

The above notices of determination were received from the indicated jurisdictional agencies by the Federal Energy Regulatory Commission pursuant to the Natural Gas Policy Act of 1978 and 18 CFR 274.104. Negative determinations are indicated by a "D" before the section code. Estimated annual production (PROD) is in million cubic feet (MMCF). An (*) before the Control (JD) number denotes additional purchasers listed at the end of the notice.

The applications for determination are available for inspection except to the extent such material is confidential under 18 CFR 275.206, at the Commission's Division of Public Information, Room 1000, 825 North Capitol St., Washington, D.C. Persons objecting to any of these determinations may, in accordance with 18 CFR 275.203 and 275.204, file a protest with the Commission within fifteen days after publication of notice in the Federal Register.

Categories within each NGPA section are indicated by the following codes:

- Section 102-1: New OCS lease
- 102-2: New well (2.5 mile rule)
- 102-3: New well (1000 ft rule)
- 102-4: New onshore reservoir
- 102-5: New reservoir on old OCS lease
- Section 107-DP: 15,000 feet or deeper
- 107-CB: Geopressed brine
- 107-CS: Coal seams
- 107-DV: Devonian shale
- 107-PE: Production enhancement
- 107-TF: New tight formation
- 107-RT: Recompletion tight formation
- Section 108: Stripper well
- 108-SA: Seasonally affected
- 108-ER: Enhanced recovery
- 108-PB: Pressure buildup

Kenneth F. Plumb,
Secretary.

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BILLING CODE 6717-01-M

ENVIRONMENTAL PROTECTION AGENCY

[OPTS-42019; TSH-FRL#2246-8]

Acetonitrile; Response to the Interagency Testing Committee

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice.

SUMMARY: In the Fourth Report of the Interagency Testing Committee (ITC) the ITC designated acetonitrile for priority consideration for health effects testing. Subsequent to the publication of the ITC report, the National Toxicology Program (NTP) began testing acetonitrile for chronic and mutagenic effects. In

addition, the American manufacturers of acetonitrile presented to the EPA a plan for additional mutagenicity and teratogenicity testing of acetonitrile. EPA believes that the collective testing activities of the NTP and the acetonitrile manufacturers respond adequately to all of the ITC recommendations other than that for an epidemiological study. EPA believes that requiring such a study is not warranted at this time. Therefore, the Agency is not, at this time, initiating rulemaking under section 4(a) of the Toxic Substances Control Act (TSCA) to require health effects testing of acetonitrile. This notice constitutes the Agency's response to the designation of acetonitrile by the ITC, as required by section 4(e) of TSCA. EPA seeks comment on the Agency's conclusions and on the adequacy of the proposed testing program.

DATE: All comments should be submitted on or before February 14, 1983.

ADDRESS: Written comments should refer to the document control number OPTS-42019 and should be submitted in triplicate to: Document Control Officer (TS-793), Office of Pesticides and Toxic Substances, Environmental Protection Agency, Rm. E-401, 401 M St. SW., Washington, D.C. 20460.

The administrative record supporting this action is available for public inspection in Rm. E-107 at the above address from 8:00 a.m. to 4:00 p.m., Monday through Friday, except legal holidays.

FOR FURTHER INFORMATION CONTACT: Douglas G. Bannerman, Acting Director, Industry Assistance Office (TS-799), Office of Toxic Substances, Environmental Protection Agency, Rm. E-511, 401 M St. SW., Washington, D.C. 20460, Toll Free: (800-424-9065); in Washington, D.C.: (554-1404); outside the USA: (operator 202-554-1404).

SUPPLEMENTARY INFORMATION:

I. Background

Section 4(a) of TSCA (Pub. L. 94-469, 90 Stat. 2006; 15 U.S.C. 2601 *et seq.*) authorizes the EPA to promulgate regulations requiring testing of chemical substances and mixtures in order to develop data relevant to determining the risks that such chemicals may present to health and the environment. Section 4(e) of TSCA established an Interagency Testing Committee (ITC) to recommend to the EPA a list of chemicals to be considered for the promulgation of testing rules under section 4(a) of the Act.

The ITC placed acetonitrile on its priority testing list in June, 1979 (44 FR 31886). The ITC recommended testing of

acetonitrile for carcinogenicity, mutagenicity, teratogenicity, and other chronic effects and also recommended epidemiology studies.

