

## Safety Data Sheet



## SECTION I – Identification

<b>Identity (As Used on Label and List)</b> NIVATOPIC PLUS CREAM	EPA Reg. No. N/A	<b>Recommended Use:</b> To manage and relieve the burning, itching and pain experienced with various types of dermatoses, including atopic dermatitis, allergic contact dermatitis and radiation dermatitis.
<b>Distributed by:</b> Tagi Parma, Inc.		<b>Emergency Telephone Number:</b> 1-800-222-1222
<b>Address (Number, Street, City, State, and ZIP Code)</b> South Beloit, IL 61080		<b>Telephone Number for Information:</b> 1-650-279-8437
<b>Formula No.:</b> NIV05		

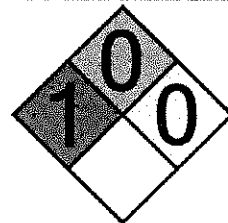
## SECTION II – Hazard Identification

**NFPA Hazard Rating: Health: 1 Flammability: 0 Reactivity: 0 Special: N/A**

**Health Hazards (Acute and Chronic)** – This product, although not typical, may cause allergic or sensitivity reactions for individuals sensitive to one or more components.

**Caution:**

Not generally considered an occupational hazard



<b>Route(s) of Entry</b>	<b>Eyes?</b> Yes	<b>Inhalation?</b> No	<b>Skin?</b> Yes	<b>Ingestion?</b> Yes
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**Signs and Symptoms of Exposure –**

**Eyes:** May cause irritation and stinging or burning.

**Inhalation:** May cause respiratory irritation in sensitive individuals.

**Skin:** Irritation or redness may occur in sensitive individuals.

**Ingestion:** Not a likely route of entry. If swallowed may cause gastrointestinal discomfort.

**Medical Conditions Generally Aggravated by Exposure -**

Not determined

## SECTION III - Composition/Information on Ingredients

## Specific Ingredient Identity

## Other Limits

Recommended

% (Opt.)

Common Name(s)	CAS No.	OSHA PEL	ACGIH-TLV	Specific Hazards	Recommended	% (Opt.)
Methylparaben	99-76-3	N/A	N/A	Not Hazardous	N/A	0.20%
Water	7732-18-5	N/A	N/A	Not Hazardous	N/A	76%
Glycerin	56-81-5	N/A	N/A	Not Hazardous	N/A	7%
Propylene Glycol	57-55-6	N/A	N/A	Not Hazardous	N/A	2%
Disodium EDTA	139-33-3	N/A	N/A	Not Hazardous	N/A	0.02%

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Octyl Palmitate	9806-73-3	N/A	N/A	Not Hazardous	N/A	3%
Cetearyl Alcohol	67762-27-0	N/A	N/A	Not Hazardous	N/A	2%
Crodafos CES	Mixture	N/A	N/A	Not Hazardous	N/A	1.5%
Theobroma Grandiflorum Seed Butter	39436-97-6	N/A	N/A	Not Hazardous	N/A	1.53%
Petrolatum	8009-03-8	N/A	N/A	Not Hazardous	N/A	2.5%
Propylparaben	94-13-3	N/A	N/A	Not Hazardous	N/A	0.05%
Polyoxyethylene	9004-98-2	N/A	N/A	Not Hazardous	N/A	1%
Dimethicone	141-62-8	N/A	N/A	Not Hazardous	N/A	2%
Tocopheryl Acetate	7695-91-2	N/A	N/A	Not Hazardous	N/A	0.5%
Sodium Hyaluronate	906732-7	N/A	N/A	Not Hazardous	N/A	0.5%
Hydroxypropyl Bispalmitamide MEA	N/A	N/A	N/A	Not Hazardous	N/A	0.10%
Sodium Hydroxide	1310-73-2	N/A	N/A	Not Hazardous	N/A	0.10%

Any substance listed as hazardous by the States of California, Florida, Illinois, Michigan, New Jersey, Ohio, Pennsylvania or Texas is described above if known present in regulated concentrations.

#### SECTION IV – First Aid Measures

##### Emergency and First Aid Procedures:

**Eyes** –Rinse eye with plenty of water. If irritation develops, call a physician. **Skin** –Rinse skin with plenty of water. If irritation develops, call a physician. **Inhalation** – Move person to fresh air. If breathing has stopped, qualified personnel should administer artificial respiration. **Ingestion** – Do not induce vomiting. Never give anything by mouth to an unconscious person. Rinse out mouth and have patient drink several glasses of water. Call a physician.

