

Revision date: 27-Aug-2009

Version: 1.0

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#### **IDENTIFICATION OF THE SUBSTANCE/PREPARATION AND THE COMPANY/UNDERTAKING** 1.

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## Material Name: OPTIMINA

Trade Name:	OPTIMINA
Chemical Family:	Mixture
Intended Use:	Food Supplement

## 2. HAZARDS IDENTIFICATION

Appearance:	Soft gelatin capsules
Statement of Hazard:	Harmful to aquatic life with long lasting effects.
Additional Hazard Information: Short Term: Long Term:	May have harmful effects on the aquatic environment. (based on components) Animal studies have shown a potential to cause adverse effects on the fetus. May have long- term effects on the aquatic environment. (based on components)
EU Risk Phrases:	R52/53 - Harmful to aquatic organisms, may cause long-term adverse effects in the aquatic environment.
Australian Hazard Classification (NOHSC):	Hazardous Substance. Non-Dangerous Goods.
Note:	This document has been prepared in accordance with standards for workplace safety, which require the inclusion of all known hazards of the active substance or its intermediates regardless of the potential risk. The precautionary statements and warnings included may not apply in all cases. Your needs may vary depending upon the potential for exposure in your workplace.

## **3. COMPOSITION/INFORMATION ON INGREDIENTS**

### Hazardous

Ingredient	CAS Number	EU EINECS/ELINCS List	Classification	%
ZINC SULPHATE	7733-02-0	231-793-3	N;R50-53	0.25-2.5
			Xn;R22-41	
Niacin (Nicotinic acid)	59-67-6	200-441-0	Not Listed	*
Manganese sulfate	7785-87-7	232-089-9	Xn;R48/20/22	<1
			N;R51-53	

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3. COMPOSITION/INFORMATION ON INGREDIENTS				
Copper	7440-50-8	231-159-6	Not Listed	*
Vitamin A	68-26-8	200-683-7	Not Listed	*
Riboflavin (Vitamin B2)	83-88-5	201-507-1	Not Listed	*
Cyanocobalamin (Vitamin B12)	68-19-9	200-680-0	Not Listed	*
Glycerin, USP	56-81-5	200-289-5	Not Listed	*
Black Iron Oxide	1317-61-9	215-277-5	Not Listed	*
Ferric oxide red	1309-37-1	215-168-2	Not Listed	*
Silica colloidal, Ph. Eur.	112945-52-5	Not listed	Not Listed	*
Sodium selenite	26970-82-1	Not listed	Not Listed	*

Ingredient	CAS Number	EU EINECS/ELINCS List	Classification	%
DHA (Docosahexanoic acid)	6217-54-5	Not listed	Not Listed	*
Ascorbic acid (Vitamin C)	50-81-7	200-066-2	Not Listed	*
Lutein	127-40-2	204-840-0	Not Listed	*
Vitamin E (D-alpha-Tocopherol)	59-02-9	200-412-2	Not Listed	*
Vitamin B6 (Pyridoxine)	65-23-6	200-603-0	Not Listed	*
Thiamin (Vitamin B1)	59-43-8	200-425-3	Not Listed	*
Beeswax	8012-89-3	232-383-7	Not Listed	*
Folic Acid	59-30-3	200-419-0	Not Listed	*
Gelatin	9000-70-8	232-554-6	Not Listed	*
Soy Lecithin	Not Assigned	Not listed	Not Listed	*

### **Additional Information:**

Ingredient(s) indicated as hazardous have been assessed under standards for workplace safety.

## For the full text of the R phrases mentioned in this Section, see Section 16

4. FIRST AID MEASURES	
Eye Contact:	Flush with water while holding eyelids open for at least 15 minutes. Seek medical attention immediately.
Skin Contact:	Remove contaminated clothing. Flush area with large amounts of water. Use soap. Seek medical attention.
Ingestion:	Never give anything by mouth to an unconscious person. Wash out mouth with water. Do not induce vomiting unless directed by medical personnel. Seek medical attention immediately.
Inhalation:	Remove to fresh air and keep patient at rest. Seek medical attention immediately.

