CAP 9C0264

NAME OF PETITIONER	INTERNATIONAL ASSOCIATION OF COLOR MANUFACTURERS
POST OFFICE ADDRESS	1620 I Street, N.W Suite 925 Washington, DC 20006 (202)-293-5800
DATE:	30 September 1998
NAME OF COLOR ADDITIVE AND PROPOSED USE:	FD&C Red No. 28 FD&C Red No. 28 Aluminum Lake For general use in food

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NAME AND ALL PERTINENT INFORMATION CONCERNING

THE COLOR ADDITIVE

SECTION A

1. FD&C Red No. 28

a. The color additive FD&C Red No. 28 is principally the disodium salt of 2',4',5',7' tetrabromo-4,5,6,7-tetrachlorofluorescein (CAS Reg. No. 18472-87-2).

b. Synonyms

FD&C Red No. 28	Phloxine B
	C.I. No. 45410 (Na Salt)
	C.I. Acid Red 92

c. Physical Properties. FD&C Red No. 28 is a blue-pink dye of the Xanthene class. It is soluble in water, alcohols and glycerin

d. Chemical Properties.

1 Empirical Formula.

FD&C Red No. 28 - $C_{20}H_2O_5Br_4Cl_4Na_2$

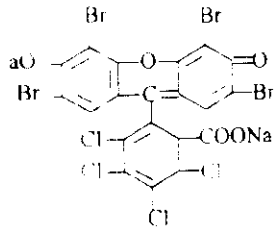
2 Molecular Weight.

FD&C Red No. 28 - 839.64 g/mol

Throughout this petition we refer to D&C No. 28 as FD&C Red No. 28 on the assumption that this will be the name of the compound once approved for use in foods.

2. Structural Formula

FD&C Red No. 28



a. Proposed Specifications. The color additive FD&C Red No. 28 shall conform to the following specifications and shall be free from impurities other than those named to the extent that such other impurities may be avoided by current good manufacturing practice. These specifications are identical to those found at 21 C.F.R § 74.1328, except for the addition of the specification for Hexachlorobenzene and the proposed reduction in the specification of Lead from 20 parts per million to 5 parts per million.

FD&C Red No. 28.

Sum of volatile matter (at 135° C), halides and sulfates (calculated as sodium salts), not more than 15 percent.

Insoluble matter (alkaline solution), not more than 0.5 percent.

Tetrachlorophthalic acid, not more than 1.2 percent.

Brominated resorcinol, not more than 0.4 percent.

2,3,4,5-Tetracloro-6-(3,5-dibromo-2,4-dihydroxybenzoyl) benzoic acid, not more than 0.7 percent

2',4',5',7'-Tetrabromo-4,5,6,7-tetrachloroflourescein, ethyl ester, not more than 2 percent

Lower halogenated subsidiary colors, not more than 4 percent.

Hexachlorobenzene (as HCB), not more than 20 parts per million.

Lead (as Pb), not more than 5 parts per million.

Arsenic (as As), not more than 3 parts per million.

Mercury (as Hg), not more than 1 part per million.

Total color, not less than 85 percent

b. Chemical and Physical Methods of Analysis. Methods of analysis developed by the Division of Color Technology for the certification of D&C Red No. 28 are adequate for analysis of FD&C Red No. 28.