#### SECTION V – Fire-Fighting Measures

##### Flash Point (Method Used)

Not Applicable

##### Flammable Limits

No Data

##### LEL

No Data

##### UEL

No Data

##### Extinguishing Media -

Not known to support combustion. All recognized methods acceptable.

**Special Fire Fighting Procedures** - Keep containers cool and vapors down with water spray. Prevent runoff from entering sewers and public waterways. Wear SCBA in chemical fires.

##### Unusual Fire and Explosion Hazards -

Not known to support combustion.

#### SECTION VI – Accidental Release Measures

##### Steps to be Taken in Case Material is Released or Spilled -

Caution, slip hazard. Wipe up small spills with an absorbent material. For large spills, pick up with a vacuum or an absorbent material. Place waste in appropriate container for disposal.

**Waste Disposal Method** - Consult local, state, and federal regulations. Do not reuse empty container.

#### SECTION VII – Handling and Storage

**Precautions to be Taken in Handling**– Avoid eye contact. Should such contact occur, wash exposed area promptly. Use with adequate ventilation. Store in cool dry location away from heat, sparks and open flame. Do not use around ignition sources such as heat, sparks, flame, etc. Do not smoke while using.

**Storage Temperatures:** Store in cool dry place, that is well ventilated

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**Other Precautions** - Follow label directions carefully. Keep out of reach of children. Keep container tightly sealed when not in use. Do not contaminate water, food or feed by use or storage. Do not swallow. Avoid inhaling mist and vapors.

**SECTION VIII – Exposure Controls/ Personal Protection**

**Respiratory Protection (Specify Type)** - Not usually necessary. Use with adequate ventilation. Use NIOSH/MSHA approved respirator if PELs or TLVs are exceeded.

Ventilation	Local Exhaust	Not usually needed	Special	None
	Mechanical (General)	Yes	Other	None

**Protective Gloves** -  
Rubber or Neoprene

**Eye Protection** -  
Wear safety glasses for splash protection.

**Other Protective Clothing or Equipment** -  
Not usually necessary. Avoid direct contact.

**Work/Hygienic Practices** -

Normal. Wash hands after use and before eating, drinking, smoking, using restrooms, etc.

**SECTION IX – Physical and Chemical Properties**

Boiling Point	ND	Specific Gravity (H <sub>2</sub> O = 1) @ 25°C	0.885 – 0.979
Vapor Pressure (mm-Hg @ 70° F)	ND	Melting Point	ND
Vapor Density (AIR = 1)	ND	Evaporation Rate (Butyl Acetate = 1)	ND
Solubility in Water	Semi soluble	Ph @ 25°C	4.00 – 5.20

**Appearance and Odor** – White Opaque Emulsion. Unfragranced Odor.

**SECTION X – Stability and Reactivity**

Stability	Unstable		
	Stable	X	Conditions to Avoid - Heat, sparks, open flames

**Incompatibility (Materials to Avoid)** -  
None known

**Hazardous Decomposition or Byproducts** -  
None known

Hazardous Polymerization	May Occur		
	Will Not Occur	X	Conditions to Avoid - None known

**SECTION XI – Toxicological Information**

<b>Carcinogenicity:</b> No Data Available.	<b>NTP?</b> No	<b>IARC Monographs?</b> No	<b>OSHA Regulated?</b> No
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**SECTION XII – Ecological Information**

No Data Available.

**SECTION XIII – Disposal Considerations**

Dispose of in-accordance with local, State and Federal regulations.

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## SECTION XIV – Transport Information

This material is not subject to transportation regulations for any known freight.

Finished packaged product transported by ground (DOT):	<b>Hazard Class:</b> Non-Hazardous <b>UN Number:</b> Not a regulated hazardous material <b>Packaging group:</b> Not Applicable	Proper Shipping Name:	N/A
Finished packaged product transported by vessel (IMDG):	<b>IMDG Class:</b> Not Applicable <b>UN Number:</b> Not a regulated hazardous material <b>Label:</b> Not Applicable <b>Packaging group:</b> Not Applicable <b>EMS Number:</b> N/A <b>Marine Pollutant:</b> N/A	Proper Shipping Name:	N/A
Finished packaged product transported by air (ICAO-TI and IATA-DGR):	<b>ICAO/IATA Class:</b> Not Applicable <b>UN/ID Number:</b> Not a regulated hazardous material <b>Label:</b> Not Applicable <b>Packaging group:</b> Not Applicable	Proper Shipping Name:	N/A

## SECTION XV – Regulatory Information

No Data Available.

