



**GONMISOL**  
FINE INGREDIENTS

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Barcelona - Spain (EU)

**Technical package**

**Dossier Técnico**  
**31/05/2023**

## PASSIONFLOWER INCARNATA EXTRACT (4% FLAVONOIDS)

### PRODUCT SPECIFICATION

Product Name	INCI Name	EINECS Number	CAS Code
PASSIONFLOWER INCARNATA EXTRACT (4% FLAVONOIDS)	Passionflower, Passiflora incarnata, ext.	277-142-7	72968-47-9
Part Used	Flower fos		
Solvents Used	Water&Ethanol		
Botanical Source	Passiflora incarnata		
ANALYSIS ITEMS	SPECIFICATION		
Assay:			
Flavones (UV)	≥4.0%		
Appearance	Fine Powder		
Color	Yellowish Brown		
Odour	Characteristic		
Identification	Identical to R.S. sample		
Sieve analysis	100 % through 80 mesh		
Loss on Drying	≤5.0 %		
Total Ash	≤10.0 %		
Bulk density	40~60 g/100mL		
Tap density	60~90g/100mL		
Contaminants			
Lead (Pb)	≤3.0 mg/kg		
Arsenic (As)	≤2.0 mg/kg		
Cadmium (Cd)	≤1.0 mg/kg		
Mercury (Hg)	≤0.1 mg/kg		

Part or total information is provided as received from our supplier. The data outlined and the Statements made are intended only as a source of information. No warranties, expressed or implied, are made. On the basis of this information it is suggested that you analyze the product on a laboratory scale prior to use in a finished product. The information contained herein should not be construed as permission for violation of patent rights.



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### PRODUCT SPECIFICATION

Benzo(a)Pyrene	≤10µg/Kg
PAH4	≤50µg/Kg
PAAs	≤400 µg/kg
ETO	≤0.01mg/kg
Solvents Residue	Meet Eur.Ph. <2.4.24>
Pesticides Residue	Meet Eur.Ph. <2.8.13>
Non Irradiated	≤700
Microbiology	
Total Plate Count	≤10000 cfu/g
Yeast & Mold	≤1000 cfu/g
E.Coli.	Negative
Salmonella	Negative

Packing&Storage Packed in paper-drums and two plastic-bags inside;

N.W:25kgs, I.D.35×H51cm;

Store in a well-closed container Away from moisture,light, oxygen.

Shelf life 36 months under the conditions above and in its original packaging.



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### GENERAL PRODUCT INFORMATION

Mesh of the product	80
Tapped density	0.6~0.9g/ml
Bulk density	0.4~0.6g/ml
Water solubility	Partly soluble in water
Type of Manufacturing process (Synthesis, Fermentation, Extraction, etc.)	Extract
Specific Origin of the product (Animal, Vegetal, etc.)	From Passiflora incarnata
Is the product FREE of GLUTEN?	Yes
Approximate Extraction Range of the Product	7:1
Solvents used during the extraction process and their %	70%water and 30%ethanol
Is the product suitable for vegans?	Yes
Is the product suitable for vegetarians?	Yes
Is the product free of fructose?	Yes
Is this product suitable for food?	Yes
Can the product be used in baby food (according to Regulation (EU) N° 609/2013, Commission Delegated Regulation (EU) 2016/127, Commission Delegated Regulation (EU) 2021/572 and amendments)?	No
Drug indication	No
Melting point	N/A
Country of origin of the raw material/s of the product	China
Storage conditions (in the warehouse)	Store in tight, light-resistant containers, avoid exposure to direct sunlight, moisture and excessive heat.
Storage conditions (during the transport/short term)	Normal temperature



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## PASSIONFLOWER INCARNATA EXTRACT (4% FLAVONOIDS)

