

Common Name	CAS-No	Composition
Zinc Gluconate	4468-02-4	0.156%
Sodium Benzoate	532-32-1	0.133%
Chromic Chloride	10025-73-7	0.001%
Ferrous Gluconate	6047-12-7	0.518%
D-Panthenol	81-13-0	0.128%
Biotin	56-85-5	0.003%
Vitamin B6 (Pyridoxine Hydrochloride)	58-56-0	0.021%
Vitamin E (acetate)	58-95-7	0.48%
Thiamine Hydrochloride	67-03-8	0.018%
Vitamin B12 (Cyanocobalamin)	68-19-9	0.014%
Molybdenum (Sodium Molybdate)	7631-95-0	< 0.001%
Iodine (Potassium Iodide)	7681-11-0	0.001%
Vitamin B2 (Riboflavin)	83-88-5	0.016%
Niacinamide	98-92-0	0.213%
Manganese Chloride	7773-01-5	0.06%
Vitamin A	127-47-9	0.192%
Vitamin C (Ascorbic Acid)	50-81-7	1.2%
Vitamin D2	50-14-6	0.04%
Edetic Acid	60-00-4	0.01%
Sucrose	57-50-1	33.33%
Citric Acid (Anhydrous)	77-92-9	0.233%
Glycerine	56-81-5	1.333%
Inactive Ingredients	Not applicable	Remainder

4. FIRST AID MEASURES

Eye Contact	In case of contact with eyes, rinse immediately with plenty of water for 15 minutes and seek medical advice
Skin Contact	Wash off with soap and plenty of water
Inhalation	Artificial respiration and/or oxygen may be necessary
Ingestion	Immediate medical attention is not required

5. FIRE-FIGHTING MEASURES

Flammable Properties	Combustible liquid.
Extinguishing Media	
Suitable Extinguishing Media	Use water spray, alcohol-resistant foam, dry chemical or carbon dioxide
Unsuitable Extinguishing Media	Do NOT use water jet.
Fire Fighting	Evacuate area and fight fire from a safe distance
Hazardous Combustion Products	Hazardous Combustion Products
Protective Equipment and Precautions for Firefighters	In the event of fire, wear self-contained breathing apparatus and special protective equipment for fire fighters.
Other Information	Flammability Class (OSHA): II

6. ACCIDENTAL RELEASE MEASURES

6. ACCIDENTAL RELEASE MEASURES

Personal Precautions	Refer to protective measures listed in Sections 7 and 8.
Environmental Precautions	Local authorities should be advised if a significant spill cannot be contained
Methods for Containment	Not available
Methods for Cleaning up	Take up mechanically and collect in suitable container for disposal

7. HANDLING AND STORAGE

Handling	Handle in accordance with good industrial hygiene and safety practices
Storage	Keep container tightly closed

8. EXPOSURE CONTROLS / PERSONAL PROTECTION

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

Glycerine	
Exposure Guideline:	10 mcg/m ³ (ACGIH)
Ethanol	
Exposure Guideline:	1900 mg/m ³
Sucrose	
Exposure Guideline:	10 mg/m ³ (ACGIH)
Chromic Chloride	
Exposure Guideline:	0.5 mg/m ³ (ACGIH)
Engineering Controls	No special precautions required.
Personal Protective Equipment	
Eye/face Protection	Avoid contact with skin and eyes.
Skin Protection	For prolonged or repeated exposure use protective gloves. No special protective clothing required under typical conditions of use.
Respiratory Protection	No personal respiratory protective equipment normally required.
General Hygiene Considerations	When using, do not eat, drink or smoke
Other	Limit access to only personnel trained in the safe handling of this material

9. PHYSICAL AND CHEMICAL PROPERTIES

Appearance	Liquid	Physical State	Liquid
Color	Clear	Odor	Not available
Odor Threshold	Not available		
pH	Not available		

Specific Gravity	Not available	Water Solubility	Not available
Solubility	Not available	Evaporation Rate	Not available
Partition Coefficient (n-octanol/water)	Not available	Vapor Pressure	Not applicable
Boiling Point	Not available	Autoignition Temperature	Not applicable
Flash Point	127°F	Method	None
Melting Point	Not applicable		
Flammability Limits in Air	Upper Not applicable	Lower Not applicable	
Upper Not applicable	Lower Not applicable		

10. STABILITY AND REACTIVITY

Chemical Stability	Stable at room temperature.
Conditions to Avoid	No data available
Materials to Avoid	No materials to be especially mentioned.
Hazardous Decomposition Products	None under normal use.
Possibility of Hazardous Reactions	None under normal use.