## **5. FIRE FIGHTING MEASURES**

Extinguishing Media:	Use carbon dioxide, dry chemical, or water spray.
Hazardous Combustion Products:	Formation of toxic gases is possible during heating or fire.
Fire Fighting Procedures:	During all fire fighting activities, wear appropriate protective equipment, including self- contained breathing apparatus.
Fire / Explosion Hazards:	Fine particles (such as dust and mists) may fuel fires/explosions.

#### 6. ACCIDENTAL RELEASE MEASURES **Health and Safety Precautions:** Personnel involved in clean-up should wear appropriate personal protective equipment (see Section 8). Minimize exposure. Measures for Cleaning / Collecting: Contain the source of spill if it is safe to do so. Collect spilled material by a method that controls dust generation. A damp cloth or a filtered vacuum should be used to clean spills of dry solids. Clean spill area thoroughly. Place waste in an appropriately labeled, sealed container for disposal. Care should be taken to **Measures for Environmental** avoid environmental release. Protections: **Additional Consideration for Large** Non-essential personnel should be evacuated from affected area. Report emergency Spills: situations immediately. Clean up operations should only be undertaken by trained personnel.

### 7. HANDLING AND STORAGE

General Handling:	If tablets or capsules are crushed and/or broken, avoid breathing dust and avoid contact with eyes, skin, and clothing. When handling, use appropriate personal protective equipment (see Section 8). Wash hands and any exposed skin after removal of PPE. Refer to Section 12 - Ecological Information, for information on potential effects on the environment. Review and implement appropriate technical and procedural waste water and waste disposal measures to prevent occupational exposure or environmental releases. Potential points of process emissions of this material to the atmosphere should be controlled with dust collectors, HEPA filtration systems or other equivalent controls. Releases to the environment should be avoided.
Storage Conditions:	Store as directed by product packaging.

### 8. EXPOSURE CONTROLS / PERSONAL PROTECTION

Refer to available public information for specific member state Occupational Exposure Limits.

Niacin (Nicotinic acid)	
Latvia OEL - TWA	Listed
Lithuania OEL - TWA	Listed
Manganese sulfate	
ACGIH Threshold Limit Value (TWA)	0.2 mg/m³ TWA
Australia TWA	1 mg/m <sup>3</sup>
Austria OEL - MAKs	Listed
Belgium OEL - TWA	Listed
Bulgaria OEL - TWA	Listed
Czech Republic OEL - TWA	Listed
Denmark OEL - TWA	Listed
Finland OEL - TWA	Listed
Germany - TRGS 900 - TWAs	0.5 mg/m <sup>3</sup>
Germany (DFG) - MAK	0.5 mg/m³ MAK
Germany - Biological Exposure Limit:	Listed
Greece OEL - TWA	Listed
Hungary OEL - TWA	Listed
Ireland OEL - TWAs	Listed
Lithuania OEL - TWA	Listed
Poland OEL - TWA	Listed
Portugal OEL - TWA	Listed
Slovenia OEL - TWA	Listed

