

SECTION 1: PRODUCT IDENTIFICATION

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|----------------------------|--|
| PRODUCT NAME | FD & C GREEN NO.3 (Fast Green FCF) (Powder) |
| PRODUCT CODE | 1277 |
| SUPPLIER | MEDISCA Inc. Tel.: 1.800.932.1039 Fax.: 1.855.850.5855 626 Tom Miller Road, Plattsburgh, NY, 12901 MEDISCA Pharmaceutique Inc. Tel.: 1.800.665.6334 Fax.: 514.338.1693 4509 Rue Dobrin, St. Laurent, QC, H4R 2L8 MEDISCA Australia PTY LTD Tel.: 1.300.786.392 Fax.: 61.2.9700.9047 Unit 7, Heritage Business Park 5-9 Ricketty Street, Mascot, NSW 2020 |
| EMERGENCY PHONE | CHEMTREC Day or Night Within USA and Canada: 1-800-424-9300 NSW Poisons Information Centre: 131 126 National Chemical Emergency Centre 44(0)1235239670 |
| RECOMMENDED USES | Pharmaceutical Manufacturing |
| RESTRICTIONS ON USE | Not applicable |

SECTION 2: HAZARDS IDENTIFICATION

| | | | |
|---|---|---------------------------------|------------------------------|
| GHS CLASSIFICATION | Acute Toxicity - Oral (Category 5) | | |
| PICTOGRAM | Not Applicable | | |
| SIGNAL WORD | Not applicable | | |
| HAZARD STATEMENT(S) | May be harmful if swallowed. | | |
| ADVERSE PHYSIOCHEMICAL, HUMAN HEALTH AND ENVIRONMENTAL EFFECTS | Repeated exposure may cause skin dryness or cracking. | | |
| PRECAUTIONARY STATEMENT(S) | Prevention | Not applicable | |
| | Response | IF SWALLOWED: Get medical help. | |
| | Storage | Not applicable | |
| | Disposal | Not applicable | |
| HMS CLASSIFICATION | Health Hazard | 1 | Flammability 0 |
| | Reactivity | 0 | Personal Protection D |

SECTION 3: COMPOSITION/INFORMATION ON INGREDIENTS

| CHEMICAL NAME | Benzenemethanaminium, N-ethyl-N-(4-((4-(ethyl((3-sulfophenyl)methyl)amino)phenyl)(4-hydroxy-2-sulfophenyl)methylene)-2,5-cyclohexadien-1-ylidene)-3-sulf- o-, hydroxide, inner salt, disodium salt | | | | | | | | |
|------------------------------------|---|---------------|-------------|-----------|-------------|------------------------------------|-----------|-----------|-----|
| BOTANICAL NAME | Not applicable | | | | | | | | |
| SYNONYM | C.I. Food Green 3 ; C.I. 42053 | | | | | | | | |
| CHEMICAL FORMULA | C ₃₇ H ₃₄ N ₂ Na ₂ O ₁₀ S ₃ | | | | | | | | |
| CHEMICAL FAMILY | Triarylmethane | | | | | | | | |
| CAS NUMBER | 2353-45-9 | | | | | | | | |
| ALTERNATE CAS NUMBER | Not applicable | | | | | | | | |
| MOLECULAR WEIGHT | 808.84 | | | | | | | | |
| COMPOSITION | <table border="1"> <thead> <tr> <th>CHEMICAL NAME</th> <th>CAS NUMBER</th> <th>EC NUMBER</th> <th>% BY WEIGHT</th> </tr> </thead> <tbody> <tr> <td>FD & C GREEN NO.3 (Fast Green FCF)</td> <td>2353-45-9</td> <td>219-091-5</td> <td>100</td> </tr> </tbody> </table> | CHEMICAL NAME | CAS NUMBER | EC NUMBER | % BY WEIGHT | FD & C GREEN NO.3 (Fast Green FCF) | 2353-45-9 | 219-091-5 | 100 |
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| FD & C GREEN NO.3 (Fast Green FCF) | 2353-45-9 | 219-091-5 | 100 | | | | | | |

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.

