

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Public Health Service

National Toxicology Program; Call for Public Comments; Chemicals Proposed for the Eighth Biennial Report on Carcinogens

Background

The National Toxicology Program (NTP) announces its intent to list additional substances in the Eighth Biennial Report on Carcinogens (BRC). This Report is a Congressionally-mandated listing of known human carcinogens and reasonably anticipated human carcinogens and its preparation is delegated to the National Toxicology Program by the Secretary, Department of Health and Human Services (HHS). Section 301(b)(4) of the Public Health Service Act, as amended, provides that the Secretary, (HHS), shall publish a report which contains a list of all substances (1) Which either are known to be human carcinogens or may reasonably be anticipated to be human carcinogens; and (2) to which a significant number of persons residing in the United States (US) are exposed. The law also states that the reports should provide available information on the nature of exposures, the estimated

number of persons exposed and the extent to which the implementation of Federal regulations decreases the risk to public health from exposure to these chemicals.

The new entries for the Eighth BRC have undergone a multiphased peer review process involving two Federal scientific review groups and one non-government, scientific peer review body (a subcommittee of the NTP Board of Scientific Counselors) which met in an open, public meeting that included a public comment session. All data relevant to the criteria for inclusion of candidate agents, substances or mixtures in the BRC have been evaluated by the three scientific review committees.

In the Eighth BRC, the NTP is adding 14 agents, substances or mixtures to the existing list, one of which is listed as a known human carcinogen. The 13 remaining agents, substances or mixtures are being added as reasonably anticipated to be human carcinogens. In addition, thiotepa, which is currently listed in previous Reports on Carcinogens as reasonably anticipated to be a human carcinogen is moved to the known human carcinogen list. These agents, substances or mixtures are provided in the following table with their Chemical Abstracts Services (CAS) Registry numbers and listing. The

Eighth BRC also contains an appendix which is a reference to certain "Manufacturing Processes, Occupations and Exposure Circumstances" that have not yet been formally reviewed by the NTP for BRC listing but have been classified by IARC as sources which are known to be carcinogenic to humans because of the associated increased incidences of cancer in workers in these settings. While not formally listed in the 8th BRC, in the interest of public health and for completeness, these occupational exposures have been referenced in an appendix to the Report with the corresponding IARC citation given.

Comments concerning the addition of these substances in the Eighth BRC will be accepted for a period of 30 days from the date of the publication of this announcement in the **Federal Register**. Comments or questions should be directed to Dr. C.W. Jameson, National Toxicology Program, Biennial Report on Carcinogens, MD WC-05, P.O. Box 12233, Research Triangle Park, NC 27709, fax number: (919)-541-2242, email: Jameson@niehs.nih.gov.

Attachment.

Dated: April 18, 1997.

Kenneth Olden,

Director, National Institute of Environmental Health Sciences.