## SECTION XVI – Other Information

Date Created 10/26/18

Prepared & Approved By: **Yanet Ramos**  
Document Control Specialist

**Company Policy or Disclaimer**

The information and data are offered in good faith as typical values and not as a product specification. No warranty, either expressed or implied, is hereby made. The recommended industrial hygiene and safe handling procedures are believed to be generally applicable. All materials may present unknown health hazards and should be used with caution. Although certain hazards are described herein, we cannot guarantee that these are the only hazards that exist. The user assumes all liability for any damages or injury that result from abnormal use, any failure to adhere to recommended practices, or from any hazards inherent in the nature of the product.

**NO INFORMATION BEYOND THIS POINT**

# HDA Standard Pharmaceutical Product Information (Rx Product Only)

© August 2014

Introduction Type:  Final Version  Post Launch Change

Date:

**PRODUCT INFORMATION**

Company Name: TIGI Pharma, Inc. Application:  Med Device  Device

Application Number for NDAs/ANDAs/BLAs (Drug: PRA510)(Med device): K133239

DUNS: 983322560 Nivatoric Plus Cream

Proprietary Name (if Applicable) and Established Name: 51224-0450-20 Individual Unit NDC:         

Spilling Unit NDC:          CVX Code:          UPC:         

UDI Nivalpic Plus Cream 450g MXX Code:         

Description: Glyceth, Ethylhexyl Palmitate

Active ingredient(s):         

URL for Additional Product Information: www.tigipharma.com

Address: 722 Progressive Lane State:          Room 205  
South Beauf City:          Zip: 61080

Key Contact: Melissa Bradley Email: mbradley@tigipharma.com

Phone Number: 815-624-7685 Fax: 815-624-7687

Product Therapeutic Classification:         

**ADDITIONAL PRODUCT INFORMATION**

Is the Product...  
 a legend device?  No  Yes  
 reverse numbered?  No  Yes  
 co-licensed?  No  Yes  
 Is the Product...  
 Direct Ship Only?  No  Yes  
 Is the Product...  
 Neither  No  Yes

If UMI Dose, Is item bar coded to unit dose for hospital scanning?  
 No  Yes

If Unit Dose NDC, indicate NDC here:         

Country of Origin: USA

Is this product covered under the Trade Agreements Act (TAA)?  
 No  Yes

**PRODUCT DESCRIPTION INFORMATION**

Size: 450g

Strength:         

Dosage Form: Cream

Product Shape: Jar

Product Color: White

Product Imprint: N/A

**FOR GENERIC DRUG PRODUCTS**

I. Orange Book Rating: N/A  Authorized Generic  If Authorized Generic, other section fields are not applicable

II. Generic Equivalent to What Brand?: Hydratoc Plus

**DRUG SUPPLY CHAIN SECURITY (DSCSA) INFORMATION**

Does supplier meet DSCSA definition of manufacturer?  No  Yes  GLN:         

Is product exempt from DSCSA?  
 If yes, select exemption:         

Other exemption - While in:         

Is product repackaged?  No  Yes  If Yes, was original product purchased direct from mfr?  Yes  No  If yes, attach documentation from FDA.

Has FDA granted writer/exemption for product?  No  Yes  If yes, attach documentation from FDA.

**Q101 PRODUCT INFORMATION**

Sanitized? If not, when? Items aggregated?	No	Yes	Item	Level	Unit	Quantity	GTIN-14
	<input type="checkbox"/>	<input type="checkbox"/>	Box/ Carton/ Bundle/ Pack		2D	<input type="text"/>	<input type="text"/>
	<input type="checkbox"/>	<input type="checkbox"/>	Case		2D	<input type="text"/>	<input type="text"/>
	<input type="checkbox"/>	<input type="checkbox"/>	Unit		2D	<input type="text"/>	<input type="text"/>
	<input type="checkbox"/>	<input type="checkbox"/>			2D	<input type="text"/>	<input type="text"/>
	<input type="checkbox"/>	<input type="checkbox"/>			2D	<input type="text"/>	<input type="text"/>
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	<input type="checkbox"/>	<input type="checkbox"/>			2D	<input type="text"/>	<input type="text"/>
	<input type="checkbox"/>	<input type="checkbox"/>			2D	<input type="text"/>	<input type="text"/>

**SPECIAL HANDLING AND STORAGE REQUIREMENTS**

a. Temperature - Indicate the USP temperature range for this product.  
 Temperature Range          Controlled Room - between 20 and 25 C (68° - 77° F)

Other Temperature Range Requirement (write in)         

Is this product to be shipped to customers on ice?  No  Yes

Is this product to be shipped to customers on dry ice?  No  Yes

b. Contact for temperature excursion questions:

Name:         

Number:         

Group E-mail:         

c. Special regulations for product in any states?

