UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

OFFICE OF
GENERAL COUNSEL

Mr. Frances Sullivan
PetroBioTech LLC
P.O. Box 813
Newport, NH 03773

MAR 7 2011

Re: Final Confidentiality Determination for dispersant formula and chemical components of BIODISPERS

Dear Mr. Sullivan:

PetroBioTech LLC ("the Company" or "PetroBioTech") has asserted a confidentiality claim for the formula and components of your product BIODISPERS (formerly PETROBIODISPERS), submitted in accordance with Subpart J of the National Contingency Plan ("NCP"), 40 CFR Part 300. This information is responsive to requests filed with the U.S. Environmental Protection Agency ("EPA" or "Agency") under the Freedom of Information Act ("FOIA"), 5 U.S.C. § 552. The requests sought the formula for oil spill dispersants on an EPA Product Schedule, the dispersant components, and any health and safety studies submitted to the Agency under Toxic Substances Control Act ("TSCA") §8(e) for the components. One request is also the subject of a current lawsuit in the Northern District of Florida, *Florida Wildlife Federation, et al. v. United States Environmental Protection Agency* (N.D. FL. 4:10 cv 293-WS/WCS).

Pursuant to 40 C.F.R. part 2, subpart B, I am issuing the final determination on your confidentiality claim. I have carefully considered the Company's claim and substantiation. For the reasons explained below, I conclude that the formula meets the elements of FOIA Exemption 4 and shall remain confidential. I also conclude that the names of the components of your specific product will not be released. However, I finally conclude that the components of BIODISPERS shall be released as part of an aggregated list of all dispersant components that are part of products on the EPA's Product Schedule. The aggregated list will not identify dispersant product names. As a result of this determination, EPA may release the health and safety data associated with the components.

With respect to EPA's implementation of this determination, subject to 40 C.F.R. § 2.205(f)(2), EPA may make the information available to the public on the tenth (10th) working day after the date of the Company's receipt of the written notice, unless the EPA legal office has first been notified of the commencement of an action in a Federal court to obtain judicial review

of the determination and to obtain preliminary injunctive relief against disclosure.

BACKGROUND

Dispersants are chemical agents that emulsify, disperse, or solubilize oil into the water column or promote the surface spreading of oil slicks to facilitate dispersal of the oil into the water column. The Clean Water Act directs EPA to prepare a schedule of dispersants, other chemicals, and oil spill mitigating devices and substances that may be used to remove or control oil discharges. Section 311(d)(2)(G), 33 U.S.C. 1321(d)(2)(G). Pursuant to Subpart J of the NCP, 40 C.F.R. part 300, EPA maintains a Product Schedule that identifies all dispersants that have been authorized for use on oil discharges. Eleven manufacturers have a total of 14 dispersant products listed on the Schedule. Each manufacturer claimed its formula and list of components as confidential. In response to the FOIA request and litigation described above, the Agency is reviewing the confidentiality claims. One company, Nalco Company, previously waived its confidentiality claim for the identity of the components for its two dispersant products, Corexit EC9500A and EC9527A.

More specifically, the Company originally claimed the formula and components of BIODISPERS as confidential when this information was submitted to the Agency. By e-mail letter dated June 7, 2010 from R. Craig Matthiessen, Director, Regulations and Policy Development Division, Office of Emergency Management, EPA requested that PetroBioTech substantiate its claims of confidentiality for BIODISPERS.

By letter dated June 18, 2010, to Craig Matthiessen, you responded to EPA's request for substantiation ("response") concerning BIODISPERS. You stated, in part, that "[t]he company spent a substantial amount of money and effort to develop the product, patent the product and safeguard the information pertaining to the product." (Response, p.1).

DISCUSSION

FOIA Exemption 4 exempts from disclosure "trade secrets and commercial or financial information obtained from a person and privileged or confidential." 5 U.S.C. § 552(b)(4). In order for information to meet the requirements of Exemption 4, EPA must find the information is either (1) a trade secret; or (2) commercial or financial information obtained from a person and privileged or confidential (commonly referred to as "Confidential Business Information" ("CBI")). "FOIA is to be interpreted with a presumption favoring disclosure and exemptions are to be construed narrowly (citation omitted)." *Washington Post Co. v. Dep't of Justice*, 863 F.2d 96, 101 (D.C. Cir. 1988). The party seeking to prevent disclosure has the burden of proving that the circumstances justify nondisclosure. *Id. See Occidental Petroleum Corp. v. Securities and Exchange Comm'n.*, 873 F.2d 325, 342 (D.C. Cir. 1989). *See also* 5 U.S.C. § 552(a)(4)(B).

Initial Considerations

EPA's regulations at 40 C.F.R. § 2.208 state that, in order for business information to be

entitled to confidential treatment, the Agency must have determined that, *inter alia*:

(1) The business has asserted a claim of confidentiality and that claim has not expired, been waived, or been withdrawn;
(2) The business has shown that it has taken reasonable measures to protect the confidentiality of the information, and that it intends to continue to take such measures;
(3) The information is not, and has not been, reasonably obtainable by a third party without the business' consent through legitimate means; and
(4) No statute specifically requires disclosure of the information.

