CORRESPONDENCE/MEMORANDUM

State of Wisconsin

DATE: December 5, 2007 FILE REF: Hazardous waste policy

TO: Suzanne Bangert, Director
Bureau of Waste and Materials Management

FROM: Joanie Burns, Section Chief
Hazardous Waste Prevention and Management Section
Waste and Materials Management Program

SUBJECT: Management of Waste Epinephrine Salts

The purpose of this memorandum is to clarify how the Wisconsin Department of Natural Resources (DNR) will regulate waste epinephrine salts in Wisconsin in consideration of the attached October 15, 2007 United States Environmental Protection Agency (EPA) memorandum.

EPA position: On October 15, 2007, EPA issued a memorandum to clarify the scope of the hazardous waste listing for the commercial chemical product epinephrine (Hazardous Waste Code P042) under the Resource Conservation and Recovery Act (RCRA) hazardous waste regulations.

The EPA memorandum states:

> "This clarification is in response to recent inquiries from some EPA regions, states, and the regulated community specifically regarding whether this listing includes epinephrine *salts*. This is of particular significance because it is our understanding that most if not all of the chemical that is in use in hospitals (e.g., most medical applications) is one of several epinephrine *salts*. As described below, **we have determined that the scope of the P042 listing does not include epinephrine *salts*.**" [emphasis added]
>
> "Finally, we note that the regulatory clarification presented in this memorandum applies to the federal hazardous waste program. As most state regulatory agencies are authorized to implement the hazardous waste program in lieu of the federal program, some states may regulate epinephrine 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 P042 listing in that state."

Wisconsin position: DNR is authorized to implement the federal hazardous waste program in Wisconsin. DNR concurs with the October 15, 2007, EPA memorandum regarding waste epinephrine salts, with the following caveats:

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1. Incineration is recommended. DNR continues to recommend the Best Management Practice of incinerating all waste pharmaceuticals, even though most are technically not regulated as hazardous wastes or infectious wastes. Hazardous waste pharmaceuticals bound for incineration must be sent to an approved hazardous waste incinerator. Non-hazardous pharmaceuticals may be incinerated in the following if their air pollution control permits allow them to burn waste pharmaceuticals: a hazardous waste incinerator, a medical waste incinerator (known in other states as a "regulated medical waste incinerator") or, if also non-infectious, in a municipal waste incinerator, boiler or industrial furnace.

2. Waste determinations are still required. Endorsement of the EPA interpretation by DNR does not relieve generators of their legal obligation to determine if each of their wastes, including various pharmaceutical and epinephrine wastes, is a hazardous waste.

   Generally speaking, typical epinephrine waste from medical applications involving aqueous solutions should fall into one or more of the following regulatory categories:

   - Characteristic hazardous waste (e.g., aerosol epinephrine inhalers may be ignitable hazardous waste due to flammable gas content).
   - Infectious waste (e.g., any waste having a syringe or intravenous needle attached or being mixed with blood). See s. NR 526.05, Wis. Adm. Code, for lists of wastes presumed to be and not to be infectious waste.
   - Non-hazardous, non-infectious solid waste.

   General information about waste determinations for pharmaceuticals can be found in the *"10 Step Blueprint for Managing Pharmaceutical Waste in the United States,"* which may be viewed and downloaded from EPA's Healthcare Environmental Resource Center website: http://www.hercenter.org (select "Hazardous Materials," then "Materials of Concern," then "Pharmaceuticals").

3. Wastewater discharge requirements still apply. Health care facilities and other generators should contact their local Wastewater Treatment Plant prior to flushing any non-domestic waste, including epinephrine salt solutions, to the sanitary sewer.

4. Hazardous waste generator status may change. DNR reminds generators that changes in how epinephrine salts are classified under hazardous waste regulations may affect their hazardous waste generator status and related requirements, such as training and recordkeeping. Generators should notify DNR of any change in their generator status by submitting form 8700-12, Notification of Hazardous Waste Activity available at http://www.dnr.state.wi.us/org/aw/wm/publications/. They should pay particular attention to the generation of other P-listed acute hazardous wastes when making a generator status determination.

Questions regarding the EPA memorandum and the Wisconsin position outlined above can be directed to DNR Regional Waste and Materials Management staff, listed at: http://dnr.wi.gov/org/aw/wm/contacts/hazard.htm.

