

FDA-COMPLIANT PRODUCTS **OVERVIEW**





Heubach is a leading supplier of pigments, pigment preparations and polymer soluble dyes for the coloration of plastics and rubber. Our customers have a growing need for information about and an understanding of regulations regarding and questions relating to the coloration of consumer goods, food packaging and children's toys. This flyer focuses on Heubach's FDA-compliant colorants and their prescribed limitations.



HEUBACH'S MAIN PRODUCT RANGES FOR THE COLORATION OF PLASTICS

PV FAST®

High performance organic pigments with outstanding heat resistance, light fastness and fastness to bleeding.

SOLVAPERM®

Polymer soluble dyes for amorphous plastics which produce brilliant, transparent coloration with outstanding heat resistance and good light fastness.

POLYSYNTHREN®

Polymer soluble dyes for brilliant and transparent coloration of engineering plastics with a focus on polyester spin dyeing. They offer excellent fastness and resistance properties.

TELALUX™

Optical brighteners for mass brightening of a wide range of plastics including polyester fibers and filaments.

FDA APPROVAL SUMMARY OF THE REGULATIONS CONCERNING FOOD PACKAGING

1. GENERAL REMARKS

The Food and Drug Administration (FDA) regulates cosmetics, medical devices, drugs, food (including food additives and food packaging) in the United States.

FDA regulations are compiled in Title 21 of the Code of Federal Regulations (21 CFR). These regulations can be amended in the Federal Register, or as described below.

FDA regulations are organized in Parts.

The Parts that are most relevant to food contact are:

- Part 175 - Adhesives and Coatings
- Part 176 - Paper and Paperboard
- Part 177 - Polymers
- Part 178 - Adjuvants, Production Aids, Sanitizers
- Part 181 - Prior Sanctions
- Part 182 - GRAS Substances
- Part 184 - Affirmed GRAS Substances
- Part 186 - Food Contact Substances Affirmed as GRAS

Detailed regulatory information is found in paragraphs, such as §178.3297, Colorants for Polymers.

2. LEGAL AND REGULATORY BACKGROUND – FDA COMPLIANCE FOR FOOD ADDITIVES

A food additive is a substance which, when used as intended, is reasonably expected to become a component of food. A food additive must be already regulated, exempt or precleared.

There are three types of food additives:

- Color Additive
(a certified food grade color ingredient added directly)
- Secondary Direct Food Additive
(a food additive that creates a technical effect in food during processing, but not in the finished food)
- Indirect Food Additive also known as Food Contact Substance (a food additive that comes into contact with food as part of packaging, holding, or processing, but is not intended to be added directly to, become a component of, or have a technical effect in or on the food.)

Indirect Food Additives (Food Contact Substances) are regulated, exempt or pre-cleared. However, this type of additive is likely to have exemptions or pre-clearances.

2.1 REGULATED COLORANTS FOR POLYMERS

2.1.1 21 CFR, § 178.3297. COLORANTS FOR POLYMERS

Colorants for polymers are listed in 21 CFR §178.3297, Colorants for Polymers. The colorants are listed with their chemical names and/or with their color index generic names. Many of the colorants are subject to restrictions on:

- Upper limit color concentration in the polymer,
- Polymer types,
- Food types, (aqueous, acidic, fatty, low alcohol, high alcohol), and/or
- Conditions of use

The conditions of use describe the temperature conditions the colored polymer may be subjected to and are described as follows:

- A. High temperature heat sterilization (e. g. over 100 °C/212 °F)
- B. Boiling water sterilization
- C. Hot filling or pasteurization above 66 °C (150 °F)
- D. Hot filling or pasteurization below 66 °C (150 °F)
- E. Room temperature filling and storage (no thermal treatment in the container)
- F. Refrigerated storage (no thermal treatment in the container)
- G. Frozen storage (no thermal treatment in the container)
- H. Frozen or refrigerated storage: ready-prepared foods intended to be reheated in the container at time of use
- I. Irradiation
- J. Cooking at temperatures exceeding 250 °F.

