

**CENTER FOR DRUG EVALUATION AND
RESEARCH**

APPLICATION NUMBER:

21-333

ENVIRONMENTAL ASSESSMENT

4.1 Minirin™ Nasal Spray, Environmental Assessment

Ferring Pharmaceuticals is submitting a new drug application for Minirin™ Nasal Spray (desmopressin acetate) 0.1% Nasal Spray.

Minirin™ (desmopressin acetate) is a synthetic analogue of 8-arginine vasopressin monoacetate. This antidiuretic hormone affects renal water conservation, and is indicated for the treatment of Central Diabetes Insipidus and Primary Nocturnal Enuresis.

Minirin™ drug substance and nasal spray are manufactured and packaged at _____ and Ferring Pharmaceuticals facilities, respectively in Sweden. Manufacture and packaging are carried out in compliance with all local and governmental regulations.

A fifth year market projection, for the United States, for all expected approved applications of DDAVP® marketed by Aventis and Ferring Pharmaceuticals and Minirin™ Nasal Spray gives approximately a total of 36.2 Kg of drug substance. From this quantity the Expected Introduction Concentration (EIC) value is calculated to be _____

Thus the effect of this product on entry into the environment does not significantly affect the quality of the human environment. As this value represents a level far below 1 ppb for the EIC, the categorical exclusion is requested.

The information provided above forms the basis for a claim for Categorical Exclusion from the environmental assessment requirements under 21 CFR Part 25.31 (c).