Special returns requirements for this product?  No  Yes

d. Store product (unit of sale) upright?

Protect product (unit of sale) from light?  Yes  No

e. Shelf life:  
 Initial shelf life at launch (if different):  Months  
 Months

**ORDER INFORMATION**

What is the NDC selling unit?  
1 Jar (Write-in, e.g. 1 Box of 10 Vials)

Minimum order quantity?         

If Yes, how many of which package type?  
 1 Jar Each  
 Inner/ Carton/ Pack  
 Case

**PHARMACY ORDER BILL UNIT**

Rec. sell unit to customer?           Each  Gram  Milliter

RR Billing unit to pharmacy:         

**ITEM AND PACKING INFORMATION**

Item:	Weight Lbs.	Dimensions (US mm/in.)	Volume	# Pieces:
		Depth Height Width	(Cube)	
Box/Carton/Bundle/ Inner Pack:	1	3.75" 4.75" 3.75"		
Case:	4	7.5" 4.75" 7.5"		
Pallet:				
Case:				
Carton:				

**COST INFORMATION**

Regular Cost

Invoice Cost (VAC) (\$)

Federal Excise Tax Per Unit of Sale

**WHOLESALE USE ONLY**

Vendor #:         

Vendor Code #:         

Product Code #:         

Signature: Melissa Bradley

For Designated Drop Ship Only Products, Please Use Page 3

Is this product (check all that apply):

- a. Cytotoxic?  No
- b. CA Prop. 65 Carcinogen or Reproductive Toxicant?  No
- Is the product a CA Prop 65 carcinogen?  No
- Is the product a CA Prop 65 reproductive toxicant?  No
- Does the product label bear a CA Prop 65 warning?  No

- c. Contact Hazard?  No
- d. Does this product require special clean-up instructions?  No
- (If yes, attach SDS with special instructions.)
- e. Does the product contain DEHP?  No

Is this product regulated for shipment by DOT or IATA? (If yes, answer a-e below and provide SDS)

- a. UN/Identification Number
- b. Proper Shipping Name
- c. DOT Hazard Class
- d. Packing Group
- e. Inhalation Hazard?  No

Is the product restricted for air shipment? If so, indicate restriction:

- Passenger
- Cargo
- Passenger & Cargo

Is this a reportable quantity?  No

Is this a marine pollutant?  No

(If yes, identify method below)

- Limited Quantity
- Consumer Commodity ORM-D
- Small Quantity (49 CFR 173.4)
- Special Permit: DOT-SP
- Special Provision (listed in Column 7 of 49 CFR 172.101):
- SP#

**ADDRESS/STORAGE INFORMATION**

Is the Product ...

Controlled Substance?  No

Controlled by State(s)?  No

ARCOS Reportable?  No

Schedule No. (inc. N for non-narcotic)

Controlled Substance Code

Listed Chemical (List I or II)

If yes, indicate which:

Is it a scheduled listed chemical product?  No

**CLASS OF TRADE RESTRICTION:**

No restriction: Select YES if sold to retail pharmacy, hospitals, clinics and physician offices  Yes

Restricted to retail pharmacy only?  No

Restricted to hospital, clinics, and physician offices only?  No

Restricted from US territories? (explain in comments)  No

Comments:

**MATERIAL HAZARD CLASSIFICATION and TRANSPORTATION**

**SDS Hazard Classification**

- Organic  Corrosive
- Inorganic  Oxidizer
- Steroid/Androgen  Contact Hazard
- Aerosol Class: Identify NFPA Storage Level:

Is the product a NIOSH hazardous drug?

If yes, indicate which:

EPA Hazardous Waste Code:

**Hazardous Waste Identification**

**REMS or REGISTRY RESTRICTIONS**

Is there a REMS on this product?  No

If yes, is it managed with a pharmacy registry?

Website URL:

Comments / Details: (For example, Pledge program?)

