TECHNICAL INFORMATION PAPER

APHC
ARMY PUBLIC HEALTH CENTER
(Provisional)

HAZARDOUS WASTE CHARACTERIZATION OF DIETARY SUPPLEMENTS

TECHNICAL INFORMATION PAPER NO. 37-052-0216

PURPOSE.

This document provides guidance for waste characterization of dietary supplements to ensure the protection of human health and to comply with Federal and state hazardous waste regulations. This document applies only to waste dietary supplements at Army healthcare facilities, on-post commissary or exchange, or other on-post retailers. This document does not apply to dietary supplements disposed by or collected from consumers, which as household hazardous waste, are exempt from hazardous waste regulation.

REFERENCES.

Food and Drug Administration (FDA). 2015. What is a dietary supplement, http://www.fda.gov/AboutFDA/Transparency/Basics/ucm195635.htm. (Accessed January 2016)

Genuis S.J., Schwalfenberg G., Siy A-KJ, Rodushkin I. 2012. Toxic Element Contamination of Natural Health Products and Pharmaceutical Preparations. PLoS ONE 7(11): e49676. doi:10.1371/journal.pone.0049676

Kinam Park, PHD. Undated. Solid Dosage Form: Capsules. http://kinam.com/Lectures/363/3.Capsules%20Text.pdf. (Accessed January 2016.)

National Institutes of Health (NIH), Office of Dietary Supplements. https://ods.od.nih.gov/factsheets/Selenium-HealthProfessional/. (Accessed 11 January 2016.)

POINTS OF MAJOR INTEREST AND FACTS.

What Are Dietary Supplements?

The FDA defines a dietary supplement as "a product intended for ingestion that contains a dietary ingredient intended to add further nutritional value to supplement the diet. A dietary ingredient may be one, or any combination, of the following substances:

- a vitamin
- a mineral
- an herb or other botanical
- an amino acid
- a dietary substance for use by people to supplement the diet by increasing the total dietary intake
- a concentrate, metabolite, constituent, or extract."

(See FDA 2015.)

How Did the Army Public Health Center (Provisional) (APHC (Prov)) Characterize Dietary Supplements?

The APHC (Prov) inventoried shelf stock at an on-post commissary and at off-post retailers (drug store, grocery, and big-box store) during December 2015 and January 2016 and identified 77 unique manufacturer/distributer-product combinations: 31 vitamins, minerals, or combinations of vitamins and minerals; 20 herb or botanical products; 19 dietary substances (including 4 probiotics); and 7 extracts (including 2 energy boosting products).

The APHC (Prov) retrieved the product label ingredients and recommended serving size from manufacture or distributer Web sites and typical capsule sizes and volumes (Park undated). The APHC (Prov) characterized the dietary supplements against Resource Conservation and Recovery Act (RCRA) criteria for toxic, ignitable, corrosive, reactive, and listed hazardous waste. Of the products evaluated, none of the dietary supplements met the criteria for ignitable, corrosive, reactive, or listed hazardous waste. Some products did meet the toxic waste criteria for certain metals.

The following explains the calculations to compare ingredient amounts against the RCRA toxic waste criteria in Title 40 Code of Federal Regulations Part 261.24 Table 1 for metals. The three steps are summarized below and worked through in examples that follow:

1. Determine the weight of the dietary ingredient in the supplement. The "Supplement Facts" panel on the label will list the weight of the dietary ingredient per serving size (e.g., 1 tablet). Note, if the listing on the "Supplement Facts"

panel for a dietary ingredient includes the source ingredient [e.g., “selenium (as sodium selenate)”], the listed weight will be for the dietary ingredient only (selenium) and is the value to be used in the following steps.

2. Convert the dietary ingredient weight to either milligrams/liter (mg/L) or parts per million (ppm). For our purposes, mg/L is equivalent to ppm.
3. If the supplement is a solid, divide the ingredient amount in mg/L or ppm by 20 and compare that value to the RCRA toxic waste criteria for that ingredient. If the product is a liquid, compare the result of step 2 above directly to the RCRA toxic waste criteria. If the result equals or exceeds the toxic waste criteria, manage as a hazardous waste.

First, obtain the weight of the dietary ingredient from the “Supplement Facts” label. Regardless of what form the ingredient is in, the weight given is the total amount of ingredient. Use that weight in the calculations that follow.

Example: For a multivitamin that contains 50 micrograms (mcg) of selenium as sodium selenite, use 50 mcg as the weight of selenium.

Second, calculate the amount of dietary ingredient per tablet, capsule, or softgel in units of either mg/L or ppm. Typically, product labels give ingredient weights in mcg per serving size, which may be 1, 2, or more tablets, capsules, or softgels. [Note that the product label may recommend multiple serving sizes per day, but ignore the daily recommended amount.] If you can, weigh the tablet, and so forth, accurately and use that actual weight in grams (g) to convert ingredient mcg per serving size to ingredient ppm per tablet. If you lack a precise enough scale, use the largest capsule volume sold for humans, 1.37 milliliters (mL) to convert ingredient mcg per serving size to ingredient mg/L per tablet. For our purposes, mg/L is equivalent to ppm. Calculations for both are shown below.