11. TOXICOLOGICAL INFORMATION

The following effects are based on the Active Pharmaceutical Ingredient.

Inactive Ingredients	
Acute Dermal Irritation	No data available
Primary Eye Irritation	No data available
Sensitization	No data available
Glycerine	
LD50 Oral	12.6 gm/kg rats, 4090 mg/kg mice
Acute Dermal Irritation	Mild irritation effect in rabbits.
Primary Eye Irritation	Irritating to rabbit eyes.
Sensitization	Not available
Biotin	
LD50 Oral	No data available
Acute Dermal Irritation	No data available
Primary Eye Irritation	No data available
Sensitization	No data available
Vitamin B6 (Pyridoxine Hydrochloride)	
LD50 Oral	No data available
Acute Dermal Irritation	No data available
Primary Eye Irritation	No data available
Sensitization	No data available

Vitamin E (acetate)	
LD50 Oral	Not applicable
Acute Dermal Irritation	Not applicable
Primary Eye Irritation	Not applicable
Sensitization	Not applicable
Vitamin B12 (Cyanocobalamin)	
LD50 Oral	Not applicable
Acute Dermal Irritation	Not applicable
Primary Eye Irritation	Not applicable
Sensitization	Not applicable
Molybdenum (Sodium Molybdate)	
LD50 Oral	No data available
Acute Dermal Irritation	No data available
Primary Eye Irritation	No data available
Sensitization	No data available
Iodine (Potassium Iodide)	
LD50 Oral	No data available
Acute Dermal Irritation	No data available
Primary Eye Irritation	No data available
Sensitization	No data available
Ethanol	
LD50 Oral	3450 mg/kg mice 7060 mg/kg rats
Acute Dermal Irritation	Moderate irritation effect in rabbits.
Primary Eye Irritation	Severely irritating to rabbit eyes.
Sensitization	Not applicable
Vitamin B2 (Riboflavin)	
LD50 Oral	No data available
Acute Dermal Irritation	No data available
Primary Eye Irritation	No data available
Sensitization	No data available
Vitamin A	
LD50 Oral	Not applicable
Acute Dermal Irritation	Not applicable
Primary Eye Irritation	Not applicable
Sensitization	Not applicable
Vitamin C (Ascorbic Acid)	
LD50 Oral	>11 gm/kg rats
Acute Dermal Irritation	No data available
Primary Eye Irritation	No data available
Sensitization	No data available
D-Panthenol	
LD50 Oral	No data available
Acute Dermal Irritation	No data available
Primary Eye Irritation	No data available
Sensitization	No data available

Thiamine Hydrochloride	
LD50 Oral	No data available
Acute Dermal Irritation	No data available
Primary Eye Irritation	No data available
Sensitization	No data available
Niacinamide	
LD50 Oral	3500 mg/kg rats 2500 mg/kg mice
Acute Dermal Irritation	No data available
Primary Eye Irritation	No data available
Sensitization	No data available
Manganese Chloride	
LD50 Oral	No data available
Acute Dermal Irritation	No data available
Primary Eye Irritation	No data available
Sensitization	No data available
Edetic Acid	
LD50 Oral	No data available
Acute Dermal Irritation	No data available
Primary Eye Irritation	No data available
Sensitization	No data available
Sucrose	
LD50 Oral	Rat 29700mg/kg
Acute Dermal Irritation	No data available
Primary Eye Irritation	No data available
Sensitization	No data available
Sodium Benzoate	
LD50 Oral	No data available
Acute Dermal Irritation	No data available
Primary Eye Irritation	No data available
Sensitization	No data available
Ferrous Gluconate	
LD50 Oral	No data available
Acute Dermal Irritation	No data available
Primary Eye Irritation	No data available
Sensitization	No data available
Vitamin D2	
LD50 Oral	No data available
Acute Dermal Irritation	No data available
Primary Eye Irritation	No data available
Sensitization	No data available
Citric Acid (Anhydrous)	
LD50 Oral	Rat 3gm/kg
Acute Dermal Irritation	No data available
Primary Eye Irritation	No data available
Sensitization	No data available

Zinc Gluconate

LD50 Oral	No data available
Acute Dermal Irritation	No data available
Primary Eye Irritation	No data available
Sensitization	No data available

Chromic Chloride

LD50 Oral	No data available
Acute Dermal Irritation	No data available
Primary Eye Irritation	No data available
Sensitization	No data available

Multiple Dose Toxicity**Inactive Ingredients**

No Toxicologic Effect Dose/Species/Study Length:	No data available
---	-------------------

