



Department of Environmental Protection

Jeb Bush
Governor

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

Colleen M. Castille
Secretary

March 28, 2006

Mr. Paul E. Gill
X-19 Biological Products, Inc.
2005 De La Cruz Boulevard, Suite 180
Santa Clara, California 95050

Re: **Bio-Gel**

Dear Mr. Gill:

The Bureau of Petroleum Storage Systems hereby accepts Bio-Gel for in situ and ex situ bioremediation of petroleum and other suitable contaminants. Bio-Gel is made from plant matter and contains only natural-occurring microorganisms. As you have indicated, it has the same constituents as X-19 for soil-only, another product offered by your firm and accepted by the Florida Department of Environmental Protection on March 8, 1999. Bio-Gel, however, differs from X-19 in that Bio-Gel is applied as a liquid. The aqueous form makes it suitable for application via direct injection, infiltration gallery or as slurry, and it can be used to treat both groundwater and soil. Laboratory analytical results for Bio-Gel parameters of interest are provided in enclosure 1.

This acceptance applies to the regulatory jurisdiction of the Bureau of Petroleum Storage Systems within the Florida Department of Environmental Protection, which is the cleanup of petroleum contamination pursuant to Chapter 62-770, Florida Administrative Code (F.A.C.). Other bureaus, government agencies and local governments may choose to recognize this acceptance if their needs and regulations are similar. The Bureau of Petroleum Storage Systems, however, is not responsible for applications beyond its jurisdiction.

There are no objections to the use of Bio-Gel provided: (a) the considerations of this letter are taken into account; (b) a Remedial Action Plan is prepared and submitted for each cleanup site where the use of Bio-Gel is proposed; (c) the site-specific Remedial Action Plan addresses the requirements of rule 62-522.300(2)(c), F.A.C., in order to obtain permission for a temporary injection zone of discharge for nitrate, boron and chloride; and (d) the Remedial Action Plan is approved by the Department. For Bio-Gel, the major regulatory considerations are set forth in enclosure 2.

While the Bureau of Petroleum Storage Systems 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 interest of public health and safety. After regulatory acceptance, vendors must market the products and processes on their 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 certification of performance. Additionally, the Bureau emphasizes a distinction between its regulatory "acceptance" and an approval. Products and processes are accepted but they are not approved.

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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, especially those of the Florida Administrative Code pertaining to underground injection control.

It is suggested that those who prepare Remedial Action Plans include a copy of this letter in the appendix, and call attention to it in the text of the plan. In this way, technical reviewers throughout the state will be informed that X-19 Biological Products has contacted the Florida Department of Environmental Protection to inquire about the environmental acceptability of Bio-Gel. To aid those reviewers, supplemental information is provided in enclosure 3.

The Department reserves the right to revoke its acceptance of a product or process if it has been falsely represented. Additionally, 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 site-specific Remedial Action Plan. You may contact Rick Ruscito by telephone at (850) 877-1133, extension 29, or at the letterhead address, Mail Station 4590, if there are any questions.

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

Enclosures: (1) Laboratory Analysis of Bio-Gel
(2) Regulatory Information
(3) Supplemental Information
(4) UIC Notification Memorandum

c: T. Conrardy - FDEP, Tallahassee/MS 4530

ENCLOSURE 1

LABORATORY ANALYSIS OF BIO-GEL †

Chemical Species or Parameter	Laboratory Value	Units	Current Florida Water Quality Standard
Electrical Conductivity	0.6	millimhos/cm	Not regulated
Calcium (Ca) ‡	32.6	mg/L	Not regulated
Magnesium (Mg) ‡	26.3	mg/L	Not regulated
Sodium (Na) ‡	18.4	mg/L	160
Chloride (Cl) ‡	<323 ▲	mg/L	250
Sulfate (SO ₄) ‡	115.3	mg/L	250
Boron (B)	0.9 ▲	mg/L	0.63
Nitrate nitrogen (as N) (NO ₃ - N)	24.4 ▲	mg/L	10
Nitrate (NO ₃)	108	mg/L	See "as N" above
Iron (Fe)	0.2	mg/L	0.3
Manganese (Mn)	<0.01	mg/L	0.05
Ammonium nitrogen (NH ₄ - N)	1.3	mg/L	2.8
Lead (Pb)	<0.01	mg/L	0.015
Copper (Cu)	0.02	mg/L	1
pH	8.2	Std. Units	Range 6.5 - 8.5

† These are analytical results for a 10:1 dilution of Bio-Gel, i.e. 10 parts de-ionized water to 1 part Bio-Gel. The Bureau of Petroleum Storage Systems emphasizes that usage is not restricted only to this ratio. For situations in which Bio-Gel will be diluted at ratios other than 10:1 prior to application, the user is hereby instructed to mathematically transform the concentrations of chemical species shown in this table to their corresponding concentrations at the new dilution ratio, and to compare the results for each species to the water quality standards set forth in Chapter 62-550, F.A.C. and Chapter 62-777, F.A.C.

‡ The laboratory analytical result for this chemical species was reported in milliequivalents per liter (meq/L). Since the water quality standards set forth in Chapters 62-550 and 62-777, F.A.C., are not reported in such units, the Bureau of Petroleum Storage Systems has converted the meq/L value to milligrams per liter (mg/L).

▲ Concentration of this species in a 10:1 (de-ionized water:Bio-Gel) solution exceeds its Florida water quality standard.

