



FDA & REACH CERTIFICATE OF COMPLIANCE FOR METAL DETECTABLE CABLE TIES & ACCESSORIES

Effective: 08/16/2018

The purpose of this letter is to provide information regarding the regulatory requirements for metal detectable cable ties & accessories produced at Advanced Cable Ties, including USFDA and Regulation (EU) 10/2011 for food contact status.

These products, as manufactured by Advanced Cable Ties, conform to the following regulations based on information provided to Advanced Cable Ties by its raw material supplier:

Regulations (EC) No. 1935/2004 and (EC) 2023/2006: Compliance with these regulations are described below:

Organoleptic Properties: These products are not known or expected to cause an unacceptable change in the composition of the food, or cause a deterioration in the organoleptic properties of the food.

Impurities:

Nylon Resin - None known or expected to be present above 1% in its portion.

Siloxane - None known or expected to be present above 2% in its portion.

Steel - None known or expected to be present above 1% in its portion.

Migration Limits:

See Regulation (EU) No. 10/2011, below.

Regulation (EU) 10/2011 and Up-Dates: Advanced Cable Ties Metal Detectable products meet the compositional requirements of Regulation (EU) 10/2011 as follows:

Component	FCM	Ref. No.	Substance Name:	SML	SML(T)	Restrictions
PA-66 Resin	305	15274	Hexamethylene Diamine	2.4		
	303	18460	Adipic Acid			
		12130 31730				
Steel Portion	80	87160	Stainless Steel			
Siloxane Portion	575	76721	Polydimethylsiloxane (MW >6 800 Da)			Viscosity at 25 °C not less than 100 cSt (100 x 10 ⁻⁶ m ² /s)
PA-6 Resin	212	14200 41840	Caprolactam		15	
Proprietary Ester	496	71680	Pentaerythritol Tetrakis[3-(3,5-di-tert-butyl-1,4-hydroxyphenyl)-propionate]			
Antioxidant	773	38840	Bis(2,4-dicumylphenyl) pentaerythritol-diphosphite	5		

FCM = Food Contact Material

SML = Specific Migration Limit

SML(T) = Specific Migration Limit (Total)

USFDA: Advanced Cable Ties Metal Detectable products meet the compositional requirements of the following regulations:

Component	Regulation	Title	FDA Part
PA-66 Resin	21 CFR 177.1500	Nylon Resins	Indirect Food Additives: Polymers
	21 CFR 176.170	Components of Paper & Paperboard in Contact with Aqueous & Fatty Foods	Indirect Food Additives: Paper & Paperboard Components
	21 CFR 176.180	Components of Paper & Paperboard in Contact with Dry Food	
Steel Portion	21 CFR 184.1375	Iron, Elemental	Direct Food Substances Affirmed as Generally Recognized as Safe
Siloxane Portion	21 CFR 181.28	Release Agents	Prior Sanctioned Food Ingredients
	21 CFR 175.105	Adhesives	Indirect Food Additives: Adhesives and Components of Coatings
	21 CFR 175.300	Resinous & Polymeric Coatings	
	21 CFR 175.320	Resinous & Polymeric Coatings for Polyolefin Films	
	21 CFR 176.170	Components of Paper & Paperboard in Contact with Aqueous & Fatty Foods	Indirect Food Additives: Paper & Paperboard Components
	21 CFR 176.180	Components of Paper & Paperboard in Contact with Dry Food	
	21 CFR 176.200	Defoaming Agents Used in Coatings	
	21 CFR 176.210	Defoaming Agents Used in the Manufacture of Paper & Paperboard	
21 CFR 177.2260	Filters, Resin Bonded	Indirect Food Additives: Polymers	
21 CFR 177.2600	Rubber Articles Intended for Repeated Use		
PA-6 Resin	21 CFR 177.1500	Nylon Resins	Indirect Food Additives: Polymers
	21 CFR 175.105	Adhesives	Indirect Food Additives: Adhesives and Components of Coatings
	21 CFR 177.1200	Cellophane	Indirect Food Additives: Polymers
	21 CFR 177.2260	Filters, Resin Bonded	
Proprietary Ester	21 CFR 177.1680	Polyurethane Resins	Indirect Food Additives: Polymers
Antioxidant	21 CFR 177.1520	Olefin Polymers	Indirect Food Additives: Polymers
	21 CFR 176.170	Components of Paper & Paperboard in Contact with Aqueous & Fatty Foods	Indirect Food Additives: Paper & Paperboard Components
	21 CFR 176.180	Components of Paper & Paperboard in Contact with Dry Food	

Based on Advanced Cable Ties Supplier data regarding Substances of Very High Concern (SVHC) (REACH): Advanced Cable Ties Metal Detectable products contain no substances on the revised SVHC list of 20-Jun-16.

Regards,

Al Maroni
 Quality Manager

