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## SECTION 1. IDENTIFICATION

<b>FINISHED PRODUCT NAME:</b>	Tri-Luma® (fluocinolone acetonide 0.01%, hydroquinone 4%, tretinoin 0.05%) Cream
<b>PRODUCT CODE(S):</b>	3 g – 0299-5950-03 30 g – 0299-5950-30
<b>DISTRIBUTOR INFORMATION:</b>	Galderma Laboratories, L.P. 14501 North Freeway Fort Worth, TX 76177
<b>EMERGENCY CONTACT:</b>	817-961-5000
<b>BUSINESS PHONE:</b>	817-961-5000
<b>RECOMMENDED USE:</b>	See product labeling.
<b>RESTRICTIONS ON USE:</b>	See product labeling.

## SECTION 2. HAZARD IDENTIFICATION

### HAZARD IDENTIFICATION:

This is a prescription product that is safe for consumers under the prescribed use. Additional information on toxicology endpoints may be available from the supplier upon request.

### ROUTES OF ENTRY: (YES/NO)

<b>INHALATION:</b>	No
<b>ABSORPTION:</b>	Yes
<b>INGESTION:</b>	Yes


### POTENTIAL EFFECTS OF EXPOSURE:

<b>INGESTION:</b>	If product is swallowed, may cause nausea, vomiting and/or diarrhea.
<b>SKIN:</b>	May be irritating to the skin in some sensitive individuals.
<b>EYES:</b>	Moderate irritation may occur.
<b>INHALATION:</b>	This product is nonvolatile; therefore, inhalation is unlikely.

## SECTION 3. COMPOSITION/INFORMATION ON INGREDIENTS

The product(s) does not contain ingredients considered hazardous as defined by OSHA, 29 CFR 1910.1200 and/or WHMIS under the HPA.

PRINCIPLE COMPONENTS	CAS NO.	CONC. %*	CLASSIFICATION
Fluocinolone acetonide		0.01%	
Hydroquinone		4%	
Tretinoin		0.05%	
Butylated hydroxytoluene			
Cetyl alcohol			
Citric acid			
Glycerin			
Glyceryl stearate			
Magnesium aluminum silicate			
Methyl gluceth-10			
Methylparaben			
PEG-100 Stearate			
Propylparaben			

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Purified water			
Sodium metabisulfite			
Stearic acid			
Stearyl alcohol			

\*Formulation proprietary, we will make this information available to medical personnel in the event of an emergency.

## SECTION 4. FIRST-AID MEASURES


<b>INGESTION:</b>	Accidental ingestion of product may necessitate medical attention. In case of accidental ingestion dilute with fluids (water or milk) and treat symptomatically. Do not induce vomiting. Never give anything by mouth to an unconscious person. Contact the nearest Poison Control Center or local emergency number. Provide an estimate of the time and amount of the substance swallowed.
<b>EYES:</b>	If the product is in the eyes, do not rub eyes. Flush with copious amount of lukewarm water for at least 15 minutes. Open and close eyelid to ensure thorough irrigation. If irritation persists contact a physician.
<b>SKIN:</b>	If redness, dryness or other signs of irritation occur wash the affected area with warm water and soap. If irritation persists contact a physician.
<b>INHALATION:</b>	If respiratory irritation occurs, remove individual to fresh air.
<b>MEDCAL CONDITIONS AGGRAVATED BY EXPOSURE:</b>	None known.

## SECTION 5. FIRE-FIGHTING MEASURES

<b>FLASH POINT:</b>	N/A
<b>AUTO IGNITION TEMPERATURE:</b>	N/A
<b>FLAMABILITY LIMITS:</b>	
<b>    LOWER EXPLOSIVE LIMIT:</b>	N/A
<b>    UPPER EXPOLSIVE LIMIT:</b>	N/A
<b>EXPLOSION HAZARD:</b>	This product is non-flammable.
<b>EXTINGUISHING METHODS:</b>	Foam, CO <sub>2</sub> , dry chemical powder, water spray, sand/earth as applicable to surrounding fire conditions.
<b>FIRE-FIGHTING PROCEDURES:</b>	As in any fire, wear MSHA/NIOSH approved self-contained breathing apparatus (pressure-demand) and full protective gear as applicable to surrounding fire conditions.

## SECTION 6. ACCIDENTAL RELEASE MEASURES

<b>PROCEDURES FOR SPILL/LEAK CLEAN-UP:</b>	Caution! Floor may become slippery. Absorb spilled material with inert material such as sawdust, sand or earth. Cleaning may require use of steam, solvents or detergents.
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<b>DISPOSAL METHOD:</b>	Sweep up and dispose of in accordance with Federal, State and local regulations.
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## SECTION 7. HANDLING AND STORAGE

<b>WORK AND HYGENE PRACTICES:</b>	Use only as directed. Avoid eye contact.
<b>STORAGE AND HANDLING:</b>	Use and store according to labeled directions. Do not store in unmarked or damaged containers or storage devices. Keep containers securely closed when not in use.
<b>SPECIAL PRECAUTIONS:</b>	Spilled material may present a slipping hazard if left unattended. Clean spills promptly.

