安成國際藥業股份有限公司
TWi Pharmaceuticals, Inc.

Safety Data Sheet

Hydroquinone Time Release Cream 4%

SECTION 1 IDENTIFICATION

Product identifier	Hydroquinone Time Release Cream 4%
other means of identification	NDC No.: 24979-144-29
Recommended use	Skin discoloration treatment cream
Supplier	
Company name	TWi Pharmaceuticals, Inc.
Address	3F, No 41, Lane 221, Kang Chien Rd, Taipei, Taiwan.
Telephone	886-2-26573350
Fax	886-2-26573391
E-mail address	QA.Service@twipharma.com
Emergency phone number	1-844-518-2989

SECTION 2 HAZARD IDENTIFICATION

Physical hazards	Not hazardous.
Health hazards	Eye Damage: Category 1 Skin Sensitizer: Category Germ Cell Mutagen: Category 2 Reproductive Toxicity: Category 1B
Label element	
Code	H317/H318/H341/H361
Signal word	Danger
Pictogram	
Hazard statement	Causes serious eye damage. May cause an allergic skin reaction. Suspected of causing genetic defects. May damage fertility of unborn child
Precautionary statement	
Prevention	Obtain special instructions before use. Do not handle until all safety precautions have been read and understood. Avoid breathing mist or spray. Contaminated clothing must not be allowed out of the workplace. Wear eye protection and protective gloves.
Response	Wash hands after handling. If in eyes: rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rising. Immediately call a poison center or doctor. If on skin: wash with plenty of soap and water. If skin irritation occurs: Get medical attention. Wash contaminated clothing before reuse. If exposed or concerned: Get medical advice/attention.
Storage	Store locked up.
Disposal	Dispose in accordance with local/national regulations.

Hazard(s) not otherwise classified (HNOC) None known.

SECTION 3 COMPOSITION/INFORMATION ON INGREDIENTS

Product/mixture name Hydroquinone Time Release Cream 4%

Active ingredient:

Chemical Name	CAS number	%
Hydroquinone	123-31-9	4%
Water	7732-18-5	Proprietary
Glycerin	56-81-5	Proprietary
Decamethylcyclopentasiloxane	541-02-6	Proprietary
Mineral Oil	92062-35-6	<5%
Polyoxyl 40 Stearate	9004-99-3	Proprietary
Cetyl Alcohol	36653-82-4	Proprietary
Glyceryl Monostearate	31566-31-1	Proprietary
Octyl Palmitate	29806-73-3	Proprietary
Sodium Metabisulfite	7681-57-4	Proprietary
Bisabolol	515-69-5	Proprietary
Butylated Hydroxytoluene	128-37-0	Proprietary
Jojoba Oil	61789-91-1	Proprietary
Benzyl Alcohol	100-51-6	<1%
Sorbitan Tristearate	26658-19-5	Proprietary
Vitamin E	7695-91-2	Proprietary
Phenoxyethanol	122-99-6	1%
Propyl gallate	121-79-9	<0.1

Ascorbyl Palmitate	137-66-6	Proprietary
Tricontanyl PVP	136445-69-7	Proprietary
Ascorbyl Tetraisopalmitate	183476-82-6	Proprietary
Acrylates/C10-30 alkyl acrylate crosspolymer	Not Available	Proprietary
Trolamine (triethanolamine)	102-71-6	Proprietary
Poloxamer 188	9003-11-6	Proprietary
Ascorbic Acid	50-81-7	Proprietary
Edetate Disodium Dihydrate	6381-92-6	Proprietary

The exact percentage (concentration) of composition has been withheld as a trade secret.

SECTION 4 FIRST-AID MEASURES

Instructions by routes of exposure

Inhalation	Remove person to fresh air. If irritation occurs or symptoms develop, get medical attention.
Skin contact	This product is intended for use on the skin. If irritation or rash develops and persists, discontinue use and get medical attention. Remove and contaminated clothing and launder it before reuse.
Eye contact	Immediately flush eyes with water while lifting the upper and lower lids for at least 20 minutes. Remove contact lenses if present and easy to do, then continue rinsing. Get immediate medical attention.
Ingestion	Rinse mouth with water. Do not induce vomiting. Never give anything by mouth to a person who is unconscious or convulsing. Get medical attention.
Most important symptoms/ effects, both acute and delayed	Causes severe eye irritation and possible damage. May cause skin irritation or allergic skin reaction. Ingestion may cause gastrointestinal distress. Suspected mutagen and reproductive toxin.
Immediate medical attention and special treatment	Immediate medical attention is required for eye contact. Contains sodium metabisulfite, a sulfite that may cause allergic-type reactions including anaphylactic symptoms and life-threatening or less severe asthmatic episodes in certain susceptible people.

