## SECTION 1: PRODUCT IDENTIFICATION

<table>
<thead>
<tr>
<th>PRODUCT NAME</th>
<th>FD &amp; C YELLOW NO.6 (Sunset Yellow FCF) (Aluminum Lake Powder)</th>
</tr>
</thead>
<tbody>
<tr>
<td>PRODUCT CODE</td>
<td>2744</td>
</tr>
<tr>
<td>SUPPLIER</td>
<td>MEDISCA Inc. Tel.: 1.800.932.1039</td>
</tr>
<tr>
<td></td>
<td>661 Route 3, Unit C, Plattsburgh, NY, 12901</td>
</tr>
<tr>
<td></td>
<td>3955 W. Mesa Vista Ave., Unit A-10, Las Vegas, NV, 89118</td>
</tr>
<tr>
<td></td>
<td>6641 N. Belt Line Road, Suite 130, Irving, TX, 75063</td>
</tr>
<tr>
<td></td>
<td>MEDISCA Pharmaceutique Inc. Tel.: 1.800.665.6334</td>
</tr>
<tr>
<td></td>
<td>4509 Rue Dobrin, St. Laurent, QC, H4R 2L8</td>
</tr>
<tr>
<td></td>
<td>21300 Gordon Way, Unit 153/158, Richmond, BC V6W 1M2</td>
</tr>
<tr>
<td></td>
<td>MEDISCA Australia PTY LTD Tel.: 1.300.786.392</td>
</tr>
<tr>
<td></td>
<td>Unit 7, Heritage Business Park</td>
</tr>
<tr>
<td></td>
<td>5-9 Ricketty Street, Mascot, NSW 2020</td>
</tr>
<tr>
<td>EMERGENCY PHONE</td>
<td>CHEMTREC Day or Night Within USA and Canada: 1-800-424-9300</td>
</tr>
<tr>
<td></td>
<td>NSW Poisons Information Centre: 131 126</td>
</tr>
<tr>
<td>USES</td>
<td>Colouring agent</td>
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</table>

## SECTION 2: HAZARDS IDENTIFICATION

| GHS CLASSIFICATION            | Based on available data, the classification criteria are not met |
| PICTOGRAM                     | Not Applicable                                                 |
| SIGNAL WORD                   | Not applicable                                                  |
| HAZARD STATEMENT(S)           | May cause an allergic reaction.                                 |
| AUSTRALIA-ONLY HAZARDS        | Repeated exposure may cause skin dryness or cracking.           |
| PRECAUTIONARY STATEMENT(S)    | Prevention Not applicable                                       |
|                              | Response Not applicable                                         |
|                              | Storage Not applicable                                          |
|                              | Disposal Not applicable                                         |

| HMIS CLASSIFICATION           | Health Hazard 1                                                |
|                              | Flammability 0                                                 |
|                              | Reactivity 0                                                   |
|                              | Personal Protection E                                          |

## SECTION 3: COMPOSITION/INFORMATION ON INGREDIENTS

| CHEMICAL NAME                 | Aluminum 6-oxido-5-[(E)-(4-sulfonatophenyl)diazeny]-2-naphtalenesulfonate |
| BOTANICAL NAME                | Not applicable                                                   |
| SYNONYM                       | CI Food Yellow 3; CI No. 15985:1                                  |
| CHEMICAL FORMULA              | C₁₆H₉AlN₂O₇S                                                    |
| CAS NUMBER                    | 15790-07-05                                                     |
| ALTERNATE CAS NUMBER          | Not applicable                                                  |
MOLECULAR WEIGHT

432.36

COMPOSITION

<table>
<thead>
<tr>
<th>CHEMICAL NAME</th>
<th>CAS NUMBER</th>
<th>% BY WEIGHT</th>
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<tbody>
<tr>
<td>FD &amp; C YELLOW No.6 (Aluminum Lake)</td>
<td>15790-07-05</td>
<td>100</td>
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</tbody>
</table>

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

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

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

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, basement 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.
SAFETY DATA SHEET

STORAGE CONDITIONS

Store in original container, tightly sealed container, protected from direct sunlight, in a dry, cool and well-ventilated area, away from incompatible materials. Store in accordance with local regulations. Eliminate all ignition sources. Separate from oxidizing materials. Containers that have been opened must be carefully resealed and kept upright to prevent leakage. Do not store in unlabelled containers. Use appropriate containment to avoid environmental contamination. Preserve in tight containers.