ENCLOSURE 2

REGULATORY INFORMATION

- a. Groundwater cleanup standards. The onus shall be on users of Bio-Gel to ensure that all applicable groundwater standards will be met at the time of project completion for the contaminants of concern, any residuals associated with the ingredients of Bio-Gel, and any by-products produced as a result of chemical or biochemical reactions involving those ingredients. The following chapters of the Florida Administrative Code are cited: Chapter 62-550, F.A.C., for primary and secondary water quality standards; Chapter 62-520, F.A.C. for groundwater classes and standards, and minimum criteria in general; 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; and Chapter 62-777, F.A.C., for cleanup target levels and minimum groundwater criteria for specific chemical species.

A noteworthy aspect of the general minimum criteria set forth in Chapter 62-520, F.A.C., is that it requires groundwater to 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. 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. Temporary injection zone of discharge. The Bureau of Petroleum Storage Systems, having reviewed a laboratory analysis for Bio-Gel parameters, advises those who prepare in situ, injection-type Bio-Gel Remedial Action Plans to seek permission for a temporary zone of discharge for nitrate-nitrogen, boron and chloride by way of rule 62-522.300(2)(c), F.A.C. In order to comply with the rule, each site-specific Remedial Action Plan must: (a) indicate that Bio-Gel could potentially cause a temporary exceedance of groundwater standards for nitrate-nitrogen, boron and chloride; (b) indicate the size of the temporary zone of discharge needed; (c) indicate the amount of time needed for the temporary zone of discharge; and (d) propose groundwater monitoring for nitrate-nitrate, boron and chloride.

The size (i.e. dimensions and shape) of a temporary aquifer injection zone of discharge will depend on the method by which the Bio-Gel is applied and on site-specific hydrogeological characteristics. There is no single, "one-size-fits all" way of determining the size and shape. Typically, for direct injections into an aquifer, it usually suffices to describe the zone of discharge as a radius of influence for an individual injection point. If several injection points are overlapped in a cluster, then the overall dimensions of the resulting conglomerate can also be used to define the size of the zone that is needed.

The duration period for a temporary zone of discharge is the amount of time that the injected Bio-Gel could cause a temporary exceedance of groundwater standards for nitrate-nitrogen, boron and chloride. The Bureau suggests that Remedial Action Plans proposing the injection of Bio-Gel can comply with the monitoring requirement of rule 62-522.300(2)(c), F.A.C., by proposing monitoring of nitrate-nitrogen, boron and chloride before injection (to establish the natural-occurring concentrations of these chemical species at a site) and after injection to demonstrate whether or not the Bio-Gel has had an effect on the concentrations of these chemical species in the groundwater. For post injection groundwater monitoring of the nitrate-nitrogen, boron and

chloride, a sampling frequency of quarterly should suffice in most cases. As each of these parameters meets its respective groundwater standard or natural-occurring background level, whichever is less stringent, the monitoring of it can cease or at least reduced in frequency.

- c. Injection permit. The issuance of a site-specific Remedial Action Plan Approval Order by the Department for injection-type aquifer remediation using Bio-Gel constitutes the granting of a Class V injection well permit. [Ref. Chapter 62-528.630(2)(c) and 62-528.640(1)(c), F.A.C.]
- d. Utilization of wells. If a remediation site happens to have an abundance of monitoring wells, then there is no objection to the use of some wells as injection points for the Bio-Gel. However, no "designated" monitoring well, dedicated to the tracking of remediation progress (by sampling) shall be used as Bio-Gel injection points. This will avoid premature conclusions that the entire site meets cleanup goals. By making sure that designated tracking wells are not also 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. 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 projects to be transmitted by Department reviewers to the Underground Injection Control Section is provided as enclosure 4.
- f. Avoidance of migration. For in situ injection-type aquifer remediation projects, injection of the Bio-Gel shall be performed in such a way that no undesirable migration of either its ingredients or the contaminants of concern in the aquifer results, pursuant to Rule 62-528.630(3), F.A.C.
- 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 Bio-Gel injection wells can be removed from the inventory-tracking list.

ENCLOSURE 3

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 fill in the blanks on the enclosure 4 memorandum, whose subject is "Proposed Injection Well(s) for In Situ Aquifer Remediation at a Contaminated Site". The completed form must be submitted to the Underground Injection Control Section at 2600 Blair Stone Road, Tallahassee, Florida, 32399-2400.
- b. Pilot study. For bioremediation or an innovative technology, per rule 62-770.700(2), F.A.C., a pilot study proposal shall be submitted for review, and a pilot test shall be performed prior to designing a full-scale treatment system. If conditions or the situation at a site do not warrant a pilot study, then a proposal explaining the rationale to forego it shall be submitted for review.
- c. Dosage and application. The Bureau of Petroleum Storage Systems recommends that prospective users contact X-19 Biological Products for advice on how to determine an appropriate Bio-Gel dose and application rate for the conditions at a specific remediation site. As indicated in the footnotes of the enclosure 1 laboratory analysis, the Bureau emphasizes that usage is not restricted to the 10:1 dilution (10 parts de-ionized water to 1 part Bio-Gel) for which the analysis was performed.

Environmental ProtectionMemorandum

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 Contaminated 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:

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 petroleum cleanup criteria set forth in Chapter 62-777, F.A.C. 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

Date: _____

Site name: _____

FDEP Facility No.: _____

those ingredients or the site's contaminants 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. Local programs are not authorized to approve underground injections into aquifers. Reason: Per agreement with the USEPA, the FDEP cannot delegate this authority. Local programs, after reviewing a Remedial Action Plan or an injection proposal document, should prepare the Approval Order and route it to Tallahassee for Bureau Chief's signature, and then complete this form. This form is primarily for use by state and local program technical reviewers, but petroleum 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 state or local program 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 an exemption or variance has been granted.