MATERIALS / SAFETY INFORMATION

Please note that this material does not legally require an SDS according to Article 31 (1) of REACH (as amended by Articles 58(2)(a) and 59(2)(a) of CLP)

- Content: polyester 94.25-96.25%, dye <0.75%, coating 0.5-5%</p>
- The raw polyester material is P E T CAS 25038-59-9
- Dye: D&C Green No. 6. C.I. 61565, CAS 128-80-3 Conforms to US 21 CFR 74.3206
- Silicone coating is a specialized medical silicone elastomer MED2174
- Animal additives are not contained within or used during the manufacturing process either as an additive, expedient, adjuvant, or as a simple utility or technical tool such as performing as a lubricant.
- Polyester is Latex free, Paraben free, TSE free, mint free does not contain Polyvinyl chloride (PVC), p-tert-Butylphenol Formaldehyde Resin (PTBP-F-R), Bisphenol A or phthalates: Benzyl butyl phthalate (BBP) Bis(2-ethyl(hexyl)phthalate (DEHP) Dibutyl phthalate (DBP) Diisobutyl phthalate (DIBP) in their basis material or coating composition
- The material complies with: California Proposition 65 (PROP65), R.O.H.S. WEEE and REACh 2006 SVHC latest revision at less than 0.1%..

POLYESTER

SECTION 1: Identification of the substance/mixture and of the company/undertaking

1.1. Product identifier

High Tenacity Polyester Filament Yarn

1.2. Relevant identified uses of the substance or mixture and uses advised against recommended use: Industrial fiber used in applications with heat resistance, chemical stability, high strength and high elasticity advantages

The fiber is intended for industrial use; however, it may after consultation with the manufacturer be deemed to be suitable for special applications such as in the food industry, or for hygiene, or in the medical or surgical sectors.

In such instances (as is the common practice) it is the responsibility of the purchaser, (not that of us the manufacturers) to demonstrate that the fiber is suitable for the purpose intended.

SECTION 2: Hazards identification

2.1. Classification of the substance or mixture
Directive criteria, 67/548/CEE, 199/45/EG and following amendments thereof:

Properties / Symbols:

None.

EC regulation criteria 1272/2008 (CLP)

The product is not classified as dangerous according to Regulation EC 1272/2008 (CLP).

Adverse physicochemical, human health and environmental effects: No other hazards

2.2. Labelling elements

No labelling is required for the product.

2.3 Other Hazards
Emergency overview
When the fiber products are cut, chopped, or manipulated in other similar handling methods, some dust may be produced.

General hazard information

This fiber may have been produced using lubricants, additives and/or finishes. If this fiber contains any of these materials in an amount that may present a hazard, or requires additional precautions during normal handling and use, additional information has been included in the appropriate section in this SDS

The fiber may have been produced with Carbon Black and/or Titanium Dioxide. These compounds, as present in this material, are not water soluble and are encapsulated in the polymer. They are not extracted or released in normal processing and handling. Therefore these compounds are not expected to present a hazard in normal handling, processing, use and disposal.

Potential health effects

Eves

Fiber particles and dusts may be mechanically irritating when in contact with eyes. Symptoms include itching, burning, redness and tearing.

Not expected to be a primary skin irritant. Fiber particles and dusts may be mechanically irritating to skin. While irritation is not expected under normal use, prolonged exposure and continuous rubbing of fiber particles on skin may produce skin irritation. Symptoms of mechanical irritation may include redness and/or itching.

Inhalation

Health injuries are not known or expected under normal use.

Ingestion

Not a likely route of entry, Ingestion of large amounts of fibers may cause gastrointestinal blockage which can cause stomach distress.

SECTION 3: Composition/information on ingredients

3.1 Substances

Not applicable 3.2 Mixture

Components	CAS#	Concentration
POLYETHYLENE TEREPHTHALATE	25038-59-9	90-99.9%
FIBER FINISH	PROPRIETARY	<1%
TITANIUM DIOXIDE	13463-67-7	0-3%

Composition comments:

The fiber product itself is not toxic. It can contain up to 1% spin finish, which is water washable

Finish is applied to most fibers and yams as a processing aid. The finish, spooling oils and sizes can generally be removed in an aqueous medium if so required.

To date, proper use of this fiber product has not been associated with any detrimental effects on health. _ May have been produced with Titanium Dioxide.

Titanium Dioxide is not water soluble and is encapsulated. It is not extracted or released in normal processing. Therefore Titanium Dioxide in this material does not present a hazard in normal handling, processing use and disposal.

Titanium dioxide does not contain Trimethylolpropane and is not classed as a nanoparticle

SILICONE COATING MED 2174

SECTION 1: Identification of the Substance/mixture and of the Company/Undertaking

1.1. Product Identifier

Product form Mixture
Product Name MED-2174
Synonyms Silicone Elastomer

1.2. Relevant Identified Uses of the Substance or Mixture and Uses Advised Against

1.2.1. Relevant Identified Uses

Use of the Substance/Mixture For professional use only.

