Dietary Status	
Kosher Status	
Kosher Certified?	<input type="checkbox"/> Yes <input type="checkbox"/> No If yes, please attach valid Kosher certificate.
Certifying Agency:	
Expiration Date:	
Halal Status	
Halal Certified?	<input type="checkbox"/> Yes <input type="checkbox"/> No If yes, please attach valid Halal certificate.
Certifying Agency:	
Expiration Date:	

Nagoya Protocol	
Does this material comply with the Nagoya Protocol?	<input type="checkbox"/> Yes <input type="checkbox"/> No

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Plant Source						
(Please also complete the Botanical Supplier – Chain of Custody Form)						
Common or Usual Name <small>(per current Herbs of Commerce)</small>	Genus & Species <small>(variety / cultivar if available)</small>	Plant Part Used	Source of reference standard use to identify species *	Country Of Origin <small>(Feed Stock/Crop)</small>	Endangered species	Pesticide Used <small>(attach Test Results)</small>
					<input type="checkbox"/> Yes <input type="checkbox"/> No	
					<input type="checkbox"/> Yes <input type="checkbox"/> No	
					<input type="checkbox"/> Yes <input type="checkbox"/> No	

* Source of reference standard: examples: botanical voucher specimen, chemical reference standard, chain of custody, etc.

Plant Source Additional Information	
Is this a plant/botanical material?	<input type="checkbox"/> Yes <input type="checkbox"/> No If yes, complete this section.
Sterilization or fumigation method(s): <small>(An Irradiation statement is required)</small>	
Pesticides Used?	<input type="checkbox"/> Yes <input type="checkbox"/> No If yes, complete this section and attach <i>Declaration of Pesticide</i> .
1. Type of Pesticide:	
2. Method of pesticide detection used:	
3. Results for detecting residual pesticide levels:	
Life stage of the plant prior to processing. Ex: ripe v. unripe, mature v. immature	

Botanical Information	
Is this material a botanical? Fill out the additional <i>Botanical Chain of Custody Form</i> .	<input type="checkbox"/> Yes <input type="checkbox"/> No If yes, complete this section
State of crude botanical prior to processing:	<input type="checkbox"/> Fresh <input type="checkbox"/> Dried <input type="checkbox"/> Other: _____
Native extraction ratio:	_____ : _____ (Crude botanical) : (finished product, less excipients)
Final extraction ratio:	_____ : _____ (Crude botanical) : (finished product)
Is the crude botanical Certified Organic?	<input type="checkbox"/> Yes <input type="checkbox"/> No If no, are you willing to use a certified organic crude botanical or to move toward certified organic farming practices? <input type="checkbox"/> Yes <input type="checkbox"/> No

Organic Status	
Is this raw material Certified Organic?	<input type="checkbox"/> Yes <input type="checkbox"/> No If yes, provide a copy of the certificate
Certifying Agency:	
Expiration Date:	

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Animal Source (Example: fish, cattle, swine, birds, mollusks, etc.)	
Is the material derived in whole or part from animal sources?	<input type="checkbox"/> Yes <input type="checkbox"/> No If yes, complete this section.
1. Animal Common Name:	
2. Animal Genus and species:	
Country of Origin of Animal(s):	
Is the product, or any of its sub-ingredients, a milk-derivative?	<input type="checkbox"/> Yes <input type="checkbox"/> No If no, fill in the information in the next 3 rows.
1. Country of Animal Slaughtering:	
2. Animal Body Part(s) Utilized:	
3. Animal Sub-ingredient(s) :	
Is your product is bovine-derived (other than from milk) and sourced from a country other than the United States?	<input type="checkbox"/> Yes <input type="checkbox"/> No If yes, then attach: 1. BSE certificate from the exporting country and/or government 2. Import certificate from the USDA.
Is the product, or any of its sub-ingredients, gelatin or gelatin derivative?	<input type="checkbox"/> Yes <input type="checkbox"/> No If yes, then attach: 1. Chain of Custody documents beginning with the starting material of the gelatin 2. Animal Health Certificate from the country of origin of the bones.

