

employees, within the District Counsel's jurisdiction. The District Counsel shall be guided by the interpretations of the DAEO on the pertinent law, executive orders, and regulations. In case of doubt regarding any question, or disagreement of interpretation between District Counsel and employee or former employees, or novel questions of broad application within VA, the District Counsel may submit the matter for consideration by the DAEO.

§ 0.735-7 Financial disclosure.

The DAEO shall administer the public financial disclosure program within the Department of Veterans Affairs. The DAEO shall administer the confidential financial disclosure program, and distribute, collect, review, certify and retain the confidential financial disclosure reports of Central Office employees. The District Counsel shall distribute, collect, review, certify and retain confidential financial disclosure reports for employees whose duty station is within their geographic jurisdiction. The DAEO and District Counsel shall maintain records and reports of the financial disclosure system(s) within their responsibility.

§ 0.735-8 Violation of regulations.

Violation of the regulations in this part by an employee may be cause for appropriate disciplinary action which may be in addition to any penalty prescribed by law.

3. Subpart B is revised to read as follows:

Subpart B—Standards of Ethical Conduct and Related Responsibilities of Employees

Sec.

0.735-10 Cross-reference to employee ethical and other conduct standards and financial disclosure regulations.

0.735-11 Other conduct on the job.

0.735-12 Standards of conduct in special areas.

Subpart B—Standards of Ethical Conduct and Related Responsibilities of Employees

§ 0.735-10 Cross-reference to employee ethical and other conduct standards and financial disclosure regulations.

Employees of the Department of Veterans Affairs (VA) should refer to the executive branch-wide Standards of Ethical Conduct at 5 CFR part 2635, the executive branch-wide Employee Responsibilities and Conduct at 5 CFR part 735, and the executive branch-wide financial disclosure regulation at 5 CFR part 2634.

§ 0.735-11 Other conduct on the job.

Relationship with beneficiaries and claimants. Employees are expected to be

helpful to beneficiaries, patients and claimants, but:

(a) An employee shall not procure intoxicants or drugs for, or attempt to sell intoxicants or drugs to, patients or members, or give or attempt to give intoxicants or drugs to them unless officially prescribed for medical use;

(b) An employee shall not abuse patients, members, or other beneficiaries, whether or not provoked.

§ 0.735-12 Standards of conduct in special areas.

(a) *Safety.* (1) Employees will observe safety instructions, signs, and normal safety practices and precautions, including the use of protective clothing and equipment.

(2) An employee shall report each work-connected injury, accident or disease he or she suffers.

(b) *Furnishing testimony.* Employees will furnish information and testify freely and honestly in cases respecting employment and disciplinary matters. Refusal to testify, concealment of material facts, or willfully inaccurate testimony in connection with an investigation or hearing may be ground for disciplinary action. An employee, however, will not be required to give testimony against himself or herself in any matter in which there is indication that he or she may be or is involved in a violation of law wherein there is a possibility of self-incrimination.

Subparts C and D [Removed]

4. Subparts C and D are removed.

[FR Doc. 93-27912 Filed 11-22-93; 8:45 am]

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ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 799

[OFPPTS-42114B; FRL-4648-1]

RIN 2070-AB94

Testing Consent Agreement for N-methylpyrrolidone

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final Consent Agreement.

SUMMARY: EPA has signed an Enforceable Consent Agreement (ECA) pursuant to the Toxic Substances Control Act (TSCA), 15 U.S.C. 2601 et seq., with Arco Chemical Company, BASF Corporation, and International Specialty Products Company, hereinafter, "the Companies" who have agreed to perform certain health effects

tests with *n*-methylpyrrolidone (CAS No. 872-50-4) (NMP). This document summarizes the ECA and amends 40 CFR 799.5000 by adding NMP to the list of chemical substances and mixtures subject to ECA's. Accordingly, the export notification requirements of 40 CFR part 707 apply to NMP.

EFFECTIVE DATE: November 23, 1993.