SECTION 4: FIRST-AID MEASURES

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| 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 |
| MEDICAL ATTENTION AND SPECIAL TREATMENT | Get emergency medical help. |
| SYMPTOMS CAUSED BY EXPOSURE | Not expected to present a significant hazard under anticipated conditions of normal use. |

SECTION 5: FIREFIGHTING MEASURES

| | |
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| 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. |
| SUITABLE & UNSUITABLE EXTINGUISHING MEDIA | Small fire: dry chemical, CO ₂ or water spray. Large fire: dry chemical, CO ₂ , 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.

REFERENCE TO OTHER SECTIONS

See Section 7 for information on safe handling. See Section 8 for information on personal protection equipment. See Section 13 for disposal information.

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 unlabeled containers. Containers that have been opened must be carefully resealed and kept upright to prevent leakage. Use appropriate containment to avoid environmental contamination.

CONDITIONS FOR SAFE STORAGE

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 unlabeled 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.

SECTION 8: EXPOSURE CONTROLS/ PERSONAL PROTECTION

Chemical Name: FD & C GREEN NO.3 (Fast Green FCF) CAS #: 2353-45-9

| | Country | Limit value-8 hours | | Limit value-Short Term | | IDLH | REL | Advisory | Notes |
|---------------|-------------|---------------------|-------------------|------------------------|-------------------|------|-----|----------|-------|
| | | ppm | mg/m ³ | ppm | mg/m ³ | | | | |
| OSHA | USA | N/L | N/L | N/L | N/L | N/L | N/L | N/A | N/A |
| ACGIH | USA | N/L | N/L | N/L | N/L | N/L | N/L | N/A | N/A |
| NIOSH | USA | N/L | N/L | N/L | N/L | N/L | N/L | N/A | N/A |
| WEEL | USA | N/L | N/L | N/L | N/L | N/L | N/L | N/A | N/A |
| HSIS | Australia | N/L | N/L | N/L | N/L | N/L | N/L | N/A | N/A |
| HSE | UK | N/L | N/L | N/L | N/L | N/L | N/L | N/A | N/A |
| GESTIS | Add Country | N/L | N/L | N/L | N/L | N/L | N/L | N/A | N/A |

N/L = Not listed ; N/A = Not Available

PELs are 8-hour TWAs = Limit value - Eight hours

Ceiling or Short-Term TWA = STEL = Limit value - Short term

EXPOSURE GUIDELINES

Consult local authorities for provincial or state exposure limits. Particulates not otherwise regulated, respirable fraction: 5 mg/m³

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. **Thermal Hazards:** For products representing a thermal hazard, appropriate Personal Protective Equipment should be used.

SPECIFIC ENGINEERING CONTROLS

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

BIOLOGICAL MONITORING

Not available

CONTROL BANDING

Not available

SECTION 9: PHYSICAL AND CHEMICAL PROPERTIES

PHYSICAL STATE

Solid

DESCRIPTION

Dark green powder.

SOLUBILITY

Soluble in water; sparingly soluble in alcohol.

ODOR

Odorless

FLAMMABILITY

May be combustible at high temperature

AUTO-IGNITION TEMPERATURE

Not available

BOILING POINT

Not available

DECOMPOSITION TEMPERATURE

Not available

EVAPORATION RATE

Not available

EXPLOSIVE LIMIT

Not available

FLASH POINT

Not available

log P (OCTANOL-WATER)

- 5.420

LOWER FLAMMABLE/EXPLOSIVE LIMIT(S)

Not available

MELTING/FREEZING POINT

290 °C, 554 °F

PARTICLE CHARACTERISTICS

Not available

OXIDIZING PROPERTY

Not available

pH

Not available

RELATIVE DENSITY (WATER = 1)

Not available

SPECIFIC GRAVITY

Not available

UPPER FLAMMABLE/EXPLOSIVE LIMIT(S)

Not available

VAPOR DENSITY (AIR = 1)

Not available

VAPOR PRESSURE

Not available

VISCOSITY

Not available

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

SECTION 10: STABILITY AND REACTIVITY

REACTIVITY

Not established.