In your substantiation, the Company stated that it sought confidential treatment for the information "for an indefinite period of time." (Response, p.1). The Company further explained that it has taken reasonable steps to maintain the confidentiality of the information at issue and that the information is not publicly available. *Id.*

Trade Secret

A trade secret for the purpose of FOIA Exemption 4 has been defined as "a secret, commercially valuable plan, formula, process, or device that is used for the making, preparing, compounding, or processing of trade commodities and that can be said to be the end product of either innovation or substantial effort." *Public Citizen Health Research Group v. FDA*, 704 F. 2d 1280, 1288 (D.C. Cir. 1983). This definition requires that there be a "direct relationship" between the information and the production process. *Id.* The product formula developed by the Company contains the percentages of each ingredient that is used to manufacture the product. Therefore, the product formula for BIODISPERS falls within the definition of a trade secret and is exempt from disclosure under FOIA Exemption 4. However, the component list, without the underlying percentage, does not fall within the definition of a trade secret. Accordingly, I will now address whether the component list for BIODISPERS qualifies as confidential business information.

Confidential Business Information ("CBI")

If the information does not reveal a trade secret, it may still be exempt from release under Exemption 4 of the FOIA if it is CBI, *i.e.*, "commercial or financial information obtained from a person and privileged or confidential." 5 U.S.C. § 552(b)(4). The terms "commercial" or "financial," for purposes of Exemption 4 of the FOIA, "should be given their ordinary meanings." *Public Citizen Health Research Group*, 704 F.2d at 1290 (citing *Washington Post Co. v. HHS*, 690 F.2d 252, 266 (D.C. Cir. 1982)). The information at issue relates to a business, thereby meeting the ordinary definition of "commercial." Since the Company meets the definition of the term "person," as defined by EPA's regulations at 40 C.F.R. § 2.201(a), the information was "obtained from a person" as required by Exemption 4 of the FOIA. Finally, in order to qualify as CBI, the information must be "privileged or confidential." You have claimed this information to be confidential, but you have not claimed this information to be privileged. The Agency has no

indication that the information is subject to a common-law privilege and will therefore limit its discussion to the issue of confidentiality.

There are two different standards for determining confidentiality depending on whether the information is submitted on a voluntary basis or is required. As the Company asserts in its substantiation, the information claimed as confidential is a required submission. For a submission to be considered required, an agency must possess the authority to require submission of information to the agency and must exercise this authority. *National Parks*, 498 F.2d at 770; *Center for Auto Safety v. NHTSA*, 244 F.3d 144, 149 (D.C. Cir. 2001); *Parker v. Bureau of Land Management*, 141 F. Supp. 2d 71, 77-79, 78 n.6 (D.D.C. 2001); *see also Critical Mass*, 975 F.2d at 878. Here, the information at issue was collected pursuant to Subpart J of the NCP, 40 C.F.R. part 300 and was therefore required to be submitted to the Agency.

Information required to be submitted to the Government is confidential if its "disclosure would be likely either '(1) to impair the Government's ability to obtain necessary information in the future; or (2) to cause substantial harm to the competitive position of the person from whom the information was obtained.'" *Critical Mass*, 975 F.2d at 878 (quoting *National Parks and Conservation Association v. Morton*, 498 F.2d 765, 770 (D.C. Cir. 1974)) (footnote omitted); *see also* 40 C.F.R. § 2.208.[1] The Company did not assert that disclosure would impair the Government's ability to obtain necessary information. Therefore, I will determine whether disclosure would likely cause substantial competitive harm.

Likelihood of Substantial Competitive Harm

I will first address whether there is a substantial likelihood of competitive harm from the release of the names of the components of BIODISPERS. Next, I will address whether the Agency may release an aggregated list of dispersant components from all products on the Product Schedule, including BIODISPERS, without identifying any product names.

1. Component Names for BIODISPERS

You have argued that the material claimed confidential, including the list of components, represents a business advantage and suggested that disclosure would allow a competitor to copy your product. You further explained that disclosure would cause substantial harm because the company has "spent a significant amount of money and effort to develop the product," BIODISPERS, to patent it, and to safeguard the product information. (Response, p.2).

The NCP Product Schedule consists of specialized products designed for oil spill removal purposes, including the Company's BIODISPERS. Under federal law, in most cases only products on the list may be used to clean-up oil spills in navigable waters of the United States.

---

1 Information submitted to the Government on a voluntary basis "is 'confidential' for the purpose of Exemption 4 if it is of a kind that would customarily not be released to the public by the person from whom it was obtained." *Critical Mass Energy Project v. Nuclear Regulatory Commission*, 975 F.2d 871, 878-79 (D.C. Cir. 1992) (*en banc*), *cert. denied*, 507 U.S. 984 (1993).

