

SECTION 1: PRODUCT IDENTIFICATION

PRODUCT NAME FD & C RED NO.3 (Erythrosine) (Powder)

PRODUCT CODE 1278

SUPPLIER MEDISCA Inc.

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MEDISCA Pharmaceutique Inc.

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MEDISCA Australia PTY LTD

Tel.: 1.300.786.392 | Fax.: 61.2.9700.9047

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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 Manufacturing and Compounding

RESTRICTIONS ON USE Not applicable

SECTION 2: HAZARDS IDENTIFICATION

GHS CLASSIFICATION Acute Toxicity - Oral (Category 4)
Chronic Aquatic Toxicity (Category 3)

PICTOGRAM

Warning

SIGNAL WORD

HAZARD STATEMENT(S) Harmful if swallowed.

Harmful to aquatic life with long lasting effects.

ADVERSE PHYSIOCHEMICAL, HUMAN Repeated exposure may cause skin dryness or cracking.

HEALTH AND ENVIRONMENTAL

EFFECTS

PRECAUTIONARY STATEMENT(S) Prevention W

Prevention Wash thoroughly after handling.

Do not eat, drink or smoke when using this product.

Avoid release to the environment

Response IF SWALLOWED: Immediately call a poison center. Get medical help. Rinse mouth.

Storage Not applicable

Disposal Dispose of contents/container to in accordance with local regulation.

HMIS CLASSIFICATION Health Hazard 1 Flammability 0



Reactivity Personal Protection

SECTION 3: COMPOSITION/INFORMATION ON INGREDIENTS

CHEMICAL NAME 3',6'-Dihydroxy-2',4',5',7'-tetraiodospiro(isobenzofuran-1(3H),9'- -(9H)xanthen)-3-one, disodium salt

BOTANICAL NAME Not applicable

C.I. Acid Red 51, C.I # 45430; CI name: food red 014; E127; Erythrosin B sodium salt **SYNONYM**

CHEMICAL FORMULA C20H6I4Na2O5 CHEMICAL FAMILY Not available **CAS NUMBER** 16423-68-0 ALTERNATE CAS NUMBER Not applicable

MOLECULAR WEIGHT 879.86

COMPOSITION **CHEMICAL NAME CAS NUMBER FC NUMBER** % BY WEIGHT 240-474-8 FD & C RED NO.3 (Erythrosine) 16423-68-0

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

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

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**

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Small fire: dry chemical, CO2 or water spray. Large fire: dry chemical, CO2, 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

CLEANUP PROCEDURE

On land, sweep or shovel into suitable containers. Minimize generation of dust.

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 SECTIONSSee 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 RED NO.3 (Erythrosine) CAS #: 16423-68-0

	Country	Limit value-8 hours		Limit value-Short Term		IDLH	REL	Advisory	Notes
		ppm	mg/m³	ppm	mg/m³				
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

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

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

EXPOSURE GUIDELINESConsult 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 Red powder or granules.

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)	- 0.290	LOWER FLAMMABLE/ EXPLOSIVE LIMIT(S)	Not available	MELTING/FREEZING POINT	>250 °C, >482 °F
PARTICLE CHARACTERISTICS	Not available	OXIDIZING PROPERTY	Not available	рН	7-9
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	Negligible	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 5 - 12.

INCOMPATIBLE MATERIALS Strong oxidants and reducing agents may destroy color.

HAZARDOUS DECOMPOSITION Toxic fumes of carbon monox

PRODUCTS

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



HAZARDOUS POLYMERIZATION

POSSIBLITY OF HAZARDOUS

REACTION

CONDITIONS TO AVOID

Will not occur.

Not established.

Moisture, sunlight and extreme temperatures.

SECTION 11: TOXICOLOGICAL INFORMATION

ACUTE TOXICITY Oral: Rat: LD50: (mg/kg): 1840

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

SKIN CORROSION/IRRITATIONDue to lack of data the classification is not possible.

SERIOUS EYE DAMAGE/EYE Due to lack of data the classification is not possible.

IRRITATION Causes serious eye irritation. pH 7-9.

RESPIRATORY SENSITIZATIONDue to lack of data the classification is not possible.

SKIN SENSITIZATIONDue to lack of data the classification is not possible.

GERM CELL MUTAGENICITYBased on available data, the classification criteria are not met.

The mutagenicity/genotoxicity of erythrosine has been investigated in a variety of in vitro and in vivo assays. Based on the data available so far it can be concluded that erythrosine is not genotoxic and not mutagenic.

CARCINOGENICITY OSHA FD & C RED NO.3 (Erythrosine) is not listed.