Acetonitrile is a polar molecule with a high dielectric constant. Its molecular formula is $H_3C-C\equiv N$. The annual production of acetonitrile for 1980 was reported to be 25.2 million pounds (Ref. 1). The Agency believes, however, that actual acetonitrile production is greater than the annual reported production because a significant portion of the total acetonitrile production is disposed of in unisolated form (Ref. 1).

The physical properties of acetonitrile make this chemical well-suited for use as a polar solvent. Thus, the commercial uses of acetonitrile utilize its solvent properties either in the separation of olefin-diolefin mixtures, as a reaction medium or intermediate for the synthesis of pharmaceuticals and pesticides, or in the crystallization of a variety of chemicals. The major commercial application for acetonitrile is as a solvent for the extractive distillation of butene-butadiene mixtures yielding high purity butadiene suitable for polymerization (Ref. 1).

Human exposure to acetonitrile appears to be limited to the workplace. The National Institute for Occupational Safety and Health (NIOSH) estimated that 25,671 workers may be exposed to acetonitrile (Ref. 2). According to NIOSH most occupational exposures to nitriles result from inhalation of vapor or aerosols, or from dermal contact (Ref. 3). The American Conference of Governmental Industrial Hygienists (ACGIH) recommended Threshold Limit Value (TLV) for workplace exposure, based on acute effects, is 40 ppm (Ref. 4). There does not appear to be any significant exposure to the general population as a result of manufacturing, processing, use, distribution or disposal of acetonitrile (Ref. 5). The Agency has no evidence that acetonitrile is contained in consumer products (Ref. 6).

II. Testing Subsequent to ITC Recommendations

Monsanto Company conducted a teratogenicity study of acetonitrile in mated Charles River rats (Ref. 7). Daily dosage levels of 125, 190, and 275 mg/kg were administered by gavage on days six to 19 of gestation at a constant volume of 10 ml/kg/day. Maternal deaths, reduced maternal body-weights and embryotoxic effects were reported for the high dose group. No teratogenic responses were observed at any of the three dose levels.

In a study by Willhite (in press), pregnant hamsters were exposed to

acetonitrile by inhalation, ingestion, or intraperitoneal injection (Ref. 8). On the eighth day of gestation, inhalation of 1,800 or 3,800 ppm acetonitrile for 60 minutes failed to induce malformations in the offspring, whereas inhalation of 5,000 or 8,000 ppm acetonitrile was associated with the production of severe axial skeletal (dysraphic) disorders. A single oral or intraperitoneal dose of 100, 200, 300 or 400 mg/kg acetonitrile in hamsters of equivalent gestational age also caused malformations identical to those noted following inhalation exposure. Some dams exposed to the highest concentrations or doses of acetonitrile displayed overt signs of poisoning.

In addition, the Agency is aware of an ongoing teratogenic study at Duquesne University by Edward G. Hyde, Jr. in which mice are being exposed to acetonitrile via intraperitoneal administration. Although verbal communications between Mr. Hyde and the Agency has provided some information on the protocol being used in this study, complete written documentation of the protocol and results will not be available to the Agency until the end of 1982 (Ref. 9).

The National Toxicology Program (NTP) is performing studies on subchronic toxicity and mutagenicity of acetonitrile. The 90-day subchronic toxicity study being performed by NTP is using inhalation as the route of exposure to both rats and mice. At each of the following atmospheric concentrations: 25 ppm, 50 ppm, 100 ppm, 200 ppm, and 400 ppm, 10 animals per sex per species will be exposed to the test atmosphere six hours per day, five days per week, for 13 weeks (Ref. 10). The results of this study will be available in January 1983 (Ref. 11). After evaluation of the data, NTP may perform a full bioassay of acetonitrile, but NTP will not commit resources to this study until subchronic and mutagenicity data are evaluated and a priority for carcinogenicity testing has been determined.

The NTP mutagenicity testing includes an Ames bioassay using *Salmonella*, *in vitro* cytogenetic testing for chromosomal aberrations with Chinese Hamster ovary cells, sister chromatid exchange using Chinese Hamster ovary cells, and tests for sex-linked recessive lethal and reciprocal translocation effects using *Drosophila*. The results of the NTP mutagenicity testing, expected in early 1983, will be obtained by the EPA when available (Ref. 12).