Disclaimer: This document is intended solely as guidance, and does not contain any mandatory requirements except where reference is made to requirements found in statute or administrative rule. This guidance does not establish or affect legal rights or obligations, and is not finally determinative of any of the issues addressed. This guidance does not create any rights enforceable by any party in litigation with the State of Wisconsin or the Department of Natural Resources. Any regulatory decisions made by the Department of Natural Resources in any manner addressed by this guidance will be made by applying the governing statues and administrative rules to the relevant facts.

Approved: **Date:**

SBangert 12/5/07

Suzanne Bangert, Director
Bureau of Waste and Materials Management

Encl.

Cc: Waste and Materials Management Team
Hazardous Waste Staff
Barb Bickford, DNR Medical Waste Coordinator
Paul Little – USEPA Region 5, DRE-9J

ATTACHMENT

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

OFFICE OF
SOLID WASTE AND EMERGENCY
RESPONSE

OCT 15 2007

MEMORANDUM

SUBJECT: Scope of Hazardous Waste Listing P042 (Epinephrine)

FROM: Matt Hale, Director
Office of Solid Waste

TO: RCRA Division Directors
EPA Regions I - X

The purpose of this memorandum is to clarify the scope of the hazardous waste listing for the commercial chemical product epinephrine (Hazardous Waste Code P042) under the Resource Conservation and Recovery Act (RCRA) hazardous waste regulations. This clarification is in response to recent inquiries from some EPA regions, states, and the regulated community specifically regarding whether this listing includes epinephrine *salts*. This is of particular significance because it is our understanding that most if not all of the chemical that is in use in hospitals (e.g., most medical applications) is one of several epinephrine *salts*. As described below, we have determined that the scope of the P042 listing does not include epinephrine *salts*.

When examining the scope of a hazardous waste listing, we first look at the relevant language in the regulations. We also review other parts of the rulemaking record and other relevant Agency materials, such as the *Federal Register* preamble discussions, background documents that support the regulation, and any further guidance as to the scope of any listing. In this case, the regulatory text of the P042 listing does not expressly include epinephrine salts. Moreover, EPA has found nothing in the record for the epinephrine listing that suggests the Agency intended to include the salts within the scope of the listing.

The language of the P042 listing lacks the words "and salts" in the description, suggesting that this listing does not include epinephrine salts. We note that there are approximately 30 other P- and U-listed wastes where the salts are specifically included in the listing description. We then reviewed the interim final rule published in the *Federal Register* on May 19, 1980 (45 *FR* 33066), as well as the final rule in the November 25, 1980 *Federal Register* (45 *FR* 78525). These are the rulemakings that resulted in the hazardous waste listing for epinephrine to be under the category of commercial chemical products that are acute hazardous wastes when discarded (see 40 CFR §261.33(e)). These *Federal Register* notices did not provide any information to suggest that epinephrine salts – or any specific formulations or uses of epinephrine – were considered when the P042 listing was developed.

The background document prepared in support of the P- and U-listed rulemaking states that the basis for including epinephrine base (identified by the Chemical Abstract Service (CAS) number 51-43-4) as a listed hazardous waste was its presence on the Toxic Substances Control Act (TSCA) 8B inventory.[1] (While we do not believe that the presence or absence of epinephrine salts on the TSCA 8B inventory is in and of itself determinative with respect to the scope of the P042 listing, we thought this information might be useful in understanding what may have been under consideration when the listing was originally promulgated.) A closer look at whether salts of epinephrine appear on the TSCA 8B inventory determined that only one epinephrine salt was present.[2] This salt, however, was not referenced in the listing background document. In addition, no information was found to suggest that EPA's original intent in citing the TSCA 8B inventory in support of the P042 listing was to include one or more of the epinephrine salts. (Of course, EPA had adequate justification to list epinephrine 'base' as an acute hazardous waste based upon its toxicity and the listing criteria in 40 CFR §261.11(a)(2)).

