



Guidance Document

Management of Disinfectant Drug Applications

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Health Canada is responsible for helping Canadians maintain and improve their health. It ensures that high-quality health services are accessible, and works to reduce health risks.

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Ligne directrice – Gestion des présentations de désinfectants assimilés aux drogues

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Document change log

Date	Change	Location (section, paragraph)	Nature of and/or reason for change
2014/01	Initial Issuance of Guidance	Not applicable	Not applicable
2018/01	Removal of references to contact lens disinfectants, and high-level disinfectants and sterilants for use on reusable semi-critical and critical medical devices	Some revisions throughout document	Removal of references to contact lens disinfectants, and high-level disinfectants and sterilants for use on reusable semi-critical and critical medical devices
2019/11/04	<ul style="list-style-type: none"> • Addition of "medical devices" product class to Appendix 1 as follow-up to January 2018 revision. • Revisions to disinfectant drug submissions types, link to April 1, 2020 cost recovery (CR) updates. 	Some revisions throughout document	<ul style="list-style-type: none"> • Addition of "medical devices" product class to Appendix 1 as follow-up to January 2018 revision. • Revisions to disinfectant drug submissions types, link to April 1, 2020 cost recovery (CR) updates.

Foreword

Guidance documents are meant to provide assistance to industry and health care professionals on how to comply with governing statutes and regulations. Guidance documents also provide assistance to staff on how Health Canada mandates and objectives should be implemented in a manner that is fair, consistent, and effective.

Guidance documents are administrative instruments not having force of law and, as such, allow for flexibility in approach. Alternate approaches to the principles and practices described in this document may be acceptable provided they are supported by adequate justification. Alternate approaches should be discussed in advance with the relevant programme area to avoid the possible finding that applicable statutory or regulatory requirements have not been met.

As a corollary to the above, it is equally important to note that Health Canada reserves the right to request information or material, or define conditions not specifically described in this document, in order to allow the Department to adequately assess the safety, efficacy, or quality of a therapeutic product. Health Canada is committed to ensuring that such requests are justifiable and that decisions are clearly documented.

This document should be read in conjunction with the accompanying notice and the relevant sections of other applicable Guidance documents.

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1. Introduction

1.1 Purpose/Overview

This guidance document provides an overview of the application streams applicable to disinfectant drugs.

1.2 Scope and application

This guidance document applies to products regulated as drugs under the Food and Drugs Act and Regulations that are represented for use as:

- disinfectants for use on non-critical medical devices and hard non-porous environmental surfaces and inanimate objects in domestic, industrial/institutional, hospital, food processing and/or barn premises, referred to as "hard surface disinfectants", and that additionally may indicate hard non-porous food and non-food contact surface sanitizer claims on their labelling, in which case they are referred to as "disinfectant-sanitizers"

All disinfectants regulated as drugs must meet the general safety, efficacy, and quality requirements outlined in the [Guidance Document Disinfectant Drugs \(2018\)](https://www.canada.ca/en/health-canada/services/drugs-health-products/drug-products/applications-submissions/guidance-documents/disinfectants/disinfectant-drugs.html) (<https://www.canada.ca/en/health-canada/services/drugs-health-products/drug-products/applications-submissions/guidance-documents/disinfectants/disinfectant-drugs.html>), except where otherwise noted, as well as the labelling requirements set out by the Food and Drugs Act and Regulations. In addition, they must meet the specific safety and efficacy requirements outlined in the guidance document:

- [Safety and Efficacy Requirements for Hard Surface Disinfectant Drugs \(2014\)](https://www.canada.ca/en/health-canada/services/drugs-health-products/drug-products/applications-submissions/guidance-documents/disinfectants/safety-efficacy-requirements-hard-surface-disinfectant-drugs.html) (<https://www.canada.ca/en/health-canada/services/drugs-health-products/drug-products/applications-submissions/guidance-documents/disinfectants/safety-efficacy-requirements-hard-surface-disinfectant-drugs.html>)

Appendix 1 of this guidance document provides information regarding the applicable regulatory frameworks for chemical products intended for use on environmental surfaces and inanimate objects (e.g., cleaners, sanitizers and disinfectants), and the associated contact information for the responsible regulatory bodies.