The Company competes with the other dispersant products on the NCP Product Schedule for consumers. Eleven companies have listed a total of 14 dispersant products on the NCP Product Schedule for sale to consumers.

Dispersant products often consist of discrete chemical components that, in the right formula and combinations, address the unique and complex properties of the wide varieties of oils potentially discharged into the environment under a wide range of ambient conditions. The development of a product for particular oil spill removal purposes (e.g. dispersion), takes time and an expenditure of resources. For example, the development requires an investment in laboratory research and development to achieve a product that performs the desired function. A manufacturer must conduct a challenging search for the right combination of surfactants, solvents and other additives that, under the appropriate conditions, reduce the interfacial surface tension between water molecules and oil molecules, have a low demonstrated toxicity, do not bioaccumulate, and generate small droplets for degradation by naturally occurring microorganisms in the environment. In addition, the manufacturer must expend resources to conduct appropriate product testing not only to validate performance but to meet other requirements under the Subpart J regulation to be listed on the Product Schedule. Given the advances in technology, there are differing views as to the ability of a party to reverse engineer a dispersant product. In light of the uncertainty regarding the ability to reverse engineer a dispersant product, I conclude that at this time disclosure of the components of a specific dispersant product would likely cause substantial competitive harm in this case.

The Company spent money, time, and effort developing the optimum combination of ingredients for its dispersant product. The Company further competes with other dispersants based on availability, pricing, and efficacy. It is reasonable to expect that competitors will attempt to duplicate the efficacy of formulations and undercut pricing if they have to invest little in formulation development. Profitability of a dispersant is greatly enhanced if costly formulation development work can be avoided. In addition, competitors outside of the United States may attempt to market a similar competing product without spending the time and resources for research, development, and testing.

In conclusion, I find that you have met your burden of demonstrating that disclosure of the dispersant components with the product name would likely result in substantial competitive harm. Therefore, this information shall be withheld under FOIA Exemption 4.

2. An Aggregated List of Dispersant Ingredients

Next, I will determine whether the list of components of BIODISPERS may be released to the public as part of an aggregated a list containing the names of all dispersant components from all the dispersant products on the Product Schedule. Such an aggregated list would not identify which components are included in which products. As explained previously, Nalco Company waived its confidentiality claim for the components in its two dispersant products, Corexit EC9500A and EC9527A. Additionally, Alabaster Corporation and Mar-Len Supply, Inc. both previously waived confidentiality claims for one ingredient.

The Company's substantiation does not identify any specific ingredient that is so unique that the release of the BIODISPERS components as part of an overall aggregated list would likely cause substantial competitive harm to your company.

As explained, the Company's formula, including the percentages, and the list of components identified by product name will remain confidential. Given the number of dispersant components, an existing competitor or new market entrant would still incur substantial development costs as described above if it attempted to develop a copy of the Company's product. Unlike the situation where a company knew the exact list of components of a specific product, a competitor or new entrant that merely had an aggregate list of all components in all products would still incur costs for creating an optimum combination of components and any necessary testing. Moreover, because it would not have the percentages or the exact list of respective components, it is speculative as to whether a competitor would be able to replicate the Company's product. In light of the time and effort still necessary to create a new competing product, releasing an aggregated list of the 57 components will not likely cause substantial competitive harm.

I have concluded that releasing an aggregate list of the 57 undisclosed chemical components contained within the dispersant products on the Product Schedule will not likely cause substantial competitive harm to the Company. In addition, it will allow the Agency to meet transparency needs and respond to public concerns regarding the chemical components and health and safety associated with them. It will also allow EPA and its partners involved in oil spill response to develop the necessary methods to monitor and detect such components in the environment should a major oil spill occur in the future.

Pursuant to EPA's regulations at 40 C.F.R. §§ 2.204(f)(6) and 2.204(f)(9), the appropriate EPA program office has been consulted about the validity of your confidentiality claims. The EPA program office supports the Company's assertions that the formula and component list of the product should be withheld under Exemption 4. The EPA program office also supports releasing the dispersant components in an aggregated list.

CONCLUSION

I find that information concerning the components (except as stated above) and formulation of BIODISPERS meets the requirements of FOIA Exemption 4, and therefore will be treated as confidential. Pursuant to EPA's regulations at 40 C.F.R. § 2.205(f), this constitutes the final EPA determination concerning PetroBioTech's business confidentiality claims.

With respect to EPA's implementation of this determination, subject to 40 CFR §2.205(f)(2), EPA may make the information available to the public on the tenth (10th) working day after the date of the business's receipt of the written notice, unless the EPA legal office has first been notified of the commencement of an action in a Federal court to obtain judicial review of the determination and to obtain preliminary injunctive relief against disclosure. Please call

Kevin Miller at 202-564-2691 if you have any questions.

Sincerely,

Kevin S. Minoli
Acting Associate General Counsel
General Law Office

cc: HQ FOI Office