Glycerine

No Toxicologic Effect Dose/Species/Study Length:	In a 180-day study in rats, 5% in drinking water caused calcification in the renal tubules. A further drinking water study in rats resulted in increased urinary levels of oxalic acid.
---	---

Biotin

No Toxicologic Effect Dose/Species/Study Length:	No data available
---	-------------------

Vitamin B6 (Pyridoxine Hydrochloride)

No Toxicologic Effect Dose/Species/Study Length:	No data available
---	-------------------

Vitamin E (acetate)

No Toxicologic Effect Dose/Species/Study Length:	Not applicable
---	----------------

Vitamin B12 (Cyanocobalamin)

No Toxicologic Effect Dose/Species/Study Length:	Not applicable
---	----------------

Molybdenum (Sodium Molybdate)

No Toxicologic Effect Dose/Species/Study Length:	No data available
---	-------------------

Iodine (Potassium Iodide)

No Toxicologic Effect Dose/Species/Study Length:	No data available
---	-------------------

Ethanol

No Toxicologic Effect Dose/Species/Study Length:	Repeated contact can dry the skin with cracking, peeling, and itching. Repeated high exposure may affect the liver and nervous system.
---	--

Vitamin B2 (Riboflavin)

No Toxicologic Effect Dose/Species/Study Length:	No data available
---	-------------------

Vitamin A

No Toxicologic Effect Dose/Species/Study Length:	Not applicable
Vitamin C (Ascorbic Acid) No Toxicologic Effect Dose/Species/Study Length:	No data available
D-Panthenol No Toxicologic Effect Dose/Species/Study Length:	No data available
Thiamine Hydrochloride No Toxicologic Effect Dose/Species/Study Length:	No data available
Niacinamide No Toxicologic Effect Dose/Species/Study Length:	No data available
Manganese Chloride No Toxicologic Effect Dose/Species/Study Length:	No data available
Edetic Acid No Toxicologic Effect Dose/Species/Study Length:	No data available
Sucrose No Toxicologic Effect Dose/Species/Study Length:	No data available
Sodium Benzoate No Toxicologic Effect Dose/Species/Study Length:	No data available
Ferrous Gluconate No Toxicologic Effect Dose/Species/Study Length:	No data available
Vitamin D2 No Toxicologic Effect Dose/Species/Study Length:	No data available
Citric Acid (Anhydrous) No Toxicologic Effect Dose/Species/Study Length:	No data available
Zinc Gluconate No Toxicologic Effect Dose/Species/Study Length:	No data available
Chromic Chloride No Toxicologic Effect Dose/Species/Study Length:	No data available
<u>Maximum Tolerated Dose (MTD), Oral</u>	

Inactive Ingredients

Carcinogenicity	No data available
Genetic Toxicity	Negative in a battery of genotoxicity tests.
Reproductive Toxicity	No data available
Developmental Toxicity	Animal studies did not show statistically significant developmental toxicological effects

Glycerine

Carcinogenicity	No data available
Genetic Toxicity	Non-mutagenic in Ames test; non-clastogenic in chromosomal aberrations assay.
Reproductive Toxicity	Studies in rats were found to have no effect on fertility.
Developmental Toxicity	No teratogenic effects were observed in mice, rats and rabbits given large oral doses of >1 g/kg/day during pregnancy. In a further study, increased rates of embryonic and fetal death were seen when rats were dosed IV at 4 mg/kg; this was not seen in rabbit or mice studies.

Biotin

Carcinogenicity	No data available
Genetic Toxicity	No data available
Reproductive Toxicity	No data available
Developmental Toxicity	No data available

Vitamin B6 (Pyridoxine Hydrochloride)

Carcinogenicity	No data available
Genetic Toxicity	No data available
Reproductive Toxicity	No data available
Developmental Toxicity	No data available

Vitamin E (acetate)

Carcinogenicity	No data available
Genetic Toxicity	No data available
Reproductive Toxicity	No data available
Developmental Toxicity	No data available

Vitamin B12 (Cyanocobalamin)

Carcinogenicity	No data available
Genetic Toxicity	No data available
Reproductive Toxicity	No data available
Developmental Toxicity	No data available

Molybdenum (Sodium Molybdate)

Carcinogenicity	No data available
Genetic Toxicity	No data available
Reproductive Toxicity	No data available
Developmental Toxicity	No data available

Iodine (Potassium Iodide)

Carcinogenicity	No data available
Genetic Toxicity	No data available
Reproductive Toxicity	No data available
Developmental Toxicity	No data available

Ethanol

Carcinogenicity	No data available
Genetic Toxicity	May cause genetic changes.
Reproductive Toxicity	See Developmental Toxicity.

