CALIFORNIA ENVIRONMENTAL PROTECTION AGENCY
DEPARTMENT OF TOXIC SUBSTANCES CONTROL

Notice of Intent to Deny Re-Certification
Hazardous Waste Environmental Technology

The California Environmental Protection Agency, Department of Toxic Substances Control (DTSC) intends to deny re-certification of the following hazardous waste environmental technology:

The Formalex technology, manufactured by S&S Company of Georgia, Inc., and marketed in California by American BioSafety, Inc., for treating formaldehyde in waste neutral buffered Formalin from histopathology specimen preservation and automated histopathology tissue processors.

Applicant: S&S Company of Georgia, Inc.
827 Pine Avenue
Albany, GA 31702

and

American BioSafety, Inc.
4322 Anthony Court, #5
Rocklin, CA 95677

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's proposed decision to deny re-certification is subject to public review and comment. Written comments must be submitted to DTSC no later than 30 days after publication of this notice. All comments will be considered and appropriate changes will be made prior to publishing DTSC's final decision.

Additional information supporting DTSC's proposed decision is available for review, including a report entitled “Formaldehyde Treatment Technologies Re-Certification Evaluation Report.” Requests for additional information or comments concerning this proposed 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
Sacramento, California 95812-0806
Attn: Dr. Bruce La Belle (916) 324-2958

Effect of Denial of Re-Certification

Health care facilities in California are no longer authorized to treat their 10% NBF hazardous wastes with S&S Company's Formalex technology under the Conditional Exemption Permitting Tier. The proposed decision to deny re-certification does not affect the status of the Formalex technology as an uncertified technology. S&S Company and American BioSafety are not authorized to use the certification seal or logo or otherwise claim to be certified by the Department of Toxic Substances Control (DTSC) in marketing Formalex.

Background

The Formalex technology was originally certified effective August 8, 1994, for treatment of 10% neutral buffered Formalin (10% NBF) from the health care industry. The certification expired on November 4, 1998. During the certification period, health care facilities were authorized to use the Formalex technology to treat 10% NBF hazardous waste under the Conditional Exemption permitting tier specified in California Health and Safety Code section 25201.5, subject to the conditions specified in that statute and in the certification decision. Since the expiration date, health care facilities have no longer been authorized to treat their 10% NBF hazardous waste using Formalex under the authority of the Conditional Exemption permitting tier.

Formalex was among the first technologies to be evaluated under the certification program. The original evaluation of Formalex in 1994 was carried out under a pilot program during the development of the certification program. The testing at that time focused on demonstrating the technology's ability to reduce the formaldehyde concentration in unused 10% NBF solution in a limited laboratory study. Recognizing that the certification was part of the pilot phase of the program, when the technology came up for recertification it was expected to meet any additional requirements adopted by the program.

On March 1, 2000, S&S Company entered into an agreement with DTSC in support of an application for re-certification of their Formalex technology.

Basis for Denial of Re-Certification

As part of the re-certification process, DTSC considered the level of testing needed to determine whether the treatments could be performed safely and effectively. DTSC concluded that Formalex should be tested on actual wastes rather than only on unused 10% NBF. This was consistent with the testing performed on another formaldehyde treatment technology evaluated by the program after the initial certification of Formalex.

The manufacturer of Formalex claims that their technology can treat formaldehyde waste to render it non-hazardous. DTSC was interested in ensuring that the technology reduced the toxicity, as well as reduce the formaldehyde concentrations, of the wastes. Formaldehyde concentrations in the waste were determined using U.S. EPA SW-846 Method 8315. Toxicity was determined using an acute aquatic LC_{50} bioassay procedure specified in Title 22, California Code of Regulations, section 66261.24(a)(6) for hazardous waste classification in California. This method is also consistent with the

intent of Title 22 California Code of Regulations (CCR) section 67450.20 for placement of certified technologies in the conditional exemption permitting tier, as described in the Statement of Reasons for that section.

The Formalex technology relies on chemical reactions to reduce the formaldehyde concentration in the wastes. The reactions may produce unidentified reaction products with unknown toxicity. Therefore, DTSC concluded that formaldehyde determinations and acute aquatic 96-hour LC_{50} bioassay toxicity testing should be performed on the wastes both before and after treatment to assess the ability of the technologies to reduce the formaldehyde concentration while also reducing the waste toxicity.