NTP FD & C RED NO.3 (Erythrosine) is not listed.

IARC FD & C RED NO.3 (Erythrosine) is not evaluated.

California This product does not contain any chemicals known to the State of California to cause

Proposition 65 cancer, birth defects, or any other reproductive harm.

ADDITIONAL CARCINOGENICITY

INFORMATION

Due to lack of data the classification is not possible.

REPRODUCTIVE TOXICITYDue to lack of data the classification is not possible.

Does not represent a reproductive toxicant. Erythrosine is not a teratogen in rats or rabbits.

SPECIFIC TARGET ORGAN TOXICITY - SINGLE EXPOSURE

SINGLE EXPOSURE

Due to lack of data the classification is not possible.

SPECIFIC TARGET ORGAN TOXICITY -

REPEATED EXPOSURE

ASPIRATION HAZARDS

EXPOSURE

Based on available data, the classification criteria are not met.

Long-term exposure to the product is not thought to produce chronic effects adverse to the health (as classified using animal models); nevertheless exposure by all routes should be minimized as a matter of course. Long term exposure to high dust concentrations may cause changes in lung function i.e. pneumoconiosis; caused by particles less than 0.5 micron penetrating and remaining in the lung.

Based on available data, the classification criteria are not met.

SIGNS AND SYMPTOMS OF ROUTES OF EXPOSURE:

Oral, Dermal, Inhalation, Eye contact

EARLY ONSET SYMPTOMS RELATED TO EXPOSURE:

Not available

DELAYED HEALTH EFFECT FROM EXPOSURE:

Not available

Allergenicity is not considered as an endpoint of relevance for erythrosine. May affect thyroid.

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



POTENTIAL HEALTH EFFECTS Inhalation May cause respiratory tract irritation. May cause drowsiness or dizziness. The material is not

> thought to produce either adverse health effects or irritation of the respiratory tract following inhalation (as classified using animal models). Nevertheless, adverse effects have been produced following exposure of animals by at least one other route and good hygiene practice requires that exposure be kept to a minimum and that suitable control measures be used in an occupational setting. Persons with impaired respiratory function, airway diseases and conditions such as emphysema or chronic bronchitis, may incur further disability if

excessive concentrations of particulate are inhaled.

Ingestion Harmful if swallowed. May cause nausea, vomiting and diarrhea. Ingestion may potentially

> worsen kidney or liver disorders. Accidental ingestion of the material may be harmful; animal experiments indicate that ingestion of less than 150 gram may be fatal or may produce

serious damage to the health of the individual.

Skin May cause mild skin irritation. Skin contact is not thought to produce harmful health effects

> (as classified using animal models). Systemic harm, however, has been identified following exposure of animals by at least one other route and the material may still produce health

damage following entry through wounds, lesions or abrasions.

Eyes May cause mild irritation, discomfort, redness, tearing, itching, tingling and other effects to

> the eyes. Although the material is not thought to be an irritant, direct contact with the eye may cause transient discomfort characterized by tearing or conjunctival redness (as with

windburn). Slight abrasive damage may also result.

SECTION 12: ECOLOGICAL INFORMATION

ECOTOXICITY EC50: 48 Hr: Crustacea: (mg/L): 8.1

LC50: 96 Hr: Fish: (mg/L): 100

EC50: 72 Hr: Algae: Freshwater Algae: (mg/L):200

PERSISTENCE AND DEGRADABILITY

BIOACCUMULATIVE POTENTIAL

MOBILITY IN SOIL

No biodegradation observed Low: Log Pow: - 0.290

Soluble in water: 70 g/L (20 °C)

Low mobility

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

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HAZCHEM Not applicable

<u>EU</u>



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 Part 372.65	EPA 40 CFR Part 355		Right-to-know Pennsylvania New Jersey Massachusetts			California Prop 65
FD & C RED NO.3	N/L	N/L	N/L	N/L	N/L	N/L	N/L	N/L
(Erythrosine) 16423-68-0								

N/L = Not Listed; X = Listed

AUSTRALIAN REGULATIONS

Chemical Name & CAS	Poisons and Therapeutic Goods	Therapeutic Goods Act	Code of Practices - Illicit Drug Precursors	Poisons Standard	Work Health and Safety Regulations	Inventory of Industrial Chemcials	
FD & C RED NO.3 (Erythrosine) 16423-68-0	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 RED NO.3 (Erythrosine) 16423-68-0	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

Not applicable

AGREEMENT

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 – Instituto 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 SUPERSEDES 03/2023

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.