III Proposed Testing

In June 1982, E. I. Dupont de Nemours and Company, Incorporated; Monsanto

Chemical Intermediates Company, and the Vistron Corporation presented to the EPA a detailed testing proposal for a eukaryotic cell gene mutation study of acetonitrile using Chinese Hamster ovary cells (Ref. 13).

In October 1982, the above named acetonitrile manufacturers presented to the EPA a detailed testing proposal for a teratology study of acetonitrile using rabbits as the test species and gavage as the route of administration. (Ref. 14.)

These tests would be initiated upon final approval of this program by the EPA. The Agency's final approval of this program is contingent upon identification of the laboratory that would perform each study, receipt and approval of the protocols to be used in conducting each study, and evaluation of all comments received on the Agency's conclusions and on the adequacy of the proposed testing program presented in this notice.

In conducting the mutagenicity and teratology studies, industry has agreed to adhere to the Good Laboratory Practice Standards issued by the Food and Drug Administration (43 FR 60013). The industry has also agreed to permit laboratory audit/inspections in accordance with the procedures outlined in TSCA section 11, at the request of authorized representatives of the EPA. These inspections may be conducted for purposes which include verification that testing has begun; that schedules are being met, that reports accurately reflect the raw data, and that the studies are being conducted according to Good Laboratory Practice Standards. EPA will also approve all test protocols and the companies will supply EPA with the data as soon as they become available.

In addition, industry has agreed that all raw data, documentation, records, protocols, specimens, and reports generated as a result of the studies will be retained as specified in the proposed TSCA Good Laboratory Practice Standards (44 FR 27334) and made available during an inspection or submitted to EPA if requested by EPA or its authorized representative.

Industry understands that TSCA section 14(b)(1)(A)(ii) governs Agency disclosure of all test data submitted pursuant to this agreement.

The Agency plans to publish quarterly in the Federal Register a notice of the receipt of any test data submitted under this agreement. Subject to TSCA section 14, the notice will provide information similar to that described in TSCA section 4(d). Except as otherwise provided in TSCA section 14, such data will be made available by the EPA for examination by any person.

Finally, industry understands that failure to conduct the testing according to the specified protocols or failure to follow Good Laboratory Practices may invalidate the tests. In such cases, a data gap may still exist, and the Agency may decide to promulgate a test rule, or otherwise require further testing.

The companies also have agreed to meet with the Agency and determine the need for oncogenicity or other further testing of acetonitrile upon completion of the ongoing NTP mutagenicity and subchronic toxicity testing and the industry-sponsored teratogenicity and mutagenicity testing. This decision would be made in 1983 after all parties have analyzed the data. In the event that test results indicate a need to perform additional testing that the companies are unwilling to perform, the Agency can promulgate a test rule.

IV. Decision Not To Initiate Rulemaking

The Agency's reasons for not initiating rulemaking to require the testing recommended by the ITC are outlined below.

1. *Teratogenicity.* Teratogenicity testing of acetonitrile has been completed using two species, the rat and hamster, and is being conducted in a third species, the mouse (see unit II).

The Monsanto study (see unit II), which found no evidence of malformation in rats, conforms to EPA's TSCA guidelines (Ref. 15) and the Organisation for Economic Cooperation and Development (OECD) guidelines (Ref. 16). It is considered by the Agency to be an adequate teratology study.

The Willhite study (see unit II), using hamsters, is considered inadequate for Agency use to fully assess the teratogenic potential of acetonitrile because acetonitrile was administered only on a single day (day 8) of gestation and because positive effects were observed only at dose levels which induced maternal toxicity. As a result, a No Observed Effect Level (NOEL) can only be determined for a single day of gestation and cannot be determined for the major period of organogenesis. Both the OECD and TSCA test guidelines recommend exposure to a test agent throughout the major period of organogenesis, which in the hamster is days 6-14. In addition, it cannot be determined if lower, non-maternally toxic dose levels administered on more than one day of gestation would result in similar teratogenic events.

Based on information obtained through verbal communication the Hyde study (see unit II), using the mouse appears to be similarly flawed in that it too does not provide for dosing the test

animals over the major period of organogenesis. Also, the Hyde study apparently has only three animals per dose group and uses a route of administration, intraperitoneal, that may present problems in interpreting the data. The Hyde study may, however, provide the agency with additional information on species sensitivity to acetonitrile as a teratogenic agent.