Finally, a review of relevant guidance shows that EPA has made prior interpretations regarding whether or not commercial chemical products listed in §261.33 include the salts of the listed chemical when the salts are not specifically described in the regulatory language. These prior interpretations are consistent with the position that unless a listing description specifically refers to the salt(s) of a chemical listed in §261.33, the salt(s) are *not* considered to be included in the scope of the listing.[3]

Based on the information stated above, epinephrine salts are not included within the scope of the P042 listing, nor did EPA intend for these salts to be included in the P042 listing. Therefore, any chemical or formulation where epinephrine salt is the sole active ingredient is not a P042 listed hazardous waste when discarded. While the epinephrine salts are not listed wastes when discarded, a chemical or formulation containing an epinephrine salt can be a RCRA hazardous waste if it exhibits a characteristic of hazardous waste when discarded. Also, any commercial chemical product, as described in §261.33 where epinephrine base (CAS# 51-43-4) is the sole active ingredient, is a P042 listed waste when discarded and must be managed in accordance with applicable Subtitle C regulations. Finally, we note that the regulatory clarification presented in this memorandum applies to the federal hazardous waste program. As most state regulatory agencies are authorized to implement the hazardous waste program in lieu of the federal program, some states may regulate epinephrine 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 P042 listing in that state.

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[1] Background Document for Section 261.33 – Hazardous Waste from Discarding Commercial Chemical Products and the Containers and Spill Residues Thereof. Office of Solid Waste, EPA. January 1981 (updated April 1981).

[2] At least one epinephrine salt appears on the TSCA 8B inventory: racepinephrine hydrochloride (HCl), CAS# 329-63-5, which is the HCl salt of the *non-stereospecific* version of epinephrine. The widely used pharmaceutical compound *l*-epinephrine HCl (CAS# 55-31-2) is not on the TSCA 8B inventory. Epinephrine bitartrate (CAS# 51-42-3), which is used in medical applications as well, is also not listed on the TSCA 8B inventory.

[3] See OSWER Directive 9441.1990(1), Memorandum from Devereux Barnes, EPA Office of Solid Waste (OSW) to Steve Johnson, EPA Office of Pesticide Programs, February 9, 1990 (RCRA Online No. 11489). See also a clarification from Alan Corson, OSW, dated November 1, 1983 (RCRA Online No. 12155). These interpretations are attached.

If you have any questions regarding the information presented above, please feel free to contact Lisa Lauer at 703-308-7418 or Ross Elliott at 703-308-8748.

Attachments (2)

ATTACHMENT 1
RCRA ONLINE# 11489

9441.1990(01)

United States Environmental Protection Agency
Washington, D.C. 20460
Office of Solid Waste and Emergency Response

February 9, 1990

MEMORANDUM

SUBJECT: RCRA Status of Dinoseb Formulations

FROM: Devereaux Barnes, Director
Characterization and Assessment Division
Office of Solid Waste (OS-330)

TO: Steve Johnson, Director
Field Operations Division
Office of Pesticide Programs (H7506C)

This is in response to your memorandum of July 7, 1988 requesting clarification of the RCRA status of four Dinoseb formulations.

In order for materials to be hazardous wastes under the RCRA program, and therefore subject to RCRA regulation, they must first be classified as solid wastes. Materials become solid waste when they are discarded or are intended for discard (40 CFR 261.2). Thus, Dinoseb formulations which are disposed of or are intended for disposal are solid wastes. They become hazardous wastes if they are "listed" in 40 CFR Part 261, Subpart D, or exhibit one or more of the hazardous waste characteristics: ignitability, corrosivity, reactivity, or extraction procedure (EP) toxicity (40 CFR 261.20-261.24).

Based upon a consideration of the regulations identified above, we have made a determination as to the regulatory status of the four Dinoseb formulations identified in your memorandum and these are provided below.

1.) DINOSEB TECHNICAL PRODUCT

In this formulation the compound (Dinoseb) is the major

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constituent (95%). The compound known as Dinoseb is listed in 40 CFR 261.33(e) when it "consists of the commercially pure grade of the chemical, any technical grades [emphasis added] of the chemical that are produced or marketed, and all formulations in which the chemical is the sole active ingredient." (See 40 CFR 261.33(d)(comment).) In a pesticidal formulation, this Dinoseb technical product becomes a "P" or acute hazardous waste and is subject to RCRA regulation when it is discarded or intended for discard.

It also should be noted that the Dinoseb technical product may be a potential "characteristic" hazardous waste because of its explosive nature (reactivity characteristic) under high temperature conditions. (See 40 CFR 261.23(b).) The material may also be a hazardous waste by virtue of its corrosivity depending upon the results of tests prescribed in 40 CFR 261.22 for corrosivity.

2.) DINOSEB IN ORGANIC SOLVENT

In this formulation, the compound dinoseb is the sole active ingredient and when discarded or intended for discard, it would be a "P" or acute hazardous waste. Additionally, because the formulation consists of a high percentage of organic solvents, it may also be hazardous by virtue of its ignitability (40 CFR 261.21(a)(1) and (3)) or corrosivity (40 CFR 261.22(a)(1) and (2)).

