

Nipro Consumer Healthcare

(d/b/a P.J. Noyes)

Globally Harmonized Safety Data Sheet (GHS)

North America (OSHA/GHS) and WHMIS compliant

Confidential

Original Preparation Date: May 28th, 2015	Revision Date: N/A	Revision: 0	Page 1 of 7
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SECTION 1: PRODUCT AND COMPANY INFORMATION

Product Name: *Selan & Zinc Anti-Fungal Cream*

Product Code: *PJSAF0000*

Recommended Use: *Anti-fungal cream*

Manufactured By: *Nipro Consumer Healthcare d/b/a P.J. Noyes, 89 Bridge Street, Lancaster, NH 03584 USA*

Marketed By: *Span-America Medical Systems Inc, 70 Commerce Center, Greenville SC 29615*

Telephone Number: *800-888-6752*

Emergency Telephone Number: *1-800-222-1222*

SECTION 2: HAZARD IDENTIFICATION

Emergency Overview		
<i>Not Classified</i>		
Physical State	Appearance	Odor
<i>Lotion</i>	<i>White</i>	<i>Faint odor</i>
Hazards not otherwise classified	<i>None</i>	

Hazard pictograms: *None*

Labeling according to Regulation (EC) No 1272/2008 [CLP/GHS]		
Signal word:	<i>None</i>	
Hazard statements:	<i>None</i>	
Precautionary statements:	<i>None</i>	

SECTION 3: COMPOSITION / INFORMATION ON INGREDIENTS

Chemical Identity	CAS number	% (w/w)	Hazard Indicator
<i>Miconazole Nitrate</i>	<i>22832-87-7</i>	<i>2.0</i>	<i>None</i>
<i>Other Ingredients</i>	<i>N/A</i>		<i>None</i>
<i>Impurities and Stabilizing Additives which are classified</i>			
<i>1,4 Dioxane</i>	<i>123-91-1</i>	<i>Less than 0.0015%</i>	<i>WHMIS-Serious eye damage/eye irritation - Category 2 Carcinogenicity - Category 2</i>
<i>Ethylene oxide</i>	<i>75-21-8</i>	<i>Less than 0.0015%</i>	<i>WHMIS-Carcinogenicity - Category 1B Reproductive toxicity - Category 1</i>
<i>Diethanolamine</i>	<i>111-42-2</i>	<i>Less than 0.0015%</i>	<i>IARC -carcinogenicity: group 2B</i>

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SECTION 4: FIRST AID MEASURES

General: *If you feel unwell, seek medical advice (show the label if possible).*

Eye: *Rinse cautiously with water for several minutes.*

Skin: *Not expected to present a significant dermal hazard under anticipated conditions of normal use. Avoid infected skin. Contains lanolin which may cause allergic reaction.*

Ingestion: *Is not expected to be harmful. If large quantities are ingested, consult medical advice.*

Inhalation: *Not expected to present a significant inhalation hazard under anticipated conditions of normal use.*

Most Important Symptoms /Effects, acute and delayed:

General: *Not expected to present a significant hazard under anticipated conditions of normal use.*

Eye: *May cause eye irritation.*

Skin: *Not irritating to skin.*

Ingestion: *None expected under normal conditions of use*

Inhalation: *Not expected to be a primary route of exposure.*

Indication of immediate medical attention and special treatment if necessary:

General: *If you feel unwell seek medical advice (show the label where possible)*

Eyes: *Seek medical attention if irritation persists.*

Skin: *N/A*

Ingestion: *N/A*

Inhalation: *N/A*

SECTION 5: FIREFIGHTING MEASURES

Flammable Properties: *Combustion is possible at high temperature*

Suitable Extinguishing Media: *Use extinguishing media appropriate for surrounding fire. Use water spray or fog for cooling exposed containers.*

Unsuitable Extinguishing Media: *Do not use heavy water stream. Use of heavy water stream may spread fire.*

Specific Hazards arising from the chemical: *Not considered flammable but may burn at high temperatures.*

Explosion Hazard: *Product is not explosive.*

Reactivity: *Hazardous reactions will not occur under normal conditions.*

Special Protective Equipment and Precautions for Fire Fighters:

Exercise caution when fire fighting.

