

## QUALITY AND REGULATORY INFORMATION

**PRODUCT NAME: COLLOIDAL OATMEAL RAW MATERIAL - 16088**

**REVISION DATE: September 26, 2019**

The following documents comprise the Quality & Regulatory documents that are within our ability to provide, as per normal industry standards. A check on the box indicates that we are able to provide that document or certificate either through internal laboratory testing or through documentation provided by the manufacturer of the product. If more detailed specifications or certifications are required, we regret that it is beyond our scope to provide them. This must be acquired through third party testing facilities or certifying agencies and would be the sole responsibility of the customer.

### Manufacturing Process

- Flow Chart
- Processed

### From Natural Sources

- Plant

### Raw Materials

- Derived from Non-Genetically Modified Plant Material
- GMO-Free (no genetically modified ingredients added)

### By-Products and Impurities

This product is:

- Heavy-Metal Declaration
- Phthalate Free
- Pesticide Declaration
- Solvent-Free

### Allergens

#### *Food allergens*

- Food Allergen Statement

#### **Fragrance allergens**

- IFRA Contact Allergens Statement

### Claims

- USP Grade
- BSE/TSE (Bovine/Transmissible Spongiform Encephalopathy) Free
- CMR Statement
- Cruelty-Free Statement
- Suitable for vegans

### Declaration

- Country of Origin
- VOC Compliant

## FLOW CHART

PRODUCT NAME: COLLOIDAL OATMEAL RAW MATERIAL - 16088



### Disclaimer & Caution

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## GMO STATEMENT

PRODUCT NAME: COLLOIDAL OATMEAL RAW MATERIAL - 16088

We hereby certify that, to the best of our knowledge, this product was not produced by gene modification, nor derived from genetically modified organisms. This material does not contain DNA or protein from genetically modified organisms.

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**NEW DIRECTIONS**  
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## HEAVY METALS DECLARATION

PRODUCT NAME: COLLOIDAL OATMEAL RAW MATERIAL - 16088

We hereby certify that, to the best of our knowledge, this product does not contain any heavy metals (mercury, lead, cadmium, arsenic, chrome, copper, nickel, cobalt) in quantity detectable by current analytical methods (0.5 mg/kg).

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## PHTHALATE-FREE STATEMENT

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We hereby certify that, to the best of our knowledge, this product was not produced with phthalates, nor does it contain any.

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## PESTICIDES DECLARATION

PRODUCT NAME: COLLOIDAL OATMEAL RAW MATERIAL - 16088

We hereby certify that, to the best of our knowledge, this product is in compliance of Regulation (EC) No 396/2005 of the European Parliament and of the Council of 23 February 2005 on maximum residue levels of pesticides.

REPORTING LIMITS (mg/kg)			
<b>Organochlorine Analytes</b>			
$\alpha$ HCH	0.005	Dicofol	0.01
$\beta$ HCH	0.005	Dieldrin	0.005
$\gamma$ HCH (lindane)	0.005	Endosulfan	0.01
2,4'-DDE	0.005	Endrin	0.005
2,4'-DDT	0.01	Heptachlor	0.005
2,4'-TDE	0.005	Heptachlor epoxide	0.005
4,4' -DDE	0.005	Hexachlorobenzene	0.005
4,4' -DDT	0.005	Quintozene	0.01
4,4' -TDE	0.005	Tecnazene	0.01
Aldrin	0.005	Tetradifon	0.01
Captan	0.01	Vinclozolin	0.01
<b>Organophosphates</b>			
Bromophos	0.01	Methidathion	0.02
Bromophos-ethyl	0.02	Mevinphos	0.01
Chlorpyrifos	0.02	Parathion	0.02
Chlorpyrifos-methyl	0.02	Parathion-methyl	0.02
Diazinon	0.01	Phenthoate	0.01
Diehlorvos	0.01	Phosalone	0.01
Ethion	0.01	Phosphamidon	0.01
Ethoprophos	0.02	Pirimiphos-ethyl	0.01
Etrimfos	0.01	Pirimiphos-methyl	0.02

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## PESTICIDES DECLARATION

PRODUCT NAME: COLLOIDAL OATMEAL RAW MATERIAL - 16088

Fenitrothion	0.05	Profenofos	0.01
Fonofos	0.01	Pyrazophos	0.05
Heptenophos	0.01	Quinalphos	0.05
Malathion	0.05	Tetrachlorvinphos	0.01
Mecarbam	0.02	Tolclofos-methyl	0.05
Methacrifos	0.02	Triazophos	0.02
<b>Carbamates</b>			
Bendiocarb	0.01	Pirimicarb	0.05
Carbaryl	0.02	Propoxur	0.05
Chlorpropham	0.02		
<b>Synthetic Pyrethroids</b>			
Bifenthrin	0.05	Deltamethrin	0.02
Cyfluthrin	0.02	Fenpropathrin	0.01
Cyhalothrin (lambda)	0.02	Fenvalerate	0.02
Cypermethrin	0.05	Pernethrin	0.02
<b>Miscellaneous Analytes</b>			
2-phenylphenol	0.01	Metalaxyl	0.02
Biphenyl	0.01	Oxadixyl	0.01
Bitertanol	0.02	Pendimethalin	0.02
Bromopropylate	0.01	Procymidone	0.01
Buprofezin	0.05	Propargite	0.01
Dicloran	0.01	Propiconazole	0.05
Ditlubenzuron	0.05	Propyzamide	0.01
Diphenylamine	0.02	Tebuconazole	0.05
Fenarimol	0.02	Trifluralin	0.01
Furalaxyl	0.01		

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## SOLVENT-FREE STATEMENT

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We hereby certify that, to the best of our knowledge, this product was not manufactured with solvent.