### TECHNICAL PRODUCT INFORMATION

IUPAC name	No
ATC Code	N/A
Molecular Formula	N/A
Chemical Structure	N/A
Stereochemistry	N/A
Molecular mass	N/A
Country of the factory (Manufacturing site)	China
Raw materials used for the manufacture of this product and their function	Dietary supplements
Frequency of analysis of each contaminant?	Every batch
Frequency of analysis of microbiology?	Every batch, Every batch
Frequency of analysis of each heavy metal?	Every batch, Every batch



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## **PASSIONFLOWER INCARNATA EXTRACT (4% FLAVONOIDS)**

### **FOREIGN MATERIAL**

Explanation of actions taken during the manufacturing process of this product to reduce the risk of appearance of foreign material:

Metal detector	No
Sieve	Yes When Sieving, through 80 mesh
Filter	Yes After extract, through ultrafilter.
X-Ray	No
Other	Yes The rotary vibration sieve outlet is mounted with a magnet to prevent foreign body contamination.



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## **PASSIONFLOWER INCARNATA EXTRACT (4% FLAVONOIDS)**

### **INGREDIENTS**

In accordance with the EU Regulation 1169/2011, amending EU Regulation 1924/2006 and EU Regulation 1925/2006, the following ones are the ingredients and their content (in %) in this product.

Passionflower Incarnata Extract	98%
Maltodextrin	2%



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## **PASSIONFLOWER INCARNATA EXTRACT (4% FLAVONOIDS)**

### **BSE/TSE**

This product does not contain and is not derived from Specified Risk Material as defined in European Commission Directive (and its amendments) and is therefore conform with the EU legislation relating to the risk of Transmission of Spongiform Encephalopathy (TSE).

### **GMO**

The following EU regulations have been published in the Official Journal of the European Union in this subject:

- Regulation (EC) No.1829/2003 of the European Parliament and the Council of 22 September 2003 on genetically modified food and feed.

- Regulation (EC) No.1830/2003 of the European Parliament and the Council of 22 September 2003 concerning tractability and labeling on genetically modified organisms and tractability of food and feed products produced from genetically modified organisms and amending Directive 2001/18/EC.

This product has not been genetically modified so there is no obligation of GMO labeling as defined by the above mentioned regulations.

### **NON IRRADIATION/NON IONIZED**

According to directives 1992/2/EC and 1999/3/EC, we confirm that this product is not made from irradiated/ionized raw materials and that this product was not irradiated/ionized.



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## **PASSIONFLOWER INCARNATA EXTRACT (4% FLAVONOIDS)**

### **PESTICIDES**

To our actual knowledge of the production process, of the raw materials and of the equipment used, the potential pesticide residues in this product comply with the European legislation on pesticide residues (esp. Regulation (EC) No. 396/2005 and amendments). However, we do not test for pesticide residues on a routine basis.

### **RESIDUAL SOLVENTS**

The product meets with:

- DIRECTIVE 2009/32/EC OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 23 April 2009 on the approximation of the laws of the Member States on extraction solvents used in the production of foodstuffs and food ingredients
- DIRECTIVE 2010/59/EU of 26 August 2010 amending Directive 2009/32/EC of the European Parliament and of the Council on the approximation of the laws of the Member States on extraction solvents used in the production of foodstuffs and food ingredients.

### **CONTAMINANTS**

The product is in accordance and meets with the Commission Regulation (EU) No. 2023/915 setting maximum levels for certain contaminants in foodstuffs.

### **PCBS AND MELAMINE**

This product is in accordance and meets with the Commission Regulation (EU) No. 2023/915 as regards the maximum levels of the contaminants Ochratoxin A, non-dioxin-like PCBS and melamine in foodstuffs.

### **ANTI-DOPING**

As per the list of 2012 of the World Anti-Doping Agency, the ingredient is not a doping substance or a combination of doping substances. The ingredient does not contain any doping substance. The ingredient does not result from a doping substance.

As per the list of 2016 of the World Anti-Doping Agency, the ingredient is not a doping substance or a combination of doping substances. The ingredient does not contain any doping substance. The ingredient does not result from a doping substance.

