

## Safety Data Sheet

### Hydroquinone Cream USP 4%

#### SECTION 1 IDENTIFICATION

<b>Product identifier</b>	Hydroquinone Cream 4%
<b>other means of identification</b>	NDC No.: 24979-141-36
<b>Recommended use</b>	Skin discoloration treatment cream
<b>Supplier</b>	
<b>Company name</b>	TWi Pharmaceuticals, Inc.
<b>Address</b>	3F, No 41, Lane 221, Kang Chien Rd, Taipei, Taiwan.
<b>Telephone</b>	886-2-26573350
<b>Fax</b>	886-2-26573391
<b>E-mail address</b>	QA.Service@twipharma.com
<b>Emergency phone number</b>	1-844-518-2989

#### SECTION 2 HAZARD IDENTIFICATION

<b>Physical hazards</b>	Not hazardous.
<b>Health hazards</b>	Eye Damage: Category 1 Skin Sensitizer: Category Germ Cell Mutagen: Category 2 Reproductive Toxicity: Category 1B
<b>Label element</b>	
<b>Code</b>	H317/H318/H341
<b>Signal word</b>	Danger
<b>Pictogram</b>	
<b>Hazard statement</b>	Causes serious eye damage. May cause an allergic skin reaction. Suspected of causing genetic defects.
<b>Precautionary statement</b>	
<b>Prevention</b>	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.
<b>Response</b>	Wash hands after handling. If in eyes: rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. 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.
<b>Storage</b>	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 Cream 4%

**Active ingredient:**

Chemical Name	CAS number	%
Hydroquinone	123-31-9	4%
Water	7732-18-5	Proprietary
Stearic Acid	57-11-4	Proprietary
Propylene Glycol	57-55-6	Proprietary
Polyoxyl 40 Stearate	9004-99-3	Proprietary
PEG-25 Propylene Glycol Stearate	1323-39-3	Proprietary
Mineral Oil	8042-47-5	Proprietary
Squalane	8042-47-5	Proprietary
Propyl Paraben	94-13-3	Proprietary
Sodium Metabisulfite	7681-57-4	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 15 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.

**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 <sup>3</sup> TWA ACGIH TLV 2 mg/m <sup>3</sup> TWA OSHA PEL
Water	None Established
Stearic Acid	None Established
Propylene glycol	10 mg/m <sup>3</sup> TWA AIHA WEEL
Polyoxyl 40 Stearate	None Established
PEG-25 Propylene Glycol Stearate	None Established
Glyceryl Monostearate	None Established
Mineral Oil	5 mg/m <sup>3</sup> TWA OSHA PEL 5 mg/m <sup>3</sup> (inhalable) TWA ACGIH TLV

Squalane	None Established
Propyl Paraben	None Established
Sodium Metabisulfite	5 mg/m <sup>3</sup> TWA ACGIH TLV

<b>Appropriate engineering controls</b>	No special ventilation required for normal use. Use with adequate general or local exhaust ventilation to minimize exposures levels.
<b>Individual protection measures, such as personal protective equipment</b>	
<b>Eye/face protection</b>	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.
<b>Skin protection</b>	This product is intended for use on the skin. Impervious gloves recommended for handling this product other than for use.
<b>Other</b>	None known
<b>Respiratory protection</b>	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

<b>Appearance</b>	
<b>Physical state/ Form/ Color</b>	Off-white cream
<b>Odor</b>	Odorless
<b>Odor threshold</b>	Not applicable
<b>pH</b>	Not determined
<b>Melting point/freezing point</b>	Not determined
<b>Initial boiling point and boiling range</b>	Not determined
<b>Flash point</b>	None
<b>Evaporation rate</b>	Same as water
<b>Flammability (solid, gas)</b>	Not applicable
<b>Upper/lower flammability or explosive limits</b>	None
<b>VOC</b>	Not determined
<b>Vapor pressure</b>	Same as water
<b>Vapor density</b>	Same as water
<b>Relative density</b>	Not determined
<b>Solubility(ies)</b>	Not determined
<b>Partition coefficient: n-octanol/water</b>	Not available
<b>Auto-ignition temperature</b>	Not available
<b>Decomposition temperature</b>	Not available
<b>Viscosity</b>	Not determined

## SECTION 10 STABILITY AND REACTIVITY

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

## SECTION 11 TOXICOLOGICAL INFORMATION

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

<b>Inhalation</b>	Inhalation of mists may cause minor irritation of the mucous membranes and upper respiratory tract
<b>Skin contact</b>	Some users have reported skin burning and irritation. May cause skin sensitization with allergic skin reaction
<b>Eye contact</b>	Contact may cause severe irritation with pain, redness and tearing and possible permanent damage
<b>Ingestion</b>	Swallowing may cause gastrointestinal distress with nausea and diarrhea
<b>Toxicology (long-term exposure)</b>	
<b>Sensitization</b>	Hydroquinone is a skin sensitizer. 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
<b>Germ Cell Mutagenicity</b>	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 <i>in vitro</i> studies in mammalian cells, and in the <i>in vivo</i> mouse micronucleus assay
<b>Carcinogenicity</b>	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.
<b>Reproductive toxicity</b>	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)
<b>Acute Toxicity Values</b>	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

<b>Ecotoxicity</b>	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)
<b>Persistence and degradability</b>	Hydroquinone is readily biodegradable
<b>Bioaccumulative potential</b>	No data is available
<b>Mobility in soil</b>	No data is available
<b>Other adverse effects</b>	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
<b>DOT</b>		Not Regulated			
<b>TDG</b>		Not Regulated			
<b>IMDG</b>		Not Regulated			
<b>IATA</b>		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

<b>Technical name</b>	Not available.
<b>Ship type</b>	Not available.
<b>Annex II</b>	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%

**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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**Version #** 01

**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.