



**CALIFORNIA ENVIRONMENTAL PROTECTION AGENCY
DEPARTMENT OF TOXIC SUBSTANCES CONTROL**

**Notice of Final Decision to Re-Certify
Hazardous Waste Environmental Technology**

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

The Scigen Neutralex technology for treating formaldehyde in waste neutral buffered Formalin from histopathology specimen preservation and use of automated histopathology tissue processors.

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

Section 25200.1.5., Health and Safety Code, enacted by Assembly Bill 2060, authorizes DTSC to certify the performance of hazardous waste environmental technologies. 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 may be certified. Incineration technologies are explicitly excluded from the certification program.

The purpose of the certification program is to provide 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 comments were received from one commentator. The commentator requested that the Neutralex ingredients be listed on the MSDS, and expressed their opinion that Neutralex may be dangerous when mixed with water, releasing SO₂ gas. During its original certification evaluation, its re-certification evaluations, DTSC asked end users and industrial health and safety staff for health care facilities whether they had encountered any problems with Neutralex. None reported any health and safety problems, nor reported any releases of gases or vapors. Scigen has stated that they consider the specific mixture of ingredients in Neutralex to be trade secret, and has worked with the Department of Industrial Relations on the language in their MSDS. The original certification language, which is retained in this re-certification, includes specific conditions to further lessen the potential for any worker exposure to a hazardous substance. DTSC therefore has concluded that the Scigen Neutralex technology will 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 or comments 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 Technology Development
P.O. Box 806
1001 I Street, 12th Floor
Sacramento, California 95812-0806
Attn: Dr. Bruce La Belle (916) 324-2958

Background

The Scigen Neutralex technology was originally certified effective June 29, 1997 for a term of three years, as specified in law. 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. A copy of this information may be obtained from DTSC. Scigen has not changed their technology since the original certification was issued.

Following a re-evaluation and proposed decision with 30-day public comment period, DTSC published a final decision to re-certify the Neutralex technology for another three-year term effective June 10, 2001. A report describing the basis for that recertification decision is available from DTSC.

DTSC re-evaluated the Neutralex technology, and proposed to recertify the technology for an additional three-year term. The proposed decision was published in the August 6, 2004 California Regulatory Notice Register. 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 Re-Certification

The previous recertification evaluation included laboratory testing of the effectiveness of Neutralex for treating 10% 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 end users of the Neutralex technology to gather additional information on its performance under the conditions of use at health care facilities.

The manager of three pathology laboratories stated that they typically recycle approximately 90% of their 10% neutral buffered formalin wastes, and treat the remainder with

Neutralex. The treatment is effective, but the treated waste sometimes requires pH adjustment (addition of acid) to achieve neutral pH for disposal to the drain. Representatives of seven other hospitals reported that Neutralex works well for them, and that the instructions for use were clear. None of the users reported any problems with using the technology. A regional health and safety manager for a hospital group indicated that he was not aware of any problems or health and safety issues at his hospitals that use Neutralex. One hospital reported that they were no longer using the product after determining that their waste did not meet hazardous waste threshold.

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 re-certification 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 re-certification decisions as published in the California Regulatory Notice Registers.

Duration of the Certification

This re-certification is effective thirty days from the publication date of this final notice, and will remain in effect until March 27, 2008 (a period of three years from its effective date), unless it is revoked for cause or amended.