

**SECTION 1: PRODUCT IDENTIFICATION**

<b>PRODUCT NAME</b>	<b>FD &amp; C BLUE NO.2 (Indigotine) (Powder)</b>
<b>PRODUCT CODE</b>	<b>1276</b>
<b>SUPPLIER</b>	<b>MEDISCA Inc.</b> Tel.: 1.800.932.1039   Fax.: 1.855.850.5855 661 Route 3, Unit C, Plattsburgh, NY, 12901 3955 W. Mesa Vista Ave., Unit A-10, Las Vegas, NV, 89118 6641 N. Belt Line Road, Suite 130, Irving, TX, 75063 <b>MEDISCA Pharmaceutique Inc.</b> Tel.: 1.800.665.6334   Fax.: 514.338.1693 4509 Rue Dobrin, St. Laurent, QC, H4R 2L8 21300 Gordon Way, Unit 153/158, Richmond, BC V6W 1M2 <b>MEDISCA Australia PTY LTD</b> Tel.: 1.300.786.392   Fax.: 61.2.9700.9047 Unit 7, Heritage Business Park 5-9 Ricketty Street, Mascot, NSW 2020
<b>EMERGENCY PHONE</b>	CHEMTREC Day or Night Within USA and Canada: 1-800-424-9300 NSW Poisons Information Centre: 131 126
<b>USES</b>	Colouring agent

**SECTION 2: HAZARDS IDENTIFICATION**

<b>GHS CLASSIFICATION</b>	Acute Toxicity - Oral (Category 4)			
<b>PICTOGRAM</b>				
<b>SIGNAL WORD</b>	Warning			
<b>HAZARD STATEMENT(S)</b>	Harmful if swallowed. May cause an allergic reaction.			
<b>AUSTRALIA-ONLY HAZARDS</b>	Repeated exposure may cause skin dryness or cracking.			
<b>PRECAUTIONARY STATEMENT(S)</b>	<b>Prevention</b>  <b>Response</b>  <b>Storage</b> <b>Disposal</b>	Wash thoroughly after handling. Do not eat, drink or smoke when using this product. Avoid breathing dust, fume, gas, mist, vapors, spray. Contaminated work clothing must not be allowed out of the workplace. Wear protective gloves.  IF SWALLOWED: Immediately call a poison center or medical professional; Rinse mouth. IF ON SKIN: Wash with plenty of water. If skin irritation or rash occurs: Get medical advice/attention. Wash contaminated clothing before reuse.		
<b>HMS CLASSIFICATION</b>	<b>Health Hazard</b>  <b>Reactivity</b>	1  0	<b>Flammability</b>  <b>Personal Protection</b>	0  E

**SECTION 3: COMPOSITION/INFORMATION ON INGREDIENTS**

YOUR TRUSTED PARTNER IN COMPOUNDING

CHEMICAL NAME	Indigotindisulfonate Sodium						
BOTANICAL NAME	Not applicable						
SYNONYM	CI Food Blue 001; CI No. 73015; E132; Indigo Carmine						
CHEMICAL FORMULA	C <sub>16</sub> H <sub>8</sub> N <sub>2</sub> Na <sub>2</sub> O <sub>8</sub> S <sub>2</sub>						
CAS NUMBER	860-22-0						
ALTERNATE CAS NUMBER	Not applicable						
MOLECULAR WEIGHT	466.35						
COMPOSITION	<table border="1"> <thead> <tr> <th>CHEMICAL NAME</th> <th>CAS NUMBER</th> <th>% BY WEIGHT</th> </tr> </thead> <tbody> <tr> <td>FD &amp; C BLUE NO.2 (Indigotine)</td> <td>860-22-0</td> <td>100</td> </tr> </tbody> </table>	CHEMICAL NAME	CAS NUMBER	% BY WEIGHT	FD & C BLUE NO.2 (Indigotine)	860-22-0	100
CHEMICAL NAME	CAS NUMBER	% BY WEIGHT					
FD & C BLUE NO.2 (Indigotine)	860-22-0	100					
NOTES	<p>There are no additional ingredients present which, within the current knowledge of the supplier and in the concentrations applicable, are classified as health hazards and hence require reporting in this section.</p> <p>Chemical family: Indole.</p>						

## SECTION 4: FIRST-AID MEASURES

IN CASE OF EYE CONTACT	Flush with copious amounts of water for 15 minutes, separating eyelids with fingers. If irritation persists seek medical aid.
IN CASE OF SKIN CONTACT	Wash with soap & water for 15 minutes. If irritation persists seek medical aid.
IF SWALLOWED	Call a physician. Wash out mouth with water. Do not induce vomiting without medical advice.
IF INHALED	Remove to fresh air. If not breathing, give artificial respiration. If breathing is difficult, give oxygen. Call a physician.
SYMPTOMS AND EFFECTS	Not expected to present a significant hazard under anticipated conditions of normal use.