Because teratogenicity data are adequate for only one species, the rat, and the OECD and TSCA test guidelines recommend adequate data in at least two mammalian species, the Agency concluded that there are insufficient data available on acetonitrile to prepare an adequate teratogenic evaluation.

The teratogenicity testing to be conducted by the manufacturers of acetonitrile (see unit III.) will provide teratogenicity data for a second mammalian species. The acetonitrile manufacturers propose to use rabbits as the test species and gavage as the route of administration.

Rats and rabbits are the recommended species for teratogenicity testing in both the OECD and TSCA test guidelines. Willhite's observation of teratogenic effects in the hamster following exposure to acetonitrile might suggest using the hamster for further teratogenicity testing of acetonitrile, since sensitivity of the species to this chemical has been demonstrated. On the other hand, the hamster is used infrequently for teratogenicity studies and the resulting lack of an historical data base on the species would make interpretation of the test data less sure than for data obtained in the rabbit. Depending on the outcome of Hyde's study, the mouse might be considered the species of choice for further evaluation of acetonitrile's teratogenic potential. EPA will consider the outcome of the Hyde study and any comments received in response to this Notice in reaching a final conclusion on the appropriate species for further teratogenicity testing of acetonitrile.

The willhite study has demonstrated that exposure to acetonitrile via gavage and inhalation produce similar teratogenic effects. As a result, the use of gavage as the route of administration in lieu of inhalation, the primary route of acetonitrile exposure to workers, is scientifically appropriate and less expensive.

The Monsanto study, in conjunction with the teratogenicity testing to be conducted by the manufacturers of acetonitrile, will provide the teratogenicity data for two mammalian species that EPA would have normally required under a section 4 test rule. These data will be sufficient to

reasonably determine or predict the teratogenic potential of acetonitrile. Therefore, it is not necessary for EPA to initiate rulemaking to require teratogenicity testing of acetonitrile.

2. Mutagenicity. The mutagenicity testing being performed by NTP (see unit II.) with the exception of a eukaryotic cell gene mutation study, will complete the first tier battery and provide the mutagenicity data that EPA would have normally required under a section 4 test rule. The eukaryotic cell gene mutation study to be conducted by the manufacturers of acetonitrile (see unit III.) will complete this first tier battery. In addition, a provision is contained in the industry testing proposal that provides for EPA and industry to evaluate the need for further mutagenicity testing at the conclusion of the NTP and industry-sponsored mutagenicity testing. In view of the ongoing and proposed tests, further mutagenicity testing is unnecessary at this time.

3. Chronic Effects. For the purposes of TSCA section 4, EPA believes that properly conducted subchronic toxicity testing normally can be used as a surrogate for chronic toxicity testing except for oncogenicity and age-related endpoints. EPA is aware of no data indicating that acetonitrile may cause those age-related effects that a subchronic toxicity study would not detect. Therefore, the NTP 90-day subchronic toxicity study of acetonitrile is likely to provide adequate data to assess its chronic toxicity for section 4 purposes. For this reason no further chronic effects testing of acetonitrile will be required at this time.

4. Carcinogenicity. The results of the short-term mutagenicity tests and the results of the NTP 90-day inhalation toxicity study will be important in determining the need for longer-term testing because carcinogenic events can occur through several mechanisms. NTP will decide whether to conduct a long-term bioassay by analyzing the results of both the mutagenicity and the 90-day subchronic toxicity studies. This decision is expected to be made in January, 1983. In anticipation that NTP will begin a long-term bioassay of acetonitrile if such a study is warranted by the data, the Agency is not initiating rulemaking to require carcinogenicity testing at this time. However, should NTP decide that it will not sponsor a two-year bioassay, the Agency, with the manufacturers of acetonitrile, will evaluate the data and determine the need for this test. If the Agency concludes carcinogenicity testing of acetonitrile is needed and the manufacturers are unwilling to perform

such testing, then the Agency will initiate rulemaking to require this test.

5. Epidemiology. The ITC recommended epidemiology testing of acetonitrile. The Agency does not believe that this study is warranted at this time because there is no documentable health hazard on which to base an epidemiologic study. However, should the additional data on acetonitrile's toxicity now being developed indicate the existence of a well-defined effect, the Agency will reevaluate the need for epidemiological studies.