3.) DINOSEB ALKANOLAMINE SALTS IN WATER

In this formulation, Dinoseb (2-sec-butyl-4,6-dinitro-phenol) is not the active ingredient. Rather, according to your memorandum, the active ingredient is "alkanol" amine dinoseb. Section 261.33(e) lists only Dinoseb. No salts are listed. Therefore, these formulations would not be considered a "P" or acute hazardous wastes. However, these materials, when they become wastes, would be hazardous wastes if they exhibited one or more of the hazardous waste characteristics. Of special concern would be the reactivity, corrosivity, and ignitability characteristics. Therefore, any Dinoseb formulations of this type should be evaluated with respect to characteristics before disposal.

4.) PESTICIDE MIXTURES/LOW CONCENTRATIONS OF DINOSEB SALTS IN WATER

As in the formulation above, the salts of Dinoseb are not listed in 40 CFR 261.33(e) as acutely hazardous wastes. Therefore this formulation, which lists "sodium dinoseb" as an active ingredient would not be an acute hazardous waste. In addition, this formulation lists "naptalam" as a second active ingredient. Thus, by virtue of there being two active ingredients, this formulation would not be a "commercial chemical product" as defined in 40 CFR 261.33(d)(comment) and therefore would not be an acute hazardous waste.

When this material is discarded, or is intended for discard, it may become a hazardous waste by virtue of exhibiting one or more of the hazardous waste characteristics and must, therefore, be evaluated with respect to the characteristics outlined in 40 CFR 261.20-261.24.

Formulations 1 and 2 listed above are acutely hazardous wastes when discarded or intended for discard and generators must comply with the requirements of RCRA with respect to generation, transportation, treatment, storage, and disposal as provided in 40 CFR Parts 261 through 264. These sections identify the specific requirements for generators, transporters, and operators of treatment, storage, and disposal (TSD) facilities.

Formulations 3 and 4 above are not acute hazardous wastes; however, they will be hazardous wastes if they exhibit any of the hazardous waste characteristics specified in 40 CFR 261.21-261.24. If these formulations are found to be characteristic hazardous wastes, they must be managed in accordance with the RCRA regulations outlined above. If these formulations are found not to be hazardous wastes, then they must be managed and disposed of in accordance with the solid waste regulations of the state in question.

If a holder or generator of the material elects to treat and/or dispose of any hazardous Dinoseb formulations on site, he will have to comply with the standards and requirements of 40 CFR Parts 264, 265 and 270 for obtaining a permit to operate a TSD facility, except to the extent that storage in containers or tanks, and treatment in tanks is allowed for 90 days under 40 CFR 262.34. (See 51 FR 10168, March 24, 1986. Further, farmers may dispose of these wastes on site under 40 CFR 262.70, subject to appropriate label instructions.

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Finally, depending upon the amount of the waste generated, a generator may be eligible for the small quantity generator exemption(s) specified in 40 CFR 261.5. Under this section, a generator who generates less than one kilogram per calendar month of acute hazardous waste, or no more than 100 kilograms of hazardous wastes per calendar month, may qualify as a conditionally exempt small quantity generator. A conditionally exempt small quantity generator's wastes are not subject to regulation under 40 CFR Parts 262 through 266, 268, Part 270, and the notification requirements of Section 3010 of RCRA provided the generator complies with requirements specified in 40 CFR Sections 262.5(f), (g), and (j).

If you have any questions pertaining to the above, please contact Ron Josephson at 475-6715.

cc: Waste Management Division Directors, Regions I - X

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ATTACHEMENT 2
RCRA ONLINE #12155

QUESTION: EPA lists certain commercial chemical products as hazardous waste if discarded. Some of these listings specify the salt or ester of the parent compound and some do not. Are the salts and esters of all the commercial chemical products included in these listings or just where specified.

ANSWER: EPA is currently controlling only those chemicals which are specifically listed in 40CFR261.33 (e) and (f). If a parent compound is listed but the salt or ester of that compound is not, then only the parent compound is controlled. Because of confusion over nomenclature, EPA has provided, through the CERCLA reportable quantity proposed rulemaking (48 FR 23552, May 25, 1983), a convenient list of Chemical Abstract Service (CAS) Registration Numbers for each of the commercial chemical products.

SOURCE: Alan Corson