1.3 Policy objectives

The purpose of this guidance document is to outline the way Health Canada will manage submissions for market authorization for disinfectants regulated as drugs submitted in accordance with the Food and Drug Regulations. It also outlines the responsibilities and expectations for applicants of disinfectant drug submissions before and throughout the application review process.

1.4 Policy statements

Applicants must provide Health Canada with sufficient information to support the safety, efficacy and quality of a disinfectant drug when used in accordance with the label's recommended conditions of use before market authorization can be granted.

Health Canada must evaluate this information and determine whether a drug identification number (DIN) should be issued.

2. Guidance for implementation

The information in this section outlines the drug application streams applicable to disinfectant drugs. Information regarding the performance standards applicable to these application streams, as well as the pause-the-clock mechanism, may be found in the following Health Canada document:

- **Guidance Document: Management of Drug Submissions and Applications** (<https://www.canada.ca/en/health-canada/services/drugs-health-products/drug-products/applications-submissions/guidance-documents/management-drug-submissions/management-drug-applications-2019/document.html>)

2.1 General application requirements

Information regarding the submission requirements for a disinfectant drug application may be found in the following Health Canada documents:

- **Guideline on Preparation of DIN Submissions** (<https://www.canada.ca/en/health-canada/services/drugs-health-products/drug-products/applications-submissions/guidance-documents/preparation-drug-identification-number-submissions.html>)
- **Guidance Document: Fees for the Review of Human Drugs and Disinfectant Submissions and Applications** (<https://www.canada.ca/en/health-canada/services/drugs-health-products/drug-products/fees/fees-review-drug-submissions-applications-2019/document.html>)

Note: Health Canada is no longer accepting paper copies of disinfectant drug applications. The following guidance documents provide information on how to file in electronic Common Technical Document (eCTD) or "non-eCTD electronic only" format:

- **Guidance Document: Preparation of Drug Regulatory Activities in the Electronic Common Technical Document Format** (<https://www.canada.ca/en/health-canada/services/drugs-health-products/drug-products/applications-submissions/guidance-documents/ectd/preparation-drug-submissions-electronic-common-technical-document.html>)

- **Guidance Document: Preparation of Regulatory Activities in the "Non-eCTD Electronic-Only" Format** (<https://www.canada.ca/en/health-canada/services/drugs-health-products/drug-products/applications-submissions/guidance-documents/ectd/preparation-drug-submissions-electronic-common-technical-document.html>)

2.1.1 General considerations for disinfectant drug applications

The following information provides clarification on the information being requested for disinfectant drugs:

For the declaration of Active Ingredients and the Non-Medicinal Ingredients on the HC/SC 3011 Drug Submission Application Form: The sum of the percent nominal concentrations of the active ingredients and non-medicinal ingredients declared in sections 56 and 57 for the formulated product should total 100%, and should be expressed as a percentage on a weight-per-weight basis (% w/w).

2.2 Administrative applications

This application stream applies to disinfectants that do not require a scientific or label review prior to market authorization. There are three types of administrative applications:

- a. **Change in Manufacturer/Sponsor's Name:** may be due to a merger/buyout, a company name change or a transfer of ownership;
- b. **Change in Product Name:** may involve either a change in the product name with the original drug identification number (DIN) being retained, or the request for an additional product name with a new DIN to be issued; and
- c. **Licensing Agreement:** involves an agreement between two companies, whereby one company (licensor) supplies a drug product to another company (licensee) for sale under the second company's name (also referred to as a cross-licensed application, or an identical "repack" copy product). Includes post-authorization label changes filed by licensees to remain identical to a licensor's drug.

These applications do not require an assessment of labelling material, therefore if there have been unapproved changes to the label submitted, except for a change in the manufacturer name and/or product name, then the application will not be eligible for processing under the Administrative pathway.