Spain OEL - TWA	Listed
Sweden OEL - TWAs	Listed
_	
er ACGIH Threshold Limit Value (TWA)	0.2 mg/m <sup>3</sup> TWA
ACGIN Threshold Linit Value (TWA)	1 mg/m <sup>3</sup> TWA
Australia TWA	$0.2 \text{ mg/m}^3$
AUSUIdila TWA	$1 \text{ mg/m}^3$
	Listed
Austria OEL - MAKs	
Belgium OEL - TWA	Listed
Bulgaria OEL - TWA	Listed
Czech Republic OEL - TWA	Listed
Denmark OEL - TWA	Listed
Estonia OEL - TWA	Listed
Finland OEL - TWA	Listed
France OEL - TWA	Listed
Germany (DFG) - MAK	0.1 mg/m <sup>3</sup> MAK
Greece OEL - TWA	Listed
Hungary OEL - TWA	Listed
Ireland OEL - TWAs	Listed
Latvia OEL - TWA	Listed
Lithuania OEL - TWA	Listed
Netherlands OEL - TWA	Listed
OSHA - Final PELS - TWAs:	0.1 mg/m <sup>3</sup>
	1 mg/m <sup>3</sup>
Portugal OEL - TWA	Listed
Romania OEL - TWA	Listed
Slovenia OEL - TWA	Listed
Spain OEL - TWA	Listed
Sweden OEL - TWAs	Listed
lavin (Vitamin B2)	
Latvia OEL - TWA	Listed
Lithuania OEL - TWA	Listed
acabalamin (Vitamin P12)	
ocobalamin (Vitamin B12)	E ma/m <sup>3</sup>
Australia TWA	5 mg/m <sup>3</sup>
Czech Republic OEL - TWA	Listed
Finland OEL - TWA	Listed
France OEL - TWA	Listed
Germany (DFG) - MAK	2 mg/m <sup>3</sup> MAK
Greece OEL - TWA	Listed
Hungary OEL - TWA	Listed
Ireland OEL - TWAs	Listed
OSHA - Final PELS - TWAs:	5 mg/m <sup>3</sup>
OSHA - Final PELs - Skin Notations:	Listed
Slovenia OEL - TWA	Listed
rin, USP	
ACGIH Threshold Limit Value (TWA)	10 mg/m³ TWA
Australia TWA	$10 \text{ mg/m}^3$
Belgium OEL - TWA	Listed
Deigiuili UEL - I WA	LISIEU

Czech Republic OFL - TM/A	Listed
Czech Republic OEL - TWA Estonia OEL - TWA	Listed
Finland OEL - TWA	Listed
France OEL - TWA	Listed
Germany (DFG) - MAK	50 mg/m <sup>3</sup> MAK
Greece OEL - TWA	Listed
Ireland OEL - TWAs	Listed
OSHA - Final PELS - TWAs:	15 mg/m <sup>3</sup> total 5 mg/m <sup>3</sup>
Poland OEL - TWA	Listed
Portugal OEL - TWA	Listed
Spain OEL - TWA	Listed
ack Iron Oxide	
ACGIH Threshold Limit Value (TWA)	1 mg/m³ TWA
Australia TWA	1 mg/m <sup>3</sup>
Belgium OEL - TWA	Listed
Bulgaria OEL - TWA	Listed
Czech Republic OEL - TWA	Listed
Finland OEL - TWA	Listed
Greece OEL - TWA	Listed
Portugal OEL - TWA	Listed
Spain OEL - TWA	Listed
rric oxide red	
ACGIH Threshold Limit Value (TWA)	1 mg/m³ TWA
	5 mg/m <sup>3</sup> TWA
Australia TWA	1 mg/m <sup>3</sup>
	5 mg/m <sup>3</sup>
Austria OEL - MAKs	Listed
Belgium OEL - TWA	Listed
Bulgaria OEL - TWA	Listed
-	Listed
Czech Republic OEL - TWA Denmark OEL - TWA	Listed
Estonia OEL - TWA	
	Listed
Finland OEL - TWA	Listed
France OEL - TWA	Listed
Germany (DFG) - MAK	1.5 mg/m <sup>3</sup> MAK
Greece OEL - TWA	Listed
Hungary OEL - TWA	Listed
Ireland OEL - TWAs	Listed
Lithuania OEL - TWA	Listed
OSHA - Final PELS - TWAs:	10 mg/m <sup>3</sup>
Poland OEL - TWA	Listed
Portugal OEL - TWA	Listed
Romania OEL - TWA	Listed
Spain OEL - TWA	Listed
Sweden OEL - TWAs	Listed
odium selenite	
ACGIH Threshold Limit Value (TWA)	0.2 mg/m³ TWA
Australia TWA	0.1 mg/m <sup>3</sup> except hydrogen selenide

