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

OFFICE OF
SOLID WASTE AND
EMERGENCY RESPONSE

NOW THE
OFFICE OF LAND AND
EMERGENCY MANAGEMENT

FEB 09 2017

Alex Chaharom
Vice President and Managing Director
GeNO LLC
2941 Oxbow Circle
Cocoa, Florida 32926

Dear Mr. Chaharom:

Thank you for your letter from February 2, 2016 and for the subsequent engagement. This correspondence explained the operational details of your GeNO permeation device and requested that EPA clarify the regulatory status of your device when discarded, in particular with regard to the applicability of the hazardous waste listings for discarded commercial chemical products under the Resource Conservation and Recovery Act (RCRA) regulations. Answers to the three questions asked in your letter are below.

Description of the GeNO Permeation Device

You stated that GeNO is developing a line of inhaled nitric oxide (NO) products, specifically, single use drug cassettes and associated reactor cartridges. These devices initially contain a glass ampoule of liquid dinitrogen tetroxide (N_2O_4) which is a dimer that forms when nitrogen dioxide (NO_2) gas is compressed. When the device is activated, the glass ampoule containing the liquid N_2O_4 is broken, releasing NO_2 gas. You stated that the temperature inside the device is greater than 45°C and liquid N2O4 boils at 22°C, thus liquid N2O4 will readily transform into NO2 gas when the device is activated. The NO2 is then converted to nitric oxide (NO) through a tubing series that contains a catalyst made of silica gel and ascorbic acid. The dispensing instrument then delivers the NO to the patient. The period of time over which the NO gas is dispensed to the patient varies depending on the amount of liquid N_2O_4 that was originally contained in the ampoule and the temperature inside the device.

Through the follow-up from GeNo on April 28, 2016, and on June 14, 2016, GeNO provided a more precise description of the process inside the device and why there is no residue of the chemicals inside the device. You described the following process. Based on the conditions within the device (i.e., temperatures over 45°C), all of N2O4 will be converted to NO2 gas and any NO2 gas that is not converted to NO and delivered to the patient that remains in the device is then driven by a concentration gradient into a neutralizing material (e.g., Sodasorb) until all of the NO_2 gas is consumed by being transformed into a solid salt, calcium nitrate ($Ca(NO_3)_2$). When all the NO_2 gas is transformed by the

neutralizing material, the pressure inside the device will reach atmospheric pressure. The quantity of neutralizing material within the device is enough to consume several times the total amount of NO_2 that is contained in the device. Additionally, any NO gas generated within the device but not delivered to the patient is converted back into NO_2 by oxygen prior to venting into the neutralizing material.

Applicability of RCRA Hazardous Waste Definition

Under RCRA, it is the responsibility of the generator to identify its waste and ensure it is disposed of appropriately. You provided no information on whether your device exhibits a RCRA hazardous waste characteristic. The hazardous characteristics must be determined prior to disposal by either applying your knowledge or testing the waste for reactivity, corrosivity, ignitability, and toxicity as outlined in the regulations at 40 CFR Part 261, Subpart C.

You requested clarification on three specific points regarding the federal regulation of your device and how the hazardous waste listings may apply. EPA's response is below:

(1) Is dinitrogen tetroxide (N_2O_4) considered a "commercial chemical product, or manufacturing chemical intermediate having the generic name listed in paragraph (e) or (f)" when discarded?

First, it is important to note that NO_2 is on the list of commercial chemical products at 40 CFR § 261.33(e) that are defined as acute hazardous wastes when discarded (EPA Waste Code P078). In addition, the EPA has previously determined that the liquid N_2O_4 dimer is also included within the scope of the P078 listing.[1] The term "commercial chemical product," as it applies to RCRA hazardous waste listings under § 261.33, is clarified in the comment in § 261.33 and located immediately after § 261.33(d):

> The phrase "commercial chemical product or manufacturing chemical intermediate having the generic name listed in..." refers to a chemical substance which is manufactured or formulated for commercial or manufacturing use which consists of the commercially pure grade of the chemical, and technical grades of the chemical that are produced or marketed, and all formulations in which the chemical is the sole active ingredient.

As previously discussed, N_2O_4 is a dimer that forms when NO_2 gas is compressed and is within the scope of the listing for NO_2 under 40 CFR 261.33(e). Your device appears to contain commercially pure or technical grade compressed NO_2 gas within the glass ampoule, which is also the sole active ingredient. Therefore, if the glass ampoule is not broken, then the NO_2 is a commercial chemical product and is regulated as a listed hazardous waste (EPA Waste Code P078) when discarded. This situation may occur if inventory expires or exceeds its shelf-life and is disposed.

On the other hand, as we understand your device, once used as intended, it is not regulated as a listed hazardous waste when discarded. This is because once the glass ampule has been broken, the device reaches atmospheric pressure and thus meets the definition of empty, as defined in 40 CFR 261.7(b)(2).

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[1] See letter from Matt Straus, U.S. EPA to Michael Fusco, Rollins Environmental Services, July 26, 1994; RCRA Online Number 13689.

(2) Is the device considered a "manufactured article" when discarded in an unused form?

EPA has previously determined that certain items that contain chemicals that are listed in § 261.33 are not considered U- or P-listed hazardous wastes when discarded. These items, which we refer to as "manufactured articles" such as batteries, fluorescent lamps and thermometers, are all designed for a purpose other than to access the chemicals that are present in these manufactured articles. Specifically, one uses these articles for electrical energy (batteries), light (lamps) or to measure temperature (thermometers). One does not use these articles in order to access the mercury or lead or other chemicals contained in them. Applying this reasoning to unused N_2O_4 contained in your device, the device would not be a manufactured article because a patient/individual specifically intends to access the chemical inside the device. For more information, manufactured articles are discussed in previous guidance documents (RCRA Online Numbers 14850, 14817, and 14012) and this topic is addressed directly in the regulatory preamble of a November 25, 1980 interim final rule (45 FR at 78541).

(3) Is the device considered to have been used for its intended purpose?

In your incoming letter, you asked that if EPA concludes for the above questions that the device is a listed hazardous waste, whether EPA would consider the device to have been used for its intended purpose and therefore, not considered a commercial chemical product and ultimately not a P-listed hazardous waste at the time of discarding or intention to discard. However, as discussed in the answer to your first question, based on the information you have provided, EPA concludes that when your device is used and thus reaches atmospheric pressure no P078 commercial chemical product hazardous waste remains in the device.

Please note that this letter only discusses the federal RCRA hazardous waste regulations. Under section 3006 of RCRA, individual states can be authorized to administer and enforce their own hazardous waste programs in lieu of the federal program. States that are authorized to implement the RCRA program have authority to promulgate regulations that are more stringent than the federal program. We are aware that Florida, as the authorized RCRA program has given you an interpretation on these questions as well. You should continue to consult with your authorized state agency for any site-specific guidance. If you have any questions about the federal hazardous waste regulations discussed in this letter, please contact Kristin Fitzgerald at (703) 308-8286, fitzgerald.kristin@epa.gov or Narendra Chaudhari at (703) 308-0454, chaudhari.narendra@epa.gov.

Sincerely,

Barnes Johnson, Director
Office of Resource Conservation and Recovery

cc: William Land, GeNO
Glen Perrigan- Florida DEP