Using actual tablet, and so forth, weight in g to calculate ingredient ppm:

$$\frac{\text{mcg}}{\text{serving size}} \text{ x } \frac{1 \text{ serving size}}{\text{\# tablets}} \text{ x } \frac{1 \text{ tablet}}{\text{tablet weight g}} = \text{\#ppm for one tablet}$$

Example: For 50-mcg selenium per recommended serving size, a recommended serving size of 2 tablets, and a tablet weight of 1.28 g:

$$50 \frac{\text{mcg}}{\text{serving size}} \text{ x } \frac{1 \text{ serving size}}{2 \text{ tablet}} \text{ x } \frac{1 \text{ tablet}}{1.28 \text{ g}} = 19.5 \text{ ppm for one tablet}$$

Or, using a maximum capsule volume of 1.37 mL to calculate ingredient mg/L:

$$\frac{\text{mcg}}{\text{serving size}} \text{ x } \frac{1 \text{ serving size}}{\text{\# tablets}} \text{ x } \frac{1 \text{ tablet}}{1.37 \text{ mL}} \text{ x } \frac{1000 \text{ mL}}{1 \text{ liter}} \text{ x } \frac{1 \text{ mg}}{1000 \text{ mcg}} = \text{\#} \frac{\text{mg}}{\text{L}} \text{ for one tablet}$$

Example: For a multivitamin containing 50-mcg selenium per serving size and with a serving size of 2 tablets:

$$\frac{50 \text{ mcg}}{\text{serving size}} \text{ x } \frac{1 \text{ serving size}}{2 \text{ tablets}} \text{ x } \frac{1 \text{ tablet}}{1.37 \text{ mL}} \text{ x } \frac{1000 \text{ mL}}{1 \text{ L}} \text{ x } \frac{1 \text{ mg}}{1000 \text{ mcg}} = 18.3 \frac{\text{mg}}{\text{L}} \text{ for one tablet}$$

Third, for solid products (tablet, capsule, or softgel) before comparing, divide the ingredient amount in mg/L or ppm by 20 to account for U.S. Environmental Protection Agency (EPA)-method dilution, then compare that result to the toxic hazardous waste criteria for that ingredient. For liquid products, compare the ingredient amount in mg/L or ppm to the toxic hazardous waste criteria for that ingredient.

Continuing the example above using 19.5 ppm:

For tablets, capsules, and softgels, account for the dilution in the EPA waste-extraction method by dividing the ingredient mg/L by 20 and round to the first decimal point.

For example, 19.5 / 20 = 0.98 ppm, rounds to 1.0 ppm, which is equivalent to the hazardous waste toxicity criteria for selenium of 1 mg/L, hence this multivitamin is hazardous waste on disposal. Using 18.3 mg/L, 18.3/20 = 0.92 mg/L, rounds to 1.0 mg/L, which again is equivalent to the hazardous waste toxicity criteria for selenium.

What Dietary Supplements Are Hazardous Waste Based on Product Label Ingredients?

Based on evaluated product label ingredients, the only dietary ingredients that exceeded the hazardous waste toxicity criteria were selenium and chromium. The APHC (Prov) evaluated four supplements containing selenium (two adult multivitamins, an eye health vitamin, and a vitamin-plant antioxidant extract mix) and two supplements containing chromium (an adult multivitamin and Garcinia Cambogia). A prostate supplement containing unpublished amounts of selenium could not be characterized. Only two of these are toxic hazardous waste for selenium, an adult multivitamin and the eye health vitamin, and only the Garcinia Cambogia was toxic hazardous waste for chromium. Chromium is a mineral that humans require in trace amounts found primarily

in two forms: trivalent (chromium 3+) (which is biologically active and found in food) and hexavalent (chromium 6+) (a toxic form that results from industrial pollution). The EPA

exempts trivalent chromium from hazardous waste regulation (Title 40 CFR Part 261.4(b)(6)). You may reasonably assume that dietary supplements contain only trivalent chromium so are not toxic hazardous waste for chromium.
Because the recommended daily serving size of selenium for adults is 55 mcg (NIH undated), any dietary supplement containing selenium and having a recommended serving size of one tablet, capsule, or softgel may be hazardous waste. Selenium supplements that contain more than 55 mcg of selenium are likely hazardous waste on disposal.

You may also consult the Military Items Disposal Instructions database (http://usaphcapps.amedd.army.mil/MIDI/) for waste characterization information on dietary supplements.

Should I Sample and Analyze Dietary Supplements?

Dietary supplements may be contaminated from metals uptake or deposition during botanical ingredient growth, during transport or processing of raw materials, or by addition of undocumented adulterants. These contaminants will not be listed on the product label. One study (Genuis 2012) that sampled dietary supplements found contaminant arsenic and mercury amounts in supplement ingredients from overseas and from fish and shellfish that were sufficient to make the dietary supplement a hazardous waste on disposal. Supplement ingredients from North America did not contain metal contaminants in such high amounts.

Some dietary supplements undergo voluntary third-party testing and verification that the supplement contains the ingredients listed on the label, in the declared strength and amounts, and does not contain certain contaminants. Example third-party verification organizations are Consumerlab.com, the United States Pharmacopeial Convention (USP), and National Sanitation Foundation International. Third-party verification organizations test dietary supplements and audit manufacturer processes against their protocols. When documenting your hazardous waste characterization of a dietary supplement, note any third-party verifications. Even without third-party verification, you may assume that product labels accurately represent ingredients, amounts, and contaminants.

At this time, the APHC (Prov) recommends that you use information from the product label or Web site to characterize waste dietary supplements or consult the MIDI database. Sampling is not recommended at this time.

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Point of Contact

For more help, contact the APHC (Prov) Waste Management Program at 410-436-3651.

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