

Department of Environmental Protection

Jeb Bush
Governor

Twin Towers Office Building
2600 Blair Stone Road
Tallahassee, Florida 32399-2400

Colleen M. Castille
Secretary

May 3, 2006

Michael T. Saul
CL Solutions, LLC
1157 Industrial Road
Cold Spring, Kentucky 41076

Re: CL-Out

Dear Mr. Saul:

The Florida Department of Environmental Protection (Department) hereby reaffirms its original December 14, 2000 acceptance of CL-Out for in situ and ex situ bioremediation of chlorinated solvents, petroleum and other suitable contaminants in soil and groundwater. This reaffirmation supersedes the original December 14, 2000 acceptance. The formulation of the product has not changed, but since there have been changes in the addresses of both CL Solutions LLC and the manufacturer, and clarifications added to our acceptance letters over the years, this is an appropriate time to update the acceptance of CL-Out.

The product is a proprietary mixture of non-pathogenic, natural-occurring bacteria and nutrients. A voucher for the manufacturer's confidential disclosure of the ingredients and their proportions is provided as Enclosure 1.

This acceptance applies only to the regulatory jurisdiction and the remediation needs of the Florida Department of Environmental Protection. Other government agencies and local governments may choose to recognize this acceptance if their needs and regulations are similar. This Department, however, is not responsible for applications beyond its jurisdiction.

For injection-type, in situ groundwater remediation via direct injection of CL-Out, there are underground injection control (UIC) regulations that must be observed. Since injection-type remediation is likely to be the most common application of this product, the bulk of the regulatory requirements discussed herein will be directed to that topic.

There are no objections to the use of CL-Out provided: (a) the considerations of this letter are taken into account; and (b) a site-specific Remedial Action Plan is approved by the Department for each site where the use of CL-Out is proposed. The major regulatory considerations that apply to CL-Out are listed in Enclosure 2.

While the Department of Environmental Protection does not provide endorsement of specific or brand name remediation products or processes, it does recognize the need to determine their acceptability from an environmental standpoint with respect to applicable rules and regulations, and the interests of public health and safety. After a product is accepted, vendors must then market it on its own merits regarding performance, cost and safety in comparison to competing alternatives in the marketplace. In no way, however, shall this regulatory acceptance letter be construed as Department certification of product performance. Additionally, the Department emphasizes a

Michael T. Saul
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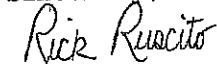
distinction between its regulatory "acceptance" and an approval. Products and processes are accepted but they are not approved.

Also, it is not a requirement that a particular remediation product or process have an official acceptance letter in order for it to be proposed in a site-specific Remedial Action Plan. The plan, however, must contain sufficient information about the product or process to show that it meets all applicable and appropriate rules and regulations.

Those who prepare Remedial Action Plans are advised to include a copy of this letter in the appendix of plans they submit, and call attention to it in the text of their document. In this way, technical reviewers throughout the state will be informed that you have contacted the Department to inquire about the environmental acceptability of CL-Out. To aid those reviewers, supplemental information is provided as Enclosure 3.

The Department reserves the right to revoke its acceptance of a product or process if it has been falsely represented. Additionally, Department acceptance of any product or process does not imply it has been deemed applicable for all cleanup situations, or that it is preferred over other treatment or cleanup techniques in any particular case. A site-specific evaluation of applicability and cost-effectiveness must be considered for any product or process, whether conventional or innovative, and adequate site-specific design details must be provided in a Remedial Action Plan. You may contact me at (850) 877-1133, extension 29 if there are any questions.

