

SAFETY DATA SHEET

**OPADRY 03F31219 GREEN**

1. IDENTIFICATION OF THE SUBSTANCE/PREPARATION AND OF THE COMPANY/UNDERTAKING

Identification of the substance or preparation

Product name : OPADRY
Product code : 03F31219
Use of the substance/preparation : Coatings / Coloring material. / Printing ink related material

Company/undertaking identification : Colorcon Limited
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2. HAZARDS IDENTIFICATION

The substance is not classified as dangerous according to Directive 67/548/EEC and its amendments.

Classification : Not classified.

See section 11 for more detailed information on health effects and symptoms.

3. COMPOSITION/INFORMATION ON INGREDIENTS

Substance/preparation : Preparation

Chemical name	CAS number	%	EC number	Classification
TALC	14807-96-6	30 - 50	238-877-9	Not classified. [2]
TITANIUM DIOXIDE	13463-67-7	5 - 10	236-675-5	Not classified. [2]

There are no additional ingredients present which, within the current knowledge of the supplier and in the concentrations applicable, are classified as hazardous to health or the environment and hence require reporting in this section.

[1] Substance classified with a health or environmental hazard

[2] Substance with a workplace exposure limit

Occupational exposure limits, if available, are listed in section 8.

4. FIRST AID MEASURES

First aid measures

Ingestion : Wash out mouth with water. Do not induce vomiting unless directed to do so by medical personnel. Get medical attention if symptoms occur. Never give anything by mouth to an unconscious person.

Skin contact : Wash contaminated skin with soap and water. Get medical attention if irritation develops.

See section 11 for more detailed information on health effects and symptoms.

5. FIRE-FIGHTING MEASURES

Extinguishing media

Suitable : Use an extinguishing agent suitable for the surrounding fire.

Not suitable : None known.

5. FIRE-FIGHTING MEASURES

- Hazardous thermal decomposition products** : Decomposition products may include the following materials:
carbon dioxide
carbon monoxide
metal oxide/oxides
- Special protective equipment for fire-fighters** : Fire-fighters should wear appropriate protective equipment and self-contained breathing apparatus (SCBA) with a full face-piece operated in positive pressure mode.
- Remark** : Fine dust clouds may form explosive mixtures with air.

6. ACCIDENTAL RELEASE MEASURES

- Personal precautions** : Keep unnecessary personnel away. Avoid breathing dust. Provide adequate ventilation. Use suitable protective equipment (section 8).
- Environmental precautions** : Avoid dispersal of spilled material and runoff and contact with soil, waterways, drains and sewers. Inform the relevant authorities if the product has caused environmental pollution (sewers, waterways, soil or air).
- Methods for cleaning up** : If emergency personnel are unavailable, carefully scoop up spilled materials and use a non-sparking or explosion-proof means to transfer material to an appropriate container for disposal by incineration. Avoid creating dusty conditions and prevent wind dispersal.

7. HANDLING AND STORAGE

- Handling** : Avoid breathing dust.
- Storage** : Keep container tightly closed. Store in a dry, cool and well-ventilated area. Store in accordance with local regulations.

8. EXPOSURE CONTROLS/PERSONAL PROTECTION

Exposure limit values

Ingredient name

Occupational exposure limits

- Recommended monitoring procedures** : If this product contains ingredients with exposure limits, personal, workplace atmosphere or biological monitoring may be required to determine the effectiveness of the ventilation or other control measures and/or the necessity to use respiratory protective equipment. Reference should be made to European Standard EN 689 for methods for the assessment of exposure by inhalation to chemical agents and national guidance documents for methods for the determination of hazardous substances.

Exposure controls

- Occupational exposure controls** : Use only with adequate ventilation. If user operations generate dust, fumes, gas, vapor or mist, use process enclosures, local exhaust ventilation or other engineering controls to keep worker exposure to airborne contaminants below any recommended or statutory limits.
- Respiratory protection** : Use a properly fitted, particulate filter respirator complying with an approved standard if a risk assessment indicates this is necessary. Respirator selection must be based on known or anticipated exposure levels, the hazards of the product and the safe working limits of the selected respirator.
- Hand protection** : Chemical-resistant, impervious gloves complying with an approved standard should be worn at all times when handling chemical products if a risk assessment indicates this is necessary.
- Eye protection** : Safety eyewear complying with an approved standard should be used when a risk assessment indicates this is necessary to avoid exposure to liquid splashes, mists or dusts.
- Skin protection** : Personal protective equipment for the body should be selected based on the task being performed and the risks involved and should be approved by a specialist before handling this product.

8. EXPOSURE CONTROLS/PERSONAL PROTECTION

Environmental exposure controls : Emissions from ventilation or work process equipment should be checked to ensure they comply with the requirements of environmental protection legislation. In some cases, fume scrubbers, filters or engineering modifications to the process equipment will be necessary to reduce emissions to acceptable levels.

9. PHYSICAL AND CHEMICAL PROPERTIES

General information

Physical state : Solid. (Powder.)

Appearance : Green Powder

Important health, safety and environmental information

Explosive properties : Fine dust clouds may form explosive mixtures with air.

Values provided should not be construed as specifications. See product specification for additional information.

10. STABILITY AND REACTIVITY

Stability : The product is stable. Under normal conditions of storage and use, hazardous polymerization will not occur.

No specific data.

Materials to avoid : No specific data.

Hazardous decomposition products : Under normal conditions of storage and use, hazardous decomposition products should not be produced.

Flammability of the product : Non-flammable.