1.2.2. Uses Advised Against

No additional information available

SECTION 2: Hazards Identification

2.1. Classification of the Substance or Mixture

Classification According to Regulation (EC) No. 1272/2008 [CLP]

Not classified

2.2. Label Elements

Labelling According to Regulation (EC) No. 1272/2008 [CLP]

No labelling applicable

2.3. Other Hazards

Contains vPvB substances >= 0.1% assessed in accordance with REACH Annex XIII

Other Hazards Not Contributing Exposure may aggravate pre-existing eye, skin, or respiratory

to the Classification conditions.

SECTION 3: Composition/Information on Ingredients

3.1. Substances

Not applicable

3.2. Mixture

Name:	Product Identifier	先	Classification According to Regulation (EC) No. 1272/2008 [CLP]
Octamethylcyclotetrasiloxane	(CAS-No.) 556-67-2 (EC-No.) 209-136-7 (EC Index-No.) 014-018-00-1	<1	Flom. Liq. 3, H226 Acute Tox. 4 (Oral), H302 Repr. 2, H3611 Aquatic Chronic 4, H413
Decamethylcyclopentasiloxane	(CAS-No.) 541-02-6 (EC-No.) 208-764-9	<1	Not classified
Dodecamethylcyclohexasiloxane	(CAS-No.) 540-97-6 (EC-No.) 208-762-8	<1	Not classified

SECTION 1: Identification of the substance/mixture and of the company/undertaking

1.1 Product identifier

Trade name : D&C GREEN 6

Product code 00000003000068804

1.2 Relevant identified uses of the substance or mixture and uses advised against

Use of the Colouring agent Substance/Mixture

SECTION 2: Hazards identification

2.1 Classification of the substance or mixture

Classification (REGULATION (EC) No 1272/2008)

Not a hazardous substance or mixture.

2.2 Label elements

Labelling (REGULATION (EC) No 1272/2008)

Not a hazardous substance or mixture

Additional Labelling

EUH210 Safety data sheet available on request

EUH208 Contains C.I. Solvent Violet 13, p-toluidine. May produce an allergic reaction.

2.3 Other hazards

This substance/mixture contains no components considered to be either persistent, bioaccumulative and toxic (PBT), or very persistent and very bioaccumulative (vPvB) at levels of 0.1% or higher.

SECTION 3: Composition/information on ingredients

3.1 Substances

Components

Chemical name	CAS-No. EC-No.	Concentration (% w/w)
C.I. Solvent Violet 13	81-48-1 201-353-5	>= 2,5 - < 10
p-toluidine	106-49-0 203-403-1	>= 0,1 - < 0,25

The material is however tested to 21CFR74.1206:

[Code of Federal Regulations]

[Title 21, Volume 1]

[Revised as of April 1, 2019]

[CITE: 21CFR74.1206]

TITLE 21--FOOD AND DRUGS

CHAPTER I-FOOD AND DRUG ADMINISTRATION

DEPARTMENT OF HEALTH AND HUMAN SERVICES

SUBCHAPTER A -- GENERAL

PART 74 -- LISTING OF COLOR ADDITIVES SUBJECT TO CERTIFICATION

Subpart B--Drug

Sec. 74.1206 D&C Green No. 6.

(a) Identity. The color additive D&C Green No. 6 is 1.4-bis[(4-methylphenyl)amino]-9,10-anthracenedione (CAS. Reg. No. 128-80-3).

(b) Specifications. The color additive D&C Green No. 6 for use in coloring externally applied drugs shall conform to the following specifications and shall be free from impurities other than those named to the extent that such other impurities may be avoided by current good manufacturing practice:

Volatile matter (at 135 deg. C), not more than 2.0 percent.

Water-soluble matter, not more than 0.3 percent.

Matter insoluble in carbon tetrachloride, not more than 1.5 percent.

p -Toluidine, not more than 0.1 percent.

1,4-Dihydroxyanthraquinone, not more than 0.2 percent.

1-Hydroxy-4-[(4-methylphenyl)amino]-9, 10-anthracenedione, not more than 5.0 percent.

Lead (as Pb), not more than 20 parts per million.

Arsenic (as As), not more than 3 parts per million.

Mercury (as Hg), not more than 1 part per million.

Total color, not less than 96.0 percent.

(c) Uses and restrictions. The <u>color</u> additive D&C Green No. 6 may be safely used for <u>coloring</u> externally applied drugs in amounts consistent with current good manufacturing practice.

(d) Labeling. The label of the color additive shall conform to the requirements of 70.25 of this chapter.

(e) Certification. All batches of D&C Green No. 6 shall be certified in accordance with regulations promulgated under part 80 of this chapter.

[42 FR 15654, Mar. 22, 1977, as amended at 47 FR 14146, Apr. 2, 1982; 47 FR 24278, June 4, 1982;

51 FR 9784, Mar. 21, 1986]