Sincerely,



Rick Ruscito, P.E.
Ecology and Environment, Inc.
Bureau of Petroleum Storage Systems
Petroleum Cleanup Section 6



Rebecca S. Lockenbach
FDEP Section Leader
Bureau of Petroleum Storage Systems
Petroleum Cleanup Section 6

c: Peter A. Vandenberg, Ph.D., Vice Pres.
Osprey Biotechnics, Inc.
1833A 57th Street
Sarasota, Florida 34243

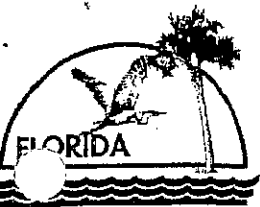
T. Conrardy - FDEP - MS 4530/Tallahassee

Enclosures: (1) Proprietary Ingredients Voucher
(2) Regulatory Information
(3) Supplemental Information
(4) Underground Injection Control Notification

History:

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ENCLOSURE 1

CL-Out PROPRIETARY INGREDIENTS VOUCHER

Department of Environmental Protection

Jeb Bush
Governor

Twin Towers Office Building
2600 Blair Stone Road
Tallahassee, Florida 32399-2400

Colleen M. Castille
Secretary

May 3, 2006

Peter A. Vandenberg, Ph.D., Vice Pres.
Osprey Biotechnics, Inc.
1833A 57th Street
Sarasota, Florida 34243

Re: CL-OUT Proprietary Ingredients Voucher

Dear Mr. Vandenberg:

The Florida Department of Environmental Protection (Department) hereby re-acknowledges receipt of a confidential disclosure dated November 18, 1999 from Osprey Biotechnics Incorporated, regarding the proprietary ingredients and their proportions in CL-Out, a bacteria product for the remediation of chlorinated solvents, petroleum and other suitable contaminants. This re-acknowledgement supersedes the original that was made on December 14, 2000. There have been no changes to the formulation of CL-Out, but since there have been changes of addresses for both Osprey Biotechnics Incorporated (the manufacturer) and CL Solutions, LLC (the Florida Agent), and clarifications added to our acceptance letters over the years, this is an appropriate time to update this voucher.

Having reviewed the confidential disclosure, we hereby vouch that the proprietary bacteria and nutrient ingredients are consistent with Osprey Biotechnics' claims about the nature of the product in its Material Safety Data Sheet and advertising bulletin. CL-Out contains only natural-occurring bacteria of the genus *Pseudomonas* but not the species *Pseudomonas aeruginosa*. Additionally, it does not contain as ingredients, but is tested to verify the absence of *Xanthomonas*, *Salmonella*, and *Shigella*.

The Department is therefore reasonably assured that the product will not violate the minimum criteria for groundwater set forth in Section 62-520.400, Florida Administrative Code, (F.A.C.), which requires that the groundwater of the state be free from substances that are harmful to plants, animals, and organisms, and free from substances that are carcinogenic, mutagenic, teratogenic or toxic to human beings. However, the obligation to comply with the minimum groundwater criteria, and all other applicable rules and regulations, ultimately rests with Osprey Biotechnics and users of the product, not the Florida Department of Environmental Protection. No ingredients, chemical species, or byproducts formed as a result of using CL-Out shall result in a violation of any applicable and appropriate rules and regulations.

Peter A. Vandenberg, Ph.D., Vice Pres.
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For underground injection control purposes, remediation plans proposing the use of CL-Out must disclose the volume and composition of the fluid to be injected into an aquifer. Since the composition is proprietary, it will suffice to indicate the overall concentration of the solution and then provide a footnote indicating that a one-time confidential disclosure regarding the composition has been submitted to the Department and accepted. Questions may be directed to Rick Ruscito at (850) 877-1133, extension 29.

Sincerely,

Rick Ruscito

Rick Ruscito, P.E.
Ecology and Environment, Inc.
Bureau of Petroleum Storage Systems
Petroleum Cleanup Section 6

Rebecca S. Lockenbach

Rebecca S. Lockenbach
FDEP Section Leader
Bureau of Petroleum Storage Systems
Petroleum Cleanup Section 6

ENCLOSURE 2

REGULATORY INFORMATION

- a. Applicable rules and regulations: The onus shall be on Osprey Biotechnics Incorporated, CL Solutions, LLC, and users of CL-Out to comply with all applicable regulations, particularly those regarding underground injection control and groundwater quality. All applicable groundwater contaminant standards shall be met at the time of project completion for the contaminants of concern, any residuals associated with the ingredients of CL-Out, and any byproducts produced as a result of chemical or biochemical reactions involving those ingredients. The following chapters of the Florida Administrative Code (F.A.C.) are cited as applicable but should not be construed as an exhaustive list: Chapter 62-550, F.A.C., for primary and secondary water quality standards; Chapter 62-520, F.A.C. for groundwater classes and standards; Chapter 62-522, F.A.C., for groundwater permitting and monitoring requirements; Chapter 62-528, F.A.C., for underground injection control, particularly Part V, for Class V, Group 4 aquifer remediation wells; and Chapter 62-777, F.A.C., for contaminant cleanup target levels.