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**FOOD ALLERGEN STATEMENT**

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Component	Present in the product
Peanut (and/or derivatives,) e.g., protein oil	No
Tree Nuts (and/or derivatives)	No
Sesame Seeds (and/or derivatives)	No
Wheat, Barley, Rye, Oats, Spelt, Kamut or their hybrids	YES
Gluten	YES
Soybeans (and/or derivatives)	No
Dairy (including lactose) or Eggs	No
Fish or their products	No
Shellfish or their products	No
Sulphites (ppm level)	No

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## IFRA FRAGRANCE ALLERGEN STATEMENT

PRODUCT NAME: COLLOIDAL OATMEAL RAW MATERIAL - 16088

Ingredients	CAS #	ppm
Alpha-Isomethyl Ionone	127-51-5	< 1
Amyl Cinnamal	122-40-7	< 1
Amylcinnamal Alcohol	101-85-9	< 1
Anise Alcohol	105-13-5	< 1
Benzyl Alcohol	100-51-6	< 1
Benzyl Cinnamate	103-41-3	< 1
Benzyl Salicylate	118-58-1	< 1
Cinnamic Alcohol	104-54-1	< 1
Cinnamic Aldehyde (Cinnamal)	104-55-2	< 1
Citral	5392-40-5	< 1
Citronellol	106-22-9	< 1
Coumarin	91-64-5	< 1
Eugenol	97-53-0	< 1
Farnesol	4602-84-0	< 1
Geraniol	106-24-1	< 1
Hexyl Cinnamic Aldehyde	101-86-0	< 1
HMPCC (LyrAl) (Hydroxyisohexyl 3- cyclohexene Carboxaldehyde)	31906-04-4	< 1

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**IFRA FRAGRANCE ALLERGEN STATEMENT (cont'd)**

PRODUCT NAME: COLLOIDAL OATMEAL RAW MATERIAL - 16088

Ingredients	CAS #	ppm
Hydroxycitronellal	107-75-5	< 1
Isoeugenol	97-54-1	< 1
Lilial (Butylphenyl Methylpropional)	80-54-6	< 1
d-Limonene	5989-27-5	< 1
Linalool	78-70-6	< 1
Methyl Heptene Carbonate (Methyl 2- Octynoate)	111-12-6	< 1
Oak Moss Extracts (Evernia Prunastri)	90028-68-5	< 1
Tree Moss Extracts (Evernia Furfuracea)	90028-67-4	< 1

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**NEW DIRECTIONS**  
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## USP DECLARATION

**PRODUCT NAME: COLLOIDAL OATMEAL RAW MATERIAL - 16088**

We hereby certify that, to the best of our knowledge, this product conforms to the following monographs:

- United States Pharmacopeia 32 – NF 27

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**DECLARATION OF BOVINE SPONGIFORM ENCEPHALOPATHY (BSE)**

PRODUCT NAME: COLLOIDAL OATMEAL RAW MATERIAL - 16088

We hereby certify that, to the best of our knowledge, this product is free of BSE.

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## CMR STATEMENT

PRODUCT NAME: COLLOIDAL OATMEAL RAW MATERIAL - 16088

We hereby certify that, to the best of our knowledge, this product does not contain any Carcinogenic, Mutagenic or Reproductive Toxins, substances that are considered CMRs in the European Union under Annex I of Directive 67/548/EEC.

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**NEW DIRECTIONS**  
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## CRUELTY-FREE STATEMENT

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We hereby certify that, to the best of our knowledge, this product has not been tested on animals.

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**NEW DIRECTIONS**  
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## VEGAN STATEMENT

PRODUCT NAME: COLLOIDAL OATMEAL RAW MATERIAL - 16088

We hereby certify that, to the best of our knowledge, this product is suitable for vegans.

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## VOLATILE ORGANIC COMPOUNDS (VOC) STATEMENT

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We hereby certify that, to the best of our knowledge, this product contains no known volatile organic compounds or any other solvent.

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**NEW DIRECTIONS**  
A R O M A T I C S

## DECLARATION OF COUNTRY OF ORIGIN

PRODUCT NAME: COLLOIDAL OATMEAL RAW MATERIAL - 16088

We hereby certify, to the best of our knowledge, that the country of origin for this product is Finland.

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