



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

OFFICE OF
SOLID WASTE AND EMERGENCY
RESPONSE

AUG 23 2010

Charlotte A. Smith, R. Ph., M.S., HEM
Director, PharmEcology Services
WM Healthcare Solutions, Inc.
12229 W. North Ave., Suite 2
Wauwatosa, WI 53226

Dear Ms. Smith,

Thank you for your May 3, 2010 email inquiry regarding the regulation of unused nicotine patches. Your question cited an EPA Hotline document that stated that nitroglycerin dermal patches were manufactured articles and therefore not defined under the Resource Conservation and Recovery Act (RCRA) regulations as a listed hazardous waste when disposed. You asked us to verify that unused dermal patches containing nicotine would be regulated as a listed hazardous waste when disposed, in apparent contrast to the explanation given for nitroglycerin patches noted above. In this letter, we are confirming that such unused patches would be listed hazardous waste when discarded.

Commercial chemical products are listed hazardous waste under RCRA when discarded in unused form (see 40 CFR 261.33). The Comment in §261.33(d) defines the term "commercial chemical product" as unused chemicals that are either (1) "commercially pure or technical grades," or (2) "formulations in which the chemical is the sole active ingredient." Nicotine in finished dosage forms, such as tablets or capsules, is regulated under RCRA, because it is a commercial chemical product formulation containing nicotine as the sole active ingredient (waste code P075; see 40 CFR 261.33). We view transdermal patches as an analogous dosage form; therefore, unused patches are also listed P075 when discarded. However, after the patch has been applied and removed, it has been used for its intended purpose. Therefore, used patches are no longer commercial chemical products and would not be listed hazardous waste when discarded.

EPA considers the definition of commercial chemical product in §261.33 to exclude manufactured articles such as batteries or fluorescent lamps (see 40 FR 78541; November 25, 1980). Manufactured articles that happen to contain a chemical listed in 261.33 are not generally known by a generic chemical name; therefore, manufactured articles that contain one of the listed chemicals would not be considered a listed waste when discarded in an unused form. For

example, EPA has included thermometers in the category of manufactured articles.¹ However, we do not view dermal patches to be “manufactured articles.” Nicotine patches are used to deliver the listed chemical in a certain dosage and may be generically referred to as the active chemical ingredient. Therefore, the use of these patches flows directly from the listed chemical. EPA provided a similar explanation for the identification of pills containing a listed P-chemical as the sole active ingredient as a commercial chemical product under §261.33.²

We are aware of the conflicting earlier interpretation of dermal patches that was included in a report for the RCRA, Superfund & EPCRA Hotline, in response to a question concerning the regulatory status of unused dermal patches containing nitroglycerin (listed as waste code P081 in §261.11). At that time, the Hotline indicated that the unused nitroglycerin patches would not be listed hazardous waste under §261.33 when discarded, because the patch was a manufactured article. That Hotline response is incorrect as explained in the above analysis.

More recently, EPA provided an answer, consistent with the answer we are providing in this letter, to essentially the same question in its response to public comments on the revisions to the mixture and derived-from rules in the Hazardous Identification Rule (HWIR; May 16, 2001, 66 FR 27266). In this rule, EPA promulgated a revision to 40 CFR 261.3 to exempt wastes listed solely for the ignitability, corrosivity, and/or reactivity characteristic, if the wastes do not exhibit the indicated characteristic. Commenters sought clarification concerning the classification of discarded nitroglycerin patches under this exemption, and in light of the earlier Hotline report that indicated patches were manufactured articles. In response to these comments, EPA stated that “The Agency will clarify manufactured articles containing these chemicals here: ordinarily, a nitroglycerine patch, if discarded unused, would be considered a P081 waste. However, under today’s rules, discarded unused nitroglycerine patches would not be considered P081 since the amount of nitroglycerine present (presumably) does not trigger the characteristic.”³

Therefore, discarded unused patches containing a chemical listed in §261.33 as the sole active ingredient would be classified as a listed hazardous waste (i.e., not a manufactured article), unless the listing was based only on a characteristic, as is the case for nitroglycerin, P081. Discarded patches of nicotine are not covered under the exemption in §261.3, because nicotine is listed for its toxicity (P075), not a characteristic. However, the classification of the unused dermal patch as a commercial chemical product (and not a manufactured article) is the same in both examples. To reiterate, unused dermal patches are not considered manufactured articles, and therefore are potentially U- or P-listed hazardous wastes when disposed, if the sole active ingredient in the patch is listed as a commercial chemical product in §261.33. Note that EPA also considers unused nicotine gum and lozenges as listed waste P075 when discarded, because these are other commercial chemical product formulations of nicotine. Similar to used patches, used gums/lozenges are no longer commercial chemical products and would not be listed hazardous waste when discarded.

We hope that this letter clarifies any confusion that may have resulted from the conflicting EPA answers in the Hotline document and in the EPA response to comments

¹ RCRA Online Number 14012; Hotline Report, August 1996.

² RCRA Online Number 13622; Hotline Report, September 1993.

³ Hazardous Waste Identification Rule: Revisions to the Mixture and Derived-From Rules Response to Comments Document, April 2001; Chapter 3, page III-28.

document for the Hazardous Waste Identification Rule. This letter intends to clearly articulate EPA's answer to this question in case there is any confusion related to these past two documents.

Finally, please be advised that States may have regulations that are more stringent or broader-in-scope than those of the Federal government. Therefore, generators should check with the appropriate state agency for the applicability of RCRA regulations for any specific facility. Should you have any further questions about the general applicability of these regulations, please contact James Michael, Chief of the Waste Characteristic Branch, at 703-308-8610.

Sincerely,



Robert W. Dellinger, Director
Material Recycling and Waste
Management Division