DTSC staff have prepared a report "Formaldehyde Treatment Technologies Re-Certification Evaluation Report," which summarizes the design of the field test and presents the test results. This document is available upon request at the address shown above, or from the DTSC web site at http://ww.dtsc.ca.gov/sppt/pptd/td/techcert.html.

Field Test Results

Formaldehyde Content of Untreated Waste. Pre-treatment formaldehyde concentrations ranged from 41000 to 47000 mg/L for the pathology waste, from 44000 to 48000 mg/L for the tissue processor waste, and 47000 and 48000 mg/L for the unused 10% NBF. Although these concentrations are higher than the concentration of approximately 37000 mg/L cited as typical for unused 10% NBF, they represent actual wastes generated in California.

Formalex-Treated Wastes. After treatment with Formalex, the residual formaldehyde concentration ranged from 2300 to 6400 mg/L in the pathology waste, from 3300 to 5800 mg/L in the tissue processor waste, and was 4700 and 5800 mg/L in the treated samples of unused 10% NBF. There did not appear to be differences in the treatment results for the three waste types. The formaldehyde content was reduced by about 85 - 95% compared with the initial concentrations in the wastes.

Acute aquatic 96-Hour LC_{50} bioassay determinations were performed on the untreated and treated wastes. The data were intended for a comparison of relative toxicity. Although the data can be compared to the hazardous waste threshold of <500 mg/L, they are not intended for waste classification of 10% NBF wastestreams.

A screening level LC_{50} determination of the wastes before treatment showed that all ten samples had LC_{50} concentrations between 500 and 549 mg/L. These values are all above the hazardous waste threshold of 500 mg/L. As a check on the ability of the screening test to provide the necessary information on the waste toxicity, the treatment and LC_{50} determinations were repeated using the definitive test. The results were very similar to the screening level tests, with LC_{50} concentrations between 505 and 574 mg/L. Although the specific wastes tested were less toxic than the hazardous waste threshold, it was recognized that the toxicity of 10% NBF wastes vary. DTSC has received LC_{50} data from other facilities which indicate that 10% NBF can be more toxic than the hazardous waste threshold. Therefore, the project was continued to determine the effects of treatment on waste toxicity and reduction of formaldehyde concentrations.

A screening level LC_{50} determination of the Formalex treated wastes, using the standard procedure showed that four of the ten wastes were more toxic after than before treatment. For these wastes the

post-treatment LC_{50} concentrations were between 354 and 477 m/L, more toxic than the <500 mg/L threshold. Two of these wastes were pathology wastes, one was a tissue processor waste, and one was unused 10% NBF. Five of the other wastes were less toxic after treatment, with LC_{50} concentrations >750 mg/L, and one waste was about the same toxicity before and after treatment, with a post-treatment LC_{50} concentration of 528 mg/L.

The finding that some wastes were more toxic after treatment than before was unexpected. Therefore, a replicate screening level experiment was performed as an additional QA/QC check. In the replicate experiment, five of the wastes were more toxic after than before treatment. These five treated wastes were all more toxic than the hazardous waste threshold of <500 mg/L. Interestingly, only two of the five samples that were toxic after treatment in the replicate experiment were the same wastes as were found to be toxic in the previous experiment, while three were from different wastes.

When the Formalex treated wastes were subjected to a modified aquatic LC_{50} analysis, without a shaking period to homogenize the waste before adding it to the fish tank, all ten samples had LC_{50} concentrations >750 mg/L.

Discussion of Field Test Results

Formalex reduced the concentration of formaldehyde in the 10% NBF waste by approximately 85-95%.

The ten wastes used in the testing exhibited LC_{50} concentrations before treatment of >500 mg/L, which is less toxic than the hazardous waste criterion. These test results were not intended to establish a hazardous waste classification for the 10% NBF wastestreams. It is recognized that the toxicity may vary within and between laboratories. Many health care facilities classify and manage their 10% NBF wastes as hazardous in CA. Only limited data has been provided to DTSC regarding testing of other 10% NBF samples for comparison to the acute aquatic 96-hour LC_{50} hazardous waste criterion of Title 22 CCR section 66261.24(a)(6). Some data received by DTSC from generators indicates that the wastes may be hazardous in some cases. Each generator of 10% NBF wastes should test their wastes for hazardous waste classification and manage them accordingly.

