



Codonics DirectVista[®] Film

Safety Data Sheet (SDS)

Section 1: Identification of Substance

1.1. Product Identifier/Article Name:

DirectVista[®] Film Blue (DVFB) and DirectVista Film Clear (DVFC)
DirectVista Film Blue-5 (DVB5), PET PLATES COATED, DryStar DT5/DRYB

1.2. Article Type and Identified Uses:

Thermographic film for medical imaging applications.

1.3. Details of Supplier Safety Data:

The information contained here is based on Codonics best knowledge and experience. This data sheet does not convey any warranty as to the properties of this article. The data sheet provides information pertaining to health, safety, and environmental concerns when the article is used as intended.

Codonics Inc., an established and reputable manufacturer of medical class equipment approved for export as indicated via FDA Certificate of Foreign Government certificate NO# 1757-11-2021, with headquarters and production facilities (FDA Establishment Registration: 1530958, Owner Operator Number: 9026554) located at 17991 Englewood Drive Middleburg Heights, OH 44130 USA

1.4. Responsible Person: Quality Assurance Manager.

1.5 Emergency Phone: If there are additional questions or you require further assistance, please call us at +1.440.243.1198 and request to speak with the Quality Assurance Manager.

Section 2: Hazards Identification

2.1 Classification of substance: Poly(oxy-1,2-ethanediyloxycarbonyl-1,4-phenylenecarbonyl

DirectVista Film and Unfinished PET Plate Coated is a direct thermographic film consisting of a support layer, an image forming layer, a top protective layer, and a bottom layer. The support layer is made of polyethylene terephthalate (PET). Its color is tinted blue for DVFB/DVB5 and is untinted for DVFC.

2.2 Label Elements:

The PET support layer accounts for about 80% of the weight of the film material. The image-forming layer mainly consists of an organic silver salt in an organic binder. This layer also contains small amounts of additives used to provide the necessary physical and sensitometric properties of the film. The transparent top layer, which is coated on top of the imaging forming layer, has a high glass transition temperature, which is both heat conductive and chemically stable to heat.

The transparent bottom layer, which is coated on the bottom of the PET support, helps to prevent individual films from sticking to each other. The total silver content of the film is < 1,0 g/m². The recording on DirectVista Film is created by a thermal printhead in Codonics printers. The recording does not require any wet chemical processing.

2.3 Other Hazards:

DirectVista Film will not cause any special health or safety hazards when used as intended. Not a hazardous substance or mixture.

Section 3: Composition

3.1 General: The molecular formula is: (C₁₀H₈O₄)_n or C₅H₄O₂ for short. The density of PET is 1.397 g/cm³, refractive index n = 1.640, A/Z = 1.915, and ionization potential I = 73.2 eV. The basic building blocks of PET are ethylene glycol and terephthalic acid, which are combined to form pellets of PET. These resin pellets are then heated to a molten liquid that can be easily extruded or molded into sheets and plates for coating.

3.2 Mixtures:

Polyethylene Terephthalate Basic information

Product Name:	<u>Polyethylene Terephthalate</u>
Synonyms:	arnitea;arnitea-049000;arnitea200;arnitefp800;arniteg;arniteg600;Cassappret sr; cassappretsr
CAS:	<u>25038-59-9</u>
MF:	C10H12O6
MW:	228.19868
Hazard Code:	Xi
Product Categories:	<u>Esters;Hydrophobic Polymers;Polymers;Polymer Science;Hydrophobic Polymers;PET;Materials Science;Polymer Science</u>
Mol File:	<u>25038-59-9.mol</u>

GHS Classification in accordance with 29 CFR 1910 (OSHA HCS)

None found.

GHS Label elements, including precautionary statements, None Found

Section 4: Health and Safety

4.1 Health Aspects: Under normal transport, storage, and use conditions, no harmful concentrations of volatile components are released from DirectVista Film. No wet chemicals are used in the imaging process.

4.2. Description of first-aid measures:

- If inhaled or if breathed in: Move person into fresh air.
- If not breathing: Give artificial respiration.
- In case of skin contact: Wash off with soap and plenty of water.
- In case of eye contact: Flush eyes with water as a precaution.
- If swallowed: Never give anything by mouth to an unconscious person. Rinse mouth with water.

Section 5: Fire Hazard and Media Extinguishment

5.1 The film support layer of DirectVista Film is made of polyethylene terephthalate and meets the "Safety Film" specifications as described in ANSI/ISO 543-1990.

Safety film passes the ignition test when ignition time is = 10 minutes.

It passes the burning time test when the burning time is > 45 seconds for a film thickness = 0.08 mm or when the burning time is > 30 seconds for a film thickness < 0.08 mm. DirectVista Film is approximately 0.20 mm thick.