A noteworthy aspect of the minimum criteria set forth in Chapter 62-520, F.A.C., is that it requires groundwater to be free from substances which are harmful to plants, animals, and organisms, and free from substances that are carcinogenic, mutagenic, teratogenic or toxic to human beings. In effect, these "free from" requirements form a catchall. They close what would otherwise be a loophole in the regulations by preventing injection of a potentially harmful product in the event that any of its ingredients is not regulated as a specific primary or secondary drinking water contaminant.

- b. Injection well permit: The issuance of a site-specific Remedial Action Plan Approval Order by the Department for injection-type aquifer remediation constitutes the granting of a Class V injection well permit. [62-528.630(2)(c) and 62-528.640(1)(c), F.A.C.]
- c. Groundwater injection standards: For in situ aquifer remediation, the composition of an injected fluid must meet the drinking water standards set forth in Chapter 62-550, F.A.C., pursuant to underground injection control Rule 62-528.600(2)(d), F.A.C., and the minimum groundwater criteria set forth in Chapter 62-520, F.A.C. If Osprey Biotechnics makes changes to the CL-Out formula in the future, then the Department should be notified, and the chemical analysis of the reformulated injection fluid compared to groundwater injection standards to determine whether permission for a temporary zone of discharge is necessary. Information about temporary injection zones of discharge can be found in the remedial action guidance publication titled *BPSS-10, In Situ Chemical Additives* at Department web page www.dep.state.fl.us.
- d. Utilization of wells: If a remediation site happens to have an abundance of monitoring wells, then the Department has no objection to the use of some wells for the application of CL-Out. However, no "designated" monitoring well, dedicated to the tracking of remediation progress (by sampling) shall be used to apply CL-Out. This will avoid premature conclusions that the entire site meets

cleanup goals. By making sure that designated tracking wells are not used for treatment, there will be more assurance that the treatment process has permeated the entire site and that it did not remain localized to the area immediately surrounding each injection well.

e. Groundwater monitoring:

1. Active and post active remediation monitoring of contaminants: During the periods of active remediation and post active remediation monitoring, groundwater shall be monitored for the contaminants of concern in accordance with an approved Remedial Action Plan.
2. Underground injection control monitoring: Since no ingredient in CL-Out exceeds a maximum contaminant level (MCL) allowed by the drinking water standards of Chapter 62-550, F.A.C., the Department, pursuant to Rules 62-528.615(1)(b)1 and (2), F.A.C., has determined that the tracking of any particular ingredient shall not be mandatory for underground injection monitoring purposes.

f. Operation:

1. Avoidance of migration: For in situ, injection-type aquifer remediation projects, injection of CL-Out shall be performed in such a way, and at such a rate and volume, that no undesirable migration of either the product's ingredients or the contaminants of concern in the aquifer results, pursuant to Rule 62-528.630(3), F.A.C.
2. Underground injection control operating permit: Although an operating permit is not required for aquifer remediation wells pursuant to Rule 62-528.640(1)(b), and 62-528.640(1)(c), F.A.C., since no movement of the contamination plume is expected to accompany the application of CL-Out, the Department requests that the information items listed in Rule 62-528.640(1)(b), F.A.C., be considered and included in Remedial Action Plan proposals as a matter of good and thorough design practice. Briefly summarized, they are: quality of water in the aquifer; quality of the injected fluid; existing and potential uses of the affected aquifer; and well construction details. Additionally, each Remedial Action Plan should clearly indicate the total volume of fluid and the concentration of products that will be injected.
3. Operating parameter measurements: Remedial Action Plans proposing the use of CL-Out should specify the frequency of measurement for bioremediation operating parameters such as dissolved oxygen levels, pH, temperature, rates of nutrient addition, etc. At some point in the cleanup, it may be appropriate to discontinue or reduce the frequency of such measurements.

