

Charlotte A. Smith
President, Pharmecology Associates, LLC
200 S. Executive Drive, Suite 101
Brookfield, WI 53005

Dear Ms. Smith,

Thank you for your January 30, 2003 letter regarding the regulation of medicinal nitroglycerine. As your letter notes, nitroglycerine in finished dosage forms, such as tablets or capsules, has been regulated under the Resource Conservation and Recovery Act (RCRA) as a 40 CFR 261.33 listed hazardous waste (P081) because it constitutes a formulation containing nitroglycerine as the sole active ingredient.

However, under the revised mixture and derived-from rules [40 CFR 261.3(g)(1)], which went into effect February 1, 2002, a waste that has been listed solely for the characteristic of ignitability, corrosivity, or reactivity is not regulated as a hazardous waste if it does not exhibit any hazardous waste characteristic. Moreover, if the waste does not exhibit a characteristic at the point of generation, it is considered to have never been a hazardous waste and does not need to meet land disposal restrictions (LDRs) (66 FR 27286, May 16, 2001).

Because P081 is listed solely for reactivity, and because we presume that medicinal nitroglycerine is not reactive, it would not be regulated as hazardous waste under the new federal rules, and also would not be subject to LDRs. The new rules took immediate effect in States that have not been authorized to carry out the base hazardous waste program.

However, because the revised mixture and derived-from rules are less stringent than the existing Federal requirements, States which are authorized for the base RCRA program are not required to adopt them. [40 CFR 271.1(i)]. If a State decides not to adopt the revised mixture and derived-from rules, then the more stringent rules continue to be in place and medicinal nitroglycerine will remain regulated as a P081 listed hazardous waste in that State. More information regarding State authorization can be found on EPA's website at <http://www.epa.gov/epaoswer/hazwaste/state/index.htm>.

Thank you again for your interest in this matter. If you have any further questions, please feel free to contact Tracy Atagi at 703-308-8672.

Sincerely,

Robert Dellinger, Director
Hazardous Waste Identification Division

cc: Laura Burrell
Frank McAlister
James Michael
Kristina Meson

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