2.1.2 FOOD CONTACT NOTIFICATIONS

As of January, 2000, the FDA no longer lists cleared substances in 21 CFR §178.3297. Rather, substances cleared by the FDA as food contact substances will be listed on the FDA webpage. For a complete listing of FDA-cleared substances, both 21 CFR §178.3297 and the FDA webpage must be researched.

The same restrictions found in 21 CFR §178.3297 would be utilized in substances cleared by food contact notifications. It is important to note that only the company listed with the cleared substance on the FDA webpage may declare their product as FDA-compliant.

2.2 EXEMPTIONS FROM FOOD ADDITIVE REGULATION

Exemptions from the Food Additive Regulation include:

- No migration
- Functional barriers
- Housewares
- Threshold of regulation

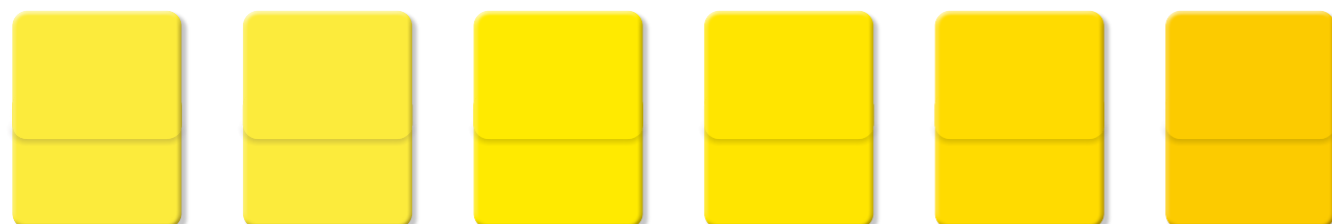
2.3 PRE-CLEARANCES FROM THE FOOD ADDITIVE REGULATION

Certain colorant pre-clearances are still recognized and utilized in business today. These include:

- Pre-1958 approvals by the FDA or USDA
- Lehman List
- Agency Letters
- Prior Sanction
- Generally Recognized as Safe (GRAS)

FDA-COMPLIANT PRODUCTS (COLORATIONS AT SD 1/3 + 1% TiO₂)

POWDER PIGMENTS



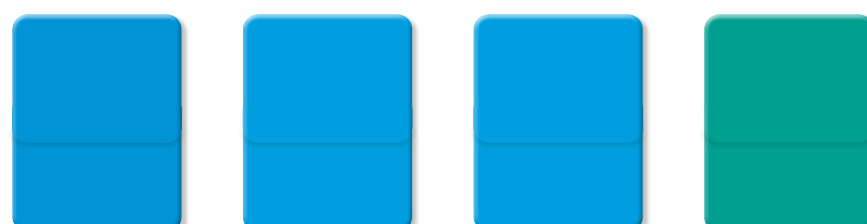
PV FAST YELLOW H9G P.Y. 214
PV FAST YELLOW H4G P.Y. 151
PV FAST YELLOW HG 01 P.Y. 180
PV FAST YELLOW HG P.Y. 180
PV FAST YELLOW H2GR P.Y. 191
PV FAST YELLOW HGR P.Y. 191



PV FAST YELLOW H3R P.Y. 181
PV FAST ORANGE H2GL P.O. 64
PV FAST SCARLET 4RF P.R. 242
PV FAST RED D3G P.R. 254
PV FAST RED HF4B P.R. 187