EPA believes that the available data, the NTP testing currently in progress and the industry-sponsored mutagenicity and teratogenicity testing respond to the concerns of the ITC and that sufficient data are likely to be provided to reasonably characterize the toxicity profile of acetonitrile. EPA also believes that the additional mutagenicity and teratogenicity data will be provided more expeditiously via the acceptance of the industry-sponsored acetonitrile testing program than under a rule. Therefore, EPA has determined not to initiate a rule to require further testing of acetonitrile at this time.

V. References

- (1) MATHTECH, Inc. 1982. Level I Economic Evaluation for Acetonitrile. Draft Report. Washington, DC: Office of Pesticides and Toxic Substances, U.S. Environmental Protection Agency. Contract 68-01-5884.
- (2) National Institute for Occupational Safety and Health (NIOSH). 1979. National Occupational Hazard Survey. Cincinnati, OH: National Institute for Occupational Safety and Health.
- (3) National Institute for Occupational Safety and Health (NIOSH). 1978. Criteria for a recommended standard: Occupational exposure to nitriles. Cincinnati, OH: U.S. Department of Health, Education, and Welfare (DHEW Pub. NIOSH 78-212).
- (4) American Conference of Governmental Industrial Hygienists (ACGIH). TLVs Threshold limit values for chemical substances in'workroom air adopted by ACGIH for 1978. Cincinnati, OH: American Conference of Government Industrial Hygienists.
- (5) IRB Associates. 1981. Health Effects Recommendations for Acetonitrile. Washington, DC: Office of Pesticides and Toxic Substances, U.S. Environmental Protection Agency. Contract 68-01-5151.
- (6) US NTP. 1982. U.S. National Institutes of Health—U.S. Environmental Protection Agency. Computer printout (CIS): Clinical toxicology of commercial products. Retrieved Oct. 28, 1982. Washington, DC: USNTP.
- (7) Monsanto. 1982. May 6 letter from Harry M. Keating to Steven D. Newburg-Rinn.
- (8) Willhite, C.C. (in press). Developmental Toxicology of Acetonitrile in the Syrian

Golden Hamster. Dr. Calvin C. Willhite to Dr. Elaine Francis.

(9) Hyde, E. 1982. Personal communication between Edward G. Hyde, Jr., Dr. Elaine Francis and David Dellarco.

(10) McCoy, J. 1981. May 15 Outline of the Protocol for NTP Toxicity Studies of Acetonitrile from Dr. James McCoy to David J. Dellarco.

(11) McCoy, J. 1981. Personal communication between Dr. James McCoy and David J. Dellarco.

(12) Zieger, E. 1982. Personal communication between Dr. E. Zieger and David J. Dellarco.

(13) DuPont, Monsanto, Vistron. 1982. June letter from Wiley M. Branant to Steven D. Newburg-Rinn.

(14) DuPont, Monsanto Vistron. 1982. October letter from Wiley M. Branant to Steven D. Newburg-Rinn.

VI. Public Record

EPA has established a public record for this testing decision (docket number OPTS-42019) which is available for inspection from 8:00 a.m. to 4:00 p.m., Monday through Friday except holidays in Rm. E-107, 401 M St., SW., Washington, D.C. 20460. This record includes basic information considered by the Agency in developing this decision. The record includes:

(1) Federal Register notice containing the designation of acetonitrile to the priority list and all comments on acetonitrile received in response to that notice.

(2) Communications received prior to industry testing proposal consisting of letters, contact reports of telephone conversations and meeting summaries of Agency-industry and Agency-public meetings.

(3) Testing proposal and protocols.

(4) Published and unpublished data.

(5) Federal Register notice requesting comment on the negotiated testing proposal and all comments received in response to that notice.

The Agency will supplement the record periodically with additional relevant information received.

(Sec. 4, 90 Stat. 2003; 15 U.S.C. 2061)

Dated: December 20, 1982.

Anne M. Gorsuch,

Administrator.

[FR Doc. 82-35278 Filed 12-23-82; 4:48 pm]

BILLING CODE 6560-50-M

[OPTS-42022; BH-FPC 2249-2]

Hexachlorocyclopentadiene; Response to the Interagency Testing Committee

AGENCY: Environmental Protection
Agency (EPA).

