

FOOD CONTACT SUBSTANCE NOTIFICATION
C.I. PIGMENT YELLOW 212; (1293)

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Section I: Environmental Assessment

1. **Date:** June 26, 2000.
2. **Name of sponsor:** Engelhard Corporation.
3. **Address:** Engelhard Corporation, Pigments and Additives Group, 3400 Banks St., Louisville, Kentucky 40212.
4. **Description of the proposed action:**
 - a. **Proposed Use:** Engelhard respectfully requests FDA to approve C.I. Pigment Yellow 212 for use as an indirect food additive for all polymers. It will be incorporated into the polymer(s) through a thermal extrusion process. The colored articles may include bottles, containers, jars, wrapping materials, etc., used in food packaging.
 - b. **Maximum Use Level of Pigment:** The pigment will be used at levels not to exceed 1.0%. The maximum thickness of the container will be 0.5 cm.
 - c. **Conditions of Use:** Based on the migration test results and the consumer exposure calculation, Engelhard is proposing that this pigment be approved for use in all polymers used to manufacture food-packaging articles for all food types as described in Table 1 of 21 CFR § 175.300(d) and § 176.170(c). In addition, Engelhard is proposing that this pigment be approved for all conditions of use A-H, as set forth in Table 2 of 21 CFR § 175.300(d) or § 176.170(c).
 - d. **Locations of Use:** The primary use of this pigment is in plastics manufacturing plants.

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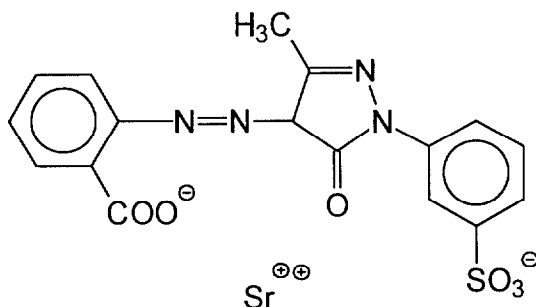
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- e. **Intended Physical Effect:** When incorporated in polymers, Engelhard's C.I. Pigment Yellow 212 will provide a bright yellowish color effect to food-packaging materials, i.e. bottles, containers, jars, wrapping materials, etc. This product will be used for decorative (physical) effects only.

5. Identification of the Food-contact substance:

- a. **Chemical Name:** Benzoic acid, 2-[(4,5-dihydro-3-methyl-5-oxo-1-(3-sulfophenyl)-1H-pyrazol-4-yl)azo]-, strontium salt (1:1)
- b. **CAS Registry Number:** 250640-73-4
- c. **Empirical and Structural Formula:**

C₁₇H₁₄N₄O₆S • Sr



- d. **Properties of the Pigment:** C.I. Pigment Yellow 212 is a yellow powder and is practically insoluble in water and organic solvents such as hydrocarbons and plasticizers. When dispersed in low-density polyethylene and other polymers, it produces a clean yellow appearance.

- **Melting Point:** Does not melt. Decomposes at 300°C.

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- Specific Gravity: 1.71
- Apparent Density: 3.2 Lbs./GAL
- pH 6.9
- Color: Yellow
- Form: Powder

6. Environmental consequences of the proposed action:

a. Production of the food contact substance: no need to provide information regarding the production of C.I. Pigment Yellow 212 because there are no extraordinary circumstances that pertain to its manufacture.

b. Use and disposal of the food contact substance: This action involves C.I. Pigment Yellow 212 that is a minor component of finished food-packaging materials present at 1.0% by weight of the finished packaging material and that remains with the packaging through its use by consumers. The principal routes of environmental introduction of C.I. Pigment Yellow 212 follow from the disposal of food packaging material containing it in municipal solid waste incinerators or in landfills. These disposal routes are governed by the US EPA regulations in 40 CFR Part 60 and Part 258, respectively. Based on the low levels of the food contact substance in the packaging material and the insignificant level of trace metals, the introduction of combustion products or introduction at landfill sites are not environmentally significant. Therefore, we do not expect that any limited increase in environmental introductions resulting from the proposed action will threaten a violation of EPA's regulations governing combustors and landfills or have any other adverse environmental effect.

7. Alternatives to the Proposed Action: There are no existing data established that suggests that this pigment would pose a significant risk to the environment. Therefore, alternatives to the proposed action need not be considered because no potential adverse effects have been identified.

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8. List of preparers:

Steven Camenisch,
Regulatory Services Manager
Chemistry, BS,

Amrit Bindra, Ph.D.
Senior Research Chemist
Chemistry, Ph.D.

- 9. Certification:** The undersigned official certifies that the information presented is true, accurate, and complete to the best knowledge of the ENGELHARD CORPORATION.

June 23, 2000



Steven C. Camenisch
Regulatory Services Manager

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