## SECTION 5: FIREFIGHTING MEASURES

SPECIFIC HAZARDS ARISING FROM THE CHEMICAL	Not applicable.
FLAMMABLE PROPERTIES	May be combustible at high temperature.
HAZARDOUS COMBUSTION PRODUCTS	Under fire conditions, hazardous fumes will be present.
EXTINGUISHING MEDIA	<b>Small fire:</b> dry chemical, CO <sub>2</sub> or water spray. <b>Large fire:</b> dry chemical, CO <sub>2</sub> , alcohol resistant foam or water spray. Do not get water inside containers.
PROTECTIVE EQUIPMENT AND PRECAUTIONS FOR FIREFIGHTERS	Wear self-contained breathing apparatus and protective clothing to prevent contact with skin and eyes.

## SECTION 6: ACCIDENTAL RELEASE MEASURES

PERSONAL PRECAUTIONS	Wear respiratory protection. Avoid dust formation. Avoid breathing vapours, mist or gas. Ensure adequate ventilation. Evacuate personnel to safe areas. Avoid breathing dust.
METHODS & MATERIAL FOR CONTAINMENT	On land, sweep or shovel into suitable containers. Minimize generation of dust.

**CLEANUP PROCEDURE**

Do not touch damaged containers or spilled material unless wearing appropriate protective clothing. Wear respirator, chemical safety goggles, rubber boots and heavy rubber gloves. Stop leak if you can do it without risk. Prevent entry into waterways, sewers, basements or confined areas. Shut off all sources of ignition. Evacuate the area. If necessary, employ water fog to disperse the vapors. Absorb the matter with compatible vermiculite or other absorbing material. Place in a suitable container and retain for disposal. Ventilate and clean the affected area. Do not flush into sewerage system or to drains.

## SECTION 7: HANDLING AND STORAGE

**PRECAUTIONS FOR SAFE HANDLING**

Do not inhale. Avoid contact with eyes, skin and clothing. Avoid prolonged or repeated exposure. Wash thoroughly after handling. Store away from incompatible materials, in a well-ventilated area. Eliminate all sources of ignition. Store in accordance with local regulations. Do not store in unlabelled containers. Containers that have been opened must be carefully resealed and kept upright to prevent leakage. Use appropriate containment to avoid environmental contamination.

**STORAGE CONDITIONS**

Store in original container, tightly sealed, protected from direct sunlight and moisture. Preserve in tight, light resistant containers.

## SECTION 8: EXPOSURE CONTROLS/ PERSONAL PROTECTION

Chemical Name: FD & C BLUE NO.2 (Indigotine) CAS #: 860-22-0

	TWA	Ceiling	STEL	REL	IDLH	Remarks
OSHA PEL	N/L	N/L	-	-	-	-
ACGIH TLV	N/L	N/L	N/L	-	-	-
NIOSH	N/L	N/L	N/L	N/L	N/L	-
AIHA WEEL	N/L	N/L	N/L	-	-	-
Safe Work Australia HSIS	N/L	N/L	N/L	-	-	-
HSE	N/L	N/L	N/L	-	-	-

N/L = Not Listed

**EXPOSURE GUIDELINES**

Consult local authorities for provincial or state exposure limits. Particulates not otherwise regulated, respirable fraction: 5 mg/m<sup>3</sup>

**PERSONAL PROTECTIVE EQUIPMENT**

**Eyes:** Wear appropriate protective eyeglasses or chemical safety goggles as described by WHMIS or OSHA's eye and face protection regulations in 29 CFR 1910.133 or European Standard EN166. **Skin:** Wear appropriate gloves to prevent skin exposure. **Clothing:** Wear appropriate protective clothing to minimize contact with skin. **Respirators:** Follow WHMIS or OSHA respirator regulations found in 29 CFR 1910.134 or European Standard EN 149. Use a NIOSH/MSHA or European Standard EN 149 approved respirator if exposure limits are exceeded or if irritation or other symptoms are experienced.

**SPECIFIC ENGINEERING CONTROLS**

Adequate mechanical ventilation. Fumehood, eye wash station, and safety shower.

## SECTION 9: PHYSICAL AND CHEMICAL PROPERTIES

**PHYSICAL STATE**

Solid

**DESCRIPTION**

Dark blue powder.

**SOLUBILITY**

Slightly soluble in water and in alcohol; practically insoluble in most other organic solvents.