SECTION 5 FIRE-FIGHTING MEASURES

Suitable extinguishing media	Use any media that is suitable for the surrounding fire.
Specific hazards arising from the chemical	Product is not flammable or combustible but may burn in a fire after the water has evaporated.
Special protective equipment and precautions for firefighters	Firefighters should wear positive pressure self-contained breathing apparatus and full protective clothing for all fires involving chemicals. Cool fire exposed containers with water.

SECTION 6 ACCIDENTAL RELEASE MEASURES

Personal precautions, protective equipment and emergency procedures	Wear appropriate protective clothing and equipment as described in Section 8.
Methods and materials for containment and cleanup	Contain and collect with an inert absorbent material. Place in appropriate container for disposal. Clean area thoroughly.
Environmental precautions	Prevent spill from entering sewers and water courses. Report releases as required by local and national authorities.

SECTION 7 HANDLING AND STORAGE

Precautions for safe handling	Avoid the generation of mists. Avoid contact with eyes and clothing. Wash thoroughly with soap and water after handling.
Conditions for safe storage, including any incompatibilities	Store as indicated on product packaging.

SECTION 8 EXPOSURE CONTROLS/PERSONAL PROTECTION

Exposure guidelines:

Hydroquinone	1 mg/m^3 TWA ACGIH TLV 2 mg/m^3 TWA OSHA PEL
Water	None Established
Glycerin	5 mg/m^3 (respirable particulate) TWA OSHA PEL 15 mg/m^3 (total particulate) TWA OSHA PEL
Decamethylcyclopentasiloxane	None Established
Mineral Oil	5 mg/m^3 TWA OSHA PEL 5 mg/m^3 (inhalable) TWA ACGIH TLV
Polyoxyl 40 Stearate	None Established
Cetyl Alcohol	None Established
Glyceryl Monostearate	None Established
Octyl Palmitate	None Established
Vitamin A Palmitate	
Sodium Metabisulfite	5 mg/m^3 TWA ACGIH TLV
Bisabolol	None Established
Butylated Hydroxytoluene	2 mg/m^3 TWA (inhalable fraction and vapor) ACGIH TLV
Jojoba Oil	None Established
Benzyl Alcohol	10 ppm TWA AIHA WEEL
Sorbitan Tristearate	None Established
Vitamin E	

Phenoxyethanol	None Established
Propyl gallate	None Established
Ascorbyl Palmitate	None Established
Tricontanyl PVP	None Established
Ascorbyl Tetraisopalmitate	None Established
Acrylates/C10-30	
alkyl acrylate crosspolymer	None Established
Trolamine (triethanolamine)	5 mg/m^3 TWA ACGIH TLV
Poloxamer 188	None Established
Ascorbic Acid	None Established
Edetate Disodium Dihydrate	None Established

Appropriate engineering controls No special ventilation required for normal use. Use with adequate general or local exhaust ventilation to minimize exposures levels.

Individual protection measures, such as personal protective equipment

Eye/face protection None required for consumer use. In laboratory, medical or industrial settings, safety glasses with side shields are recommended. The use of goggles or full face protection may be required depending on the industrial exposure setting. Contact a health and safety professional for specific information.

Skin protection This product is intended for use on the skin. Impervious gloves recommended for handling this product other than for use.

Other None known

Respiratory protection None needed under normal use conditions. If exposure levels are excessive and irritation is experienced, a NIOSH approved particulate respirator is recommended. Selection of respiratory protection depends on the contaminant type, form and concentration. Select in accordance with OSHA 1910.134 and good Industrial Hygiene practice.

SECTION 9 PHYSICAL AND CHEMICAL PROPERTIES

Appearance

Physical state/ Form/ Color Off-white to yellowish cream

Odor Odorless

Odor threshold Not applicable

pH 5.0-7.0

Melting point/freezing point Not determined

Initial boiling point and boiling range Not determined

Flash point None

Evaporation rate Same as water

Flammability (solid, gas) Not applicable

Upper/lower flammability or explosive limits None

VOC Not determined

Vapor pressure	Same as water
Vapor density	Same as water
Relative density	Not determined
Solubility(ies)	Not determined
Partition coefficient: n-octanol/water	Not available
Auto-ignition temperature	Not available
Decomposition temperature	Not available
Viscosity	10,000-90,000 cps

SECTION 10 STABILITY AND REACTIVITY

Reactivity	Not reactive under normal conditions of use
Chemical stability	Stable
Possibility of hazardous reactions	None known
Conditions to avoid	Avoid excessive heat.
Incompatible materials	Avoid oxidizing agents
Hazardous decomposition products	Thermal decomposition may yield carbon oxides

SECTION 11 TOXICOLOGICAL INFORMATION

Information on the likely routes of exposure (short-term exposure)

Inhalation	Inhalation of mists may cause minor irritation of the mucous membranes and upper respiratory tract
Skin contact	Some users have reported skin burning and irritation. May cause skin sensitization with allergic skin reaction
Eye contact	Contact may cause severe irritation with pain, redness and tearing and possible permanent damage
Ingestion	Swallowing may cause gastrointestinal distress with nausea and diarrhea