Note: Licensing agreement applications that reference only certain aspects of the licensor's drug product will not be eligible for processing under the Administrative pathway. This includes deviations from the licensor in terms of labelling (exclusive to label design elements), or in terms of the chemistry and manufacturing information or product formulation. These changes will require the filing of a Labelling Only application. It is not permitted to cross-license an already cross-licensed product.

For information regarding administrative application requirements, the following Health Canada documents should be referenced:

- **Guidance Document: Regulatory requirements for Drug Identification Numbers (DINs)** (<https://www.canada.ca/en/health-canada/services/drugs-health-products/drug-products/applications-submissions/guidance-documents/regulatory-requirements-drug-identification-numbers/document.html>)
- **Guidance Document: Administrative Processing of Submissions and Applications Involving Human or Disinfectant Drugs** (<https://www.canada.ca/en/health-canada/services/drugs-health-products/drug-products/applications-submissions/guidance-documents/administrative-processing-human-disinfectant-drugs-2019.html>)

2.3 Monograph applications

This type of application stream applies to disinfectants that do not require a scientific review prior to market authorization, and allows for an abbreviated review process for disinfectants that have a well characterized safety and efficacy profile under specific conditions of use and labelling requirements (e.g., defined active ingredients; minimum in-use concentrations; minimum contact times; and limited efficacy claims). This type of application requires an attestation of compliance with a Monograph, and does not require the submission of supporting efficacy, safety or quality data. The applicable cost recovery fee category is "Labelling Standard".

2.4 Labelling only applications

This application stream applies to disinfectants that require an assessment of their labelling as part of their market authorization, but do not include supporting safety, efficacy or quality data, with the exception of safety updates submitted in support of Division 8 "new drugs" for disinfectants, which may include data to support the safety update. There are three types of labelling only applications:

- a. submissions in support of changes to the labelling of disinfectants that do not require supporting data (e.g., DIN amendment applications for changes that are not permitted via a post-authorization Division 1 change (PDC) notification);
- b. submissions in support of safety updates for disinfectants that received market authorization under Part C, Division 8 of the *Food and Drug Regulations* as "new drugs", and which may include data to support the safety update; and
- c. submissions in support of a change in the manufacturer's name or brand name that requires processing outside of the Administrative pathway due to deviations from the previously authorized labelling or drug product information.

2.5 Full review applications

When a proposed disinfectant or its labelling is outside the scope of a published Monograph, applicants are required to submit evidence to Health Canada to support the safety, efficacy and

quality of the product when used in accordance with the label directions; these applications require a scientific assessment as part of their market authorization. The applicable cost recovery fee category is "Disinfectant - Full Review".

2.6 Post-authorization division 1 change (PDC) notification

For disinfectants regulated under Division 1 of the Food and Drug Regulations that have received market notification, applicants are permitted to make certain post-market changes through the post-authorization Division 1 change (PDC) notification process, and should consult the following Health Canada document:

- [Guidance Document on Post-Drug Identification Number \(DIN\) Changes](https://www.canada.ca/en/health-canada/services/drugs-health-products/drug-products/applications-submissions/guidance-documents/post-drug-identification-number-changes.html) (https://www.canada.ca/en/health-canada/services/drugs-health-products/drug-products/applications-submissions/guidance-documents/post-drug-identification-number-changes.html)

Applicants should notify Health Canada within 30 days of making a permitted change. There is currently no cost recovery fee for eligible PDC notifications.

Note: After obtaining market authorization for a cross-licensed product under the Administrative pathway, all aspects of the authorization for the licensee's product must remain identical in every way to that of the licensor's throughout the product's life-cycle, with the exception of the manufacturer name and/or product name. Should a licensee wish to significantly deviate from the licensor in terms of labelling (exclusive to label design elements), or in terms of the chemistry and manufacturing information or product formulation, then these changes will not be eligible for processing under the post-authorization Division 1 change (PDC) notification pathway, and will require the filing of a Labelling Only application.

2.6.1 Considerations for changes to the recommended premises for hard surface disinfectants

The following information provides clarification on the change identified in the post-drug identification number (DIN) change guidance document as #6 - Addition, removal or change to the recommended premises for a disinfectant drug.

