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

OFFICE OF
SOLID WASTE AND EMERGENCY
RESPONSE

FEB 17 2012

MEMORANDUM

SUBJECT: Scope of Hazardous Waste Listing P046 (Phentermine)

FROM: Betsy Devlin, Acting Director
Materials Recovery and Waste Management Division
Office of Resource Conservation and Recovery

TO: RCRA Division Directors
EPA Regions 1-10

The purpose of this memorandum is to clarify the scope of the hazardous waste listing of the commercial chemical product phentermine (P046) under the Resource Conservation and Recovery Act (RCRA) hazardous waste regulations. Recently, we have received numerous inquiries on the listing status of phentermine salts, specifically phentermine hydrochloride (i.e., phentermine HCl). As explained below, phentermine HCl is not included within the scope of the P046 listing.

Phentermine is listed in 40 CFR 261.33(e) as P046 under the name alpha, alpha-dimethylphenethylamine (and the CAS name, benzeneethanamine, alpha,alpha-dimethyl-), with the CAS number 122-09-8. In order to examine the scope of this listing, the Agency reviewed the preambles from the interim final and final rules that resulted in the listing of alpha, alpha-dimethylphenethylamine as P046 (45 FR 33066, May 19, 1980 and 45 FR 78525, November 25, 1980, respectively). These *Federal Register* notices did not indicate that any specific formulations or uses of phentermine were considered when the listing was developed. In addition, the background document prepared in support of the 1980 rulemaking indicated that alpha, alpha-dimethylphenethylamine was listed due to its oral toxicity to humans; however, there are no references to salts or other formulations of phentermine.[1]

As was noted in the October 15, 2007, memorandum that clarifies the scope of the hazardous waste listing P042 for epinephrine (RCRA Online No. 14778),[2] there are a number of P- and U-listed wastes where the salts are specifically included in the listing description. In addition, as illustrated in the epinephrine memo, EPA has made several previous interpretations stating that

[1] Background Document for Section 261.33 – Hazardous Waste from Discarding Commercial Chemical Products and the Containers of Spill Residues Thereof, Office of Solid Waste, EPA. January 1981 (updated April 1981).
[2] http://yosemite.epa.gov/osw/rcra.nsf/0c994248c239947e85256d090071175f/2F701627EB73B2AB852573D2005E0B4F/$file/14778.pdf

commercial chemical products listed in §261.33(e) and (f) include the salts of the listed chemical only when the salts are specifically described in the regulatory language (RCRA Online Nos. 11489 and 12155). Thus the clarification that phentermine HCl is not within the scope of the P046 listing is consistent with previous EPA positions. Therefore, unless a listing description specifically refers to the salt(s) of the chemical listed in §261.33(e) or (f), the salt(s) are *not* considered to be included in the scope of the listing.

Thus, to reiterate, the Agency has concluded that phentermine salts are not within the scope of the P046 listing. Therefore, any chemical or formulation where phentermine HCl is the sole active ingredient is not a P046 listed hazardous waste when discarded. While phentermine HCl is not a listed waste when discarded, it can still meet the definition of a RCRA hazardous waste if it exhibits any of the four hazardous waste characteristics (ignitability, corrosivity, reactivity or toxicity).

Please note that this regulatory clarification presented in the memorandum applies to the federal hazardous waste program. Some states may regulate phentermine salts more stringently than the federal regulations. Therefore, we recommend that the regulated community contact their state regulatory agencies to ascertain the scope of the P046 listing in that state.

If you have any questions regarding the information presented above, please feel free to contact James Michael at 703-308-8610 or michael.james@epa.gov.

cc: James Michael, MRWMD, ORCR