Contaminates/Safety	
Radioactivity testing is performed on:	<input type="checkbox"/> Crude Botanical <input type="checkbox"/> Finished Product <input type="checkbox"/> Both <input type="checkbox"/> Not Tested
Microbiological testing is performed on:	<input type="checkbox"/> Crude Botanical <input type="checkbox"/> Finished Product <input type="checkbox"/> Both <input type="checkbox"/> Not Tested
Aflatoxin testing is performed on:	<input type="checkbox"/> Crude Botanical <input type="checkbox"/> Finished Product <input type="checkbox"/> Both <input type="checkbox"/> Not Tested
Aflatoxin test results:	
Heavy metals testing is performed on:	<input type="checkbox"/> Crude Botanical <input type="checkbox"/> Finished Product <input type="checkbox"/> Both <input type="checkbox"/> Not Tested
Heavy metals test method used (e.g. ICP-MS vs. AA):	
Can you provide documentation for the following assessments? Check all that apply and provide documentation.	<input type="checkbox"/> Clinical studies <input type="checkbox"/> In vitro toxicity studies <input type="checkbox"/> In vivo (animal) toxicity studies <input type="checkbox"/> Efficacy studies
Is the product a protein and/or an amino acid?	<input type="checkbox"/> Yes <input type="checkbox"/> No If yes, please provide: 1. A certification that the product is tested for the absence of melamine contamination (i.e. levels less than 2.5 mg/kg).
Material Safety Data Sheet (MSDS)	<i>Please provide a MSDS.</i>

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Allergen/Hypersensitivity Status

1. Does this ingredient contain, or is it derived from any of the following? (check box below)
 2. Are any of the following processed on the same equipment as the material you provide to us? (check box below)

Allergen/Sensitizing Agent	Contains/ Derived From		Processed on same Equipment	Allergen/Sensitizing Agent	Contains/ Derived From		Processed on same Equipment
	Yes	No	Yes		Yes	No	Yes
Artificial Colors				Peach			
Artificial Flavors				Peanut			
Artificial Preservatives				Polysorbate			
Barley				Polysorbate level:			
Buckwheat				Rye			
Caffeine				Sesame			
Carmine				Shellfish			
Celery				Soft Animal/Cephalopods (e.g., octopus, cuttlefish, squid etc.)			
Cocineal Extract				Soy		<input type="checkbox"/>	
Corn				Spelt			
Crustacea (Shellfish) (e.g., crab, lobster, shrimp, etc.)				Sugar			
Egg				Sulfites			
Fish				Naturally occurring Sulfite?	Yes	No	
Gluten				Sulfite level (ppm):			
Kamut				Tomato			<input type="checkbox"/>
Kiwi				Tree Nuts			
Lactose				Specify type of nut:			
Lupin				Triticale (i.e., secale cereal)			
Mango				Wheat			
Milk				Yeast			
Mollusks (Shellfish) (e.g., oysters, clams, mussels, scallops, etc.)				Other Nuts			
Mustard				Specify nut:			
Oats				Natural Latex contact	Yes	No	

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Documentation Checklist	
Please attach the following documents to this completed questionnaire:	
Required Documents	
<input type="checkbox"/>	DSHEA Regulatory Status
	GMO Statement (IP certificate and PCR results when applicable)
	Manufacturing Flow Chart (include critical processing parameters e.g. time, temperature, etc.)
	Product Specification (include shelf-life and storage conditions)
	Statement of Non-Irradiation/non-ETO /non-chemical sterilization
	Nutrient Profile or Proximate Analysis
	Certificate of Analysis (C of A) – Example
	Material Safety Data Sheet (MSDS)
Other Documents (if applicable)	
	GRAS Status: Notice reference and/or GRAS Documentation
	European Purity supporting documents
	Monograph: Pharmacopeial /compendia grade supporting documents/monograph
	Nagoya Protocol Documentation
	Flavor Statement (in accordance to country specific Regulations)
	Declaration of Pesticide
	Organic Certificate
	Chain of Custody Form (for Botanicals)
	Certificate of Melamine Testing (for protein or amino acids)
	Bovine Spongiform Encephalopathy (BSE) Certificate (for animal derived ingredients if from outside the USA)
	Import Certificate from USDA if from outside the USA (for animal derived ingredients)
	Chain of Custody (for the bones used in gelatin)
	Animal Health Certificate (for gelatin)
	Kosher Certificate
	Halal Certificate
	Clinical studies
	In vitro tox studies
	Animal tox studies
	Efficacy studies

I certify that the information provided in this document is true and correct.

Form Completed By			
Name:		Date:	
Title/Department:		Phone Number:	
Company:		Email:	