8. EXPOSURE CONTROLS / P	ERSONAL PROTECTION
Austria OEL - MAKs	Listed
Belgium OEL - TWA	Listed
Bulgaria OEL - TWA	Listed
Czech Republic OEL - TWA	Listed
Denmark OEL - TWA	Listed
Estonia OEL - TWA	Listed
Finland OEL - TWA	Listed
Germany - TRGS 900 - TWAs	0.05 mg/m <sup>3</sup>
Germany (DFG) - MAK	0.05 mg/m <sup>3</sup> MAK
Greece OEL - TWA	Listed
Hungary OEL - TWA	Listed
Ireland OEL - TWAs	Listed
Lithuania OEL - TWA	Listed
OSHA - Final PELS - TWAs:	0.2 mg/m <sup>3</sup>
Poland OEL - TWA	Listed
Portugal OEL - TWA	Listed
Romania OEL - TWA	Listed
Slovenia OEL - TWA	Listed
Spain OEL - TWA	Listed
Sweden OEL - TWAs	Listed
Engineering Controls:	Engineering controls should be used as the primary means to control exposures. General room ventilation is adequate unless the process generates dust, mist or fumes. Keep airborne contamination levels below the exposure limits listed above in this section.
Environmental Exposure Controls:	Refer to specific Member State legislation for requirements under Community environmental legislation.
Personal Protective Equipment:	Refer to applicable national standards and regulations in the selection and use of personal protective equipment (PPE).
Hands:	Impervious gloves are recommended if skin contact with drug product is possible and for bulk processing operations.
Eyes:	Wear safety glasses or goggles if eye contact is possible.
Skin:	Impervious protective clothing is recommended if skin contact with drug product is possible and for bulk processing operations.
Respiratory protection:	If the applicable Occupational Exposure Limit (OEL) is exceeded, wear an appropriate respirator with a protection factor sufficient to control exposures to below the OEL.

## 9. PHYSICAL AND CHEMICAL PROPERTIES

Physical State:	Soft gelatin capsule	Color:	No data available.
Molecular Formula:	Mixture	Molecular Weight:	Mixture

## **10. STABILITY AND REACTIVITY**

Stability: Conditions to Avoid: Incompatible Materials: Stable under normal conditions of use. Fine particles (such as dust and mists) may fuel fires/explosions. As a precautionary measure, keep away from strong oxidizers

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## 11. TOXICOLOGICAL INFORMATION

General Information:	The information included in this section describes the potential hazards of the individual ingredients.			
Acute Toxicity: (Species, Route, End Point, Dose)				
<b>Folic Acid</b> Mouse Oral LD 50 10 g/kg				
<b>Black Iron Oxide</b> Rat Oral LD50 >1000 mg/kg				
<b>Ascorbic acid (Vitamin C)</b> Rat Oral LD 50 11.9 g/kg				
<b>Vitamin E (D-alpha-Tocopherol)</b> Mouse Oral LD 50 >25 mL/kg	]			
<b>Vitamin A</b> Rat Oral LD 50 2 g/kg				
<b>Manganese sulfate</b> Rat Oral LD50 2150 mg/kg				
Glycerin, USP Mouse Oral LD50 4090 mg/kg Rat Oral LD50 12.6 g/kg Rabbit Dermal LD50 > 10 g Rat Inhalation LC50 1hr > 570 Rat Dermal LD 50 >21.9 g/kg Acute Toxicity Comments:	y/kg ) mg/m <sup>3</sup>			
Irritation / Sensitization: (Study Typ	e, Species, Severity)			
Glycerin, USP Eye Irritation Rabbit Mild				
Carcinogen Status:	None of the components of this formulation are listed as a carcinogen by IARC, NTP or OSHA.			
Silica colloidal, Ph. Eur. IARC:	Group 3			
Ferric oxide red IARC:	Group 3			
Sodium selenite IARC:	Group 3			

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Environmental Overview:	Environmental properties of the formulation have not been investigated. Releases to the environment should be avoided.			
Aquatic Toxicity: (Species, Method, End Point, Duration, Result)				
ZINC SULPHATE				
Oncorhynchus mykiss (Rainbow Trout)	LC50 96 Hours 0.27-0.48 mg/L			
Lepomis macrochirus (Bluegill Sunfish)	5			
Daphnia Magna (Water Flea) EC50	5			
Pimephales promelas (Fathead Minnow				
Glycerin, USP				
Oncorhynchus mykiss (Rainbow Trout)	LD50 96 Hours 50 mg/L			
Daphnia magna (Water Flea) EC50				
	·			
13. DISPOSAL CONSIDERATIO	)NS			
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### **Disposal Procedures:**

