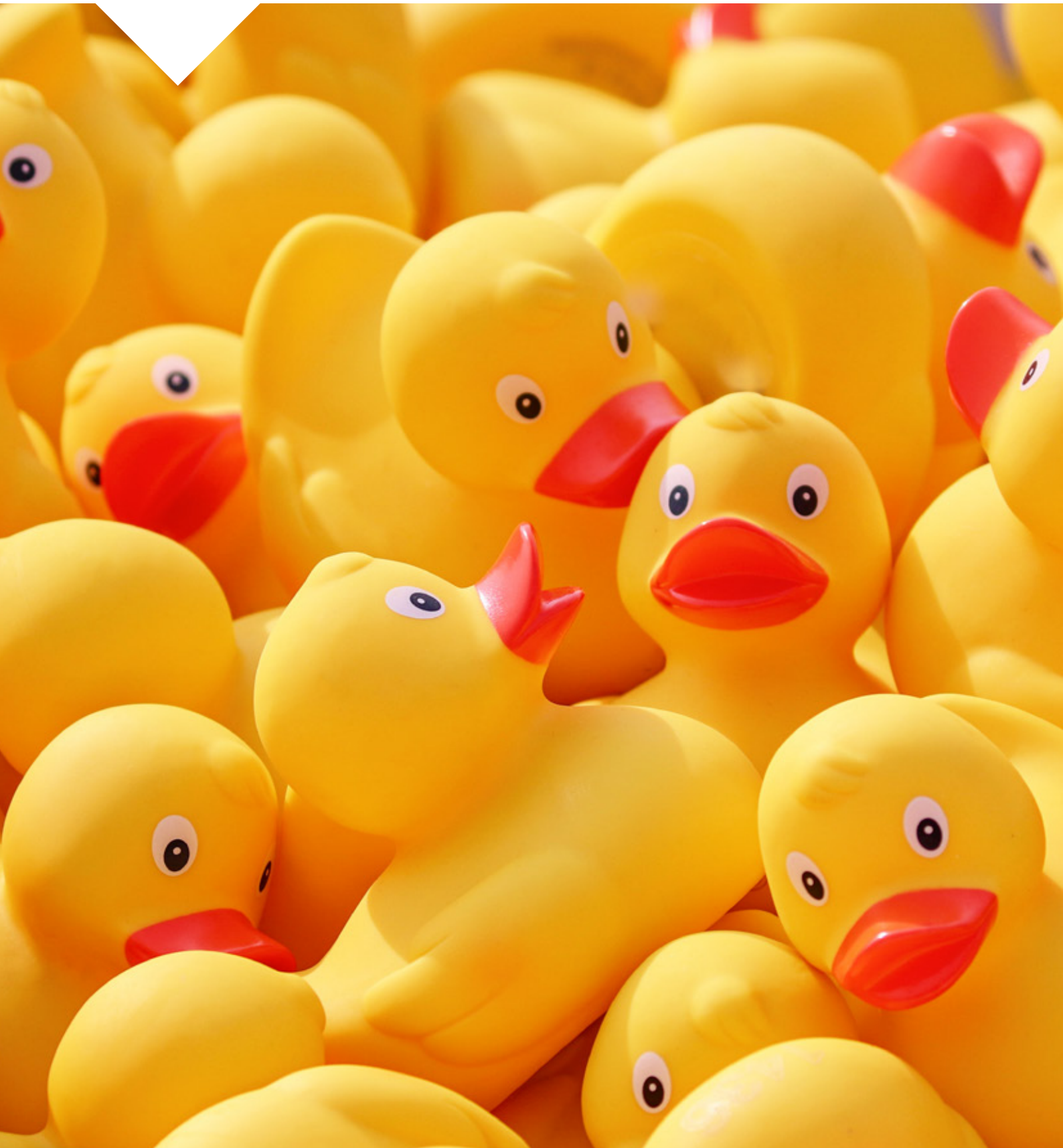


FDA-COMPLIANT PIGMENTS FOR LATEX DISPERSIONS



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FDA APPROVAL SUMMARY OF THE REGULATIONS

COMPLIANCE OVERVIEW

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

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.

REGULATED COLORANTS FOR POLYMERS

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. Hightemperature 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.



	NAME	CI NAME	UPPER CONCENTRATION IN FINISHED ARTICLE in % by weight
	PV FAST YELLOW H4G	PY 151	5
	VYNAMON YELLOW 118303	PY 183	3
	PV FAST ORANGE H2GL	PO 64	1
	PV FAST RED D3G	PR 254	1
	PV FAST RED E3B	PV 19	FDA-compliant color without limitations in 21 CFR 178.3297
	PV FAST RED E5B	PV 19	FDA-compliant color without limitations in 21 CFR 178.3297
	ULTRAZUR HGIN-62 R	PB 29	FDA-compliant color without limitations in 21 CFR 178.3297
	HOSTAPERM BLUE CBR	PB 15:0	FDA-compliant color without limitations in 21 CFR 178.3297
	PV FAST BLUE A2R	PB 15:1	FDA-compliant color without limitations in 21 CFR 178.3297
	PV FAST BLUE A4R	PB 15:1	2.7
	VYNAMON BLUE 515309	PB 15:3	FDA-compliant color without limitations in 21 CFR 178.3297
	PV FAST BLUE BG	PB 15:3	18
	PV FAST GREEN GNX	PG 07	FDA-compliant color without limitations in 21 CFR 178.3297





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Due to possible changes in our products and applicable national and international regulations and laws, the status of our products could change. Material Safety Data Sheets (MSDS) which include relevant safety precautions for handling and storage, are available upon request and are provided in accordance with applicable legal requirements. Users are advised to obtain and review the relevant MSDS prior to handling any product. Users shall bear sole responsibility for determining the suitability of our products for their intended applications whether or not the end application is known to us.

As the performance of colorants is influenced by factors like additives, polymers, and processing conditions, customers are strongly advised to conduct their own testing to verify suitability in end-use applications. Any deviation from recommended usage or processing conditions may adversely affect product performance and results. (Version 1/2026)

Caution: We offer a select range of colorants, some of which are designed to meet regulatory requirements for sensitive application areas such as cosmetics, personal care applications, food packaging materials, toys and others. In such sensitive applications, only products designated for these applications should be used. We do not recommend that any of our products are used in sensitive applications which may come in contact with internal body organs or body fluids. For additional information, please contact us. (Version 1/2026)

Color Reproduction: For technical reasons connected with color reproduction, the colors shown may not exactly match the pigment colors and do not represent a particular finish. (Version 1/2026)