The recommended premises (i.e., drug use areas) for disinfectants are chosen by applicants during the market authorization process by selecting the appropriate drug use areas on the HC/SC 3011 Drug Submission Application Form (i.e., domestic, industrial/institutional, hospital, food processing, barn, or any combination of these). Applicants seeking to amend the recommended premises for a product following its market authorization should take note of the following situations to determine whether a PDC notification would be appropriate for the proposed change:

- a. **Addition of type of premise (e.g., product originally approved only for domestic use, and applicant wants to add industrial/institutional uses):** This change is not acceptable through the notification process, and therefore an appropriate review application is required to proceed with the proposed change.

- b. **Removal of type of premise (e.g., product originally approved for both domestic and industrial/institutional uses, and applicant wants to remove the domestic uses):** This change is acceptable through the notification process, provided that the product label is revised to remove all uses of the product within that premise. For disinfectants that received authorization under the administrative licensing agreement pathway, should a licensee wish to deviate from the licensor in terms of the authorized drug use areas, these changes will not be eligible for processing under the post-authorization Division 1 change (PDC) notification pathway, and will require the filing of a Labelling Only application
- c. **Addition, change or removal of references to specific areas, surfaces or objects within authorized premises:** This change is acceptable through the notification process, provided that the areas, surfaces and/or objects are appropriate for the authorized types of premises. For disinfectants that received authorization under the administrative licensing agreement pathway, should a licensee wish to deviate from the licensor in terms of the specific areas, surfaces or objects within authorized drug use areas, these changes might be eligible for processing under the post-authorization Division 1 change (PDC) notification pathway, provided that the resulting label revisions are not significant.

2.7 New drug submission (NDS) applications

When a proposed disinfectant meets the definition of "new drug" as per Part C, Division 8 of the Food and Drug Regulations (e.g., contains a new active ingredient or a new combination of active ingredients, or is intended for a new condition of use), then a new drug submission (NDS) application is required. If a disinfectant was approved as an NDS and is making subsequent changes such as a new condition of use, a supplement to a new drug submission (SNDS) is required. The submission of evidence to Health Canada for both of these types of applications is required to support the safety, efficacy and quality of the product when used in accordance with the proposed conditions of use. The applicable cost recovery fee category is "Disinfectant - Full Review". It is recommended that applicants of proposed disinfectant drugs which fall into the NDS or SNDS category request a pre-submission meeting prior to filing an application with Health Canada, as outlined in the [Guidance Document: The Management of Drug Submissions and Applications](https://www.canada.ca/en/health-canada/services/drugs-health-products/drug-products/applications-submissions/guidance-documents/management-drug-submissions/management-drug-applications-2019/document.html) (<https://www.canada.ca/en/health-canada/services/drugs-health-products/drug-products/applications-submissions/guidance-documents/management-drug-submissions/management-drug-applications-2019/document.html>). The purpose of a pre-submission meeting is to discuss the data requirements considered necessary to support the application, and additionally such meetings:

- Familiarize Health Canada review staff with the application prior to its arrival; and
- Provide an opportunity for the applicant to obtain feedback regarding areas of concern identified by Health Canada review staff (i.e. whether the proposed supporting data is considered adequate to establish the safety, efficacy and quality of the drug).

2.8 Post notice of compliance (NOC) changes

For disinfectants regulated as "new drugs" under Part C, Division 8 of the Food and Drug Regulations that have received market authorization, applicants are permitted to make various post-market changes, and should consult the following Health Canada documents:

- **Guidance Document - Post-Notice of Compliance (NOC) Changes: Framework Document** (<https://www.canada.ca/en/health-canada/services/drugs-health-products/drug-products/applications-submissions/guidance-documents/post-notice-compliance-changes/framework-2019/document.html>)
- **Guidance Document - Post-Notice of Compliance (NOC) Changes: Safety and Efficacy Document** (<https://www.canada.ca/en/health-canada/services/drugs-health-products/drug-products/applications-submissions/guidance-documents/post-notice-compliance-changes/safety-efficacy-2019/document.html>)
- **Guidance Document - Post-Notice of Compliance (NOC) Changes: Quality Guidance** (<https://www.canada.ca/en/health-canada/services/drugs-health-products/drug-products/applications-submissions/guidance-documents/post-notice-compliance-changes/quality-document/guidance.html>)