FOR FURTHER INFORMATION CONTACT: Susan B. Hazen, Director, Environmental Assistance Division (7408), Office of Pollution Prevention and Toxics, Rm. E-543B, 401 M St., SW., Washington, DC 20460. (202) 554-1404, TDD (202) 554-0551.

SUPPLEMENTARY INFORMATION: This document amends 40 CFR 799.5000 by adding NMP to the list of chemical substances and mixtures subject to ECAs and export notification requirements.

I. Background

NMP is a possible substitute for methylene chloride for use in paint stripper formulations. Its annual production volume exceeds 55 million pounds. Approximately 2.7 million consumers and more than 71,000 workers may be exposed to NMP.

On March 28, 1990 (55 FR 11398), EPA issued a Notice of Proposed Rulemaking, proposing that NMP manufacturers test NMP for oncogenicity, mutagenicity, developmental and reproductive toxicity, neurotoxicity, and subchronic toxicity. EPA deferred proposing pharmacokinetics testing in the NMP proposed rule because a test guideline for pharmacokinetics was not yet available. The NMP proposed test rule contained a chemical profile of NMP, a discussion of EPA's TSCA section 4(a) findings, and the proposed test standards and reporting requirements.

In addition, in the *Federal Register* of July 15, 1991 (56 FR 32292) EPA reopened the comment period on NMP to permit further comment in relation to EPA's proposed statement of policy for interpreting its legal authority to make TSCA section 4(a)(1)(B) findings.

After EPA issued the Notice of Proposed Rulemaking for NMP, it received data adequate for evaluating the potential mutagenicity and developmental and reproductive toxicity effects of NMP.

On January 29, 1992 EPA's Office of Pollution Prevention and Toxics placed NMP into risk management evaluation after an initial review of the data. On April 15, 1992, EPA informed the NMP manufacturers by letter that it was concerned that there is a potential for adverse health effects on reproduction

and development to persons exposed to NMP. In that letter, EPA also requested additional exposure information, industrial hygiene information, and historical control data not submitted with the reproductive toxicity study.

In response to EPA's April 15, 1992 letter, on May 20, 1992 and June 22, 1992 the manufacturers submitted additional information on use and exposure, glove permeability, on-going testing, and product stewardship.

II. Enforceable Consent Agreement Negotiations

EPA published a **Federal Register Notice** (57 FR 31714; July 17, 1992) announcing an "open season." The "open season" was a time during which manufacturers could submit to EPA proposals for testing chemical substances which had been proposed for testing by EPA but had not been subject to a final test rule. In that notice, EPA indicated that it would review the submissions and select candidates for negotiation of enforceable consent agreements (ECA) pursuant to 40 CFR part 790. EPA also indicated that it would later publish a **Federal Register notice** soliciting persons interested in

participating in or monitoring negotiations for the development of consent agreements on the chemicals selected.

On September 11, 1992, the Synthetic Organic Chemical Manufacturers Association (SOCMA) on behalf of "The Companies" submitted a proposal for testing NMP under an ECA. On October 30, 1992, SOCMA sent EPA another letter that added a 2-year oncogenicity bioassay to their testing proposal.

EPA published a **Federal Register notice** (59 FR 16669; March 30, 1993) announcing candidates selected for consent order negotiations and requesting that interested parties identify themselves to EPA. The notice established EPA's priority for initiating negotiations on the chemicals selected, and because the proposal submitted by SOCMA was similar to the testing proposed in EPA's proposed test rule, NMP was among the chemicals assigned a high priority. This **Federal Register notice** also announced a tentative date for starting negotiations on NMP and the other high priority chemicals.

EPA met with identified interested parties, on April 28, 1993 to discuss the testing proposal submitted. EPA

conducted subsequent negotiations by letter. Once EPA determined that consensus had been reached it provided a final ECA to the Companies for signature.

