

Florida Department of Environmental Protection

Bob Martinez Center
2600 Blair Stone Road
Tallahassee, Florida 32399-2400

Charlie Crist
Governor

Jeff Kottkamp
Lt. Governor

Michael W. Sole
Secretary

August 12, 2008

Mr. Michael D. Lee, Ph.D.
Terra Systems Inc.
1053 Philadelphia Pike, Suite E
Wilmington, Delaware 19809

Re: TSI DC

Dear Mr. Lee:

The Bureau of Waste Cleanup (the Bureau) hereby accepts TSI DC for in-situ anaerobic bioremediation of chlorinated hydrocarbons in groundwater. There are no objections to the use of TSI DC for the remediation of contaminated sites in Florida, provided a site-specific Remedial Action Plan is approved by the Department. The product is a microbial consortium and the specific make-up of the product has been declared proprietary. Therefore, a proprietary analysis voucher is provided in Enclosure 1. Regulatory information is provided in Enclosure 2, and supplemental information is provided in Enclosure 3.

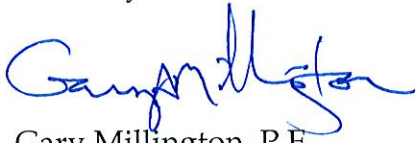
The Department does not provide endorsement of specific or brand name remediation products or processes, however, it does recognize the need to determine their acceptability in the context of environmental regulations, and the protection of public health and safety. In no way shall this regulatory acceptance be construed as an endorsement or certification of product performance. Additionally, the Department emphasizes a distinction between its regulatory "acceptance" letter and an approval. Products and processes are accepted but they are not approved. Vendors and environmental consulting companies must market the products and processes on their own merits regarding performance, cost, and safety in comparison to competing alternatives in the marketplace.

Remedial Action Plans that include use of an accepted product or process should include a copy of the acceptance letter in the plan's appendix, and reference it in the text of the document. 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 rules and regulations.

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The Department reserves the right to revoke its acceptance of a product or process if it has been falsely or incompletely 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 design details must be provided in a site-specific Remedial Action Plan submitted for Department review and approval. Please contact me at (850) 245-7502, if there are any questions.

Sincerely,

A handwritten signature in blue ink, appearing to read "Gary Millington".

Gary Millington, P.E.
Program and Technical Support Section
Bureau of Waste Cleanup

c: T. Conrardy - DEP/Tallahassee
R. Cowdery - DEP/Tallahassee



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Terra Systems Inc.
1053 Philadelphia Pike, Suite E
Wilmington, Delaware 19809

Re: Proprietary Analysis Voucher

Dear Mr. Lee:

The Bureau of Waste Cleanup (Bureau) hereby acknowledges receipt of a confidential disclosure dated July 25, 2008, by Terra Systems, Inc., regarding the proprietary analyses of the following materials associated with its TSI DC product:

Component 1: a microbiological formulation

Having reviewed the confidential disclosure, the Bureau hereby vouches for the analyses and that this product meets the requirements of Chapters 62-522 and 62-528, F.A.C. A temporary injection zone of discharge is not needed for this product.

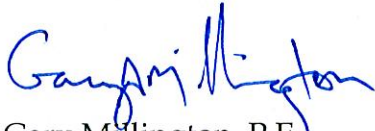
Each site-specific Remedial Action Plan that proposes to use TSI DC must include information that is required by Chapters 62-522 and 62-528, F.A.C. Enforceable approval orders for Remedial Action Plans containing this information, when issued by the Department, will constitute approval of the site-specific plan and will meet the requirements of the underground injection control (UIC) program.

For underground injection control purposes, remediation plans proposing to use the TSI DC product 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 proprietary analyses has been submitted to the Department and accepted. Reference should be made to the original July 25, 2008, disclosure, and a copy of this voucher should be included as an appendix in the plan.

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Reviewers of cleanup site remedial plans involving the use of TSI DC may contact Gary Millington at 850.245.7502.

Sincerely,

A handwritten signature in blue ink, appearing to read "Gary Millington". The signature is fluid and cursive, with the first name "Gary" and last name "Millington" clearly distinguishable.

Gary Millington, P.E.
Program and Technical Support Section
Bureau of Waste Cleanup

c: T. Conrardy - DEP/Tallahassee
R. Cowdery - DEP/Tallahassee

REGULATORY INFORMATION

1. Regulations: Users of TSI DC shall comply with all applicable regulations. This includes meeting all applicable groundwater contaminant standards for the residual concentrations of chemical and biological agents used to remediate the contaminants, and any byproducts of concern produced by chemical and biological reactions induced by those agents, within the applicable regulatory timeframes. The following chapters of the Florida Administrative Code (F.A.C.) may be applicable in determining these timeframes: 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 projects; Chapters 62-780, 62-782, and 62-785, F.A.C., for cleanup criteria; and Chapter 62-777, F.A.C., for cleanup target levels.
2. Underground Injection Control permit: Per Rule 62-528.630(2)(c), F.A.C., Class V injection-type aquifer remediation wells are exempt from the permitting requirements of Rule 62-528.635, F.A.C., provided they are authorized under the provisions of a Remedial Action Plan (RAP) or other enforceable mechanism, and the requirements of the rules governing the remediation project, as well as the construction, operation, and monitoring requirements of Chapter 62-528, F.A.C., are met. The issuance of an enforceable, site-specific Remedial Action Plan Approval Order by the Department for injection-type aquifer remediation constitutes the granting of a Class V injection well construction/clearance permit.