- g. Abandonment of wells: Upon issuance of a Site Rehabilitation Completion Order, or a declaration of "No Further Action", injection wells shall be abandoned pursuant to Section 62-528.645, F.A.C. The Underground Injection Control Section of the Department shall be notified so that the injection wells can be removed from the inventory-tracking list.

ENCLOSURE 3

SUPPLEMENTAL INFORMATION

- a. Nature of the product: CL-Out is a mixture of non-pathogenic, natural-occurring bacteria and nutrients. It is shipped in a freeze-dried state and must be re-hydrated prior to use.
- b. Department of Environmental Protection reviewers of in situ injection-type aquifer remediation plans, regardless of whether in Tallahassee or district offices, must fill in the blanks on the Enclosure 4 memorandum, whose subject is "Proposed Injection Well(s) for In Situ Aquifer Remediation at a Remedial Action Site". The completed form must be submitted to the Underground Injection Control Section at 2600 Blair Stone Road, Tallahassee, Florida 32399-2400.

Only the Florida Department of Environmental Protection or its district offices may approve in situ injection-type remediation plans in which the approval constitutes the state's issuance of a Class V injection permit. Local programs contracted by the state to review Remedial Action Plans at the county or city level are not authorized to grant such approvals. Reason: Although an arrangement between the U.S. Environmental Protection Agency and the Florida Department of Environmental Protection delegates underground injection control authority to the Department, it does not allow the Department to delegate that authority any further. This includes delegation to counties and other local governments that may be contracted by the Department to conduct reviews. These contracted local programs, however, can still conduct reviews of injection-type remediation plans but must make arrangements with the Department for Department-issuance of approval orders for them.

- c. Pilot study: For bioremediation, a pilot study proposal should be submitted for review, and a pilot test performed prior to designing a treatment system. If conditions or the situation at a site do not warrant a pilot study, then the rationale for a decision not to perform a pilot study should be provided.
- d. Underground injection control inventory: Remedial Action Plans proposing in situ injection-type aquifer remediation shall include information pursuant to Rule 62-528.630(2)(c)1 through 6, F.A.C., for the inventory purposes of underground injection control. Per Rule 62-528.630(2)(c), F.A.C., aquifer remediation projects involving injection wells may be authorized under the provisions of a Remedial Action Plan, provided the construction, operation, and monitoring requirements of Chapter 62-528, F.A.C., are met. A memorandum outlining the inventory information about injection-type aquifer remediation plans to be transmitted by Department reviewers to the Underground Injection Control Section is provided as Enclosure 4.
- e. Bacteria: It is generally reported (on a total weight basis) that bacteria are approximately 70 to 80 percent water. On a dry weight basis, approximately 95 percent of the composition is represented by 5 elements: carbon, oxygen, nitrogen, hydrogen, and phosphorus. Depending on a site's specific conditions, these elements must either be available naturally, or added as macronutrients in order

to stimulate bioremediation. Micronutrients must also be present for bacteria to grow.

- f. Dosage and application rate: The Department recommends that dosages and application rates of remediation products be determined on a site-specific basis. Generally, however, per information submitted to the Department, and discussion with Osprey Biotechnics Incorporated and CL Solutions, LLC, 3.5 pounds of freeze-dried CL-Out is re-hydrated with 55 gallons of tap water and held at 23 to 29 deg. C (73 to 84 deg. F) for 24 hours prior to use. This mixture of 3.5 pounds of CL-Out and 55 gallons of water is equivalent to a CL-Out concentration of 0.763% by weight. Distilled water may be substituted for tap water when preparing CL-Out batches in locations where the tap water is highly chlorinated, since too much chlorine will kill the bacteria.

For rule-of-thumb and estimating purposes, each 55-gallon batch of the re-hydrated mixture is capable of remediating approximately 240 tons of contaminated soil or approximately 165,000 gallons of contaminated groundwater. A second application, 30 days after the initial application, is recommended.