After treatment with Formalex, about one-half the wastes were more toxic than before treatment and more toxic than the hazardous waste threshold, when tested using the Standard Method specified in Title 22 CCR section 66261.24(a)(6). This standard method shakes an aliquot of the wastes with water to homogenize them prior to adding the waste to the fish tanks. When the method was modified to test the waste with less shaking, the wastes were all >750 mg/L after treatment.

The toxicity of the post-treatment wastes could not be determined from a visual inspection of the treated wastes. Wastes with large amounts of precipitate, as well as wastes with little or no precipitate were found to be toxic (LC_{50} <500 mg/L) in some cases. For wastes treated with Formalex, the toxicity of the waste after treatment, and whether the waste would meet a hazardous waste criterion after treatment, could not be established using the HACH test kit recommended by the Formalex manufacturer.

The Formalex technology is a proprietary formulation based on the acid-catalyzed condensation reactions of urea with formaldehyde. The mechanism of toxicity of wastes treated with Formalex is

unknown. A consideration of potential chemical or physiological mechanism of toxicity was beyond the scope of the evaluation. An open-ended research project would be required to develop and test alternative hypotheses. It is not obvious what requirements could be placed on the technology to ensure that it would be safe and effective when used at health care facilities.

The post-treatment pH values of the Formalex treated wastes were in the range of pH 3.5 - 4.1. Local POTWs may require neutralization of such wastes before disposal to the sanitary sewer system.

One pre-treatment sample had an anomalously low pH. The low pH of this sample (sample 391, pH 1.5) did not affect the toxicity of the pre-treatment waste or the ability of the technologies to treat the formaldehyde in the waste. The post-treatment formaldehyde concentrations for this sample were similar to those for the other samples. The post-treatment toxicity for this sample was >750 mg/L after treatment.

What the Data Show. The data show that, before treatment, all ten wastes were slightly less toxic than the hazardous waste threshold. After treatment with Formalex, about one-half of the samples in each batch were ***more toxic after treatment than before treatment***, and ***more toxic than the hazardous waste threshold***.

The increased toxicity for the Formalex treated wastes may depend on the conditions under which the toxicity test was performed. When the toxicity test was performed under the modified procedures (without homogenization of the waste) the waste was less toxic. The toxicity does not appear to depend on how rapidly the reaction occurs (precipitate forms) or how much precipitate is generated. To investigate the toxicological mechanism, or how changes in waste management practices could increase or decrease the toxicity, would require an extensive, open-ended research project. This is beyond the scope of the program. In the absence of an understanding of the reasons for the varying toxicities, DTSC is unable to specify operating conditions under which it is confident that the technologies can be used safely and effectively.

Other problems with the Formalex technology. HML staff found the instructions to be unclear. The product is not supplied with a Lot Number or expiration date. A test kit provided with the technology for determining treatment completion is ineffective at measuring formaldehyde concentration in the wastes. The instructions state a 30 - 90 minute time for the reaction mixture to turn cloudy, and that treatment is complete when the precipitate settles to the bottom of the container. HML found that some of the samples required >4 hours for the solution to turn cloudy, and that the precipitate continued to settle for in excess of 24 - 48 hours.

S&S Company Review/Comments on the Field Test Results

DTSC Provided a copy of its Formaldehyde Treatment Technologies Re-Certification Evaluation Report to S&S Company and American BioSafety for their comments. At S&S Company's request, DTSC extended the review/comment period an additional 90 days for S&S Company to determine the cause of the increased toxicity. On May 29, 2001, S&S Company of Georgia, Inc. submitted data from analyses performed by Sequoia Analytical (Sequoia), a company with a group of analytical laboratories in California. The Sequoia submittal did not comment directly on the DTSC field tests. An initial review of the Sequoia data package by DTSC staff identified critical problems with the Sequoia data set. On July 16, 2001, American Bio-Safety, Inc., the California distributor of Formalex,

submitted a letter via e-mail acknowledging data quality problems with the Sequoia data package.

The reasons for increased toxicity after treatment with Formalex when tested using the standard bioassay procedure (which includes an extended shaking period) are still unknown. The design of the Sequoia Analytical work did not provide any information that may explain the high toxicity results determined during the DTSC field tests.