SUMMARY FOR AGENTS, SUBSTANCES OR MIXTURES TO BE LISTED IN THE EIGHTH BIENNIAL REPORT ON CARCINOGENS

Chemical/CAS number	Primary uses	To be listed as
AZACITIDINE/320-67-2	Used as a cytostatic agent in the treatment of acute leukemia	Reasonably Anticipated to be a Human Carcinogen.
p-CHLORO-o-TOLUIDINE and its HCl salt/95-69-2.	Used to produce azo dyes for cotton, silk acetate and nylon and as intermediate in production of Pigment Red 7 and Pigment Yellow 49. Also an impurity in and a metabolite of the pesticide chlordimeform	Reasonably Anticipated to be a Human Carcinogen.
CHLOROZOTOCIN/54749-90-5 ...	Used as a cytostatic agent in the treatment of cancers of the stomach, large intestine pancreas and lung; melanoma; and multiple myeloma	Reasonably Anticipated to be a Human Carcinogen.
CYCLOSPORIN/59865-13-3	Used as an immunosuppressive agent in the prevention and treatment of graft-vs-host reactions in bone marrow transplantation and for the prevention of rejection of kidney, heart, and liver transplants	Known to be a Human Carcinogen.
DANTHRON/(1,8-Dihydroxyanthraquinone) 117-10-2.	Used as a laxative and as an intermediate in the manufacture of dyes	Reasonably Anticipated to be a Human Carcinogen.
1,6-DINITROPYRENE/42397-64-8	Not used commercially, detected in ambient atmospheric samples and as a constituent of diesel exhaust	Reasonably Anticipated to be a Human Carcinogen.
1,8-DINITROPYRENE/42397-65-9	Not used commercially, detected in ambient atmospheric samples and as a constituent of diesel exhaust	Reasonably Anticipated to be a Human Carcinogen.
DISPERSE BLUE 1/(1,4,5,8-Tetraaminoanthraquinone) 2475-45-8.	Used as an anthraquinone based dyestuff in hair color formulations and in coloring fabrics and plastics	Reasonably Anticipated to be a Human Carcinogen.
FURAN/100-00-9	Used as an intermediate in the synthesis and production of other organic compounds	Reasonably Anticipated to be a Human Carcinogen.
o-NITROANISOLE/91-23-6	Used as a precursor in the synthesis of o-anisidine which is used in the manufacture of over 100 azo dyes	Reasonably Anticipated to be a Human Carcinogen.
6-NITROCHRYSENE/7495-02-8 ..	Not used commercially, detected in ambient atmospheric samples	Reasonably Anticipated to be a Human Carcinogen.
1-NITROPYRENE/5522-43-0	Not used commercially, detected in ambient atmospheric samples and as a constituent of diesel and gasoline engine exhaust	Reasonably Anticipated to be a Human Carcinogen.
4-NITROPYRENE/57835-92-4	Not used commercially, detected in ambient atmospheric samples	Reasonably Anticipated to be a Human Carcinogen.

SUMMARY FOR AGENTS, SUBSTANCES OR MIXTURES TO BE LISTED IN THE EIGHTH BIENNIAL REPORT ON CARCINOGENS—
Continued

Chemical/CAS number	Primary uses	To be listed as
THIOTEPA/52-24-4	Used as a cytostatic agent in the treatment of lymphomas and a variety of solid tumors, such as breast and ovary. It has also been used at high doses in combination chemotherapy with cyclophosphamide in patients with refractory malignancies treated with autologous bone transplantation	Known to be a Human Carcinogen.
1,2,3-TRICHLOROPROPANE/96-18-4.	Used as a polymer crosslinking agent, paint and varnish remover, solvent and degreasing agent.. It has been found as an impurity in certain nematicides and soil fumigants and has been detected in drinking and ground water in various parts of the United States	Reasonably Anticipated to be a Human Carcinogen.

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BILLING CODE 4140-01-M

**DEPARTMENT OF HEALTH AND
HUMAN SERVICES****Substance Abuse and Mental Health
Services Administration****Current List of Laboratories Which
Meet Minimum Standards To Engage in
Urine Drug Testing for Federal
Agencies, and Laboratories That Have
Withdrawn From the Program**

AGENCY: Substance Abuse and Mental Health Services Administration, HHS. (Formerly: National Institute on Drug Abuse, ADAMHA, HHS)

ACTION: Notice.

SUMMARY: The Department of Health and Human Services notifies Federal agencies of the laboratories currently certified to meet standards of Subpart C of Mandatory Guidelines for Federal Workplace Drug Testing Programs (59 FR 29916, 29925). A similar notice listing all currently certified laboratories will be published during the first week of each month, and updated to include laboratories which subsequently apply for and complete the certification process. If any listed laboratory's certification is totally suspended or revoked, the laboratory will be omitted from updated lists until such time as it is restored to full certification under the Guidelines.

If any laboratory has withdrawn from the National Laboratory Certification Program during the past month, it will be identified as such at the end of the current list of certified laboratories, and will be omitted from the monthly listing thereafter.

This Notice is now available on the internet at the following website: <http://www.health.org>.

FOR FURTHER INFORMATION CONTACT: Mrs. Giselle Hersh or Dr. Walter Vogl, Division of Workplace Programs, Room

13A-54, 5600 Fishers Lane, Rockville, Maryland 20857; Tel.: (301) 443-6014.

SUPPLEMENTARY INFORMATION: Mandatory Guidelines for Federal Workplace Drug Testing were developed in accordance with Executive Order 12564 and section 503 of Public Law 100-71. Subpart C of the Guidelines, "Certification of Laboratories Engaged in Urine Drug Testing for Federal Agencies," sets strict standards which laboratories must meet in order to conduct urine drug testing for Federal agencies. To become certified an applicant laboratory must undergo three rounds of performance testing plus an on-site inspection. To maintain that certification a laboratory must participate in a quarterly performance testing program plus periodic, on-site inspections.