CHEMICAL STABILITY

Stable under recommended storage conditions. Color remains stable at pH: 2-11.

| | |
|--|--|
| INCOMPATIBLE MATERIALS | Strong oxidants and reducing agents may destroy color. |
| 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 SENSITIZATION | Due to lack of data the classification is not possible. |
| SKIN SENSITIZATION | Due to lack of data the classification is not possible. |
| 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). Animal experiments showed mutagenic and teratogenic effects. |
| CARCINOGENICITY | OSHA FD & C GREEN NO.3 (Fast Green FCF) is not listed. NTP FD & C GREEN NO.3 (Fast Green FCF) is not listed. IARC FD & C GREEN NO.3 (Fast Green FCF) is listed in group 3 (not classifiable as to its carcinogenicity to humans). California Proposition This product does not contain any chemicals known to the State of California to cause cancer, birth defects, or any other reproductive harm. |
| ADDITIONAL CARCINOGENICITY INFORMATION | Due to lack of data the classification is not possible. |
| REPRODUCTIVE TOXICITY | Due to lack of data the classification is not possible. |
| SPECIFIC TARGET ORGAN TOXICITY - SINGLE EXPOSURE | Due to lack of data the classification is not possible. |
| SPECIFIC TARGET ORGAN TOXICITY - REPEATED EXPOSURE | Due to lack of data the classification is not possible. |
| ASPIRATION HAZARDS | Based on available data, the classification criteria are not met. |

SIGNS AND SYMPTOMS OF EXPOSURE
ROUTES OF EXPOSURE:

Oral, Dermal, Inhalation, Eye contact

EARLY ONSET SYMPTOMS RELATED TO EXPOSURE:

Not available

DELAYED HEALTH EFFECT FROM EXPOSURE:

Not available

Not expected to present a significant hazard under anticipated conditions of normal use.

POTENTIAL HEALTH EFFECTS

Inhalation May be harmful if inhaled. May cause respiratory tract irritation.

Ingestion May be harmful if swallowed. May cause irritation of the gastrointestinal tract.

Skin May be harmful if absorbed through skin. May cause skin irritation

Eyes May cause eye irritation.

SECTION 12: ECOLOGICAL INFORMATION

ECOTOXICITY

EC50: 48 Hr: Crustacea: Daphnia: (mg/L): 336000

LC50: 96 Hr: Fish: (mg/L): 12400000

EC50: 72 Hr: Algae: Freshwater Algae: (mg/L): 62.9

PERSISTENCE AND DEGRADABILITY

The substance is not readily biodegradable

BIOACCUMULATIVE POTENTIAL

Low: Log Pow: -5.420

BCF : 3.2. The substance is non bioaccumulative.

MOBILITY IN SOIL

Soluble in water: 20.0 g/100 mL (25°C)

The substance has strong adsorption to soil and negligible migration potential to ground water.

OTHER ADVERSE EFFECTS

Not available

This product is not intended to be released into the environment

SECTION 13: DISPOSAL CONSIDERATIONS

DISPOSAL METHODS

Dispose of in accordance with federal / local laws and regulations. Avoid release into the environment.