Developmental Toxicity	Repeated exposure may cause spontaneous abortions, as well as birth defects and other developmental problems (fetal alcohol syndrome).
Vitamin B2 (Riboflavin)	
Carcinogenicity	No data available
Genetic Toxicity	No data available
Reproductive Toxicity	No data available
Developmental Toxicity	No data available
Vitamin A	
Carcinogenicity	No data available
Genetic Toxicity	Not applicable
Reproductive Toxicity	No data available
Developmental Toxicity	No data available
Vitamin C (Ascorbic Acid)	
Carcinogenicity	Under the conditions of the National Toxicology Program (NTP) studies, there was no evidence of Carcinogenicity activity in male or female rats or mice.
Genetic Toxicity	No studies to assess the mutagenic potential have been performed.
Reproductive Toxicity	No data available
Developmental Toxicity	Studies to evaluate the teratogenic potential have not been performed.
D-Panthenol	
Carcinogenicity	No data available
Genetic Toxicity	No data available
Reproductive Toxicity	No data available
Developmental Toxicity	No data available
Thiamine Hydrochloride	
Carcinogenicity	No data available
Genetic Toxicity	No data available
Reproductive Toxicity	No data available
Developmental Toxicity	No data available
Niacinamide	
Carcinogenicity	No data available
Genetic Toxicity	AMES Test :Negative- Nonmutagenic
Reproductive Toxicity	No data available
Developmental Toxicity	No data available
Manganese Chloride	
Carcinogenicity	No data available
Genetic Toxicity	No data available
Reproductive Toxicity	No data available
Developmental Toxicity	No data available
Edetic Acid	
Carcinogenicity	No data available
Genetic Toxicity	No data available
Reproductive Toxicity	No data available
Developmental Toxicity	No data available
Sucrose	
Carcinogenicity	No data available
Genetic Toxicity	No data available

Reproductive Toxicity	No data available
Developmental Toxicity	No data available
Sodium Benzoate	
Carcinogenicity	No data available
Genetic Toxicity	No data available
Reproductive Toxicity	No data available
Developmental Toxicity	No data available
Ferrous Gluconate	
Carcinogenicity	No data available
Genetic Toxicity	No data available
Reproductive Toxicity	No data available
Developmental Toxicity	No data available
Vitamin D2	
Carcinogenicity	No data available
Genetic Toxicity	No data available
Reproductive Toxicity	No data available
Developmental Toxicity	No data available
Citric Acid (Anhydrous)	
Carcinogenicity	No data available
Genetic Toxicity	No data available
Reproductive Toxicity	No data available
Developmental Toxicity	No data available
Zinc Gluconate	
Carcinogenicity	No data available
Genetic Toxicity	No data available
Reproductive Toxicity	No data available
Developmental Toxicity	No data available
Chromic Chloride	
Carcinogenicity	No data available
Genetic Toxicity	No data available
Reproductive Toxicity	No data available
Developmental Toxicity	No data available
Inactive Ingredients	
Target Organ(s) of Toxicity	No data available
Glycerine	
Target Organ(s) of Toxicity	No data available
Biotin	
Target Organ(s) of Toxicity	No data available
Vitamin B6 (Pyridoxine Hydrochloride)	
Target Organ(s) of Toxicity	No data available
Vitamin E (acetate)	
Target Organ(s) of Toxicity	No data available

Vitamin B12 (Cyanocobalamin)	
Target Organ(s) of Toxicity	No data available
Molybdenum (Sodium Molybdate)	
Target Organ(s) of Toxicity	No data available
Iodine (Potassium Iodide)	
Target Organ(s) of Toxicity	No data available
Ethanol	
Target Organ(s) of Toxicity	No data available
Vitamin B2 (Riboflavin)	
Target Organ(s) of Toxicity	No data available
Vitamin A	
Target Organ(s) of Toxicity	No data available
Vitamin C (Ascorbic Acid)	
Target Organ(s) of Toxicity	No data available
D-Panthenol	
Target Organ(s) of Toxicity	No data available
Thiamine Hydrochloride	
Target Organ(s) of Toxicity	No data available
Niacinamide	
Target Organ(s) of Toxicity	No data available
Manganese Chloride	
Target Organ(s) of Toxicity	No data available
Edetic Acid	
Target Organ(s) of Toxicity	No data available
Sucrose	
Target Organ(s) of Toxicity	No data available
Sodium Benzoate	
Target Organ(s) of Toxicity	No data available
Ferrous Gluconate	
Target Organ(s) of Toxicity	No data available
Vitamin D2	
Target Organ(s) of Toxicity	No data available
Citric Acid (Anhydrous)	
Target Organ(s) of Toxicity	No data available
Zinc Gluconate	
Target Organ(s) of Toxicity	No data available

Chromic Chloride
Target Organ(s) of Toxicity No data available

12. ECOLOGICAL INFORMATION

The following effects are based on the Active Pharmaceutical Ingredient.