Do not enter fire area without proper protective equipment including respiratory equipment.

Hazardous combustion products are Carbon Oxides (CO, CO₂)

Reference to section 9 for flammability properties.

SECTION 6: ACCIDENTAL RELEASE MEASURES

Personal Precautions, Protective Equipment, and Emergency Procedures: *Not required under normal conditions of use. In the event of an emergency, contact the local emergency response.*

Emergency Personnel: *Equip clean-up crew with proper protection. Contain spill and ventilate area.*

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Environmental Precautions: Contain and collect as any solid. Dispose material in accordance with Federal, State and local laws. TCLP determination may be required under RCRA for Zinc oxide impurities of lead and cadmium.

Methods and materials for containment: Contain and collect as any solid. Dispose material in accordance with Federal, State and local laws.

Reference section 8 for exposure controls and personal protection

SECTION 7: HANDLING AND STORAGE

Precautions for safe handling: None.

Hygiene Measures: Wash hands and other areas that were exposed with mild soap and water.

Conditions for safe storage including any incompatibilities:

KEEP OUT OF REACH OF CHILDREN

Store in a cool dry area in closed containers.

Keep containers sealed when not in use

Avoid extremely high or low temperatures.

Keep away from heat or open flame.

Incompatible Materials: Keep away from strong acids, bases, and oxidizers.

SECTION 8: EXPOSURE CONTROLS/PERSONAL PROTECTION

Control Parameters:

	ACGIH TLV	OSHA PEL (TWA)
Zinc oxide (CAS 1314-13-2)	2 mg/m ³ total dust	15mg/m ³ total dust 5 mg/m ³ respirable fraction

Appropriate Engineering controls: Ensure all national/local regulations are observed.

Individual Protection measures: Not required under normal conditions of use.

Ventilation: Local/General Exhaust may be used.

Respiratory Equipment: Not required under normal conditions of use.

Protective Gloves: Not required under normal conditions of use.

Eye Protection: Not required under normal conditions of use.

Other Protective Equipment/Clothing: Not required under normal conditions of use.

Skin and Body Protection: Not required under normal conditions of use.

Environmental Exposure Controls: Contain and collect as any solid. Dispose material in accordance with Federal, State and local laws.

TCLP determination may be required under RCRA for Zinc oxide impurities of lead and cadmium.

Consumer Exposure controls: Not required under normal conditions of use.

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SECTION 9: PHYSICAL AND CHEMICAL PROPERTIES

Appearance: White cream

Odor: Faint odor

Odor threshold: Not Applicable

pH: 6.0

Melting point/Freezing point: Not Available

Boiling range: Not Applicable

Flash point: Not Available

Evaporation rate: Not Available

Flammability (solid, gas): Not Available

Upper/Lower Flammability or explosive limits: Not Available

Vapor pressure: Not Applicable

Vapor density: Not Applicable

Relative density: Not Determined

Solubility: Water (slightly)

Partition coefficient (n-octanol/water): Not Available

Auto-ignition temperature: Not Available

Decomposition temperature: Not Available

Viscosity: 45,000 cPs

Explosion Data – Sensitivity to Mechanical Impact: Not expected to present an explosion hazard due to mechanical impact.

Explosion Sensitivity to Discharge: Not expected to present an explosion hazard due to static discharge.

SECTION 10: STABILITY AND REACTIVITY

Reactivity: Hazardous reactions will not occur under normal conditions.

Stability: Stable under recommended handling and storage conditions (see section 7).

Possibility of Hazardous Reactions: Hazardous Polymerization will not occur.

Conditions to avoid: Direct sunlight, extreme high and low temperatures, ignition sources, and incompatible materials.

Incompatible Materials: Strong acids, bases, and oxidizers.

Hazardous Decomposition Products: Carbon Oxides (CO, CO₂)

SECTION 11: TOXICOLOGICAL INFORMATION

Routes of exposure: Inhalation or ingestion. Not absorbed through skin or mucous membranes.

