



October 7, 2019

Declaration of Material Content

I, the undersigned declare and certify that the goods described below:

Name of the Manufacturer: Codonics Incorporated

Name of the Product: Codonics DIRECT VISTA THERMAL FILM -FILM RADIOGRAPHIC

DirectVista Blue and Clear

Various Size Direct Vista Film labeled as

Medical Imaging Film DVB, DVB5

Blue and Clear Film-8x10, 11x14, 14x17

Blue Film-14x36, and 14x51

Supplied: Approved Distributor/Importer in 500 sheet case lots, (5) 100 sheet cassettes/case, Thermographic film for medical imaging applications.

Current Method of Analysis: Manufacturer process confirmation of content, characteristics, and specific LOT/Expiry date labeling

is (1) Quality Assured and Packaged in the United States of America from Raw Materials originating in Belgium, (2) film is prepared to Codonics specification in the United States, cut, finished, and shipped to our registered FDA Establishment for QA, test, packaging, medical product labeling, and distribution, (3) comprised of a proprietary formulation which includes:

- PET plastic base (a) below
- Latex binder (b) below
- Silver Salt Suspension of Silver Behenate to Codonics specification (c) below

Details:

1. **Article name:** Codonics DIRECT VISTA THERMAL FILM -FILM RADIOGRAPHIC

2. **Article type:** Thermographic Hardcopy film for Radiography

Sensitometry of Emulsion	Thermal Sensitivity: 0.2–500 μ J/pixel to produce an O.D. range of 0.20 Dmin to 3.20 Dmax. Images are not created via Radiation (XRAY) or Light
Gray Scale	4096 (Horizon Series) shades of gray
Resolution	12.6 pixels/mm
Continuous Tone	YES

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3. Composition:

DIRECT VISTA film is a direct thermographic film, basically consisting of a support, an image forming layer and a protective layer. The support is made of polyethylene terephthalate (PET). Its color may vary according to the application (Blue or Clear). Generally, the support stands for more than 80 weight percent of the total weight of the film material. The image forming layer mainly consists of an organic silver salt in an organic binder. Furthermore, this layer also contains small amounts of additives required to provide the necessary physical and sensitometric properties to the film. The transparent protective layer, which is coated on top of said image forming layer, has a high glass transition temperature, that is heat conducting and that is chemically stable to heat. The recording on the DirectVista film is done by a thermal printhead in the Codonics Horizon printer. The imaging does not require any wet chemical processing.

4. Health and Safety

4.1. General: DIRECTVISTA film will not cause any special health or safety hazard, when it is used as intended.

4.2. Health aspects: under normal conditions of storage, transport and use, no harmful concentrations of volatile components are set free from the DIRECTVISTA film. No wet chemicals are involved in the imaging process.

4.3. Fire hazard and extinguishing media:

– The film base is made of polyethylene terephthalate and meets the "Safety Film" specifications as described in ISO 18906-2000. Safety photographic film passes the ignition time test when the ignition time is ≥ 10 min. It passes the burning time test when the burning time is > 45 sec. for a film thickness ≥ 0.08 mm or when the burning time is > 30 sec. for a film thickness < 0.08 mm. The nature of the combustion products is dependent on the physical characteristics of the burning process and on the degree of combustion, whereby different gases can be generated, such as e.g. water vapour, carbon dioxide, carbon monoxide and small concentrations of organic and inorganic degradation products.

– Combustion of DIRECTVISTA film can lead to the formation of gases, mainly similar in composition to the volatile inorganic and degradation products of the PET support.

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

5. Waste disposal

The regulations about waste disposal may differ from one country to another. Please consult the local regulations on the subject matter. In most countries DIRECTVISTA film is considered as industrial waste and consequently it is not allowed to dispose of it as household waste.

We recommend to have waste DIRECTVISTA film hauled away by a licensed company for recovering the silver. When the film waste is disposed of through



incineration, we refer to par. 4.3 relating to the composition of the fumes. Waste DIRECTVISTA film should be treated separately from conventional PET-based film waste, when the latter is to be subjected to PET-recycling

6. Transport and labelling regulations

The labelling of the product fulfills the legal requirements for medical devices. Photographic film is an article. It is not subject to the regulations on labelling, health, safety and environment that apply to chemical substances and preparations. The product is not hazardous according to transport regulations. Transboundary transport of silver-containing waste is subject to legislation based on the Basel Treaty and OECD Rules.

7. Storage

For specific information on optimal storage conditions of DIRECTVISTA film, we refer to the general instructions for use of this article.

8. Other information

None

The data given hereabove are based upon our best knowledge and current experience. This Sheet does not convey any warranty as to the properties of this Article. The Sheet provides information pertaining to health, safety and environment when the Article is used as intended in normal professional conditions.

(a) Composition of POLYETHYLENE TEREPHTHALATE (MYLAR):

Density (g/cm³) =1.40000E+00, Mean Excitation Energy (eV) =78.700000. Atomic Number 1=0.041959, Atomic Number 6=0.625017, Atomic Number 8=0.333025. A polyester of terephthalic acid and ethylene glycol obtained by the poly= condensation of dimethyl terephthalate (q.v.) with ethylene glycol, and terephthalic acid with ethylene glycol or ethylene oxide. Thickness of sheets is nominal 195um (0.2mm+0.0/-0.01mm)

(b) A **latex binder composition** comprising a binder dispersed in water where the binder is a reaction product of monomers consisting essentially of (a) about 30 to about 70 parts by weight of one or more conjugated diene monomers having from 4 to 8 carbon atoms and (b) from about 70 to about 30 parts by weight of one or more vinyl-substituted aromatic monomers having from 8 to 12 carbon atoms, the total amount of said (a) and (b) monomers being 100 parts by weight, and from about 0.1 to about 3 parts by weight of an acrylamide monomer or a derivative thereof wherein said derivative is N-alkyl acrylamide, N,N-dialkyl acrylamide, dialkyl acrylamide or N,N-cycloalkyl acrylamide, or combinations thereof, and wherein said alkyl group has from 1 to 8 carbon atoms, and optionally from about 0.1 to about 10 parts by weight of an unsaturated carboxylic acid monomer other than methacrylic acid and less than 2 parts by weight of acrylic acid, for every 100 parts by weight of said one or more (a) and (b) monomers, and from about 0.1 to about 6 parts by weight of a methacrylic



acid monomer and from about 0.1 to about 5 parts by weight of N-methylol-functional ethylenically unsaturated monomer which is N-methylolacrylamide or N-methylolmethacramide or both including derivatives thereof, for every 100 parts by weight of said (a) and (b) monomer.

(c) **Silver Behenate** is a silver salt of a long chain carboxylic acid ($\text{AgC}_{22}\text{H}_{43}\text{O}_2$) with a metric weight of 447.44 (CAS Number 2489-05-6).

Codonics certifies that DV Film (*Blue and Clear Base*) is FDA approved and approved in every medical market including USD, Europe, Japan, China, and Brazil as an equivalent medical film product. We further certify that DirectVista Film, Blue and Clear, does not contain any bovine or other animal content.

This declaration is valid for all shipments of these products dispatched from Codonics USA.

I undertake to inform Authorities immediately if this declaration is no longer valid.

I undertake to make available to authorities any further supporting documents required on demand.

Respectively submitted,

A handwritten signature in blue ink, appearing to read "Gary W. Enos", written over a horizontal line.

Gary W. Enos
Vice President, Business & Technology Integration and International Affairs
Codonics, Inc.