**ODOR**

Odorless to light odor

**FLAMMABILITY**

May be combustible at high temperature

<b>ODOR THRESHOLD</b>	Not available	<b>pH</b>	Not available	<b>MELTING POINT</b>	>300 °C, >572 °F
<b>BOILING POINT</b>	Not available	<b>FREEZING POINT</b>	>300 °C, >572 °F	<b>FLASH POINT</b>	Not available
<b>SPECIFIC GRAVITY</b>	Not available	<b>EVAPORATION RATE</b>	Not available	<b>EXPLOSIVE LIMIT</b>	Not available
<b>UPPER FLAMMABLE/ EXPLOSIVE LIMIT(S)</b>	Not available	<b>LOWER FLAMMABLE/ EXPLOSIVE LIMIT(S)</b>	Not available	<b>VAPOR PRESSURE</b>	Not available
<b>VAPOR DENSITY (AIR = 1)</b>	15	<b>RELATIVE DENSITY (WATER = 1)</b>	1.06 g/mL (20°C)	<b>log P (OCTANOL-WATER)</b>	-3.570
<b>AUTO-IGNITION TEMPERATURE</b>	Not available	<b>DECOMPOSITION TEMPERATURE</b>	Not available	<b>VISCOSITY</b>	Not available

**NOTES**

The physical data presented above are typical values and should not be construed as a specification.

## SECTION 10: STABILITY AND REACTIVITY

**REACTIVITY**

Not established.

**STABILITY**

Stable under recommended storage conditions. Remains stable at pH 1 - 10.

**MATERIALS TO AVOID**

Oxidants and reducing agents may destroy color. Alkaline metals and peroxides.

**HAZARDOUS DECOMPOSITION  
PRODUCTS**

Toxic fumes of carbon monoxide, carbon dioxide, nitrogen oxides and other gases may occur.

**HAZARDOUS POLYMERIZATION**

Will not occur.

**POSSIBILITY OF HAZARDOUS  
REACTION**

Not established.

**CONDITIONS TO AVOID**

Moisture, sunlight and extreme temperatures.

## SECTION 11: TOXICOLOGICAL INFORMATION

**ACUTE TOXICITY**

Oral: Rat: LD50: (mg/kg): 2000  
 Dermal: Rabbit: LD50: (mg/kg): Not available  
 Inhalation: Rat: LC50: (mg/L/4hr): Not available

**SKIN CORROSION/IRRITATION**

Due to lack of data the classification is not possible.

**SERIOUS EYE DAMAGE/EYE  
IRRITATION**

Due to lack of data the classification is not possible.

**RESPIRATORY OR SKIN  
SENSITIZATION**

Respiratory sensitization: Due to lack of data the classification is not possible.  
 Skin sensitization: Based on available data, the classification criteria are not met. Limited evidence of respiratory and skin sensitization.

**GERM CELL MUTAGENICITY**

Based on available data, the classification criteria are not met.  
 Suspected mutagen: CAESAR Mutagenicity model in VEGA (Q)SAR platform predicts that the chemical is Mutagen (moderate reliability); KNN Mutagenicity model in VEGA (Q)SAR platform predicts that the chemical is Mutagen (moderate reliability); SARPY Mutagenicity model in VEGA (Q)SAR platform predicts that the chemical is Mutagen (moderate reliability)

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<b>CARCINOGENICITY</b>	<b>OSHA</b>	FD & C BLUE NO.2 (Indigotine) is not listed.
	<b>NTP</b>	FD & C BLUE NO.2 (Indigotine) is not listed.
	<b>IARC</b>	FD & C BLUE NO.2 (Indigotine) is not evaluated.
	<b>California Proposition 65</b>	This product does not contain any chemicals known to the State of California to cause cancer, birth defects, or any other reproductive harm.
<b>ADDITIONAL CARCINOGENICITY INFORMATION</b>		Based on available data, the classification criteria are not met. 1 % Oral feed study; Result: Not carcinogenic; Species: Rat; Test Duration: 2 years
<b>REPRODUCTIVE TOXICITY</b>		Due to lack of data the classification is not possible.
<b>SPECIFIC TARGET ORGAN TOXICITY - SINGLE EXPOSURE</b>		Due to lack of data the classification is not possible.
<b>SPECIFIC TARGET ORGAN TOXICITY - REPEATED EXPOSURE</b>		Due to lack of data the classification is not possible.
<b>ASPIRATION HAZARDS</b>		Based on available data, the classification criteria are not met.
<b>SIGNS AND SYMPTOMS OF EXPOSURE</b>		Not expected to present a significant hazard under anticipated conditions of normal use. May cause nausea, vomiting, hypertension, and bradycardia, and occasionally hypersensitivity reactions such as skin rash, pruritus and bronchoconstriction.  Symptoms related to the physical, chemical, and toxicological characteristics Gastrointestinal disturbances.
<b>POTENTIAL HEALTH EFFECTS</b>	<b>Inhalation</b>	May be harmful if inhaled. May cause respiratory tract irritation.
	<b>Ingestion</b>	Harmful if swallowed. May cause irritation to the gastrointestinal tract. Symptoms may include nausea, vomiting and diarrhea.
	<b>Skin</b>	May be harmful if absorbed through skin. May cause skin irritation. May cause allergic reaction.
	<b>Eyes</b>	May cause eye irritation.