### **NANOMATERIALS**

According to the definition of 'Nanomaterials' of the UE Regulation No 1169/2011 of the European Parliament and of the Council of 25th of October 2011 (amending Commission Regulation (EC) 1924/2006 and Commission Regulation (EC) 1925/2006) on the provision of food information to consumers, we hereby attest that no nanomaterials are used in the manufacture, in the formulation nor in the packaging materials of this product.





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## **PASSIONFLOWER INCARNATA EXTRACT (4% FLAVONOIDS)**

### **PACKING**

We confirm that the packing used for this product is in compliance with:

- Regulation (EC) No. 1935/2004 of the European Parliament and of the Council of 27th of October 2004 on materials and articles intended to come into contact with food and repealing Directives 80/590/EEC and 89/109/EEC
- Commission Regulation (EU) No. 10/2011 of 14 January 2011 on plastic materials and articles intended to come into contact with food.

### **ETHYLENE OXIDE (ETO) & 2-CHLORO-ETHANOL**

Ethylene Oxide (& 2-Chloroethanol) is not used in any phases of the process of manufacture or storage of this product. This product does not enter in contact with Ethylene Oxide (& 2-Chloroethanol) in any phases of the process of manufacture or of storage. Therefore, this product is compliant with the limit established in Commission Regulation (EC) No. 396/2005.



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## PASSIONFLOWER INCARNATA EXTRACT (4% FLAVONOIDS)

### ALLERGENS

In accordance with Regulation (EU) No. 1169/2011, amending Commission Regulation (EC) No. 1924/2006 and Commission Regulation (EC) No. 1925/2006, we confirm the following information:

Does this product contain or is derived from or could be cross-contaminated by any of the following allergens?

Cereals containing gluten (i.e. wheat, rye, barley, oats, spelt, kamut or their hybridised strains) and products thereof	No
Crustaceans and products thereof	No
Eggs and products thereof	No
Fish and products thereof	No
Peanuts and products thereof	No
Soybeans and products thereof (with exceptions established in Annex II)	No
Milk and products thereof (including lactose) (with exceptions established in Annex II)	No
Nuts (i.e. almond, hazelnut, walnut, cashew, pecan nut, Brazil nut, pistachio nut, macadamia nut and Queensland nut) and products thereof (with exceptions established in Annex II)	No
Celery and products thereof	No
Mustard and products thereof	No
Sesame seeds and products thereof	No
Sulphur dioxide and sulphite at concentrations of more than 10 mg/kg or 10 mg/l expressed as SO <sub>2</sub>	No
Lupine and products thereof	No
Molluscs and products thereof	No



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## PASSIONFLOWER INCARNATA EXTRACT (4% FLAVONOIDS)

### ALBA LIST (ALLERGENS)

Note: 'Yes' means that there is contamination from

- 1) recipe contents,
- 2) other products handled on the same production line or
- 3) other products handled at same side.

	Cross contamination (mg/kg)?	Where?
Cow milk protein	No	-
Lactose	No	-
Chicken egg	No	-
Soya protein	No	-
Soya oil	No	-
Gluten	No	-
Wheat	No	-
Rye	No	-
Cattle	No	-
Pork	No	-
Chicken	No	-
Fish	No	-
Shellfish and Crustaceae	No	-
Corn	Yes	1
Cocoa	No	-
Leguminous plants	No	-
Nuts	No	-
Nut oil	No	-
Peanut	No	-
Peanut oil	No	-
Sesame	No	-
Sesame oil	No	-
Glutamate	No	-
Sulphide (E220 to E228)	No	-
Coriander	No	-
Celery	No	-
Carrot	No	-
Lupines	No	-

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## **PASSIONFLOWER INCARNATA EXTRACT (4% FLAVONOIDS)**

### **NUTRITIONAL INFORMATION**

Approximative Nutritional Information of this product is as follows:

Unit Weight 100 gram

Amount Per Unit

Total Fat 2gram

Saturated Fat 0 gram

Trans Fat 0 gram

Cholesterol 0 gram

Total Carbohydrate 48gram

Dietary Fiber 2gram

Sugars 0gram

Protein 5.1 gram

Sodium 0gram

Calcium 0.004gram

Total Calories 978.7KJ /233KCalorie



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## **PASSIONFLOWER INCARNATA EXTRACT (4% FLAVONOIDS)**

### **RESIDUE LIMITS (GELATIN, COLLAGEN)**

We herewith certify that this product in compliance with: Commission Regulation (EU) No. 2016/355 of 11st of March 2016, amending Annex III to Commission Regulation (EC) No. 853/2004 of the European Parliament and of the Council as regards the specific requirements for gelatine, collagen and highly refined products of animal origin intended for human consumption.

### **HYGIENE OF FOODSTUFFS**

We herewith certify that this product complies with Commission Regulation (EC) No. 852/2004 of the European Parliament on the hygiene of foodstuffs and all its amendments.

### **FULL TRACEABILITY**

This product complies with the full traceability criteria as mentioned in Commission Regulation (EC) No. 178/2002 of the European Parliament and of the Council of 28th of January 2002, laying down the general principles and requirements of food law, establishing the European food safety authority and laying down procedures in matters of food safety.



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## **PASSIONFLOWER INCARNATA EXTRACT (4% FLAVONOIDS)**

### **FACTORY ACCREDITATIONS/CERTIFICATIONS**

ISO 9001	Yes
ISO 22000	Yes
HACCP	No
GMP	Yes
FAMI QS	No



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## **PASSIONFLOWER INCARNATA EXTRACT (4% FLAVONOIDS)**

### **NON ANIMAL TESTING**

We certify that the product has not been tested on animals.



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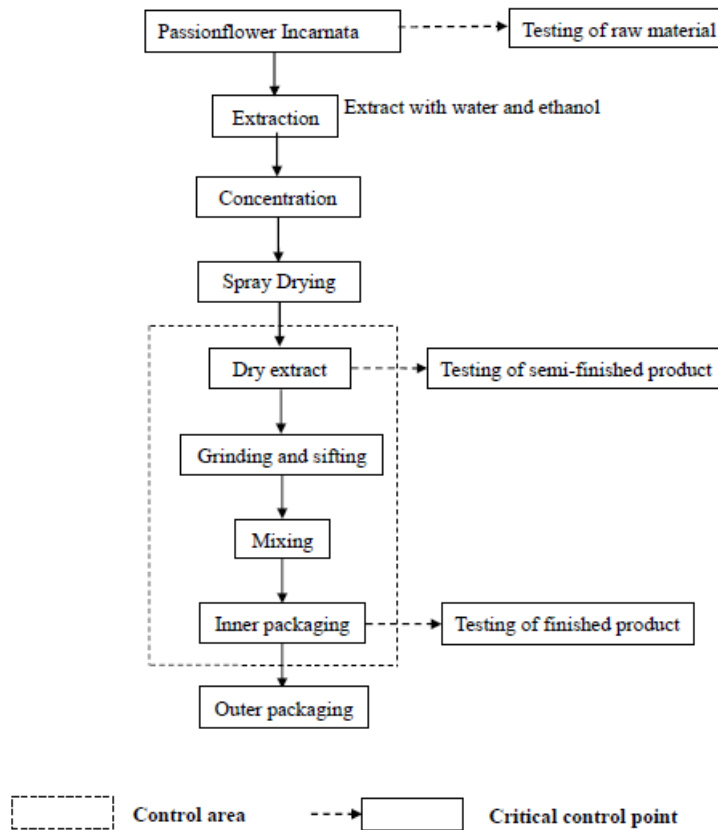
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## PASSIONFLOWER INCARNATA EXTRACT (4% FLAVONOIDS)

### Flow Chart







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**Material Safety Data  
Sheet**