**Florida Department of
Environmental Protection**

Memorandum

TO: Richard Deuerling, Mail Station 3530
Division of Water Resource Management
Underground Injection Control Section
Florida Department of Environmental Protection
2600 Blair Stone Road, Tallahassee, FL 32399-2400

FROM: _____ [see Note 1.]

DATE: _____

SUBJ: **Proposed Injection Well(s) for In Situ Aquifer
Remediation at a Remedial Action Site**

Pursuant to paragraph 62-528.630(2)(c), F.A.C., inventory information is hereby provided regarding the proposed construction of temporary injection well(s) for the purpose of in situ aquifer remediation at a contaminated site.

Site name: _____
Site address: _____
City/County: _____
Latitude/Longitude: _____
FDEP Facility Number: _____

Site owner's name: _____
Site owner's address: _____

Well contractor's name: _____ [see Note 2.]
Well contractor's address: _____

Brief description of the in situ injection-type aquifer remediation project:

Richard Deuerling

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Date: _____

Site name: _____

FDEP Facility No.: _____

Summary of major design considerations and features of the project:

Areal extent of contamination (square feet): _____

Number of injection wells: _____

Composition of injected fluid [see Note 3.]

(ingredient, wt. %): _____

Injection volume per well (gallons): _____

Single or multiple injection events: _____

Injection volume total (all wells, all events): _____

A site map showing the areal extent of the groundwater contamination plume, and the location and spacing of injection wells and associated monitoring wells is attached.

The following is a summary description of the affected aquifer:

Name of aquifer: _____

Depth to groundwater (feet): _____

Aquifer thickness (feet): _____

The injection well(s) features are summarized below, and/or a schematic of the injection well(s) is attached.

Direct-push or HSA/Mud rotary (*circle the appropriate well type*)

Diameter of well(s) (i.e., riser pipe & screen) (inches): _____

Total depth of well(s) (feet): _____

Screened interval: _____ to _____ feet below land surface

Grouted interval: _____ to _____ feet below land surface

Casing diameter, if applicable (inches): _____

Cased depth, if applicable: _____ to _____ feet below land surface

Casing material, if applicable: _____

The in situ injection-type aquifer remediation plan for this contaminated site is intended to meet the groundwater cleanup criteria set forth in Chapter 62-777, F.A.C., for the

Richard Deuerling

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Date: _____

Site name: _____

FDEP Facility No.: _____

contaminants of concern. Additionally, all other groundwater standards will be met at the time of project completion for any residuals associated with the ingredients of the injected remediation products, and any by-products or intermediates produced as a result of the chemical or biochemical transformation of those ingredients or the contaminants of concern during their use. Applicable primary and secondary drinking water standards are set forth in Chapter 62-550, F.A.C., and additional groundwater quality criteria are set forth in Chapters 62-520 and 62-777, F.A.C.

The remediation plan estimates that site remediation will take _____ months. We will notify you if there are any modifications to the remediation strategy which will affect the injection well design or the chemical composition and volume of the injected remediation product(s).

The proposed remediation plan was approved on _____ by an enforceable approval order. A copy is attached. The remediation system installation is expected to commence within 60 days. Please call me at _____ if you require additional information.

Note 1. This form is primarily for use by Florida Department of Environmental Protection technical reviewers or Department-designated reviewers. Remediation contractors may fill in all blanks except those labeled "FROM" and "DATE" on page 1, and the approval date and telephone number blanks in the last paragraph. Those blanks should be completed only by a Department reviewer or a Department-designated reviewer.

Note 2. If an injection well installation contractor has not yet been selected, then indicate the name and address of the project's general remediation contractor/consultant.

Note 3. Complete chemical analysis of injected fluid is required by Chapter 62-528, F.A.C. Proprietary formulations shall make confidential disclosure. Injected fluids must meet drinking water standards of Chapter 62-550, F.A.C., unless permission for a temporary zone of discharge has been granted by way of Rule 62-522.300(2), F.A.C., or a variance.