GHS Properties	Classification
Acute Toxicity	OSHA HCS 2012 • Classification criteria not met
Serious eye damage/irritation	OSHA HCS 2012 • Classification criteria not met
Skin corrosion/irritation	OSHA HCS 2012 • Classification criteria not met
Respiratory or Skin Sensitization	OSHA HCS 2012 • Classification criteria not met
Germ Cell Mutagenicity	OSHA HCS 2012 • Classification criteria not met
Carcinogenicity	OSHA HCS 2012 • A4: Not classifiable as a human carcinogen
Reproductive Toxicity	OSHA HCS 2012 • Classification criteria not met
Specific Target Organ Toxicity (Repeat exposure)	OSHA HCS 2012 • Classification criteria not met
Specific Target Organ Toxicity (Single Exposure)	OSHA HCS 2012 • Classification criteria not met
Aspiration Hazard	OSHA HCS 2012 • Classification criteria not met

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Target Organs: None

ACUTE EXPOSURE

Symptoms/Injuries after Inhalation: Not expected to be a primary route of exposure.

Symptoms/Injuries after Skin Contact: Not irritating to skin.

Symptoms/Injuries after Eye Contact: May cause eye irritation.

Symptoms/Injuries after Ingestion: None expected under normal conditions of use.

CHRONIC EXPOSURE

Symptoms: None expected under normal conditions of use.

Information on Toxicological Effects-Ingredient(s)

Component	CAS #	LD50 Oral	LD50 Dermal	LC50 inhalation
Miconazole Nitrate	22832-87-7	920 mg/kg rat	Not Available	Not Available
Polywax (Alcohols, C16-18)	67762-27-0	>5,000 mg/kg rat	Not Available	Not Available
Propylene glycol	57-55-6	>5,000 mg/kg rat	>2,000 mg/kg rabbit	>2,000 mg/kg rabbit
Dimethicone (Polydimethylsiloxane)	63148-62-9	>2,000 mg/kg rat	>2,000 mg/kg rabbit	Not Available
Zinc oxide	1314-13-2	>5,000 mg/kg rat	Not Available	5.7 mg/L rat

SECTION 12: ECOLOGICAL INFORMATION

Ecotoxicity: Not classified

Component	CAS #	LC50
Miconazole Nitrate	22832-87-7	N/D
Propylene glycol	57-55-6	EC50 > 100 mg/l for 96 hr
Dimethicone (Polydimethylsiloxane)	63148-62-9	EC50 > 10,000 mg/l for 48 hr - Species: Daphnia magna

Persistence and degradability:

Component	CAS #	Comments
Miconazole Nitrate	22832-87-7	N/D
Propylene glycol	57-55-6	Moderately biodegradable
Dimethicone (Polydimethylsiloxane)	63148-62-9	Readily biodegradable in water.
Zinc oxide	1314-13-2	Not biodegradable

Bioaccumulative potential:

Component	CAS #	Log Pow
Miconazole Nitrate	22832-87-7	N/D
Dimethicone (Polydimethylsiloxane)	63148-62-9	N/D
Zinc oxide	1314-13-2	N/D

Mobility in the soil: Not available.

Other adverse effects: N/A

SECTION 13: DISPOSAL CONSIDERATIONS

Waste Disposal Method: Each disposal facility must determine proper disposal methods to comply with Local, State, and Federal Environmental Regulations.

TCLP determination may be required under RCRA for Zinc oxide impurities of lead and cadmium.