These guidance documents provide criteria to determine what is meant as a "significantly different" change, and provide applicants with the data recommendations considered necessary to enable Health Canada to make an accurate determination of the impact of a change to the safety, efficacy and quality of the drug. Within these guidance documents, disinfectants are scoped into the human pharmaceutical drug category. Health Canada encourages disinfectant drug applicants to contact Health Canada in advance of filing a post NOC change should they require clarification regarding the specified filing requirements. Depending on the issue or concern, a pre-submission meeting may be arranged as outlined in the **Guidance Document: The Management of Drug Submissions and Applications** (<https://www.canada.ca/en/health-canada/services/drugs-health-products/drug-products/applications-submissions/guidance-documents/management-drug-submissions/management-drug-applications-2019/document.html>), to allow more in-depth discussion between the applicant and Health Canada.

For safety updates submitted in support of Division 8 "new drugs" for disinfectants, the applicable cost recovery fee category is "Labelling Only - Disinfectant". All other post NOC changes that are not eligible for a Level III - Annual Notification are to be filed as a supplement to a new drug submission (SDNS); the applicable cost recovery fee category is "Disinfectant - Full Review". Post-market changes classified as a Level I - Supplement change may not be implemented until a Notice of Compliance (NOC) has been issued for the change.

Appendices

Appendix A – Regulation of chemical products for use on environmental surfaces and inanimate objects

In Canada, chemical products represented for use on environmental surfaces and inanimate objects (e.g., cleaners, sanitizers and disinfectants) may be regulated under a number of different frameworks, according to their represented use or purpose. The following table and sections provide general information regarding the different product classes, their corresponding legislation and responsible regulatory body, and examples of their represented uses.

Table 1: Regulation of chemical products for use on environmental surfaces and inanimate objects

Product class	Legislation and responsible regulatory body	Examples of represented uses
Disinfectant drugs	Food and Drugs Act Food and Drug Regulations	<ul style="list-style-type: none"> • hard surface disinfectants • hard surface disinfectants with hard non-porous food contact and non-food contact surface sanitizer claims
	Natural and Non-prescription Health Products Directorate Health Canada	
Medical devices	Food and Drugs Act Medical Devices Regulations	
	Medical Devices Bureau Therapeutic Products Directorate Health Canada	<ul style="list-style-type: none"> • high-level disinfectants and sterilant solutions • contact lens disinfectants
Pest control products	Pest Control Products Act Pest Control Products Regulations	<ul style="list-style-type: none"> • non-food contact surface sanitizers • soft surface sanitizers • greenhouse disinfectants • swimming pool and spa disinfectants
	Pest Management Regulatory Agency Health Canada	
Consumer products	Canada Consumer Product Safety Act Consumer Chemicals and Containers Regulations	<ul style="list-style-type: none"> • cleaning products for use by consumers

	Consumer and Hazardous Products Safety Directorate Health Canada	
	Hazardous Products Act Hazardous Products Regulations	
Controlled products	Consumer and Hazardous Products Safety Directorate Health Canada	<ul style="list-style-type: none"> • cleaning products for use in work places
	Food and Drugs Act Food and Drug Regulations	
Incidental additives	Food Directorate Health Canada	<ul style="list-style-type: none"> • hard surface disinfectants for use in food processing facilities • food contact surface sanitizers
	Food and Drugs Act Food and Drug Regulations	
Non-food chemicals	Canadian Food Inspection Agency	<ul style="list-style-type: none"> • hard surface disinfectants for use in federally registered food establishments • sanitizers for use in federally registered food establishments

1. Disinfectant drugs

Most chemical products represented for disinfectant uses on hard, non-porous environmental surfaces and inanimate objects are regulated by Health Canada as disinfectant drugs under the Food and Drugs Act and Regulations.

Chemical products regulated as disinfectant drugs may also be represented for use as food-contact or non-food contact sanitizers on hard, non-porous environmental surfaces and inanimate objects; these products are referred to as "disinfectant-sanitizers".

