



This is provisional English translation of an excerpt from the original full report.

Risk Assessment Report

OTC 20% for fishery use [Bio] NC (Veterinary Medicinal Products)

Food Safety Commission of Japan (FSCJ)
March 2018

ABSTRACT

FSCJ conducted a risk assessment of OTC 20% for fishery use [Bio] NC, a feed additive for use in the Order *Tetraodontiforme* which contains Oxytetracycline Hydrochloride as the active substance based on application documents for the reevaluation of veterinary medicinal products.

As for an ADI for oxytetracycline hydrochloride, the active substance of this product, FSCJ has specified an ADI of 0.03 mg/kg bw/day as a group ADI for oxytetracycline, chlortetracycline and tetracycline.

Regarding the additives used in this product, FSCJ concluded that considering the usage, existing toxicity data, and the dosage and administration, the risk to human health from the intake of these additives through this product is negligible.

To the extent that the documents presented for reevaluation of this product were concerned, no finding to suggest any concern for food safety of this product were reported during the reevaluation.

Hence, FSCJ concluded that the risk to human health from the intake of this product through consumption of foods is negligible as long as it is appropriately used.

In use of this product, special attention needs to be paid for the risk assessment of antimicrobial-resistant bacteria that will be conducted later since oxytetracycline chloride is a tetracycline antimicrobial agent.