

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

APRIL 25, 1988

Michael Geary
Bio-Ecological Services, Inc.
6525 Morrison Blvd.
P.O. Box 2048
Charlotte, NC 28226

Dear Mr. Geary:

This letter is in response to your March 24, 1988, request for clarification of the status of certain antineoplastic drug wastes. Your request was for an interpretation of 40 CFR 261.33, with respect to excess antineoplastic drug formulations which are not needed and thus are discarded.

If an antineoplastic drug is mixed with diluents, such as water or saline solution, the excess diluted or undiluted amount to be discarded is unused commercial chemical product. If the discarded unused commercial chemical product is listed in 40 CFR 261.33, the material is a listed hazardous waste regardless of dilution with water or saline because the product still would be the sole active ingredient. However, it is not considered a "spent material." Section 261.1 (c) (1) defines & spent material as any material that has been used and as a result of contamination can no longer serve the purpose for which it was produced without processing. The portion antineoplastic drug, if diluted, has not yet been used for its intended function, nor is it contaminated.

If an antineoplastic drug is mixed with diluents and with other pharmaceuticals for use, the unused mixed excess portion that is discarded is a solid waste. If the antineoplastic drug is listed in 40 CFR 261.33, the unmixed excess portion is a listed hazardous waste provided the antineoplastic drug is the sole active ingredient in the mixed formulation. If it is not the sole active ingredient, the mixture would not be the listed hazardous wastes; he????? the formulation may still be hazardous if it exhibits any of the hazardous waste characteristics.

In all of the situations you described, the material (if it met the listing in 40 CFR 261.33) would have to be sent to a permitted or interim status hazardous waste management facility, if the facility generates more than 1 kg per month of acutely hazardous waste, or more than 100 kg/month of non-acutely hazardous waste. See 40 CFR 261.5(f) and (g) for the hazardous waste management options for conditionally exempt small quantity generators of hazardous waste.

In addition, any State in which you generate, transport, treat, store, or dispose of these formulations may have regulations that are more stringent than the Federal hazardous waste rules. You therefore should check with the State agencies to determine what regulations, if any, apply to handling these materials.

If you have further questions regarding the status of wastes containing P-listed or U-listed commercial chemical products, please contact Wanda LeBleu-Biswas at (202) 382-7392.

Sincerely,

Devereaux Barnes, Director
Characterization and
Assessment Division

B.E.S.

BIO-ECOLOGICAL SERVICES, INC.

6525 Morrison Blvd. P.O. Box 2048 Charlotte, North Carolina 28226
Telephone (704) 364-1039
800-533-7994

March 24, 1988

U.S. E.P.A.
Office of Solid Waste
Sylvania Lawrence, Acting Director
WH-562A
401 M Street Southwest
Washington, D.C. 20460

Dear Ms. Lawrence:

I am in need of clarification involving the de-listing of U-listed antineoplastic drugs used in cancer treatment wards at hospitals and clinics. Specifically, if a U-listed antineoplastic is mixed for treatment purposes and the remaining material is sent for disposal, is the material still U-listed?

Please address specifically:

- 1) Antineoplastics mixed with diluents like water or saline.
 - a) Is unused portion "spent" or still U-listed?
- 2) Antineoplastics mixed with diluents and other pharmaceuticals.
 - a) Is the antineoplastic in the remaining portion still the "sole active component", thus still maintaining the U-listing?
 - b) Is the unusual portion "spent" or still U-listed?

I do understand that virgin product, spill material, and offspec product are listed. Are the antineoplastics mixed for treatment still listed?

If no U-listing remains, then do these materials have to be sent to a hazardous waste incinerator or treated as hazardous waste?

My concern is due to the fact that there are no published Threshold Limit values or LD50 values materials. Also that there is no clear definition to determine whether these materials are "spent".

Please clarify these questions in the agencies opinion. The response will be used to determine our corporate position on matters concerning antineoplastic disposal.

If you have any questions, please contact me at (704) 364-1039.

Sincerely,

BIO-ECOLOGICAL SERVICES INC.

Michael J. Geary
Manager of Environmental and Compliance

MJG/cbr

FaxBack # 11343