**Documento MSDS  
23/03/2009**

## **PASSIONFLOWER INCARNATA EXTRACT (4% FLAVONOIDS)**

### **MSDS (Material Safety Data Sheet)**

#### **1. CHEMICAL PRODUCT AND COMPANY IDENTIFICATION**

Product Name: PASSIONFLOWER INCARNATA EXTRACT (4% FLAVONOIDS)  
CAS Number: 72968-47-9

#### Supplier Information:

Productos Químicos Gonmisol S.A.  
Camino de la Verneda 47-49  
08930 - San Adrian del Besos  
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#### **2. COMPOSITION/INFORMATION ON INGREDIENTS**

##### Assay

4% Total Flavonoids

#### **3. HAZARDS IDENTIFICATION**

##### Potential Health Effects

##### Eye

Dust can cause eye irritation. Symptoms include stinging, tearing, redness, and swelling of eyes.

##### Skin

May cause skin irritation. Symptoms may include redness, burning, and swelling of skin.

##### Swallowing

Swallowing this material is not likely to be harmful.

##### Inhalation

This material is a dust or may produce dust. Breathing small amounts of this material during normal handling is not likely to cause harmful effects. Breathing large amounts may be harmful.

##### Symptoms of Exposure

Signs and symptoms of exposure to this material through breathing, swallowing, and/or passage of the material through the skin may include: mouth and throat irritation (soreness, dry or scratchy feeling, cough).

##### Target Organ Effects

No data



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**Material Safety Data  
Sheet**

**Documento MSDS  
23/03/2009**

## **PASSIONFLOWER INCARNATA EXTRACT (4% FLAVONOIDS)**

### **MSDS (Material Safety Data Sheet)**

#### Developmental Information

There are no data available for assessing risk to the fetus from maternal exposure to this material.

#### Cancer Information

There is no information available. The chance of this material causing cancer is unknown. This material is not listed as a carcinogen by the International Agency for Research on Cancer, the National Toxicology Program, or the Occupational Safety and Health Administration.

#### Other Health Effects

This material can form dust which may cause skin or mucous membrane irritation. Symptoms may include redness, burning, and swelling. Although they may cause respiratory tract irritation, nuisance dusts do not form scar tissue or affect the structure of air spaces in the lungs. Their effects on the tissues are potentially reversible.

#### Primary Route(s) of Entry

Inhalation, Skin contact, Eye contact.

#### 4. FIRST AID MEASURES

##### Eyes

If symptoms develop, immediately move individual away from exposure and into fresh air. Flush eyes gently with water for at least 15 minutes while holding eyelids apart; seek immediate medical attention.

##### Skin

Remove contaminated clothing. Wash exposed area with soap and water. If symptoms persist, seek medical attention. Launder clothing before reuse.

##### Swallowing

First aid is not normally required. If symptoms develop, seek medical attention.

##### Inhalation

If symptoms develop, move individual away from exposure and into fresh air. If symptoms persist, seek medical attention. If breathing is difficult, administer oxygen. Keep person warm and quiet; seek immediate medical attention.

##### Note to Physicians

No data



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**Documento MSDS  
23/03/2009**

## **PASSIONFLOWER INCARNATA EXTRACT (4% FLAVONOIDS)**

### **MSDS (Material Safety Data Sheet)**

#### **5. FIRE FIGHTING MEASURES**

Flash Point

Not applicable

Explosive Limit

Not applicable

Autoignition Temperature

No data

Hazardous Products of Combustion

May form: carbon dioxide and carbon monoxide.

Fire and Explosion Hazards

Organic dusts can form explosive mixtures in air.

Extinguishing Media

regular foam, water fog, carbon dioxide, sand.

Fire Fighting Instructions

Wear a self-contained breathing apparatus with a full facepiece operated in the positive pressure demand mode with appropriate turn-out gear and chemical resistant personal protective equipment. Refer to the personal protective equipment section of this MSDS.

NFPA Rating

Health - 1, Flammability - 0, Reactivity - 0

#### **6. ACCIDENTAL RELEASE MEASURES**

Small Spill

Sweep up material for disposal or recovery.

Large Spill

Shovel material into containers. Thoroughly sweep area of spill to clean up any residual material.