The Companies signed the ECA on September 9, 1993, and the Assistant Administrator for EPA's Office of Prevention, Pesticides, and Toxic Substances signed the ECA on November 15, 1993. Because EPA has determined that the data submitted for mutagenicity, developmental, and reproductive toxicity testing required in the proposed test rule is adequate, the final ECA does not require testing for those end points. This ECA is a final action by EPA on NMP; therefore, the NMP proposed test rule will not be adopted as final.

III. Testing Program

The following Table 1 describes the tests, the test standards, and reporting requirements for NMP under the ECA. This testing program will allow EPA to further characterize the potential health hazards resulting from exposure to NMP.

TABLE 1.—REQUIRED TESTING, TEST STANDARDS AND REPORTING REQUIREMENTS FOR NMP

Description of Tests	Test Standard (40 CFR citation)	Deadline for Final Report ¹ (Months)	Interim Reports ² Required Number
Pharmacokinetics; oral, dermal ³ , inhalation, and intravenous routes.	795.232 as amended (Appendix I)	15	2
28 day subchronic toxicity range finding study	OECD guideline #407 (adopted in 1981) (Appendix II).	6	0
90 day subchronic toxicity range finding study	798.2650 as amended (Appendix III)	24	3
Functional Observation Battery: subchronic	798.6050 as amended (Appendix IV)	24	3
Motor Activity Test: subchronic	798.6200 as amended (Appendix V)	24	3
Neuropathology: subchronic	798.6400 as amended (Appendix VI)	24	3
Oncogenicity in the mouse and rat administered orally	798.3300 as amended (Appendix VII)	72	12

¹ Number of months after the effective date of the consent order. This reporting requirement includes 19 months for obtaining information from the 28- and 90-day range finding and pharmacokinetics studies.

² Interim reports are required every 6 months from the effective date until the final report is submitted. This column shows the number of interim reports required for each test.

³ The dermal pharmacokinetics consists of a single administration, low dose, dermal exposure group.

IV. Export Notification

The issuance of the ECA subjects any persons who export or intend to export the chemical substance, NMP (CAS No. 872-50-4), of any purity, to the export notification requirements of section 12(b) of TSCA. The listing of the chemical substance at 40 CFR 799.5000 serves as a notification to persons who export or intend to export a chemical substance or mixture that is the subject of an ECA that 40 CFR part 707 applies.

V. Public Record

A. Supporting Documentation

EPA has established a record for this ECA under docket number OPPTS-42114B, which is available for inspection Monday through Friday, excluding legal holidays, in the TSCA Nonconfidential Information Center, East Tower, rm. G-102, 401 M St., SW., Washington, DC 20460 from 8 a.m. to 12 noon and from 1 p.m. to 4 p.m. Information claimed as Confidential Business Information (CBI), while part of the record, is not available for public

review. This record contains the basic information considered in developing this Consent Order, and includes the following information:

- (1) Testing Consent Agreement for NMP and associated testing protocols attached as appendices.
- (2) **Federal Register** notices pertaining to this notice and consent order consisting of:
 - (a) Notice of Proposed Rulemaking for N-methylpyrrolidone, (March 28, 1990, 55 FR 11398)
 - (b) Notice announcing opportunity to initiate Negotiations for TSCA Section 4

Testing Consent Agreements (July 17, 1992, 57 FR 31714)

(c) Notice announcing Testing Consent Agreement Development for Tier I Chemical Substances; Solicitation for Interested Parties (March 30, 1993, 58 FR 16669)

(3) Communications consisting of:

(a) Written Letters.

(b) Contact reports of telephone summaries.

(c) Meeting summaries.

(4) Reports - published and unpublished factual materials.

VI. Regulatory Assessment Requirements

The Office of Management and Budget (OMB) has approved the information collection requirements contained in the Consent Agreement under the provisions of the Paperwork Reduction Act of 1980, 44 U.S.C. 3501 *et seq.*, and has assigned OMB control 2070-0033.

Public reporting burden for this collection of information is estimated to average 586 hours per response. The estimates include time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information.