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SECTION 14: TRANSPORT INFORMATION

Marine Pollutant: *No*

Regulatory information	UN Number	Proper Shipping Name	Classes	PG	Environmental hazards	Special precautions
DOT Classification	None	Not applicable	-	-	None	None
IMDG Class (Intl Maritime Dangerous Goods)	-	-	-	-	-	Not Regulated
IATA-DGR Class (Intl Air Transportation)	-	-	-	-	-	Not Regulated
TDG (Canada)	-	-	-	-	-	Not Regulated
ADR (Intl Carriage of Dangerous Goods by Road)	-	-	-	-	-	Not Regulated

SECTION 15: REGULATORY INFORMATION

United States Federal Regulations

HCS Classification: *Not regulated*

TSCA (8a&b): *This material is listed or exempted.*

CERCLA RQ: *40CFR 302.4(a) – Not Listed*

RCRA 261: *TCLP determination Pb, Cd*

SARA 302/304: *No components were found*

SARA 311/312 Hazards identification: *Not regulated*

SARA 313: *Compounds of Zn, Pb*

Clean Air Act 112/602 (HAPs): *Not listed*

United States State Regulations Right To Know (RTW)

Component	CAS No.	MA	NJ	NY	PA	MN	IL	MI	FL	RI	CA
Polywax (Alcohols, C16-18)	67762-27-0	-	Yes	-	Yes	-	-	-	-	-	Yes
Propylene glycol	57-55-6	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	-
Dimethicone (Polydimethylsiloxane)	63148-62-9	-	Yes	-	Yes	-	-	-	-	-	-
Zinc oxide	1314-13-2	Yes	Yes	-	Yes	Yes	-	-	-	-	Yes
Miconazole Nitrate	22832-87-7	-	Yes	-	-	-	-	-	-	-	-

California Prop. 65

This product does contain chemicals requiring a warning under Cal Prop 65. (see table below)

Component	CAS No.	Carcinogen	Reproductive	No significant risk level	Max acceptable dosage level
1,4 Dioxane	123-91-1	X		30 µg/day	-
Ethylene oxide	75-21-8	X	X	2 µg/day	20 µg/day

Canadian Regulations:

WHMIS Hazard Classification: *Non-controlled*

Component	CAS No.	Canada DSL	Canada NDSL	WHMIS Classification
Polywax (Alcohols, C16-18)	67762-27-0	Listed	Not Listed	Not Listed
Dimethicone (Polydimethylsiloxane)	63148-62-9	Listed	Not Listed	Not Listed
Propylene glycol	57-55-6	Listed	Not Listed	Not Listed
Zinc oxide	1314-13-2	Listed	Not Listed	Not Listed
Miconazole Nitrate	22832-87-7	Listed	Not Listed	Not Listed
Methyl paraben	99-76-3	Listed	Not Listed	Not Listed
1,4 Dioxane	123-91-1	Listed	Not Listed	Serious eye damage/eye irritation – Category 2 Carcinogenicity - Category 2
Ethylene oxide	75-21-8	Listed	Not Listed	Carcinogenicity - Category 1B Reproductive toxicity - Category 1
Diethanolamine	111-42-2	Listed	Not Listed	IARC -carcinogenicity: group 2B

Canada Controlled Products Regulation: *This product has been classified in accordance with the hazard criteria of the Controlled Products Regulations (CPR) and the SDS contains all of the information required by CPR.*

EU Classifications: *This product is not currently sold in the EU.*

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SECTION 16: OTHER INFORMATION

Disclaimer/Statement of Liability:

The information contained herein is believed to be accurate but is not warranted to be so. Data and calculations are based on information furnished by the manufacturer of the product and manufacturers of the components of the product. Users are advised to confirm in advance of need that information is current, applicable and suited to the circumstance of use. Vendor assumes no responsibility for injury to vendee or third persons proximately caused by the material if reasonable safety procedures are not adhered to as stipulated in the data sheet. Furthermore, vendor assumes no responsibility for injury caused by abnormal use of this material even if reasonable safety procedures are followed. Any questions regarding this product should be directed to the manufacturer of the product as described in Section 1.

This document has been prepared in accordance with the SDS requirements of the OSHA Hazard Communication Standard 29 CFR 1910.1200, Appendix D. (OSHA HCS 2012)

Prepared by: Nipro Customer Healthcare Inc., d/b/a P.J. Noyes.

Key to abbreviations

N/A = Not Available N/D=Not Determined N/E= Not Established

DSL = Canadian Domestic Substances List

NDSL = Canadian Ingredient Disclosure List