Disinfectant drugs require a pre-market assessment and issuance of a drug identification number (DIN) prior to being sold in Canada. As part of the pre-market assessment, the efficacy, safety and quality of the drug is evaluated, and as a condition of market authorization applicants are required to submit draft labelling for assessment to Health Canada.

Inspectors monitor and enforce the compliance of disinfectant drugs through post-market regulatory activities under the purview of Health Canada's Health Products and Food Branch Inspectorate.

For information regarding the pre-market authorization requirements for disinfectant drugs, inquiries should be directed to the:

Natural and Non-prescription Health Products Directorate

(email: <http://www.hc-sc.gc.ca/contact/dhp-mps/hpfb-dgpsa/nhpd-dpsn-eng.php>)

Health Products and Food Branch
Health Canada

2. Medical devices

Chemical products represented for disinfectant uses on invasive medical devices as high-level disinfectants and sterilant solutions (including contact lens disinfectants) are regulated by Health Canada as Class II medical devices under the Food and Drugs Act and Medical Devices Regulations.

Medical devices require a pre-market assessment and issuance of a Medical Device Licence prior to being sold in Canada. As part of the pre-market assessment, the efficacy, safety and quality of the device is evaluated, and as a condition of market authorization applicants are required to submit draft labelling for assessment to Health Canada.

Inspectors monitor and enforce the compliance of medical devices through post-market regulatory activities under the purview of Health Canada's Health Products and Food Branch Inspectorate.

For information regarding the pre-market authorization requirements for medical devices, inquiries should be directed to the:

Medical Devices Bureau

(email: <http://www.hc-sc.gc.ca/contact/dhp-mps/hpfb-dgpsa/mdb-bmm-eng.php>)

Therapeutic Products Directorate

Health Products and Food Branch

3. Pest control products

Chemical products represented for use as non-food contact sanitizers on hard, non-porous environmental surfaces and inanimate objects without any associated disinfectant drug claims are regulated as pest control products by the Pest Management Regulatory Agency under the Pest Control Products Act and Regulations.

Chemical products which are represented for use as disinfectants or sanitizers on porous surfaces and inanimate objects (e.g., carpets, fabrics and textiles) are regulated as pest control products. These products may also be represented for disinfectant drug uses provided that they have also been authorized for use as disinfectant drugs (i.e., a drug identification number has been issued).

Chemical products represented for disinfectant uses in controlling plant pathogens (e.g., greenhouse disinfectants) and for uses in swimming pools or spas are regulated as pest control products and not as disinfectant drugs.

Pest control products require a pre-market assessment and issuance of a registration number prior to being sold in Canada. As part of the pre-market assessment, the efficacy, safety and quality of the product is evaluated, and as a condition of market authorization applicants are required to submit draft labelling for assessment to the Pest Management Regulatory Agency.

Inspectors monitor and enforce the compliance of pest control products through post-market regulatory activities.

For information regarding the pre-market authorization requirements for pest control products, inquiries should be directed to the:

Pest Management Regulatory Agency

(email: <http://www.hc-sc.gc.ca/contact/cps-spc/pmra-arla/infoserv-eng.php>)

Health Canada

4. Consumer cleaning products

Chemical products intended for use on environmental surfaces and inanimate objects that do not make an expressed antimicrobial activity claim on their label are regulated as cleaners; those represented for use by consumers (i.e., for non-commercial purposes) are regulated as consumer products under the Canada Consumer Product Safety Act and the Consumer Chemicals and Containers Regulations. Cleaning products may contain recognized antimicrobial ingredients (e.g., sodium hypochlorite, quaternary ammonium compounds, hydrochloric acid) as part of their formulation, however in the absence of an expressed antimicrobial claim a product is regulated as only a cleaner.

There is no requirement for the pre-market approval of consumer cleaning products; however as a condition of sale suppliers are required to appropriately label products with hazard symbols and standardized wording as specified in the Consumer Chemicals and Containers Regulations, and to perform mandatory reporting and record keeping as specified in the Canada Consumer Product Safety Act.