**REMS:**

REMS Program Manager Name:  Phone:

Supplier Manages REMS registry exclusively:

Wholesale distributor support:

Provider Name:

Site Enrollment Number assigned by Supplier:

DEA #:

PCPPD #:

NPI #:

Comments:

Registry:

Registry Program Contact Name:  Phone:

Comments:

**RETURN INSTRUCTIONS**

Contact tel. # if product received damaged:  815-624-7685

Is product returnable for credit:  Yes

URL/Link to returns policy:

Special regulations or returns requirements for this product in certain states?  No

If so, which states? Other requirements? Comments?

**MISCELLANEOUS NOTES and/or Image of Product Barcode**

Release DATE

**Order Method for Designated Drop Ship Product**

FOR DESIGNATED DROP SHIP PRODUCT ONLY - If not a designated drop ship, do not complete.

**Standard Order Receipt and Processing**

Purchase orders may be accepted by:

- a. EDI \_\_\_\_\_
- b. Autofax \_\_\_\_\_
- c. Fax \_\_\_\_\_
- d. Phone only \_\_\_\_\_
- e. Supplier Web Site only \_\_\_\_\_

Fax Number: \_\_\_\_\_  
 Fax Number: \_\_\_\_\_  
 Phone No.: \_\_\_\_\_  
 Site Address: \_\_\_\_\_

Minimum Order Quantity: \_\_\_\_\_  
 Supplier's Customer Service Number: \_\_\_\_\_  
 Contracted 3PL company / contact #: \_\_\_\_\_

Name: \_\_\_\_\_  
 Phone: \_\_\_\_\_

Purchase order daily receipt cut off time by supplier \_\_\_\_\_

Out of time: \_\_\_\_\_

Shipping lead time of PO: \_\_\_\_\_ Hours \_\_\_\_\_ Days

Ships same day for next day receipt: \_\_\_\_\_

Ships for second day receipt: \_\_\_\_\_

Ships regular ground for 3-10 days receipt: \_\_\_\_\_

**Expedited Freight Charges or Other Designated Drop Ship Fees:**

Expedited freight fees billed with each order: \_\_\_\_\_

Drop Ship service fee billed with each order: \_\_\_\_\_

Drop Ship miscellaneous fees billed: \_\_\_\_\_

Comments: \_\_\_\_\_

**Overnight and Priority Overnight PO Processing**

Overnight receipt available: \_\_\_\_\_

PO Receipt cut off time: \_\_\_\_\_

Days of week overnight is available: \_\_\_\_\_

Monday
Tuesday
Wednesday
Thursday
Friday

Priority Overnight receipt available: \_\_\_\_\_

PO Receipt Cut off time: \_\_\_\_\_

**Class of Trade Restriction:**

No restriction. Select YES if sold to retail pharmacy, hospitals, clinics and physician offices \_\_\_\_\_

Restricted to retail pharmacy only: \_\_\_\_\_

Restricted to hospital, clinics, and physician offices only: \_\_\_\_\_

Restricted from US territories? (explain in comments) \_\_\_\_\_

Comments: \_\_\_\_\_

**Other Data Information Required to Process PO:**

Patient Procedure Date: \_\_\_\_\_

Physician Name: \_\_\_\_\_

Physician/Clinic Phone #: \_\_\_\_\_

Physician State License #: \_\_\_\_\_

Physician/Clinic DEA #: \_\_\_\_\_

Physician/Clinic Specialty: \_\_\_\_\_

**Miscellaneous Notes:**

\_\_\_\_\_

\_\_\_\_\_

\_\_\_\_\_

**Return Instructions**

Overnight Fees apply: \_\_\_\_\_

Other fees apply: \_\_\_\_\_

Order receipt method: \_\_\_\_\_

Phone #: \_\_\_\_\_

Fax #: \_\_\_\_\_

EDI: \_\_\_\_\_

PO Receipt Cut off time: \_\_\_\_\_

PO Receipt available: \_\_\_\_\_

PO Receipt Cut off time: \_\_\_\_\_

Phone #: \_\_\_\_\_

Fax #: \_\_\_\_\_

EDI: \_\_\_\_\_

Other fees apply: \_\_\_\_\_

Other requirements? Comments? \_\_\_\_\_

Special regulations or returns requirements for this product in certain states? \_\_\_\_\_

URL/link to returns policy: \_\_\_\_\_

Is product returnable for credit: \_\_\_\_\_

Contact # if product is received damaged: \_\_\_\_\_

**ADDITIONAL INFORMATION**

Is product order for scheduled patient procedure? \_\_\_\_\_

Is product order for restocking purposes? \_\_\_\_\_