Send comments regarding the burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden, to Chief, Information Policy Branch, 2131, U.S. Environmental Protection Agency, 401 M St., SW., Washington, DC 20460; and to the Office of Management and Budget, Paperwork Reduction Project (2070-0033), Washington, DC 20503.

List of Subjects in 40 CFR Part 799

Environmental protection, Chemicals, Chemical export, Hazardous substances, Health effects, Laboratories, Reporting and recordkeeping requirements, Testing.

Dated: November 15, 1993.

Victor J. Kimm,

Acting Assistant Administrator for Prevention, Pesticides and Toxic Substances.

Therefore, 40 CFR chapter I, part 799 is amended as follows:

PART 799—[AMENDED]

1. The authority citation for part 799 continues to read as follows:

Authority: 15 U.S.C. 2603, 2611, 2625.

2. Section 799.5000 is amended by revising the section heading to read as set forth below and by adding *N*-methylpyrrolidone to the table in CAS Number order, to read as follows:

§ 799.5000 Testing Consent Agreements for Substances and Mixtures with Chemical Abstract Service Registry Numbers.

* * * * *

CAS Number	Substance or mixture name	Testing	FR Publication Date
872-50-4	<i>N</i> -methylpyrrolidone	Health effects	November 23, 1993

[FR Doc. 93-28734 Filed 11-22-93; 8:45 am]
BILLING CODE 6560-50-F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Care Financing Administration

42 CFR Parts 401, 488 and 489

[HSQ-159-F]

RIN 0938-AF17

Medicare Program; Granting and Withdrawal of Deeming Authority to National Accreditation Organizations

AGENCY: Health Care Financing Administration (HCFA), HHS.

ACTION: Final rule.

SUMMARY: This rule implements section 1865(a) of the Social Security Act, as amended by sections 2345 and 2346 of the Deficit Reduction Act of 1984 and section 6019 of the Omnibus Budget Reconciliation Act of 1989. The amendments expand the types of providers and suppliers of services that we may consider to meet conditions of participation or certification, nursing home requirements, or conditions for coverage by virtue of their accreditation by a national accreditation program; these providers and suppliers are also subject to validation surveys. The rule

also extends confidentiality to accreditation surveys, other than home health agency surveys, done by accreditation programs in addition to the Joint Commission on Accreditation of Healthcare Organizations, except that we may disclose survey and related information to the extent that such information relates to an enforcement action we take on the basis of accreditation survey findings. The rule also provides for: the release to, and use by, HCFA of all accreditation surveys and other relevant information even if a provider or supplier is not subject to a validation survey; the removing of deemed status of a facility based on a validation survey, an accreditation survey, or other information related to either; and appeal procedures for denied or withdrawn approval.

EFFECTIVE DATE: This rule is effective February 22, 1993. The provisions of this rule also apply as of the effective date to any accreditation organization that previously received approval of deeming authority.

FOR FURTHER INFORMATION CONTACT: Irene Gibson, (410) 966-6768.

SUPPLEMENTARY INFORMATION:

I. Background

In order to participate in the Medicare program, providers and most types of

suppliers of health care services (such as hospitals and rural health clinics) must meet requirements specified in the Social Security Act (the Act) and any others specified by the Department of Health and Human Services. These requirements are called conditions of participation for providers, conditions of participation for coverage for suppliers, conditions of certification for rural health clinics (RHCs), or long-term care requirements for skilled nursing facilities (SNFs). Any provider or supplier who does not meet these requirements is considered out of compliance and risks having its participation in the Medicare program terminated or may be subject to other adverse actions.

State health departments or similar agencies under contract with HCFA (in accordance with section 1864 of the Act) survey providers and some types of suppliers to ascertain compliance with the conditions of participation, conditions for coverage, or long term care requirements, and to certify their findings to HCFA. On the basis of these State survey agency certifications, HCFA determines whether the provider or supplier qualifies, or continues to qualify, for participation in the