Inspectors monitor and enforce the compliance of consumer cleaning products through post-market regulatory activities under the purview of Health Canada's Consumer and Hazardous Products Safety Directorate.

For information regarding the legislative requirements for consumer cleaning products, inquiries should be directed to the:

Consumer and Hazardous Products Safety Directorate

(email: <http://www.hc-sc.gc.ca/contact/cps-spc/hecs-dgsesc/pso-bsp-eng.php>)

Healthy Environments and Consumer Safety Branch

Health Canada

5. Workplace cleaning products

Chemical products intended for use on environmental surfaces and inanimate objects that do not make an expressed antimicrobial activity claim on their label are regulated as cleaners; those represented for use in Canadian workplaces are regulated as controlled products under the Hazardous Products Act and the Hazardous Products Regulations. Cleaning products may contain recognized antimicrobial ingredients (e.g., sodium hypochlorite, quaternary ammonium compounds, hydrochloric acid) as part of their formulation, however in the absence of an expressed antimicrobial claim a product is regulated as only a cleaner.

There is no requirement for the pre-market approval of workplace cleaning products; however as a condition of sale suppliers are required to meet the hazard communication standards of the Workplace Hazardous Materials Information System (WHMIS).

Compliance activities relating to work place cleaning products are conducted through Health Canada and the provincial, territorial and federal agencies responsible for occupational health and safety.

For information regarding the legislative requirements for workplace cleaning products and the WHMIS hazard communication standards, inquiries should be directed to the:

Consumer and Hazardous Products Safety Directorate

(email: <http://www.hc-sc.gc.ca/contact/ahc-asc/hecs-dgsesc/ghs-sgh-eng.php>)

Health Canada

6. Incidental additives

Incidental additives are chemical products used in food processing facilities which are often not intended to come into direct contact with food but which may potentially become residues in food. They are evaluated by the Bureau of Chemical Safety within Health Canada's Food Directorate under the authority of the Food and Drugs Act and Regulations.

Within the Food and Drugs Act and Regulations there is no mandatory requirement for the pre-clearance of incidental additives prior to their use in food processing plants, however there may be certain use conditions where pre-market clearance may be a mandatory requirement under other legislation and certification programs. Manufacturers intending to supply their chemical products to food processors are encouraged to contact the Bureau of Chemical Safety for clarification regarding whether a mandatory pre-market clearance is required. When the pre-market clearance is not mandatory, manufacturers may request that a voluntary evaluation of their product be conducted to determine the acceptability of using the intended incidental additives in food processing plants. If a product is considered by the Bureau of Chemical Safety to be safe for its intended uses, a No Objection Letter (NOL) is issued which can be presented by the manufacturer to prospective food processors.

Sanitizers used on surfaces or inanimate objects that may come into direct contact with food or beverages, also called food contact surface sanitizers, are considered to be incidental additives, and the Bureau of Chemical Safety is the regulatory body within Health Canada responsible for reviewing their safety.

For information regarding the evaluation requirements for incidental additives and for guidance regarding their appropriate labelling, inquiries should be directed to the:

Bureau of Chemical Safety

(email: <http://www.hc-sc.gc.ca/contact/fn-an/hpfb-dgpsa/bcs-bipc-eng.php>)

Health Products and Food Branch

Health Canada

7. Non-food chemicals

Chemical products (such as disinfectants, sanitizers, cleaners), used in federally registered meat establishments and that are not intended to become part of the food, are considered to be non-food chemicals. The Canadian Food Inspection Agency (CFIA) deals with the safe use of non-food chemicals in federally registered meat establishments.

Manufacturers intending to supply their chemical products to federally registered meat establishments are encouraged to contact the Canadian Food Inspection Agency for clarification regarding whether a mandatory evaluation of the acceptability of the product for its intended uses is required.

For further information regarding the use of non-food chemicals in meat plants, inquiries should be directed to the:

Canadian Food Inspection Agency

(email: <http://www.inspection.gc.ca/about-the-cfia/contact-us/eng/1299860523723/1299860643049>)