11. TOXICOLOGICAL INFORMATION

Potential acute health effects

Exposure to airborne concentrations above statutory or recommended exposure limits may cause irritation of the nose, throat and lungs.

Ingestion : No known significant effects or critical hazards.

Skin contact : No known significant effects or critical hazards.

This product may irritate eyes upon contact.

Acute toxicity

Ingredient name	CAS #	Result	Species	Dose	Exposure
TITANIUM DIOXIDE	13463-67-7	LD Intratracheal	Rat	>100 ug/kg	-
		TDLo Intratracheal	Rat	5 mg/kg	-
		TDLo Intratracheal	Rat	1.6 mg/kg	-
		TDLo Intratracheal	Rat	1.25 mg/kg	-
		TDLo Oral	Rat	60 g/kg	-
HYPROMELLOSE	9004-65-3	LD50 Intraperitoneal	Rat	5200 mg/kg	-

Chronic effects

Ingredient name	ACGIH	IARC	EPA	NIOSH	NTP	OSHA
TALC	A4	3	-	-	-	-
TITANIUM DIOXIDE	A4	2B	-	-	-	-

Additional information :

titanium dioxide: Titanium dioxide has been characterized by IARC as possibly carcinogenic to humans (Group 2B) through inhalation (not ingestion). This classification is based upon animal inhalation studies. It has not been characterized as a potential carcinogen by either NTP or OSHA. Additionally, the Joint Evaluation Committee on Food Additives (JECFA) has reviewed the safety of titanium dioxide finding no problems for its use in food applications and establishing an acceptable daily intake (ADI) for safe use. In lifetime inhalation studies of rats, airborne respirable size titanium dioxide particles have been shown to cause an increase in lung tumors at concentrations associated with substantial particle lung burdens and consequential pulmonary overload and inflammation. The potential for these adverse health effects appears to be closely related to the particle size and the amount of exposed surface area that comes in contact with the lung. However, tests with other laboratory animals, such as mice and hamsters, indicate that rats are significantly more susceptible to the pulmonary overload and inflammation that causes lung cancer. In lifetime inhalation studies of rats, airborne respirable size titanium dioxide particles have been shown to cause an increase in lung tumors at concentrations associated with substantial particle lung burdens and consequential pulmonary overload and inflammation. The potential for these adverse health effects appears to be closely related to the particle size and the amount of exposed surface area that comes in contact with the lung. However, tests with other laboratory animals, such as mice and hamsters, indicate that rats are significantly more susceptible to the pulmonary overload and

11. TOXICOLOGICAL INFORMATION

inflammation that causes lung cancer.

Other toxic effects on humans

No known significant effects or critical hazards. Handling and/or processing of this material may generate a dust which can cause mechanical irritation of the eyes, skin, nose and throat. Avoid prolonged contact with eyes, skin and clothing.

Specific effects on humans

Mutagenicity / Teratogenicity / Reproductive toxicity : No known significant effects or critical hazards.

Over-exposure signs/symptoms

Inhalation : Adverse symptoms may include the following:
respiratory tract irritation
coughing

Ingestion : No specific data.

Skin : No specific data.

Eyes : Adverse symptoms may include the following:
irritation
redness

12. ECOLOGICAL INFORMATION

Environmental effects : No known significant effects or critical hazards.

Aquatic ecotoxicity

Product/ingredient name	Test	Result	Species	Exposure
TITANIUM DIOXIDE	-	Acute EC50 >1000000 ug/L Fresh water	Daphnia - Water flea - Daphnia magna	48 hours
	-	Acute LC50 5.5 ppm Fresh water	Daphnia - Water flea - Daphnia magna	48 hours
	-	Acute LC50 >1000000 ug/L Marine water	Fish - Mummichog - Fundulus heteroclitus	96 hours
	-	Chronic NOEC 500 ppm Fresh water	Daphnia - Water flea - Daphnia magna	48 hours
	-	Chronic NOEC 1 ppm Fresh water	Daphnia - Water flea - Daphnia magna	48 hours
	-			

13. DISPOSAL CONSIDERATIONS

Methods of disposal : The generation of waste should be avoided or minimized wherever possible. Avoid dispersal of spilled material and runoff and contact with soil, waterways, drains and sewers. Disposal of this product, solutions and any by-products should at all times comply with the requirements of environmental protection and waste disposal legislation and any regional local authority requirements.

European waste catalogue (EWC) : 070399

Hazardous waste : Within the present knowledge of the supplier, this product is not regarded as hazardous waste, as defined by EU Directive 91/689/EEC..

14. TRANSPORT INFORMATION

Not regulated.

15. REGULATORY INFORMATION

EU regulations

Classification and labeling have been determined according to EU Directives 67/548/EEC and 1999/45/EC (including amendments) and take into account the intended product use.

Risk phrases : This product is not classified according to EU legislation.

Product use : Classification and labeling have been determined according to EU Directives 67/548/EEC and 1999/45/EC (including amendments) and take into account the intended product use.
- Industrial applications.

15. REGULATORY INFORMATION

Europe inventory : Europe inventory: Not determined.

16. OTHER INFORMATION

History

Date of issue : 20 April 2009

Date of previous issue : 20 April 2009

Version : 1

Indicates information that has changed from previously issued version.

Notice to reader

To the best of our knowledge, the information contained herein is accurate. However, neither the above-named supplier, nor any of its subsidiaries, assumes any liability whatsoever for the accuracy or completeness of the information contained herein.

Final determination of suitability of any material is the sole responsibility of the user. All materials may present unknown hazards and should be used with caution. Although certain hazards are described herein, we cannot guarantee that these are the only hazards that exist.

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