

Health Canada Application and Notification Form for Exceptional Release of Disinfectant and Sanitizing Products

Due to the unprecedented demand and urgent need for disinfectants and hand sanitizers during the COVID-19 pandemic, an interim measure has been implemented to expedite access to supplies of products that may not fully meet regulatory requirements under the *Food and Drugs Act*. Persons requesting to undertake exceptional release of disinfectants or sanitizers are required to complete this form. As part of this submission, persons are asked to self-triage their proposal. Please submit the completed form to: hc.covid19healthproducts-produitsdesante.sc@canada.ca. Level 1 or 2 requests only require notification to Health Canada by submitting this completed form. Level 3 or 4 requests require a case-by-case review by Health Canada. For any questions related to this process, please contact Health Canada at: hc.covid19healthproducts-produitsdesante.sc@canada.ca.

Note that any product associated with false or misleading claims or that is found to pose a risk to health will be subject to enforcement action by Health Canada, including but not limited to refusing shipments at the border and product seizures.

Part I: Company Identifier		Part II: Self-Triage		
Company Name		<input type="checkbox"/>	Level 1	Product authorized in Canada, but not fully compliant with requirements (e.g. English-only labelling; Hand sanitizers that meet the NNHPD's Antiseptic skin cleansers monograph requirements and have a DIN or NPN for personal commercial use or for a different dosage form)*
Company Address				
Key Contact Details	Name	<input type="checkbox"/>	Level 2	Product not authorized in Canada but is authorized or registered in the United States or an MRA country.
	Phone Number		Level 3	Product not authorized in Canada but is authorized or registered in a country other than the United States or an MRA partner.
	Email address		Level 4	Unauthorized product that is not currently marketed in any country.
Part III: Product Identifiers				
Name of Product To be Imported		Name of Canadian Reference Product (required for Level 1, if available for other Levels)		
Country of import and manufacturer (site)	Foreign Registration Number and Country of Registration (Required for Level 1 and 2)	Canadian DIN or NPN, if applicable		
<p>*For Level 1, please provide an explanation of the difference(s) between the approved and unapproved product. Please include a copy of the product label that will be distributed in Canada.</p>				
Part IV: Shipment Details (if available at time of application/notification)				
Date of Import		Port of Entry		
Destination		Tracking Number		
Quantity		Lot number(s) if available		
Signature:	Company Position or Title:		Date:	

All information collected on this form will be protected according to Government of Canada security standards. All government departments are required to comply with the Access to Information and Privacy (ATIP) regulations.