## SECTION 8. EXPOSURE CONTROLS/PERSONAL PROTECTION


<b>VENTILATION AND ENGINEERING CONTROLS:</b>	None required.
<b>RESPIRATORY PROTECTION:</b>	None required.
<b>EYE PROTECTION:</b>	None required under normal conditions or use. Avoid eye contact, moderate irritation may result. May cause irritation in some sensitive individuals.
<b>HAND PROTECTION:</b>	Not required under normal conditions of use. May cause skin irritation in some sensitive individuals.
<b>BODY PROTECTION:</b>	None required.

## SECTION 9. PHYSICAL AND CHEMICAL PROPERTIES

<b>VAPOR DENSITY:</b>	N/A
<b>BOILING POINT:</b>	N/A
<b>MELTING POINT:</b>	N/A
<b>EVAPORATION RATE:</b>	N/A
<b>VAPOR PRESSURE:</b>	N/A
<b>WATER SOLUBILITY:</b>	Insoluble
<b>MOLECULAR WEIGHT:</b>	N/A
<b>COLOR:</b>	Yellow
<b>FRAGRANCE:</b>	Characteristic
<b>APPEARANCE:</b>	Creamy
<b>pH @ 25°C:</b>	N/A
<b>SPECIFIC GRAVITY @ 25°C:</b>	N/A

## SECTION 10. STABILITY AND REACTIVITY

<b>STABILITY:</b>	This product is stable.
<b>REACTIVITY:</b>	Stable
<b>HAZARDOUS DECOMPOSITION PRODUCTS:</b>	Not determined.

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<b>HAZARDOUS POLYMERIZATION:</b>	Will not occur.
<b>CONDITIONS TO AVOID:</b>	Avoid exposure to atmospheric oxygen, oxidizing agents, metals, light and warming.
<b>INCOMPATABLE SUBSTANCES:</b>	None known.

## SECTION 11. TOXICOLOGICAL INFORMATION

<b>TOXICITY DATA:</b>	<p>Dermal toxicity studies for the triple combination product conducted on mini pigs, rats and rabbits demonstrated dose-related severity of irritation on application sites. Reproductive and fertility effects consisted of weight loss in the female rats at low concentration of the product, and small testes and hypospadias in male mini pigs, at full concentration of the product. Morphological abnormalities were seen in rat fetuses, and decreased <i>in utero</i> growth and survival in rabbit fetuses, with maternal exposure to full concentration of the product. The human equivalent dose for the full concentration mini pig dose is approximately 60 times the actual prescribed dosing. Accidental or intentional overuse of the product may result in systemic toxicity or local irritation.</p>
<b>CHRONIC TOXICITY:</b>	Finished product is not expected to have chronic health effects.
<b>SUSPECTED CARCINOGEN:</b>	Finished product is not expected to be carcinogenic. There is no specific data for this product.

## SECTION 12. ECOLOGICAL INFORMATION


<b>ENVIRONMENTAL STABILITY:</b>	There is no specific data for this product.
<b>EFFECTS ON PLANTS AND ANIMALS:</b>	There is no specific data for this product.
<b>EFFECTS ON AQUATIC LIFE:</b>	There is no specific data for this product.

## SECTION 13. DISPOSAL CONSIDERATIONS

<b>WASTE DISPOSAL:</b>	Dispose of in accordance to federal, state, and local regulations.
<b>SPECIAL CONSIDERATIONS:</b>	Dispose of in accordance to federal, state, and local regulations.

## SECTION 14. TRANSPORT INFORMATION

<b>49 CFR (GRND):</b>	Not regulated.
<b>IATA (AIR):</b>	Not regulated.
<b>IMDG (OCN):</b>	Not regulated.
<b>TGDR (CANADIAN GRND):</b>	Not regulated.
<b>ADR/RID (EU):</b>	Not regulated.
<b>SCT (MEXICO):</b>	Not regulated.
<b>ADGR (AUSTRALIA):</b>	Not regulated.

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## SECTION 15. REGULATORY INFORMATION

<b>SARA 313/302/304/311/312 CHEMICALS:</b>	None
<b>OSHA:</b>	This product contains no chemicals which are hazardous by definition of the Hazard Communication Standard (29 CFR 1910.1200).
<b>TSCA:</b>	All chemical substances in this product are listed on the TSCA inventory or are otherwise exempt from inventory status.
<b>CERCLA REPORTABLE QUANTITY (RQ):</b>	None
<b>OTHER FEDERAL REQUIREMENTS:</b>	This product complies with the appropriate sections of the Food and Drug Administration, Code of Federal Regulations (CFR) Title 21.

## SECTION 16. OTHER INFORMATION

<b>REVISION INFORMATION:</b>	Latest revision number and revision date is listed in the header of this document.
<b>REVISION HISTORY:</b>	00 – Original version – 04/2015 01 – Updated Sections 1, 3 to include Hydroquinone content – 05/2015
<b>DISCLAIMER:</b>	<p>The information provided in this Safety Data Sheet is furnished without any warranty of any kind, expressed or implied. Information on this Data Sheet has been assembled by the manufacturer based on its own studies and the work of others, and is believed to be correct as of the date issued. However, no warranty of any kind is expressed or implied as to the accuracy, completeness or adequacy of the information contained herein. The distributor shall not be liable, regardless of fault, to the vendee, the vendee's employees or anyone for any direct, special or consequential damages arising out of or in connection with the accuracy, completeness or adequacy of the information herein. It is intended to assist in the normal safe usage of the product. Users should make independent determinations of the suitability and completeness of information from all sources to assure proper use and disposal of these materials and the safety and health of employees and customers.</p>