

## Summary of Public Comments received on the Challenge substance Mitotane (CAS 53-19-0) Draft Screening Assessment Report for Batch 12 and the associated Risk Management Scope

TOPIC	COMMENT	RESPONSE
Risk Management	<p>In Canada, mitotane is currently the treatment of choice for inoperable adrenal cortical carcinoma (ACC), a rare malignancy that is often diagnosed at an advanced stage. ACC has a poor overall five-year survival rate, and in many patients with ACC, advanced disease at presentation precludes surgery or is followed by local relapse or distant metastatic disease that cannot be managed surgically. This makes mitotane (which is approved in Canada for treatment of ACC) the major chemotherapeutic option for the management of inoperable ACC and a medically necessary drug.</p> <p>The quantity of mitotane required annually by ACC patients varies, but quantities imported into Canada typically range between 100–1000 kg per year. Given its medical necessity, the importation of mitotane into Canada should be allowed.</p>	<p>The submitted information on substance quantities has been used in the analyses described in the final Screening Assessment Report (SAR) for this substance. As outlined in the Risk Management Approach document, no risk management actions are being proposed to control the use of mitotane as a therapeutic cancer drug.</p>