#### **7. HANDLING AND STORAGE**

Handling

Containers of this material may be hazardous when emptied. Since emptied containers retain product residues (vapor, liquid, and/or solid), all hazard precautions given in the data sheet must be observed. Use good personal hygiene practices. Wash hands before eating, drinking, smoking, or using toilet facilities. Promptly



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**Documento MSDS  
23/03/2009**

## PASSIONFLOWER INCARNATA EXTRACT (4% FLAVONOIDS)

### MSDS (Material Safety Data Sheet)

remove soiled clothing and wash before reuse. Shower after work using plenty of soap and water.

#### Storage

Store in a cool, dry place at 75 degrees F or lower.

### 8. EXPOSURE CONTROLS/PERSONAL PROTECTION

#### Eye Protection

Wear safety glasses in compliance with OSHA regulations. (Consult your safety representative.)

#### Skin Protection

Wear resistant gloves such as: latex.

#### Respiratory Protections

3M Dust respirator No. 8710 or 9900 is recommended or a NIOSH/MSHA jointly approved dust respirator. (See your safety equipment supplier.)

#### Engineering Controls

Provide sufficient mechanical (general and/or local exhaust) ventilation to maintain exposure below level of overexposure (from known, suspected or apparent adverse effects).

#### Exposure Guidelines

#### Component

-----  
Passionflower P.E. 4% Flavonoids

No exposure limits established

### 9. PHYSICAL AND CHEMICAL PROPERTIES

#### Boiling Point

No data

#### Vapor Pressure

No data

#### Specific Vapor Density

No data

#### Specific Gravity

No data

#### Liquid Density

No data

#### Percent Volatiles

No data



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**Material Safety Data  
Sheet**

**Documento MSDS  
23/03/2009**

## **PASSIONFLOWER INCARNATA EXTRACT (4% FLAVONOIDS)**

### **MSDS (Material Safety Data Sheet)**

Evaporation Rate

No data

Appearance

No data

State

SOLID

Physical Form

POWDER

Color

Brown-Yellow

Odor

No data

pH

No data

#### **10. STABILITY AND REACTIVITY**

Hazardous Polymerization

Product will not undergo hazardous polymerization.

Hazardous Decomposition

May form: carbon dioxide and carbon monoxide.

Chemical Stability

Stable.

Incompatibility

No data

#### **11. TOXICOLOGICAL INFORMATION**

No data

#### **12. ECOLOGICAL INFORMATION**

No data

#### **13. DISPOSAL CONSIDERATION**

Waste Management Information

Dispose of with other normal, solid waste



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## **PASSIONFLOWER INCARNATA EXTRACT (4% FLAVONOIDS)**

### **MSDS (Material Safety Data Sheet)**

#### 14. TRANSPORT INFORMATION

DOT Information - 49 CFR 172.101

DOT Description:

NON-REGULATED BY D.O.T.

Container/Mode:

25KG/DRUM/ PACKAGE

NOS Component:

None

RQ (Reportable Quantity) - 49 CFR 172.101

Not applicable

#### 15. REGULATORY INFORMATION

US Federal Regulations

CERCLA RQ - 40 CFR 302.4(a)

None listed

CERCLA RQ - 40 CFR 302.4(b)

Materials without a "listed" RQ may be reportable as an "unlisted hazardous substance". See 40 CFR 302.5 (b).

SARA 302 Components - 40 CFR 355 Appendix A

None

Section 311/312 Hazard Class - 40 CFR 370.2

Immediate( ) Delayed( ) Fire( ) Reactive( ) Sudden

Release of Pressure( )

SARA 313 Components - 40 CFR 372.65

None

International Regulations

Inventory Status

Not determined

State and Local Regulations

California Proposition 65

None

#### 16. OTHER INFORMATION

The information accumulated herein is believed to be accurate but is not warranted to be whether originating with the company or not. Recipients are advised to confirm in advance of need that the information is current, applicable, and suitable to their circumstances.