

Safety Data Sheet



SECTION I – Identification

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

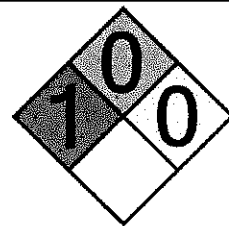
SECTION II – Hazard Identification

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



Route(s) of Entry	Eyes? Yes	Inhalation? No	Skin? Yes	Ingestion? 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.
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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 ₂ 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

Carcinogenicity: No Data Available.	NTP? No	IARC Monographs? No	OSHA Regulated? 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):	Hazard Class: Non-Hazardous UN Number: Not a regulated hazardous material Packaging group: Not Applicable	Proper Shipping Name:	N/A
Finished packaged product transported by vessel (IMDG):	IMDG Class: Not Applicable UN Number: Not a regulated hazardous material Label: Not Applicable Packaging group: Not Applicable EMS Number: N/A Marine Pollutant: N/A	Proper Shipping Name:	N/A
Finished packaged product transported by air (ICAO-TI and IATA-DGR):	ICAO/IATA Class: Not Applicable UN/ID Number: Not a regulated hazardous material Label: Not Applicable Packaging group: 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

For Designated Drop Ship Only Products, Please Use Page 3
MATERIAL HAZARD CLASSIFICATION and TRANSPORTATION

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

RQ Threshold: _____

Is this a marine pollutant? No

Is this product shipped utilizing an authorized DOT exception or Special Permit?
 No (if yes, identify method below)

<input type="checkbox"/>	Limited Quantity
<input type="checkbox"/>	Consumer Commodity, ORM-D
<input type="checkbox"/>	Small Quantity (49 CFR 173.4)
<input type="checkbox"/>	Special Permit: DOT-SP
<input type="checkbox"/>	Special Provision (listed in Column 7 of 49 CFR 172.101):
<input type="checkbox"/>	SP# _____

ADDITIONAL 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, hospital, clinic 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: _____

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: _____

Hazardous Waste Identification

EPA Hazardous Waste Code: _____

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, IPledge program?) _____

REMS:

REMS Program Manager Name: _____ Phone: _____

Supplier Manages REMS registry exclusively: _____

Wholesale distributor support: _____

Provider Name: _____

Site Enrollment Number assigned by Supplier: _____

DEA #: _____

PCPDP #: _____

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: Selected 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: _____

Return Instructions

Contact # if product is received damaged: _____

Is product returnable for credit: _____

URL/link to returns policy: _____

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

If so, which states? Other requirements? 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: _____

ADDITIONAL INFORMATION

Is product order for scheduled patient procedure? _____

Is product order for restocking purposes? _____