

40 CFR Part 799

[OPTS-420473; FRL-2945-2]

**Quinone; Withdrawal of Proposed Rule**

**AGENCY:** Environmental Protection Agency (EPA).

**ACTION:** Withdrawal of proposed rule.

**SUMMARY:** This document withdraws a proposed rulemaking to test quinone (*p*-Benzoquinone, CAS No. 106-51-4) for certain health and environmental effects under the Toxic Substances Control Act. Comments and data received in

response to the proposal indicate that human and environmental exposure to quinone are so small as to be unlikely to present an unreasonable risk to humans or to the environment.

**FOR FURTHER INFORMATION CONTACT:** Edward A. Klein, Director, TSCA Assistance Office (TS-799), Office of Toxic Substances Environmental Protection Agency, Rm. E-543, 401 M St., SW., Washington, DC 20460. Toll free: (800-424-9065). In Washington, DC: (554-1404). Outside the USA: (Operator-202-554-1404).

**SUPPLEMENTARY INFORMATION:** EPA has decided to withdraw the proposed rulemaking for health and environmental effects testing of quinone.

**I. Background**

Section 4(a) of the Toxic Substances Control Act (TSCA) (Pub. L. 94-469, 90 Stat. 2006 *et seq.*; 15 U.S.C. 2603 *et seq.*) authorizes the Administrator of EPA to promulgate rules which require manufacturers and processors to test chemical substances and mixtures. Data developed through these test programs are used by EPA in assessing the risks that the chemicals may present to health and the environment.

Section 4(e) of TSCA established the Interagency Testing Committee (ITC) to recommend chemical substances or mixtures for priority testing consideration by EPA under section 4(a) of the Act. The ITC designated quinone (CAS No. 106-51-4) for priority consideration in its fifth Report, published in the Federal Register on December 7, 1979 (44 FR 70664). The ITC based its recommendation for carcinogenicity and teratogenicity testing on its belief that there was potentially high exposure of humans to quinone in manufacturing and processing operations.

The ITC also recommended environmental fate testing for quinone because, if released to the environment, it would possibly form a potentially stable oxidation/reduction system involving hydroquinone and a theoretical intermediate, semiquinone.

EPA's response to this designation was published in the Federal Register on January 4, 1984 (49 FR 456) as a proposed rule on quinone. EPA proposed that the following tests be performed on quinone by industry.

**PROPOSED TESTING**

	ITC recommendation	EPA proposal
Health effects:		
Teratology	x	
Carcinogenicity		x

**PROPOSED TESTING—Continued**

	ITC recommendation	EPA proposal
Environmental fate	x	x
Environmental effects		x

EPA did not propose teratogenicity testing of quinone; there were no data providing evidence under TSCA section 4(a)(1)(A) for the potential unreasonable risk of teratogenic effects.

**II. EPA's Response to Public Comments**

The Agency received comments from the Eastman Kodak Company, the National Association of Photographic Manufacturers, and from the Chemical Manufacturer's Association (CMA). The Tennessee Eastman Company, a subsidiary of Eastman Kodak, is the sole producer of quinone in the U.S.

EPA reported in the proposed rule, based on the EPA Toxic Substances Inventory, that from 100,000 to 1,000,000 pounds of quinone were produced in the United States in 1977. Kodak has reported that in 1983 they produced 170,000 pounds of isolated quinone as a water-wet, crystalline solid product (Refs. 1 and 3). The bulk of the quinone produced, greater than 98 percent, is not part of this portion that is isolated. It remains nonisolated in the process equipment for quinone's primary use, which is as an intermediate in the production of hydroquinone.

The major comments from the industry focused on the small number of people (less than 50) involved in the production of quinone and the low exposure levels. Kodak reports that "in the last 15 years, the highest average airborne concentration of hydroquinone and quinone ever monitored in the manufacturing workplace was 0.2 mg/m<sup>3</sup>". They added that, because the method measures total hydroquinone and quinone, the average concentration of quinone is actually lower (Ref. 1). These are summary data provided by industry; EPA is unable to interpret these further since frequency, averaging time and other supporting documentation were not provided.

Eastman Kodak also commented that they have developed a new manufacturing process for hydroquinone which does not involve the production of quinone as an intermediate (Ref. 4). Because the production of hydroquinone will no longer involve quinone in an intermediate step, the overall production of quinone is expected to decline.

Exposure to quinone through its minor uses is expected to be negligible. As an in-process polymerization inhibitor, it is

added during vinyl monomer manufacture at levels of 500 to 2,000 ppm; after distillations to produce the purified vinyl monomer, quinone and its decomposition products remain in the still bottoms (Ref. 1). Quinone is also used to stabilize unsaturated polyester resins against undesired crosslinking during manufacture, shipment and storage. Formulations, typically containing about 500 ppm quinone, are sold to fabricators who add other chemicals to form plastic products. Although low levels of quinone are incorporated into the fabricated articles (Ref. 1), EPA does not expect migration and release of quinone. Kodak's 1983 isolated quinone production volume was 170,000 pounds, of which approximately one-third was for a company-limited use (Ref. 1).

