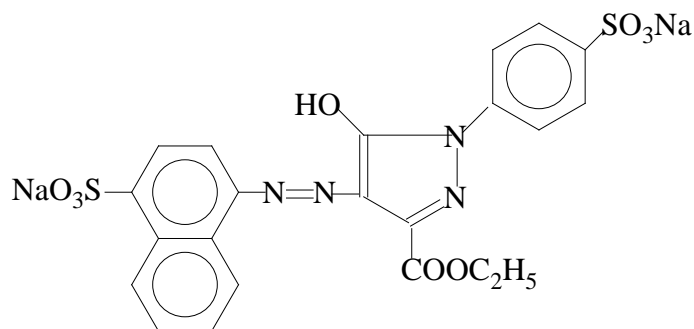


Color Additives Monographs

Orange B

Structure



Chemical Formula: C₂₂H₁₆N₄O₉S₂ • 2Na
Molecular Weight: 590.49

Synonyms

Acid Orange 137

Identifiers

CAS No. 53060-70-1
EEC No. None
C.I. No. 19235

Physical Properties

Orange B is principally the disodium salt of 1-(4-sulfophenyl)-3-ethyl-carboxy-4-(4-sulfonaphthylazo)-5-hydroxy-pyrazole.

Dye Classification: Pyrazolone

Manufacturing Process : React phenylhydrazine-p-sulfonic acid with the sodium derivative of diethyl hydroxylmaleate; partially hydrolyze to remove one ethyl group; then couple with diazotized naphthionic acid.

USFDA Specifications

Orange B shall conform to the following specifications (21 CFR 74.250):

- Volatile matter (at 135 ° C), not more than 6.0 percent.
- Chlorides and sulfates (calculated as the sodium salts), not more than 7.0 percent.
- Water insoluble matter, not more than 0.2 percent.
- 1-(4-Sulfophenyl)-3-ethylcarboxy-5-hydroxypyrazolone and 1-(4-sulfophenyl)-3-carboxy-5-hydroxypyrazolone , not more than 0.7 percent.
- Naphthionic acid, not more than 0.2 percent.
- Phenylhydrazine-p-sulfonic acid, not more than 0.2 percent.
- The trisodium salt of 1-(4-sulfophenyl)-3-carboxy-4-(4-sulfonaphthylazo)-5-hydroxypyrazole, not more than 6.0 percent.
- Other subsidiary dyes, not more than 1.0 percent.
- Lead (as Pb), not more than 10 parts per million.
- Arsenic (as As), not more than 1 part per million.
- Total color, not less than 87.0 percent.

Regulatory Approvals/Consumption Limits

JECFANo information Available

EEC No information Available

USA Orange B may be safely used for coloring the casings or surfaces of frankfurters and sausages subject to the restrictions that the quantity of the color additive does not exceed 150 parts per million by weight of the finished food.

Common Uses

Orange B is used for coloring the casings or surfaces of frankfurters and sausages at a level not exceeding 150 ppm by weight of the finished food.

Safety Reviews

The International Agency for Research on Cancer (IARC) and the Joint FAO/WHO Expert Committee on Food Additives (JECFA) have not reviewed Orange B.

Safety Assessment

Genotoxicity

Orange B was not mutagenic in the *Salmonella*/microsome (rat liver) tests using aerobic or anaerobic conditions (Brown *et al.*, 1978). However *p*-naphthylamine, a metabolite of Orange B was carcinogenic and mutagenic in a *Salmonella*/microsome test (McCann *et al.*, 1975).

Reproductive/Developmental Toxicity

No effects upon any of the maternal (body weight, corpora lutea, empty implantation sites, early resorption, late resorptions, and live or dead fetuses) or fetal parameters (mean body weight, sex, external, internal and skeletal abnormalities) evaluated were seen when orange B was administered to pregnant rats and rabbits *via* gavage at dose levels of 50, 150, or 500 mg/kg/bw on days 6-15 and 6-18 of gestation, respectively (IRDC, 1973a; IRDC, 1973 b).

In a multigeneration reproduction study in which orange B was fed to rats at dosage levels of 5, 50, 150 & 500 mg/kg/day, no compound related adverse effects were observed in parental rats or pups (IRDC, 1974).

NO DATA AVAILABLE ON: Acute/Short-term toxicity, Metabolism/ Pharmacodynamics, or long-term toxicity/carcinogenicity.

REFERENCES

Brown J.P., Roehm G.W., and Brown, R.J. (1978) Mutagenicity testing of certified food colors and related azo, xanthene and triphenylmethane dyes with the *Salmonella*/microsome system. *Mutation Research* **56**, 249-271.

International Research and Development Corporation (IRDC) (1973a) Teratology study in rats. Unpublished Report. Project no. 306-004A.

International Research and Development Corporation (1973b) Teratology study in rabbits. Unpublished Report. Project no. 306-003A.

International Research and Development Corporation (1974) Multigeneration reproduction study in rats. Unpublished Report. Project no. 306-012.

McCann J., Choi E., Yamasaki E., and Ames B.N. (1975) Detection of carcinogens as mutagens in the *Salmonella*/microsome test: Assay of 300 chemicals. *Medical Sciences* **72**, 5135.