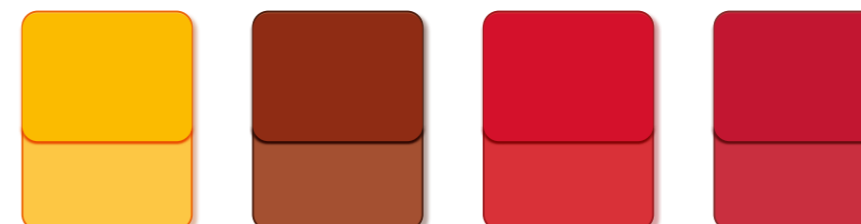


PV FAST RED E3B P.V. 19
PV FAST RED E5B P.V. 19
PV FAST PINK E P.R. 122
PV FAST PINK E 01 P.R. 122
PV FAST PINK E2B P.R. 122

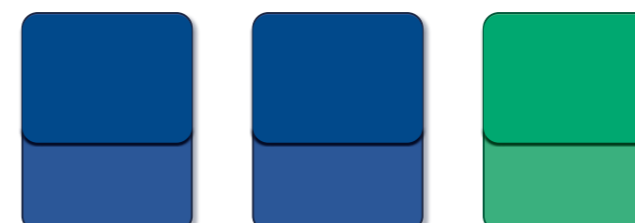


PV FAST BLUE A4R P.B. 15:1
PV FAST BLUE A2R P.B. 15:1
PV FAST BLUE B9 P.B. 15:3
PV FAST GREEN GNX P.G. 7

POLYMER SOLUBLE DYES IN PET

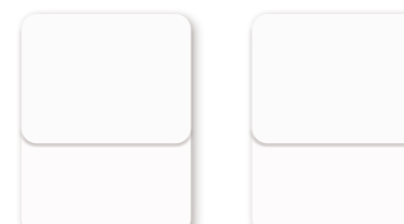


POLYSYNTHREN YELLOW NG P.Y. 147
POLYSYNTHREN BROWN R S.Br. 53
POLYSYNTHREN RED GFP S.R. 135
SOLVAPERM RED BB S.R. 195



POLYSYNTHREN BLUE RLS S.B. 45
SOLVAPERM BLUE 2B S.B. 104
SOLVAPERM GREEN G S.G. 28

OPTICAL BRIGHTENERS



TELALUX KS
TELALUX KS 1

FDA-COMPLIANT COLORANTS WITH PRESCRIBED LIMITATIONS

PRODUCT NAME	C.I. GENERIC NAME	POLYMER	UPPER CONCENTRATION in % by weight	CONDITIONS OF USE as defined in 21 CFR 176.170	FOOD TYPES
Colorant					
PV FAST YELLOW H4G	Pigment Yellow 151	All	5	A-H	All foods
PV FAST YELLOW H9G	Pigment Yellow 214	All	1	A-H	All foods
PV FAST YELLOW HG 01	Pigment Yellow 180	All	1	B-G	All foods
PV FAST YELLOW HG	Pigment Yellow 180	All	1	B-G	All foods
PV FAST YELLOW H2GR	Pigment Yellow 191	All	1	B-H	All foods
PV FAST YELLOW HGR	Pigment Yellow 191	All	1	B-H	All foods
PV FAST YELLOW H3R	Pigment Yellow 181	All	1	B-H	All foods
PV FAST ORANGE H2GL	Pigment Orange 64	All	1	B-H	All foods
PV FAST SCARLET 4RF	Pigment Red 242	All	2	A-H	Aqueous, acidic, low alcohol
				Article thickness not to exceed 2 mils	
PV FAST RED D3G	Pigment Red 254	All	1	B-H	All foods
PV FAST RED HF4B	Pigment Red 187	All	1	B-H	All foods
PV FAST RED E3B	Pigment Violet 19			FDA-compliant color without limitations in 21 CFR 178.3297	
PV FAST RED E5B	Pigment Violet 19			FDA-compliant color without limitations in 21 CFR 178.3297	
PV FAST PINK E	Pigment Red 122	All	1	D-G	Aqueous, acidic, low alcohol
			0.5	D-G	Fatty foods
			0.2	A-H	All foods
PV FAST PINK E 01	Pigment Red 122	All	1	D-G	Aqueous, acidic, low alcohol
			0.5	D-G	Fatty foods
			0.2	A-H	All foods
PV FAST PINK E2B	Pigment Red 122		1	D-G	Aqueous, acidic, low alcohol
			0.5	D-G	Fatty foods
			0.2	A-H	All foods
PV FAST BLUE A4R	Pigment Blue 15:1			FDA-compliant color without limitations in 21 CFR 178.3297	
PV FAST BLUE A2R	Pigment Blue 15:1			FDA-compliant color without limitations in 21 CFR 178.3297	
PV FAST BLUE BG	Pigment Blue 15:3			FDA-compliant color without limitations in 21 CFR 178.3297	
PV FAST GREEN GNX	Pigment Green 7			FDA-compliant color without limitations in 21 CFR 178.3297	