ACTION: Notice.

SUMMARY: This notice constitutes EPA's response to the Interagency Testing Committee's recommendation that EPA require health and environmental effects testing of hexachlorocyclopentadiene (HCCP) under section 4(a) of the Toxic Substances Control Act (TSCA). EPA is not initiating rulemaking under section 4(a) to require further health or environmental effects testing of HCCP at this time. EPA does not believe that there is a sufficient basis to find that the current manufacture, distribution in commerce, processing, use, or disposal of this substance may present an unreasonable risk to the environment or of mutagenic or teratogenic health effects, or that there is substantial or significant human exposure or substantial environmental release. In addition, adequate data exist to reasonably predict the chronic health effects of HCCP and an oncogenicity bioassay is under way. Therefore, additional testing for these effects is unnecessary.

FOR FURTHER INFORMATION CONTACT: Douglas C. Bannerman, Acting Director, Industry Assistance Office (TS-799), Office of Toxic Substances, Environmental Protection Agency, 401 M St., SW., Washington, D.C. 20460, Toll free: (800-424-9065), In Washington, D.C.: (554-1404), Outside the USA: (Operator-202-554-1404).

SUPPLEMENTARY INFORMATION:

I. Background

Section 4(e) of TSCA (Pub. L. 94-469, 90 Stat. 2003 *et seq.*; 15 U.S.C. 2801 *et seq.*) established an Interagency Testing Committee (ITC) to recommend a list of chemicals for EPA to consider for promulgation of testing rules under section 4(a) of the Act. The ITC may designate substances on the list for priority consideration by EPA. TSCA requires EPA to respond to these designations by initiating rulemaking under section 4(a) or by stating its reasons in the Federal Register for not initiating rulemaking. The ITC designated hexachlorocyclopentadiene (HCCP) for priority consideration in its Fourth Report, published in the Federal Register of June 1, 1979 (44 FR 31866), recommending that HCCP be considered for testing for carcinogenicity, mutagenicity, teratogenicity, and other chronic effects. The Committee also recommended testing consideration for environmental effects, with emphasis on chronic effects in aquatic and terrestrial systems.

The ITC's recommendations were based on evidence of substantial production, potential human exposure in the workplace and more generally as a

result of industrial release and disposal, and indications of a potential for persistence and bioaccumulation in the environment. Since that time, new information has become available or is under development that, in EPA's judgment, indicates that further testing of HCCP is not warranted at this time.

This notice provides EPA's response to the ITC's designation of HCCP for testing.

II. Decision Not To Initiate Rulemaking

EPA has decided not to initiate rulemaking to require testing of HCCP under section 4 of TSCA because EPA does not believe that there is a sufficient basis to find that the current manufacture, distribution in commerce, processing, use or disposal of HCCP may present an unreasonable risk of injury to the environment or of mutagenic and teratogenic health effects. Neither has EPA found evidence that there is substantial or significant human exposure to or substantial environmental release of HCCP. In addition, certain new studies have become available since the ITC's report or are under way, making additional testing for chronic and oncogenic effects unnecessary.

A. Release and Exposure

The ITC indicated that annual production of HCCP was greater than 8 million pounds, which the Agency considers to be a substantial quantity. EPA has received confidential information from the manufacturer which leads the Agency to believe that current and expected production continue to be substantial.

Velsicol Chemical Company is the sole producer of HCCP in the United States. It manufactures the chemical at two locations: Marshall, Illinois and Memphis, Tennessee. All of the chemical produced at the Marshall location is used at that location in the production of a registered pesticide product. Part of the HCCP produced at Memphis, Tennessee is used at that site in the production of registered pesticide products and other chemicals, principally chlorendic anhydride (Ref. 5). There is one major customer for the rest (Ref. 6).

In assessing the potential exposure to HCCP, EPA cannot identify any uses other than as a chemical intermediate, almost entirely in the production of a number of pesticides and of chlorendic anhydride. Because of HCCP's extreme acute toxicity (exposure to 1.5 ppm for 7 hours killed 3 of 3 rabbits, 4 of 5 mice, 1 of 4 rats (Ref. 14)), all reactions are carried out in tightly-controlled closed