SECTION 14: TRANSPORT INFORMATION

UN PROPER SHIPPING NAME

Not dangerous good

UN NUMBER

Not applicable

CLASS

Not applicable

PACKING GROUP

Not applicable

AUSTRALIA
HAZCHEM

Not applicable

EU

**TRANSPORT IN BULK ACCORDING
TO ANNEX II OF MARPOL 73/78
AND THE IBC CODE**

Not listed

**ENVIRONMENTAL HAZARDS
SPECIAL SHIPPING
INFORMATION**

Not available

Not applicable

SECTION 15: REGULATORY INFORMATION
UNITED STATES REGULATIONS

| Chemical Name & CAS | CERCLA 40 CFR Part 302.4 | SARA (Title III) 40 CFR | EPA 40 CFR Part 355 Appendix A | EPA 40 CFR Part 355 Appendix B | Pennsylvania | Right-to-know New Jersey | Massachusetts | California Prop 65 |
|--|--------------------------|-------------------------|--------------------------------|--------------------------------|--------------|--------------------------|---------------|--------------------|
| FD & C GREEN NO.3 (Fast Green FCF) 2353-45-9 | N/L | N/L | N/L | N/L | N/L | X | N/L | N/L |

N/L = Not Listed; X = Listed

AUSTRALIAN REGULATIONS

| Chemical Name & CAS | Poisons and Therapeutic Goods | Therapeutic Goods Act | Code of Practices - Illicit Drug | Poisons Standard | Work Health and Safety Regulations | Inventory of Industrial Chemicals |
|--|-------------------------------|-----------------------|----------------------------------|------------------|------------------------------------|-----------------------------------|
| FD & C GREEN NO.3 (Fast Green FCF) 2353-45-9 | N/L | N/L | N/L | N/L | N/L | N/L |

N/L = Not Listed

EU REGULATIONS

| Chemical Name & CAS | REACH ANNEX XVII | REACH ANNEX XIV | EC 1005/2009 | EC 850/2004 | EC 1107/2009 | PIC - Prior Informed Consent Regulation | EC 2012/18 |
|--|------------------|-----------------|--------------|-------------|--------------|---|------------|
| FD & C GREEN NO.3 (Fast Green FCF) 2353-45-9 | N/L | N/L | N/L | N/L | N/L | N/L | N/L |

N/L = Not Listed; X = Listed

Any EU regulation not listed above is not applicable to this product.

**SUBJECT TO INTERNATIONAL
AGREEMENT**

Not applicable

SECTION 16: OTHER INFORMATION
REFERENCES

Available upon request

ABBREVIATIONS AND ACRONYMS

ACGIH - American Conference of Governmental Industrial Hygienists; **AIHA WEEL** – American Industrial Hygiene Association Workplace Environment Exposure Levels; **CAESAR** – Computer Assisted Evaluation of industrial chemical Substances According to Regulations; **CAS** – Chemical Abstract Service; **CERCLA** – Comprehensive Environmental Response, Compensation, and Liability Act; **EC50** – Effective Concentration, 50%; **EPA** – Environmental Protection Agency; **GHS** – Global Harmonized System; **HMIS** – Hazardous Materials Information System; **HSE** – Health and Safety Executive; **HSIS** – Hazardous Substances Information System; **IARC** – International Agency for Research on Cancer; **IDLH** - Immediately Dangerous to Life or Health; **IRFMN** – Ready Biodegradability Model; **ISS** – Istituto Superiore Sanità; **LC50** – Lethal Concentration, 50%; **LD50** – Lethal Dose, 50%; **MSHA** - Mine Safety and Health Administration; **NIOSH** – National Institute for Occupational Safety and Health; **NTP** – National Toxicology Program; **OSHA PEL** – Occupational Safety & Health Administration Permissible Exposure Limits; **QSAR** – Quantitative Structure-activity relationship; **REL** - Recommended Exposure Limit; **SARA** – Superfund Amendments and Reauthorization Act; **STEL** – Short Term Exposure Limit; **TLV** – Threshold Limit Value; **TWA** – Time Weighted Average; **WHMIS** – Workplace Hazardous Materials Information System

LAST REVISION

03/2023

SUPERSEDES

03/2021

For a list of changes to the SDS since the last version, please communicate with MEDISCA at www.medisca.com

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® 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.

SUPPLEMENTARY INFORMATION

For all country specific requirements not outlined on this Safety Data Sheet, please request Supplementary Page to this Safety Data Sheet.