PRODUCT NAME	C.I. GENERIC NAME	POLYMER	UPPER CONCENTRATION in % by weight	CONDITIONS OF USE as defined in 21 CFR 176.170	FOOD TYPES
Colorant					
POLYSYNTHREN YELLOW NG	Pigment Yellow 147	PET	0.25	E-F-G	All Foods
			0.25	D-E-F-G	Food types III, IV – A, and V
POLYSYNTHREN RED GFP	Solvent Red 135	PET	0.2	E-F-G	Aqueous, acidic, low alcohol
			0.045	C-D	Aqueous, acidic, low alcohol, high alcohol, fatty foods
POLYSYNTHREN BLUE RLS	Solvent Blue 45	PET	0.4	C-G	Aqueous, acidic, low alcohol
POLYSYNTHREN BROWN R	Solvent Brown 53	PET	0.2	C-G	All Foods
SOLVAPERM RED BB	Solvent Red 195	PET	0.2	E-F-G	Aqueous, acidic, low alcohol
SOLVAPERM BLUE 2B	Solvent Blue 104	PET	0.2	E-F-G	Aqueous, acidic, low alcohol
SOLVAPERM GREEN G	Solvent Green 28	PET	0.2	E-F-G	Aqueous, acidic, low alcohol
Optical Brighteners					
TELALUX KS	N/A	Rigid/Semi Rigid PVC	0.05	D-E-F-G	All foods
		All	0.03	D-E-F-G	All foods
TELALUX KS 1	N/A	All	0.025	Temperatures not to exceed 275 °F	Food types I, II, VI-A, VI-B, VII-B, VIII

Legend for Food Contact Conditions:

- A Container is sterilized over 212 °F
- B Container is sterilized with boiling water
- C Container is hot filled or pasteurized above 150 °F
- D Container is hot filled or pasteurized below 150 °F
- E Room temperature filled and stored.
No thermal treatment in the container
- F Refrigerated storage. No thermal treatment in the container
- G Frozen storage. No thermal treatment in the container
- H Frozen or refrigerated storage. Ready-prepared foods intended to be reheated or microwaved in container at time of use

Legend for Food Types:

- I. Nonacid, aqueous products; may contain salt or sugar or both (pH above 5.0).
- II. Acid, aqueous products; may contain salt or sugar or both, and including oil-in-water emulsions of low or high fat content.
- III. Aqueous, acid or nonacid products containing free oil or fat; may contain salt and include water-in-oil emulsions of low or high fat content.
- IV. Dairy products and modifications:
 - A. Water-in-oil emulsions, high or low fat.
 - B. Oil-in-water emulsions, high or low fat.
- V. Low-moisture fats and oils.
- VI. Beverages:
 - A. Containing up to 8 percent alcohol.
 - B. Non-alcoholic.
 - C. Containing more than 8 percent alcohol.
- VII. Bakery products other than those included under Types VIII or IX of this table:
 - A. Moist bakery products with surface containing free fat or oil.
 - B. Moist bakery products with surface containing no free fat or oil.
- VIII. Dry solids with the surface containing no free fat or oil (no end test required).
- IX. Dry solids with the surface containing free fat or oil.

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