Toxicology (long-term exposure)

Sensitization	Hydroquinone, bisabolol and propyl gallate are skin sensitizers. Contains sodium metabisulfite, a sulfite that may cause allergic-type reactions including anaphylactic symptoms and life-threatening or less severe asthmatic episodes in certain susceptible people. The overall prevalence of sulfite sensitivity in the general population is unknown and probably low. Sulfite sensitivity is seen more frequently in asthmatic than in non-asthmatic people
Germ Cell Mutagenicity	Published studies have demonstrated that hydroquinone is a mutagen and a clastogen. Treatment with hydroquinone has resulted in positive findings for genetic toxicity in the Ames assay in bacterial strains sensitive to oxidizing mutagens, in *in vitro* studies in mammalian cells, and in the *in vivo* mouse micronucleus assay
Carcinogenicity	None of the components are listed as carcinogens by IARC, NTP or OSHA. Hydroquinone is classified in the EU CLP Annex VI as a category 2 carcinogen, however, IARC reviewed all the data reported and assigned it to group 3.
Reproductive toxicity	Animal reproduction studies have not been conducted with topical hydroquinone. No adverse effects on reproduction or fertility were observed in a 2-generation study with rats at any dose level, and the results indicate that

	hydroquinone is not a reproductive toxicant. The NOEL values for general and reproductive toxicity are 15 and 150 mg/kg/d, respectively. No potential for developmental or reproductive toxicity was observed in a study in rats. The NOEL for both maternal and developmental toxicity was 100 mg/kg bw (NOAEL of 300 mg/kg bw). This product contains vitamin A palmitate (retinyl). The various forms of vitamin A are developmental toxins.
Acute Toxicity Values	Acute Oral Toxicity Estimate (ATE) calculated: 9091 mg/kg Hydroquinone: LD50 oral rat 367 mg/kg; LD50 dermal rat >2000 mg/kg

SECTION 12 ECOLOGICAL INFORMATION

Very toxic to aquatic organisms with long-lasting effects

Ecotoxicity	Hydroquinone is classified in the EU as very toxic to aquatic organisms, with an M factor of 10 for chronic toxicity. EC50 daphnia magna 0.134 mg/L/48 hr. NOEC daphnia magna 0.0057 mg/L/21 d. (OECD 211)
Persistence and degradability	Hydroquinone is readily biodegradable
Bioaccumulative potential	No data is available
Mobility in soil	No data is available
Other adverse effects	None known

SECTION 13 DISPOSAL CONSIDERATIONS

Disposal instructions	Dispose in accordance with all local, state and federal regulations. No specific disposal method is recommended

SECTION 14 TRANSPORT INFORMATION

	UN Number	Proper shipping name	Hazard Class	Packing Group	Environmental Hazard
DOT		Not Regulated			
TDG		Not Regulated			
IMDG		Not Regulated			
IATA		Not Regulated			

Note: This product is classified as a Marine Pollutant (Environmentally Hazardous Substance) in accordance with the IMDG Code and the UN Model Regulations. However, it is packaged in either single packages or inner packagings in combination packages containing net quantities of less than 5 kg/5 L (IMDG Code 2.10.2.7; ICAO Special Instruction A197, 49CFR 171.4(c)(2)). Shipment may be regulated if contents are removed from inner packaging and combined into containers exceeding 5 L or 5 kg.

Transport in bulk according to Annex II of MARPOL 73/78 and the IBC code: Not applicable – product is transported only in packaged form.

Technical name	Not available.
Ship type	Not available.
Annex II	Not available.

SECTION 15 REGULATORY INFORMATION

Safety, health, and environmental regulations specific for the product in question.

CERCLA: Hydroquinone has a reportable quantity of 100 lbs. Many states have more stringent release reporting requirements. Report spills as required under federal, state and local regulations.

SARA Hazard Category (311/312): Acute Health, Chronic Health

EPA SARA 313: This product contains the following chemicals regulated under SARA Title III, section 313:

Hydroquinone 123-31-9 4%

Phenoxyethanol (glycol ether) 1%

EPA TSCA Inventory: This product is a drug and not subject to TSCA.

CANADA:

Canadian CEPA: This product is a drug and not subject to CEPA regulations

SECTION 16 OTHER INFORMATION

NFPA Rating:	Health = 3	Flammability =	0	Instability = 0
HMIS Rating:	Health = 3	Flammability =	0	Physical Hazard = 0

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Disclaimer	TWi Pharmaceutical, Inc. cannot anticipate all conditions under which this information and its product, or the products of other manufacturers in combination with its product, may be used. It is the user's responsibility to ensure safe conditions for handling, storage and disposal of the product, and to assume liability for loss, injury, damage or expense due to improper use. The information in the sheet was written based on the best knowledge and experience currently available.