PLEASE NOTE:

The SciGen, Inc. Neutralex Technology for the Treatment of Aqueous Formaldehyde Wastes was recertified on May 1, 2011 and will expire on May 1, 2014. Additional information regarding this certification is available in the 2008 recertification notice that can be found at

http://www.dtsc.ca.gov/TechnologyDevelopment/TechCert/upload/scigen_2008_recert_notice.pdf.

CALIFORNIA ENVIRONMENTAL PROTECTION AGENCY
DEPARTMENT OF TOXIC SUBSTANCES CONTROL

Final Decision to Recertify
Hazardous Waste Environmental Technology

The California Environmental Protection Agency, Department of Toxic Substances Control (DTSC) has reached a final decision to recertify the following hazardous waste environmental technology:

The SCIGEN NEUTRALEX technology for treating aqueous formaldehyde in ten percent neutral buffered Formalin waste resulting from histopathology tissue specimen preservation and automated processor activities.

Applicant: SCIGEN, Inc.
333 East Gardena Blvd.
Gardena, California 90249

Section 25200.1.5., Health and Safety Code, authorizes DTSC to certify the performance of hazardous waste environmental technologies. DTSC certifies only technologies which are determined to not pose a significant potential hazard to the public health and safety or to the environment when used under specified operating conditions.

Due to the current budget shortfall for the State of California, and associated budget uncertainty, DTSC is not accepting any new applications into its hazardous waste technology certification program. DTSC considers recertification requests for technologies already certified which have not changed their design, formulation, or operation.

The certification program provides an independent technical evaluation of technologies to identify those meeting applicable quality standards, so as to facilitate regulatory and end-user acceptance and to promote and foster growth of California's environmental technology industry.

DTSC makes no express or implied warranties as to the performance of the manufacturer's product or equipment. The end-user is solely responsible for complying with the applicable federal, state, and local regulatory requirements. Certification does not limit DTSC's authority to require additional measures for protection of public health and the environment.

By accepting certification, the manufacturer assumes, for the duration of certification, responsibility for maintaining the quality of the manufactured equipment and materials and their operation at a level equal to or better than was provided to obtain certification and agrees to be subject to quality monitoring by DTSC as required by the statute under which certification is granted.

DTSC's final decision to re-certify the Scigen Neutralex technology is based on a proposed decision which was subject to a public review and comment period. During the comment period no comments were received.

DTSC has concluded that the Scigen Neutralex technology does not pose a significant potential threat to public health or the environment when used according to the manufacturer's instructions and the conditions in the certification.

Requests for additional information concerning this final decision should be submitted to the following address:

California Environmental Protection Agency
Department of Toxic Substances Control
Office of Pollution Prevention and Green Technology
P.O. Box 806
1001 I Street, 12th Floor
Sacramento, California 95812-0806
Attn: Dick Jones (916) 322-3292

Background

The Scigen Neutralex technology was originally certified effective June 29, 1997, for a three-year term. The final decision to certify was published in the May 30, 1997, California Regulatory Notice Register, Volume 97, Number 22-Z. The original certification included a description of the technology, the certification statement and associated conditions and limitations, and the technical basis for the original certification decision. These documents are at:

http://dtsc-cm/TechnologyDevelopment/TechCert/scigen-batch-treat-formaldehyde-techcert.cfm

or may be obtained from DTSC.

Following re-evaluations and proposed decisions with 30-day public comment periods, DTSC published final decisions to recertify the Neutralex technology for three-year terms effective June 10, 2001 and, after a one year extension, March 25, 2005. The technology was recertified again on May 16, 2008. Reports describing the basis for these recertification decisions are available from DTSC.

DTSC recently re-evaluated the Neutralex technology, and proposed to recertify the technology for an additional three-year term. The proposed decision was published in the California Regulatory Notice Register, February 18, 2011, Register 2011, Volume Number 7-Z. DTSC has reached a final decision to re-certify the Neutralex technology for an additional three-year term.

Effect on Current Certification Status

Pursuant to Title 22, California Code of Regulations, section 68100, the existing certification remained valid during the re-certification.

The certification will remain in effect for an additional three-year period from the effective date of this final certification decision.

Basis for Recertification

Previous recertification evaluations included laboratory testing of the effectiveness of Neutralex for treating ten percent neutral buffered Formalin wastes, and discussions with end users. According to Scigen, the Neutralex technology has not changed since it was originally certified. For the current recertification evaluation, DTSC staff contacted three more end users of the Neutralex technology to confirm previous information on its performance under the conditions of use at health care facilities. All were satisfied with the product. Most found the directions clear and followed them. None of the users contacted had any problems with the technology. A regional health and safety manager representing approximately thirty regional hospitals again reported no problems. They use the technology to treat 40,000 gallons of formalin waste per year.

In earlier certification reviews, DTSC did extensive investigations and lab tests of the Neutralex product. The results were consistently positive. Later reviews used customer interviews and again produced positive results. DTSC has not received nor is aware of any complaints or reports of problems with the Neutralex technology.

Regulatory Considerations

Title 22, California Code of Regulations, Section 67450.20, specifies that treatment of formaldehyde by health-care facilities using any technology certified as effective for that purpose is authorized for operation under a grant of conditional exemption. The treatment must be operated pursuant to the conditions imposed on the certification. In addition, the generator conducting the treatment must comply with the conditions of the Conditional Exemption in Section 25201.5 of the Health and Safety Code. The reader should refer to these statutory and regulatory sections for additional information.

Certification Conditions

The conditions of the original certification, published in the May 30, 1997, California Regulatory Notice Register, Volume 97, Number 22-Z remain in effect.

Certification Reference

As a holder of a valid hazardous waste environmental technology certification, Scigen is authorized to use the certification seal (California Registered Service Mark Number 046720) during the term of the certification. Scigen shall cite the certification number and date of issuance in conjunction with the certification seal whenever it is used.

When providing information on the certification to an interested party, Scigen shall, at a minimum, provide the full text of the original and recertification decisions as published in the California Regulatory Notice Register.

Duration of the Certification

This recertification is effective thirty days from the publication date of this final notice, and will remain in effect until May 1, 2014 (a period of three years from its effective date), unless it is amended or revoked for cause.