Per Rule 62-780.700(2), F.A.C., if a pilot study is proposed for a cleanup site, a pilot study work plan shall be submitted for review to determine the need for UIC or other permits. This would typically be done before a remedial action plan (RAP) is submitted. In that case, approval of the work plan would grant approval for the UIC well.

3. Underground Injection Control notification: RAPs proposing in-situ, injection-type aquifer remediation shall include information pursuant to Rules 62-528.630(2)(c)1 through 6, F.A.C., for the inventory purposes of the underground injection control program. Reviewers of those plans, upon issuance of an enforceable Remedial Action Plan Approval Order by the Department, must submit a completed copy of the Underground Injection Control inventory notification memorandum. This notification must be submitted by the reviewer, whose name must appear in the "From:____" area on the first page, not the name of the environmental consulting company that prepared the remediation plan.
4. Temporary injection zone of discharge: Rule 62-522.300(2)(c), F.A.C., allows a temporary injection zone of discharge (ZOD) for closed-loop re-injection systems, for the prime constituents of the reagents used to remediate site contaminants, and

for the secondary standards for ground water, as specified in a Department-approved remedial action plan that addresses the duration and size of the ZOD, and ground water monitoring requirements. For the injection of TSI DC, permission for a temporary injection zone of discharge is not necessary. However, injecting other materials along with TSI DC may require that a ZOD be sought as part of the Remedial Action Plan pursuant to paragraph 62-522.300(2)(c), F.A.C.

In order to obtain permission for a temporary zone of discharge via paragraph 62-522.300(2)(c), F.A.C., a site-specific Remedial Action Plan must indicate: (a) the chemical species of concern with respect to the minimum groundwater criteria of Chapter 62-520, F.A.C.; (b) the size of the zone that is needed; (c) the amount of time that the zone will be needed; and (d) a groundwater monitoring plan for the injected chemical species of concern. The size of the temporary injection zone of discharge in item (b) above will usually be just the radius of influence when the treatment system is a single injection point. For a multiple point system, the zone of discharge can usually be expressed and illustrated as the total area of a cluster formed by all the injection points, located side-by-side with overlapping radii of influence.

5. Utilization of wells: If a remediation site has an abundance of monitoring wells, then the Department has no objection to the use of some existing wells as injection points for remediation agents. However, no monitoring well dedicated to the tracking of remediation progress (by sampling) shall be used as a treatment point. This will avoid a premature conclusion that the entire site meets cleanup goals. By making sure that designated monitoring wells are not used for the introduction of remediation agents, there will be more assurance that the agents have permeated and treated the entire site, and that they did not remain localized to the immediate area surrounding each treatment point.
6. Avoidance of migration: Per Rule 62-528.630(3), F.A.C., in-situ, injection-type aquifer remediation projects shall be conducted in such a way that there is no undesirable migration of either the remediation agents used or the contaminants of concern.
7. Abandonment of wells: Upon issuance of a Site Rehabilitation Completion Order, injection wells shall be abandoned pursuant to Section 62-528.645, F.A.C., and the Underground Injection Control Section of the Department shall be notified so that the treatment wells can be removed from the injection well inventory tracking list.

SUPPLEMENTAL INFORMATION

- A. Department of Environmental Protection reviewers of in situ injection-type aquifer remediation plans, regardless of whether in Tallahassee or district offices, must complete the UIC memorandum, "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 reviewers within the Department and its district offices may approve in situ injection-type remediation plans in which the approval constitutes the issuance of a Class V injection permit; local programs are not authorized to grant such approvals. The reason: although an arrangement between the US Environmental Protection Agency and the Department delegates underground injection control authority to the Department, it does not allow the Department to delegate that authority any further. This includes delegation to the Department's contracted remediation review agencies such as those operated by the counties and other local governments.

- B. Pilot study: Per Rule 62-780.700(2), F.A.C., if a pilot study is proposed for a cleanup site, a pilot study work plan shall be submitted for review to determine the need for UIC or other permits. This would typically be done before a remedial action plan (RAP) is submitted. In that case, approval of the work plan would grant approval for the UIC well.
- C. Dosage: The exact dosage of its products will vary from site to site, depending on the volume of contaminated media and the mass of contaminants present. Therefore, each site-specific Remedial Action Plan must indicate the amount of the product to be used in order to comply with underground injection control requirements.