## SECTION 12: ECOLOGICAL INFORMATION

<b>TOXICITY</b>	EC50: 48 Hr: Crustacea: (mg/L): Not available LC50: 96 Hr: Fish: (mg/L): Not available EC50: 72 or 96 Hr: Algae (or other aqua plants): (mg/L): Not available
<b>PERSISTENCE AND DEGRADABILITY</b>	Suspected persistent in the environment: Ready biodegradability model (IRFMN) in VEGA (Q)SAR platform predicts that the chemical is Possible NON Readily Biodegradable (moderate reliability);The Danish QSAR database contains information indicating that the substance is predicted as non readily biodegradable.
<b>BIOACCUMULATIVE POTENTIAL</b>	Low: LogPow: -3.570
<b>MOBILITY IN SOIL</b>	Slightly soluble in water: 1.00E+04 mg/L (25°C)
<b>OTHER ADVERSE EFFECTS</b>	Not available.  This product is not intended to be released into the environment.

## SECTION 13: DISPOSAL CONSIDERATIONS

<b>WASTE DISPOSAL</b>	Dispose of in accordance with federal / local laws and regulations. Avoid release into the environment.
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## SECTION 14: TRANSPORT INFORMATION

YOUR TRUSTED PARTNER IN COMPOUNDING

## UNITED STATES & CANADA

UN PROPER SHIPPING NAME	Not dangerous good
UN NUMBER	Not applicable
CLASS	Not applicable
PACKING GROUP	Not applicable

## AUSTRALIA

UN PROPER SHIPPING NAME	Not dangerous good
UN NUMBER	Not applicable
CLASS	Not applicable
PACKING GROUP	Not applicable
HAZCHEM	Not Applicable

ENVIRONMENTAL HAZARDS Not available

SPECIAL SHIPPING INFORMATION Not applicable

## SECTION 15: REGULATORY INFORMATION

Chemical Name & CAS	CERCLA 40 CFR Part 302.4	SARA (Title III) 40 CFR Part 372.65	EPA 40 CFR Part 355		Pennsylvania	Right-to-know		California Prop 65
			Appendix A	Appendix B		New Jersey	Massachusetts	
FD & C BLUE NO.2 (Indigotine) 860-22-0	N/L	N/L	N/L	N/L	N/L	N/L	N/L	N/L

N/L = Not Listed; X = Listed

## AUSTRALIAN REGULATIONS

Chemical Name & CAS	Poisons and Therapeutic Goods Regulation	Therapeutic Goods Act	Code of Practices - Illicit Drug Precursors
FD & C BLUE NO.2 (Indigotine) 860-22-0	N/L	N/L	N/L

## SECTION 16: OTHER INFORMATION

### REFERENCES

Available upon request

### ABBREVIATIONS AND ACRONYMS

**CAS** – Chemical Abstract Service; **GHS** – Global Harmonized System; **OSHA PEL** – Occupational Safety & Health Administration Permissible Exposure Limits; **TWA** – Time Weighted Average; **HSIS** – Hazardous Substances Information System; **STEL** – Short Term Exposure Limit; **AIHA WEEL** – American Industrial Hygiene Association Workplace Environment Exposure Levels; **LD50** – Lethal Dose, 50%; **IARC** – International Agency for Research on Cancer; **NTP** – National Toxicology Program; **WHMIS** – Workplace Hazardous Materials Information System; **SARA** – Superfund Amendments and Reauthorization Act; **EPA** – Environmental Protection Agency; **CERCLA** – Comprehensive Environmental Response, Compensation, and Liability Act; **HMIS** – Hazardous Materials Information System; **NIOSH** – National Institute for Occupational Safety and Health; **MSHA** - Mine Safety and Health Administration; **ACGIH** - American Conference of Governmental Industrial Hygienists; **IDHL** - Immediately Dangerous to Health or Life; **TLV** – Threshold Limit Value; **HSE** – Health and Safety Executive; **REL** - Recommended Exposure Limit

**LAST REVISION**

10/2018

**SUPERSEDES**

08/2015

**DISCLAIMER**

This document was created in accordance with OSHA, Safe Work Australia and WHMIS regulations. The above information is believed to be correct but does not purport to be all inclusive and shall be used only as a guide. The information in this document is based on the present state of our knowledge and is applicable to the product with regard to appropriate safety precautions. It does not represent any guarantee of the properties of the product. MEDISCA<sup>®</sup> shall not be held liable for any damage resulting from handling or from contact with the above product. Recipients of the product must take responsibility for observing existing laws and regulations.