SECTION 8: EXPOSURE CONTROLS/ PERSONAL PROTECTION

Chemical Name: FD & C YELLOW No.6 (Aluminum Lake)    CAS #: 15790-07-05

<table>
<thead>
<tr>
<th></th>
<th>TWA</th>
<th>Ceiling</th>
<th>STEL</th>
<th>REL</th>
<th>IDLH</th>
<th>Remarks</th>
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<tr>
<td>OSHA PEL</td>
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<tr>
<td>ACGIH TLV</td>
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<td>N/L</td>
<td>N/L</td>
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<tr>
<td>NIOSH</td>
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<td>N/L</td>
<td>N/L</td>
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<tr>
<td>AIHA WEEL</td>
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<td>N/L</td>
<td>N/L</td>
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<tr>
<td>Safe Work Australia HSIS</td>
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<tr>
<td>HSE</td>
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<td>N/L</td>
<td>-</td>
<td>-</td>
<td>-</td>
</tr>
</tbody>
</table>

N/L = Not Listed

EXPOSURE GUIDELINES

Consult local authorities for provincial or state exposure limits.

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.

NOTES

Particulates not otherwise regulated. Respirable dust: 5 mg/m^3

SECTION 9: PHYSICAL AND CHEMICAL PROPERTIES

PHYSICAL STATE

Solid

DESCRIPTION

Reddish powder. Is odorless.

SOLUBILITY

Insoluble in water.

ODOR

Odorless

FLAMMABILITY

May be combustible at high temperature

ODOR THRESHOLD

Not available

PH

Not available

MELTING POINT

Not available

BOILING POINT

Not available

FREEZING POINT

Not available

FLASH POINT

Not available

SPECIFIC GRAVITY

Not available

EVAPORATION RATE

Not available

EXPLOSIVE LIMIT

Not available

UPPER FLAMMABLE/EXPLOSIVE LIMIT(S)

Not available

LOWER FLAMMABLE/EXPLOSIVE LIMIT(S)

Not available

VAPOR PRESSURE

Not available
### SECTION 10: STABILITY AND REACTIVITY

<table>
<thead>
<tr>
<th>Reactivity</th>
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<tbody>
<tr>
<td>Stability</td>
<td>Stable under recommended storage conditions</td>
</tr>
<tr>
<td>Materials to Avoid</td>
<td>Strong oxidants and reducing agent may destroy color</td>
</tr>
<tr>
<td>Hazardous Decomposition Products</td>
<td>Toxic fumes of carbon monoxide, carbon dioxide, nitrogen oxides and other gases may occur</td>
</tr>
<tr>
<td>Hazardous Polymerization</td>
<td>Will not occur</td>
</tr>
<tr>
<td>Possibility of Hazardous Reaction</td>
<td>Not established</td>
</tr>
<tr>
<td>Conditions to Avoid</td>
<td>Moisture, sunlight and extreme temperatures</td>
</tr>
</tbody>
</table>

### SECTION 11: TOXICOLOGICAL INFORMATION

#### Acute Toxicity
- **FD & C YELLOW NO.6 (Sunset Yellow FCF):**
  - Oral: Rat: LD50: (mg/kg): >10 000
  - Dermal: Rabbit: LD50: (mg/kg): Not available
  - Inhalation: Rat: LD50: (mg/L/4hr): Not available

#### Skin Corrosion/Irritation
- Not available

#### Serious Eye Damage/Eye Irritation
- Not available

#### Respiratory or Skin Sensitization
- **FD & C YELLOW NO.6 (Sunset Yellow FCF):** Sensitivity reactions have been reported. There is some evidence that inhaling this product is more likely to cause a sensitization reaction in some persons compared to the general population. There is limited evidence that, skin contact with this product is more likely to cause a sensitization reaction in some persons compared to the general population.

#### Germ Cell Mutagenicity
- **FD & C YELLOW NO.6 (Sunset Yellow FCF):** Did not show any genotoxic activity

#### Carcinogenicity
- OSHA: **FD & C YELLOW NO.6 (Sunset Yellow FCF):** is not listed.
- NTP: **FD & C YELLOW NO.6 (Sunset Yellow FCF):** is not listed.
- IARC: **FD & C YELLOW NO.6 (Sunset Yellow FCF):** is listed in group 3 (not classifiable as to its carcinogenicity to humans).
- California Proposition 65: 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
- Although some evidence of carcinogenicity was found in early animal studies subsequent work failed to confirm these findings. Some azo dyes may be able to cause mutations and be associated with the development of bladder cancer.