Dispose of waste in accordance with all applicable laws and regulations. Member State specific and Community specific provisions must be considered. Considering the relevant known environmental and human health hazards of the material, review and implement appropriate technical and procedural waste water and waste disposal measures to prevent occupational exposure and environmental release. It is recommended that waste minimization be practiced. The best available technology should be utilized to prevent environmental releases. This may include destructive techniques for waste and wastewater.

## **14. TRANSPORT INFORMATION**

Not regulated for transport under USDOT, EUADR, IATA, or IMDG regulations.

## **15. REGULATORY INFORMATION**

### EU Risk Phrases:

R52/53 - Harmful to aquatic organisms, may cause long-term adverse effects in the aquatic environment.

#### OSHA Label:

Harmful to aquatic life with long lasting effects.

### Canada - WHMIS: Classifications

#### WHMIS hazard class:

None required

This product has been classified in accordance with the hazard criteria of the CPR and the MSDS contains all of the information required by the CPR.

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15. REGULATORY INFORMATION	
Ascorbic acid (Vitamin C)	
Inventory - United States TSCA - Sect. 8(b)	Listed
Australia (AICS):	Listed
REACH - Annex IV - Exemptions from the	Present
obligations of Register:	
EU EINECS/ELINCS List	200-066-2
Lutein	
Inventory - United States TSCA - Sect. 8(b)	Listed
Australia (AICS):	Listed
EU EINECS/ELINCS List	204-840-0
ZINC SULPHATE	
CERCLA/SARA 313 Emission reporting	1.0% de minimis concentration
CERCLA/SARA Hazardous Substances	1000 lb final RQ
and their Reportable Quantities:	454 kg final RQ
Inventory - United States TSCA - Sect. 8(b)	Listed
Australia (AICS):	Listed
Standard for the Uniform Scheduling	Schedule 6
for Drugs and Poisons:	
EU EINECS/ELINCS List	231-793-3
Niacin (Nicotinic acid)	
Inventory - United States TSCA - Sect. 8(b)	Listed
Australia (AICS):	Listed
Standard for the Uniform Scheduling	Schedule 3
for Drugs and Poisons:	
EU EINECS/ELINCS List	200-441-0
Vitamin E (D-alpha-Tocopherol)	
Inventory - United States TSCA - Sect. 8(b)	Listed
Australia (AICS):	Listed
EU EINECS/ELINCS List	200-412-2
Manganese sulfate	
CERCLA/SARA 313 Emission reporting	1.0% de minimis concentration
Inventory - United States TSCA - Sect. 8(b)	Listed
Australia (AICS):	Listed
EU EINECS/ELINCS List	232-089-9
Copper	
CERCLA/SARA 313 Emission reporting	1.0% de minimis concentration
	1.0% de minimis concentration does not include copper
	phthalocyanine compounds substituted only with hydrogen and/or
	bromine and/or chlorine
CERCLA/SARA Hazardous Substances	2270 kg final RQ
and their Reportable Quantities:	5000 lb final RQ
Inventory - United States TSCA - Sect. 8(b)	Listed
Australia (AICS):	Listed
EU EINECS/ELINCS List	231-159-6