The nature of any combustion products is dependent on the physical properties of the combustion process and on the degree of combustion, whereby different gases can be generated, such as water vapor, carbon dioxide, carbon monoxide, and small concentrations of organic and inorganic degradation products.

5.2 Combustion of DirectVista Film can lead to the formation of gases similar in composition to the volatile organic and inorganic degradation products of the polyethylene terephthalate support layer.

5.3 Fire extinguishing media: water spray, carbon dioxide, extinguishing powder or foam.

Section 6: Accidental Release

6.1 Flat film plates are inert and there are no special environmental precautions required.

Section 7: Handling and Storage

7.1 For specific information on storage conditions of DirectVista Film, please refer to the general instructions for use of this article. The storage conditions are:

- Store between 0°C (32°F) min and 25°C (77°F) max
- Keep dry
- Avoid exposure to light and background radiation higher than 90nGy/h

These conditions are also mentioned on the product label.

Section 8: Exposure Control/Personal Protection

None

Section 9: Physical and Chemical Properties

Polyethylene Terephthalate Chemical Properties

Melting point	250-255°C (482-491°F)
Boiling point	>170°C (338°F) (Press: 10 Torr)
density	1.68 g/mL at 25°C (77°F)
storage temp.	Room Temperature
form	sheets
color	Clear with blue tint
EPA Substance Registry System	<u>Poly(ethylene terephthalate) (25038-59-9)</u>

Section 10: Stability and Reactivity

10.1 Reactivity: No data available

10.2 Chemical Stability: Stable under recommended storage conditions.

10.3 Possibility of hazardous reactions: No data available

10.4 Conditions to avoid: No data available

10.5 Incompatible Materials: Strong oxidizing agents

Section 11: Toxicological Information

11.1 Acute toxicity

- Oral: No data available
- Inhalation: No data available
- Dermal: No data available
- Skin corrosion/irritation: No data available
- Serious eye damage/eye irritation: No data available
- Respiratory or skin sensitization: No data available
- Germ cell mutagenicity: No data available
- Carcinogenicity IARC: No ingredient of this product present at levels greater than or equal to 0.1% is identified as probable, possible or confirmed human carcinogen by IARC.
- NTP: No ingredient of this product present at levels greater than or equal to 0.1% is identified as a known or anticipated carcinogen by NTP.
- OSHA: No component of this product present at levels greater than or equal to 0.1% is on OSHA's list of regulated carcinogens.
- Reproductive toxicity: No data available
- Specific target organ toxicity - single exposure: No data available
- Specific target organ toxicity - repeated exposure: No data available
- Aspiration hazard: No data available

Section 12: Ecological Information

12.1 Toxicity: No data available

12.2 Persistence and degradability: No data available

12.3 Bio accumulative potential: No data available

12.4 Mobility in soil: No data available

12.5 Results of PBT and vPvB assessment: PBT/vPvB assessment not available as chemical safety assessment not required/not conducted

12.6 Endocrine disrupting properties: No data available

12.7 Other adverse effects: No data available

Section 13: Waste Disposal

Regulations concerning waste disposal differ from country to country. Please consult the local regulations on this subject. In most countries, DirectVista Film is considered as industrial waste and consequently it is not allowed to be disposed of as household waste. Codonics recommends waste DirectVista Film be hauled away by a licensed company for silver reclamation. Waste DirectVista Film should be treated separately from conventional PET-based waste, when the latter is subjected to PET recycling. These films, when discarded, are not regulated as a hazardous waste under the Resource Conservation and Recovery Act (RCRA).

Section 14: Transport and Labeling Regulations:

DirectVista Film is an article as defined in 29 CFR1910.1200 and is thus not subject to the regulations on transport, labeling, health, safety, and environment that apply to chemical substances and preparations. Transboundary transport of silver-containing waste is subject to legislation based on the Basel Treaty and OECD Rules.

- DOT (US): Not dangerous goods
- IMDG: Not dangerous goods
- IATA: Not dangerous goods
- Further information: Not classified as dangerous in the meaning of transport regulations.

Section 15: Regulatory

- SARA 302 Components: No chemicals in this material are subject to the reporting requirements of SARA Title III, Section 302.
- SARA 313 Components: This material does not contain any chemical components with known CAS numbers that exceed the threshold (De Minimis) reporting levels established by SARA Title III, Section 313.
- SARA 311/312 Hazards: No SARA Hazards
- California Prop. 65 Components: This product does not contain any chemicals known to the State of California to cause cancer, birth, or any other reproductive defects.

Section 16: Other Information

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