Chemical Fate Information Not available

Ecotoxicity Not available

13. DISPOSAL CONSIDERATIONS

Waste Disposal Method 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

Transport Information This material is regulated for transportation as a hazardous material/dangerous goods.

Proper Shipping Name: Ethyl alcohol solution
Identification Number: UN 1170
Hazard Class: 3
Packing Group: III
Flashpoint: 52.78 °C (127 °F)

Exceptions: For small quantities packed in combination packaging [limited to inner packaging <= 5.0 L (1.3 gal) and outer packaging <= 30 kg (66 lb.) gross weight], the following will apply. In addition, see "excepted quantity" provisions if applicable.

Note: If your commodity meets the definition of a limited quantity and is packaged for retail sale, it may be considered a **Consumer Commodity** and excepted from additional requirements as applicable.

U.S. Department of Transport (DOT)

Proper Shipping Name Consumer Commodity
Hazard Class ORM-D

International Air Transport Association (IATA)

Proper Shipping Name Consumer Commodity
Hazard Class 9
UN-No ID 8000

International Maritime Dangerous Goods (IMDG)

Proper Shipping Name Ethyl alcohol solution, Ltd. Qty.
Hazard Class 3
UN-No UN 1170
Packing Group III
Flashpoint: 52.78 °C (127 °F)

Transport of Dangerous Goods by Road (ADR)

Proper Shipping Name Ethyl alcohol solution, Ltd. Qty.

Hazard Class 3
UN-No UN 1170
Packing Group III

15. REGULATORY INFORMATION

USA

Federal Regulations

OSHA Regulatory Status

This material is considered hazardous by the OSHA Hazard Communication Standard (29 CFR 1910.1200)

SARA 313

Section 313 of Title III of the Superfund Amendments and Reauthorization Act of 1986 (SARA). This product contains a chemical or chemicals which are subject to the reporting requirements of the Act and Title 40 of the Code of Federal Regulations, Part 372:

Common Name	CAS-No	Concentration
Zinc Gluconate	4468-02-4	<1%
Chromic Chloride	10025-73-7	<1%

SARA 311/312 Hazardous Categorization

Acute Health Hazard	No
Chronic Health Hazard	No
Fire Hazard	No
Sudden Release of Pressure Hazard	No
Reactive Hazard	No

This product does not contain any HAPs.

State Regulations

California Proposition 65

This product contains the following Proposition 65 chemicals: Retinol/Retinyl esters, when in daily doses in excess of 10,000 IU or 3,000 retinal equivalents. Listed on Proposition 65 as Developmental.

Canada

Not Determined

WHMIS Hazard Class

Non-controlled

European Union

Not Determined

16. OTHER INFORMATION

Prepared By	Wyeth Department of Environment, Health & Safety
Format	This MSDS was prepared in accordance with ANSI Z400.1-2004.
List of References	See Patient Package Insert for more information.
Revision Summary	Changes to Section 14

Disclaimer:

The information, data, recommendations, and suggestions appearing in this material safety data sheet (MSDS) and/or in materials regarding our active pharmaceutical ingredients (APIs) or products are based upon tests and data believed to be reliable as of the date of publication. NO REPRESENTATIONS OR WARRANTIES, EITHER EXPRESSED OR IMPLIED, INCLUDING WITHOUT LIMITATION ANY WARRANTIES OF MERCHANTABILITY, FITNESS FOR A PARTICULAR PURPOSE, OR ANY OTHER WARRANTY IS MADE WITH REGARD TO THE INFORMATION PROVIDED IN THE MSDS, REGARDING THE API, OR THE PRODUCT TO WHICH THE INFORMATION PERTAINS. Accordingly, Wyeth will not be responsible for any damages resulting from use of, or reliance upon, this information as conditions of use are beyond our control. Users are responsible for assuring the safety of their workers and safe operating conditions, and for determining whether the API or product is suitable for their particular purposes. Users shall assume all risks of their use, handling, and disposal of the API and/or product in accordance with all appropriate and applicable regulations. This information relates only to the API or product designated herein, and does not relate to its use in combination with any other API, material, product, or process. No permission is granted for the use of any API or product in a manner that might infringe on existing patents.

End of MSDS