## Vitamin A

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15. REGULATORY INFORMATION	
California Proposition 65	developmental toxicity, initial date 7/1/89 (in daily doses greater than 10,000 IU or 3,000 retinol equivalents. Retinol/retinyl esters are required and essential for maintenance of normal reproductive function. The recommended daily level during pregnancy is 8,000 IU).
Inventory - United States TSCA - Sect. 8(b)	Listed
Australia (AICS):	Listed
Standard for the Uniform Scheduling	Schedule 4
for Drugs and Poisons:	
EU EINECS/ELINCS List	200-683-7
Vitamin B6 (Pyridoxine)	
Inventory - United States TSCA - Sect. 8(b)	Listed
Australia (AICS):	Listed
EU EINECS/ELINCS List	200-603-0
Riboflavin (Vitamin B2)	Listad
Inventory - United States TSCA - Sect. 8(b)	Listed
Australia (AICS):	Listed
EU EINECS/ELINCS List	201-507-1
Thiamin (Vitamin B1)	
Inventory - United States TSCA - Sect. 8(b)	Listed
Australia (AICS):	Listed
EU EINECS/ELINCS List	200-425-3
Cyanocobalamin (Vitamin B12) CERCLA/SARA 313 Emission reporting	1.0% de minimis concentration $X+CN$ - where $X = H+$ or any other
-	group where a formal dissociation can be made. For example KCN or Ca(CN)2.
Inventory - United States TSCA - Sect. 8(b)	Listed
Australia (AICS):	Listed
EU EINECS/ELINCS List	200-680-0
Beeswax	
Inventory - United States TSCA - Sect. 8(b)	Listed
Australia (AICS):	Listed
EU EINECS/ELINCS List	232-383-7
Folic Acid	
Inventory - United States TSCA - Sect. 8(b)	Listed
Australia (AICS):	Listed
Standard for the Uniform Scheduling	Schedule 2
for Drugs and Poisons:	Schedule 4
EU EINECS/ELINCS List	200-419-0
Gelatin	
Inventory - United States TSCA - Sect. 8(b)	Listed
Australia (AICS):	Listed
EU EINECS/ELINCS List	232-554-6
Glycerin, USP Inventory - United States TSCA - Sect 8(b)	Listed
Inventory - United States TSCA - Sect. 8(b)	LIGUU

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15. REGULATORY INFORMATION	
Australia (AICS):	Listed
EU EINECS/ELINCS List	200-289-5
Black Iron Oxide	
Inventory - United States TSCA - Sect. 8(b)	Listed
Australia (AICS):	Listed
Standard for the Uniform Scheduling	Schedule 2
for Drugs and Poisons:	Schedule 4
	Schedule 5
	Schedule 6
EU EINECS/ELINCS List	215-277-5
Ferric oxide red	
Inventory - United States TSCA - Sect. 8(b)	Listed
Australia (AICS):	Listed
Standard for the Uniform Scheduling	Schedule 2
for Drugs and Poisons:	Schedule 4
	Schedule 5
	Schedule 6
EU EINECS/ELINCS List	215-168-2
Silica colloidal, Ph. Eur.	
Australia (AICS):	Listed
Sodium selenite	
CERCLA/SARA 313 Emission reporting	1.0% de minimis concentration
CERCLA/SARA Hazardous Substances	100 lb final RQ
and their Reportable Quantities:	45.4 kg final RQ
CERCLA/SARA - Section 302 Extremely Hazardous	100 lb lower threshold TPQ
TPQs	10000 lb upper threshold TPQ
CERCLA/SARA - Section 302 Extremely Hazardous Substances EPCRA RQs	100 lb

## **16. OTHER INFORMATION**

### Text of R phrases mentioned in Section 3

R22 - Harmful if swallowed. R41 - Risk of serious damage to eyes. R48/20/22 - Harmful: danger of serious damage to health by prolonged exposure through inhalation and if swallowed. R50/53 - Very toxic to aquatic organisms, may cause long-term adverse effects in the aquatic environment. R51/53 - Toxic to aquatic organisms, may cause long-term adverse effects in the aquatic environment.

**Data Sources:** 

Publicly available toxicity information. Safety data sheets for individual ingredients.

Prepared by:

**Toxicology and Hazard Communication** Pfizer Global Environment, Health, and Safety Operations

Pfizer Inc believes that the information contained in this Material Safety Data Sheet is accurate, and while it is provided in good faith, it is without warranty of any kind, expressed or implied. If data for a hazard are not included in this document there is no known information at this time.

**End of Safety Data Sheet**