#### Reproductive Toxicity
- Not available

#### Specific Target Organ Toxicity - Single Exposure
- Not available
SAFETY DATA SHEET

FD & C YELLOW NO.6 (Sunset Yellow FCF): Limited evidence suggests that repeated or long-term occupational exposure may produce cumulative health effects involving organs or biochemical systems. 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. Prime symptom is breathlessness; lung shadows show on X-ray.

SPECIFIC TARGET ORGAN TOXICITY - REPEATED EXPOSURE

ASPIRATION HAZARDS
Not available

SIGNS AND SYMPTOMS OF EXPOSURE
Not expected to present a significant hazard under anticipated conditions of normal use.

FD & C YELLOW NO.6 (Sunset Yellow FCF): Hypersensitivity reactions including severe abdominal cramps and Quincke’s oedema have been recorded in individual patients receiving medication that was coloured with sunset yellow FCF. Sensitive individuals may react at dose levels within the ADI of 0-2.5 mg/kg bw/day.

SIGNS AND SYMPTOMS OF EXPOSURE

INHALATION
May be harmful if inhaled. May cause respiratory tract irritation. The material is not thought to produce adverse health effects or irritation of the respiratory tract (as classified using animal models). Nevertheless, good hygiene practice requires that exposure be kept to a minimum and that suitable control measures be used in an occupational setting.

INGESTION
Although ingestion is not thought to produce harmful effects, the material may still be damaging to the health of the individual following ingestion, especially where pre-existing organ (e.g. liver, kidney) damage is evident. Gastrointestinal tract discomfort may produce nausea and vomiting. In an occupational setting however, ingestion of insignificant quantities is not thought to be cause for concern. Sunset Yellow FCF is absorbed from the gastrointestinal tract to only a small extent and thus most of an orally administered dose is excreted via the faeces.

SKIN
The material is not thought to produce adverse health effects or skin irritation following contact (as classified using animal models). Nevertheless, good hygiene practice requires that exposure be kept to a minimum and that suitable gloves be used in an occupational setting.

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.

NOTES
The aluminium lake of the colour could add to the daily intake of aluminium for which a TWI of 1 mg aluminium/kg bw/week has been established (EFSA, 2008b).

SECTION 12: ECOLOGICAL INFORMATION

TOXICITY
EC50: 48 Hr: Daphnia magna: (mg/L): Not available
LC50: 96 Hr: Fish: (mg/L): Not available
IC50: 72 Hr: Algae: (mg/L): Not available

PERSISTENCE AND DEGRADABILITY
Biodegradation of azo dyes can occur in both aerobic and anaerobic environments.

BIOACCUMULATIVE POTENTIAL
Although azo dyes are generally not readily or inherently biodegradable, bioaccumulation or adsorption to sediment is not expected.

MOBILITY IN SOIL
Insoluble in water.

OTHER ADVERSE EFFECTS
Not available

This product is not intended to be released into the environment

SECTION 13: DISPOSAL CONSIDERATIONS

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

SECTION 14: TRANSPORT INFORMATION
SAFETY DATA SHEET

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

<table>
<thead>
<tr>
<th>Chemical Name &amp; CAS</th>
<th>CERCLA 40 CFR Part 302.4</th>
<th>SARA (Title III) 40 CFR Part 372.65</th>
<th>EPA 40 CFR Part 355 Appendix A</th>
<th>Pennsylvania</th>
<th>Right-to-know New Jersey</th>
<th>Massachusetts</th>
<th>California Prop 65</th>
</tr>
</thead>
<tbody>
<tr>
<td>FD &amp; C YELLOW No.6 (Aluminum Lake), 15790-07-05</td>
<td>N/L</td>
<td>N/L</td>
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<td>N/L</td>
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N/L = Not Listed; X = Listed

AUSTRALIAN REGULATIONS

<table>
<thead>
<tr>
<th>Chemical Name &amp; CAS</th>
<th>Poisons and Therapeutic Goods Regulation</th>
<th>Therapeutic Goods Act</th>
<th>Code of Practices - Illicit Drug Precursors</th>
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</thead>
<tbody>
<tr>
<td>FD &amp; C YELLOW No.6 (Aluminum Lake), 15790-07-05</td>
<td>N/L</td>
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</tbody>
</table>

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
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.