MINISTRY OF ENVIRONMENT
PROVINCE OF BRITISH COLUMBIA

Water Quality Guidelines for Pharmaceutically-active Compounds (PhACs): 17 α-ethinylestradiol (EE2)

Overview Report

Prepared for:

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SUMMARY

This document establishes ambient water quality guidelines for the pharmaceutically active compound (PhAC) 17α-ethinylestradiol (EE2) for British Columbia. Guidelines are safe conditions or levels that have province-wide application. The report consists of two parts: this, an overview report, and a technical appendix upon which this overview summary is based.

A major use of the guidelines is to set ambient water quality objectives. The objectives are the guidelines modified or adapted to protect the most sensitive designated water use in a particular body of water. The water quality objectives are used in managing waste discharges and ambient water quality.

It is recommended that the 30-d average concentration of 17α-ethinylestradiol (EE2) in water should not exceed 0.5 ng L^{-1} with no single value to exceed 0.75 ng L^{-1} (no more than 50% above the guideline value) to protect freshwater aquatic life from adverse effects.

Water quality guidelines to protect marine life and other water uses such as wildlife, agriculture (i.e., livestock watering and irrigation), drinking water and recreational were not recommended because relevant data were not available from the literature.

PREFACE

The BC Ministry of Environment develops province-wide ambient water quality guidelines for variables that are important in the surface waters of British Columbia. This work has the following goals:

- to provide guidelines that protect the most sensitive aquatic species and life stage indefinitely
- to provide guidelines for the evaluation of data on water, sediment and biota
- to provide guidelines for the establishment of site-specific ambient water quality objectives

Ambient water quality objectives for specific waterbodies will be based on the guidelines and also consider present and future uses of the resource, waste discharges, hydrology/limnology/ oceanography, and existing background water quality. The process for establishing water quality objectives is more fully outlined in Principles for Preparing Water Quality Objectives in British Columbia, which is available online from the Ministry webpage.

The definition adopted for a guideline is:

> A maximum and/or a minimum value for a physical, chemical or biological characteristic of water, sediment or biota, which should not be exceeded to prevent specified detrimental effects from occurring to a water use, including aquatic life, under specified environmental conditions.

The guidelines are province-wide in application, are use-specific, and are developed for some or all of the following specific water uses:

- Raw drinking, public water supply and food processing
- Aquatic life and wildlife
- Agriculture (livestock watering and irrigation)
- Recreation and aesthetics
- Industrial (water supplies)

The guidelines are set after considering the scientific literature, guidelines from other jurisdictions, and general conditions in British Columbia. The scientific literature gives information on the effects of toxicants on various life forms. This information is not always conclusive because it is usually based on laboratory work which, at best, only approximates actual field conditions. To compensate for this uncertainty, guidelines have built-in safety factors.

The site-specific water quality objectives are, in most cases, the same as guidelines. However, in some cases, such as when natural background levels exceed the guidelines, the objectives could be less stringent than the guidelines. In relatively rare instances, for example if the resource is unusually valuable or of special provincial significance, the safety factor could be increased to set objectives which are more stringent than the guidelines.

Guidelines are subject to review and revision as new information becomes available.

1.0 RECOMMENDED GUIDELINES

The freshwater aquatic life guideline is based on the Technical Appendix titled 'Water Quality Guidelines for Pharmaceutically-active Compounds (PhACs): 17 α-ethinylestradiol (EE2)' by Narender Nagpal and Cindy Meays, September, 2009. The technical report is based on toxicity studies and data from the scientific literature.

To protect freshwater aquatic life from adverse effects, it is recommended that the 30-day average concentration of 17α-ethinylestradiol (EE2) should not exceed 0.5 ng L^{-1} with no single value to exceed 0.75 ng L^{-1} (no more than 50% above the guideline value).

The guideline refers to total concentration of EE2 in an unfiltered sample. Where laboratories filter samples, analysis can be conducted separately on the aqueous and solids and summed together (Hamilton -Axys, personal communication). Water quality guidelines for 17α-ethinylestradiol were not recommended for other water uses such as marine life, wildlife, agriculture (i.e. livestock watering and irrigation), drinking water and recreational water because of the lack of data.

1.1 RATIONALE

The recommended guideline is derived from the lowest observed effect concentration (LOEC) of 1.0 ng L^{-1} EE2 for reproduction/egg production (Parrott and Blunt 2005; Jobling et al. 2004;

Thorpe et al. 2003). A safety factor of 2 was applied to arrive at the recommended guideline. This is consistent with British Columbia Ministry of Environment protocol for the derivation of aquatic life guideline (Singleton et al. 1995). The protocol recommends that a safety factor of 2 to 10 may be employed with the chronic LOEC, based on science and /or professional judgment. Given a narrow spread between measured NOECs and LOECs for the most sensitive species, the use of safety factor of 2 was considered appropriate.

Current detection limits at BC laboratories (lowest MDL of 5 ng L^{-1}), presently do not meet our precision objectives of 1/10 guideline value), however laboratories (e.g. Axys and PESC) have indicated that method development could be done to improve the MDLs. Users of this guideline are advised to use the lowest detection limit available at a laboratory in BC, until such time that our precision objective is met (to give an MDL of 0.05 ng L^{-1}).

The guideline is based on fish species that are resident in British Columbia/North America (fathead minnow, rainbow trout).

The recommended guideline is close to the predicted no effect concentration (PNEC) derived by Caldwell et al. (2008) using a SSD approach and published NOECs. This PNEC was not adopted in this document directly because of several factors that may influence the results of the model used:

- It was noted that the results of the SSD could be different depending on the NOEC used; Caldwell et al. (2008) discarded some data and manipulated others to compute some of the NOECs used.
- The NOECs used in the SSD model were literature values which may be influenced by the experimental design (e.g. concentration levels and intervals used in the toxicity study). A statistically based (effect concentration of 10% of individuals) EC_{10} is considered to be a better estimate of the true NOEC.
- The NOEC is not only a function of test conditions but also varies with the end point employed in the toxicity test. Obviously, the PNEC based on NOECs with mixed end points will be different and less desirable than that obtained from NOECs with single end point (e.g. reproductive effects). The PNEC by Caldwell et al. (2008) was based on NOECs with mixed end points.
- SSD is not an approved method of guideline development for BC since it does not follow the guiding principles of protection of the most sensitive species and life stage indefinitely.

There were some data which yielded lower LOEC (0.1 ng EE2 L^{-1}) than 1.0 ng EE2 L^{-1}. These data were not used for purpose of guideline development because the data was considered to be an anomaly for reasons explained in the rationale section of the Technical Appendix.

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