Laboratories which claim to be in the applicant stage of certification are not to be considered as meeting the minimum requirements expressed in the HHS Guidelines. A laboratory must have its letter of certification from SAMHSA, HHS (formerly: HHS/NIDA) which attests that it has met minimum standards.

In accordance with Subpart C of the Guidelines, the following laboratories meet the minimum standards set forth in the Guidelines:

Aegis Analytical Laboratories, Inc., 624 Grassmere Park Rd., Suite 21, Nashville, TN 37211, 615-331-5300

Alabama Reference Laboratories, Inc., 543 South Hull St., Montgomery, AL 36103, 800-541-4931/334-263-5745

American Medical Laboratories, Inc., 14225 Newbrook Dr., Chantilly, VA 22021, 703-802-6900

Associated Pathologists Laboratories, Inc., 4230 South Burnham Ave., Suite 250, Las Vegas, NV 89119-5412, 702-733-7866/800-433-2750

Associated Regional and University Pathologists, Inc. (ARUP), 500 Chipeta Way, Salt Lake City, UT 84108, 801-583-2787/800-242-2787

Baptist Medical Center—Toxicology Laboratory, 9601 I-630, Exit 7, Little Rock, AR 72205-7299, 501-202-2783, (formerly:

Forensic Toxicology Laboratory Baptist Medical Center)

Bayshore Clinical Laboratory 4555 W. Schroeder Dr., Brown Deer, WI 53223, 414-355-4444/800-877-7016

Cedars Medical Center, Department of Pathology, 1400 Northwest 12th Ave., Miami, FL 33136, 305-325-5784

Centinela Hospital Airport Toxicology Laboratory, 9601 S. Sepulveda Blvd., Los Angeles, CA 90045, 310-215-6020

Clinical Reference Lab, 8433 Quivira Rd., Lenexa, KS 66215-2802, 800-445-6917

CompuChem Laboratories, Inc., 1904 Alexander Drive, Research Triangle Park, NC 27709, 919-549-8263/800-833-3984, (formerly: CompuChem Laboratories, Inc., A Subsidiary of Roche Biomedical Laboratory, Roche CompuChem Laboratories, Inc., A Member of the Roche Group)

Cox Health Systems, Department of Toxicology, 1423 North Jefferson Ave., Springfield, MO 65802, 800-876-3652/417-269-3093, (formerly: Cox Medical Centers)

Dept. of the Navy, Navy Drug Screening Laboratory, Great Lakes, IL, P. O. Box 88-6819, Great Lakes, IL 60088-6819, 847-688-2045/847-688-4171

Diagnostic Services Inc., dba DSI, 4048 Evans Ave., Suite 301, Fort Myers, FL 33901, 941-418-1700/800-735-5416

Doctors Laboratory, Inc., P.O. Box 2658, 2906 Julia Dr., Valdosta, GA 31604, 912-244-4468

DrugProof, Division of Dynacare/Laboratory of Pathology, LLC, 1229 Madison St., Suite 500, Nordstrom Medical Tower, Seattle, WA 98104, 800-898-0180 / 206-386-2672, (formerly: Laboratory of Pathology of Seattle, Inc., DrugProof, Division of Laboratory of Pathology of Seattle, Inc.)

DrugScan, Inc., P.O. Box 2969, 1119 Mearns Rd., Warminster, PA 18974, 215-674-9310

ElSohly Laboratories, Inc., 5 Industrial Park Dr., Oxford, MS 38655, 601-236-2609

General Medical Laboratories, 36 South Brooks St., Madison, WI 53715, 608-267-6267

Harrison Laboratories, Inc., 9930 W. Highway 80, Midland, TX 79706, 800-725-3784/915-563-3300, (formerly: Harrison & Associates Forensic Laboratories)

Jewish Hospital of Cincinnati, Inc., 3200 Burnet Ave., Cincinnati, OH 45229, 513-569-2051

LabOne, Inc., 8915 Lenexa Dr., Overland Park, Kansas 66214, 913-888-3927/800-