ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 799

[OPPTS-42134F; FRL-4924-7]

RIN 2070-2033

Revocation of Final Multi-substance Rule for the Testing of Neurotoxicity

AGENCY: Environmental Protection

Agency (EPA).

ACTION: Final Rule Revocation.

SUMMARY: This document announces EPA's decision to revoke the Multi-Substance Rule for the Testing of Neurotoxicity, that required manufacturers and processors of acetone (CAS No. 67-64-1), technical grade namyl acetate (CAS No. 628-63-7), 1butanol (CAS No. 71-36-3), n-butyl acetate (CAS No. 123-86-4), diethyl ether (CAS No. 60-29-7), 2ethoxyethanol (CAS No. 110-80-5), ethyl acetate (CAS No. 141-78-6), isobutyl alcohol (CAS No. 78-83-1), methyl isobutyl ketone (CAS No. 108-10-1), and tetrahydrofuran (CAS No. 109–99–9) to conduct testing for neurotoxicity. EPA is revoking this rule as part of a settlement agreement reached with the manufacturers of these chemicals, who have agreed to perform certain neurotoxicity and in vivo hydrolysis testing of 7 of the 10 chemicals under enforceable consent agreements ("ECAs").

EFFECTIVE DATE: January 23, 1995.

ADDRESSES: A public version of the administrative record supporting this action, with any confidential business information deleted, is available for inspection at the TSCA Nonconfidential Information Center, also known as the TSCA Public Docket Office (7407), Rm. NE B607, Office of Pollution Prevention and Toxics, Environmental Protection Agency, 401 M St., SW., Washington, DC 20460 from 12 noon to 4:00 p.m. Monday through Friday, except legal holidays.

FOR FURTHER INFORMATION CONTACT:

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SUPPLEMENTARY INFORMATION: EPA has determined that it is appropriate to revoke the multi-substance rule for the testing of neurotoxicity because the manufacturers of 7 of the 10 chemicals

subject to the final test rule have agreed to conduct a modified set of neurotoxicity and in vivo hydrolysis testing under ECAs that accomplish many of the goals of the test rule. The following seven chemical substances will be tested pursuant to ECAs: acetone (CAS No. 67-64-1), technical grade n-1amyl acetate (CAS No. 628-63-7), nbutyl acetate (CAS No. 123-86-4), ethyl acetate (CAS No. 141-78-6), isobutyl alcohol (CAS No. 78-83-1), methyl isobutyl ketone (CAS No. 108-10-1), and tetrahydrofuran (CAS No. 109-99-9). Testing is currently underway for *n*butyl acetate and isobutyl alcohol. In vivo hydrolysis testing will be conducted on butyl acetate to determine if its test results for neurotoxicity can be used to assess the neurotoxicity of its metabolite, 1-butanol.

I. Background

On July 27, 1993 (58 FR 40262) EPA issued a test rule under TSCA section 4 that required manufacturers and processors of 10 substances to conduct testing for neurotoxicity (Ref. 1). The test rule required all the testing proposed for the 10 substances on March 4, 1991 (56 FR 9105). The required testing was the same for all 10 substances and included acute and subchronic functional observational battery and motor activity, and subchronic neuropathology and schedule-controlled operant behavior (SCOB). These 10 substances are listed below:

Chemical name	CAS No.
acetone	67–64–1
n-amyl acetate, technical grade	628–63–7
1-butanol	71–36–3
n-butyl acetate	123–86–4
diethyl ether	60–29–7
2-ethoxyethanol	110–80–5
ethyl acetate	141–78–6
isobutyl alcohol	78–83–1
methyl isobutyl ketone	108–10–1
tetrahydrofuran	109–99–9
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The manufacturers of these substances petitioned for review of the final rule under TSCA section 19 in the Fifth Circuit Court of Appeals (Ref. 2). Subsequent to the filing of this challenge to the rule, EPA, the Chemical Manufacturers Association ("CMA"),

and authorized representatives of all parties challenging the rule, entered into settlement negotiations to resolve the lawsuit.

As a result of these settlement discussions, the parties to the lawsuit agreed, subject to certain conditions set forth in the settlement agreement (Ref. 3), to conduct neurotoxicity and *in vivo* hydrolysis testing of 7 chemical substances under ECAs to be negotiated pursuant to EPA regulations. Testing on two of the chemicals subject to the final rule, *n*-butyl acetate and isobutyl alcohol, was already underway. It was CMA's and the test sponsors stated intent that such testing continue on schedule during the pendency of this proceeding (Ref. 3).

In turn, EPA agreed to propose to withdraw the final test rule. EPA was aware that the settlement agreement contemplated testing fewer chemicals and a reduced set of testing on some of those chemicals than the testing regimen required by the final rule. Although EPA believed that the rulemaking record contained substantial evidence to support the testing requirements in the final rule, EPA believed that the settlement agreement was in the public interest as it allowed testing to proceed on an expedited basis, without the uncertainties of protracted litigation. CMA's lawsuit was dismissed without prejudice by the 5th Circuit Court of Appeals on May 13, 1994, in response to a joint motion for a stay, but it can be reinstated by either party upon filing of a letter with the court (Ref. 4).

On June 27, 1994, EPA published three notices in the Federal Register: a Stay of the final test rule (59 FR 33184), a proposal to revoke the final test rule (59 FR 33187), and an announcement of a public meeting to initiate negotiation of consent agreement testing (59 FR 33191). The Stay suspended all requirements of the final test rule until EPA either lifted the Stay or revoked the test rule. Final revocation of the test rule was conditional on the successful negotiation of testing to be performed under ECAs. The public meeting announcement solicited interested parties to participate in the negotiation and/or observation of negotiations. On July 28, 1994, EPA held the public meeting to initiate the negotiations. The ECAs which resulted were signed in November 1994 and January 1995 and required the neurotoxicity and in vivo hydrolysis testing of the following 7 substances: