



**UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
REGION 8**

1595 Wynkoop Street
DENVER, CO 80202-1129
Phone 800-227-8917
<http://www.epa.gov/region08>

October XX, 2011

Ref: 8P-W

Mr. Rod McNeil
Montana Department of Environmental Quality
Water Quality Standards Section
1520 East Sixth Avenue
P.O. Box 200901
Helena, Montana 59820

Dear Mr. McNeil:

This will respond to your request for assistance from U.S. Environmental Protection Agency (EPA) Region 8 in establishing standards or health advisories for two pesticides of interest to Montana. These pesticides include:

Butylate (2008-41-5)
Chlorothalonil (1897-45-6)

The priority order for establishing human health standards by the Region is the Maximum Contaminant Level (MCL) established under the provisions of the Safe Drinking Water Act, a national Lifetime Health Advisory (LHA) established by the EPA Office of Water, and finally a Region 8 Lifetime Health Advisory using publicly available toxicity information. Neither of these pesticides has a drinking water MCL. However, butylate has a national LHA of 0.4 mg/L.

A National LHA or a Region 8 Advisory is calculated taking into account the toxicity information used to establish a Chronic Reference Dose (RfD, or safe exposure level) or the Oral Cancer Slope Factor (if one has been established). The standard exposure scenario for drinking water assumes that a 70 kg person consumes 2 liters of water per day. For an advisory based on the chronic RfD, the Relative Source Contribution (RSC) is also used. The RSC is applied to ensure that the total exposure to the chemical from all environmental media (drinking water, food, and air) is below the RfD. In the absence of reliable information from food and air, the Drinking Water Program uses a value of 0.2 for the RSC.

The general equation for an advisory based on the RfD is:

$$\text{LHA or Region 8 Advisory} = \text{RfD (mg/kg-day)} \times 70 \text{ kg} \times 1 \text{ day/2 Liters} \times \text{RSC}$$

The calculated value is rounded to one significant digit.

The general equation for an advisory based on the Oral Cancer Slope Factor is:

Region 8 Advisory = Target Cancer Risk x 70 kg x 1 day/2 L x 1/Oral Cancer Slope Factor

Montana uses a Target Cancer Risk level of 10^{-5} (1 in 100,000). The calculated value is rounded to one significant digit.

For some chemicals considered to be carcinogenic to humans, the Pesticide Program has determined that a linear at low dose extrapolation is not appropriate based on the mode of action of the chemical and alternative approach using a non-linear extrapolation is appropriate. For chlorothalonil the Pesticide Program has decided that a Margin of Exposure (MOE) approach is protective of the cancer endpoint.

If you have any questions, please call me at (303) 312-7070.

Sincerely,

Robert Benson, Ph.D.
Toxicologist, Water Program

Enclosure

cc: Tonya Fish

Recommended Health Advisories

Butylate

The national LHA is based on the RfD of 0.05 mg/kg-day.

$$\text{LHA} = 0.05 \text{ mg/kg-day} \times 70 \text{ kg} \times 1 \text{ day}/2 \text{ Liters} \times 0.2 = 0.4 \text{ mg/L}$$

The Pesticide Program has assigned butylate to Cancer Group E (evidence of non-carcinogenicity for humans)

References:

2011 Edition of the Drinking Water Standards and Health Advisories
Registration Eligibility Decision for Butylate, November 1993

Chlorothalonil

The EPA Pesticide Program RfD is 0.02 mg/kg-day. Based on the standard formula, the advisory is:

$$\text{Advisory} = 0.02 \text{ mg/kg-day} \times 70 \text{ kg} \times 1 \text{ day}/2 \text{ Liters} \times 0.2 = 0.1 \text{ mg/L}$$

The Pesticide Program has concluded that the weight of evidence supports a cancer classification as “likely” by all routes of exposure. The Oral Cancer Slope Factor is $0.00766 \text{ [mg/kg-day]}^{-1}$. However, the Pesticide Program has further concluded that a non-linear approach using the Margin of Exposure (MOE) should be used and will be protective for the cancer endpoint. Calculations using both the Oral Cancer Slope Factor and the Margin of Exposure are presented below.

$$\text{Advisory} = \text{Target Cancer Risk} \times 70 \text{ kg} \times 1 \text{ day}/2 \text{ L} \times 1/\text{Oral Cancer Slope Factor}$$

Montana uses a Target Cancer Risk level of 10^{-5} (1 in 100,000)

The Oral Cancer Slope factor is $0.00766 \text{ [mg/kg-day]}^{-1}$

$$\text{Advisory} = 0.0001 \times 70 \text{ kg} \times 1 \text{ day}/2 \text{ L} \times 1/0.00766 = 0.05 \text{ mg/L}$$

$$\text{MOE} = \text{No Observed Effect Level (NOEL)}/\text{Exposure from Water}$$

The MOE is 100

The NOEL is 1.5 mg/kg-day

$$100 = 1.5 \text{ mg/kg-day}/\text{Exposure} = 1.5 \text{ mg/kg-day}/0.015 \text{ mg/kg-day}$$

$$\text{Advisory} = \text{Exposure} \times 70 \text{ kg} \times 1 \text{ day}/2 \text{ L} = 0.015 \text{ mg/kg-day} \times 70 \text{ kg} \times 1 \text{ day}/2 \text{ L} = 0.5 \text{ mg/L}$$

The recommended Region 8 advisory is 0.1 mg/L, the lower value of the approach based on the RfD or the MOE.

References:

Registration Eligibility Decision for Chlorothalonil April 1999

Memorandum: Carcinogenicity Peer Review of Chlorothalonil – Fourth, October 20, 1997