Quinone is not currently used in the photographic developing trade (Refs. 1 and 2).

### III. Decision Not To Require Testing

EPA has decided not to promulgate a rule to require the testing proposed for this substance, for the reasons stated below.

#### A. Health Effects

Oncogenicity was the only health effect for which testing was proposed in the January 4, 1984 notice. Kodak commented that their scientific analysis, provided by Dr. Robert Squire, indicates that EPA based its proposed testing on two flawed studies. Dr. Squire commented that the papers by Takizawa and Kanizawa (Ref. 5) and Otsu (Ref. 6) were flawed by improper methodologies; they do not provide for an accurate assessment of the effects, by current standards, or even when applying standards typical when the papers were published (Ref. 7). While EPA does believe the two studies in question provide some suggestive evidence, the Agency agrees with the commenters that the flawed nature of the studies detracts from their credibility.

Kodak also points out that there is little potential for human exposure, with the highest air sample recorded as 0.2 mg/m<sup>3</sup> and the fact that there are less than 50 workers employed by Kodak who manufacture of process quinone.

Given the small number of people exposed, the low levels of exposure and the lack of credible data, EPA has determined that a section 4(a)(1)(A) finding cannot be supported.

Therefore, EPA is withdrawing the rule for carcinogenicity testing of quinone.

#### B. Chemical Fate and Environmental Effects

EPA is withdrawing the proposal to require chemical fate and environmental effects studies for quinone. After considering the comments and new data, the Agency has decided that a section 4(a)(1)(A) finding for this substance cannot be supported.

In the proposed rule the Agency stated that it believed that hydroquinone is released to surface waters from photoprocessing operations and that a substantial portion of this material is converted to quinone. These levels were believed to possibly pose an unreasonable risk to freshwater and saltwater aquatic species.

After review of the comments provided by CMA, Kodak, and Goodyear and examination of additional monitoring data, EPA now believes that any releases of hydroquinone are very limited (<5µg/L) and, accordingly, any quinone formed from the oxidation of hydroquinone would also be extremely low levels. A more complete discussion of this issue appears elsewhere in this issue of the Federal Register in the final test rule for hydroquinone [OPTS-42048B].

#### IV. Public Record

EPA has established a public record for this decision not to pursue section 4 testing [docket number OPTS-42047]. This record includes:

##### A. Supporting Documentation

- (1) Federal Register notice of the ITC designation of quinone to the priority list (44 FR 70684).
- (2) Communications consisting of:
  - (a) Written public comments.
  - (b) Summaries of telephone conversations.
  - (c) Meeting summaries.
  - (d) Reports—published and unpublished factual materials, including contractors reports.
- (3) Federal Register notice of the proposed test rule on quinone. (49 FR 456, January 4, 1984).
- (4) Federal Register notice on quinone announcing the final decision not to require testing.

##### B. References

- (1) Chemical Manufacturer's Association. Comments on EPA's proposed rule for quinone. April 10, 1984.
- (2) National Association of Photographic Manufacturer's, Inc. Comments of NAPM on Hydroquinone/Quinone Proposed Test Rules. April 8, 1984.

(3) Eastman Kodak Company. "Comments by Eastman Kodak Company on EPA's Proposed Test Rules: Hydroquinone, 49 FR 438 and Quinone, 49 FR 456." April 10, 1984.

(4) Eastman Kodak. Letter to Gary Tim. Test Rules Development Branch. Aug 1984.

(5) Takizawa, E., Kanizawa S. "Experimental induction of pulmonary carcinoma." *Jpn. J. Cancer Clin.* 9:172-173, 1963.

(6) Otsu H. "The study of the malignant changes of bronchial epithelial cells in mice induced by the inhalation of parabenzquinone." *J. Chiba Med. Soc.* 46:461-472, 1970.

(7) Chemical Manufacturer's Association. Testimony of the Program Panel on Hydroquinone/Quinone before the Environmental Protection Agency. Washington, DC. April 18, 1984.

This record, which includes the basic information considered by the Agency in developing this decision, is available for inspection from 8 a.m. to 4 p.m. Monday through Friday except legal holidays in Rm. E-107, 401 M St., SW., Washington, DC 20460. The Agency will supplement the record with additional relevant information as it is received.

#### PART 779—[AMENDED]

Therefore, the proposal to add § 779.3600 to 40 CFR Part 799 is hereby withdrawn.

Authority: 15 U.S.C. 2503.

Dated: December 20, 1985.

J.A. Moore,

Assistant Administrator for Pesticides and Toxic Substances.

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