



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

OFFICE OF CHEMICAL SAFETY
AND POLLUTION PREVENTION

VIA E-MAIL, RETURN RECEIPT REQUESTED

9/21/2018

Subject: Label Changes Necessary for Sodium Hypochlorite, Calcium Hypochlorite, and Potassium Hypochlorite in Accordance with EPA's May 2018 Interim Registration Review Decision

Dear Sir or Madam:

You are receiving this letter because your company holds one or more active registrations for sodium hypochlorite, calcium hypochlorite, and/or potassium hypochlorite products and your product label(s) must be amended in accordance with the Environmental Protection Agency's (EPA's) *Interim Registration Review Decision for Sodium Hypochlorite, Calcium Hypochlorite, and Potassium Hypochlorite* (dated March 27, 2018; announced in the *Federal Register* on May 1, 2018). This document may be found in the public docket for pesticides at <http://www.regulations.gov/> under docket numbers EPA-HQ-OPP-2012-0004¹ and EPA-HQ-OPP-2014-0157.² EPA has determined that label changes are necessary to ensure that sodium hypochlorite, calcium hypochlorite, and potassium hypochlorite continue to meet the safety standards of the Federal Insecticide Fungicide Rodenticide Act (FIFRA).

In response to comments received after the official public comment period for the Interim Decision, the Agency has added clarification to the label amendments in the table below. Footnotes 1,2,3 and 4 below provide guidance that was not included in the *Interim Registration Review Decision for Sodium Hypochlorite, Calcium Hypochlorite, and Potassium Hypochlorite* regarding reader's notes, service bulletins, and placement on the labels.

¹ Direct link: <https://www.regulations.gov/document?D=EPA-HQ-OPP-2012-0004-0032>

² Direct link: <https://www.regulations.gov/document?D=EPA-HQ-OPP-2014-0157-0016>

Summary of Labeling Changes for Hypochlorites

Description	Labeling Language for Hypochlorites	Placement on Label
Drinking Water Disinfection End Use Products		
For drinking water uses	<p>“The following practices help to minimize degradant formation in drinking water disinfection:</p> <ul style="list-style-type: none"> • It is recommended to minimize storage time. • It is recommended that the pH solution be in the range of 11-13. • It is recommended to minimize sunlight exposure by storing in opaque containers and / or in a covered area. Solutions should be stored at lower temperatures. Every 5° C reduction in storage temperature will reduce degradant formation by a factor of two. • Dilution significantly reduces degradant formation. For products with higher concentrations, it is recommended to dilute hypochlorite solutions with cool, softened water upon delivery, if practical for the application.” 	Precautionary Statements, on applicable labels ^{1, 2, 3}
Pool, Spa, Hot Tub, and Fountain End Use Products⁴		
<p>For end use formulations used to treat commercial and residential swimming pools, hot tubs, spas, and fountains</p> <p>Note: Registrants must only include approved use sites in the Discharge Directions statement</p>	<p>“Discharge Directions for [Commercial] and [Residential] [Pool,] [Spa,] [Hot Tub,] and [Fountain] Uses</p> <p>Before draining a treated [pool,] [spa,] [hot tub,] or [fountain] contact your local sanitary sewer and storm drain authorities and follow their discharge instructions. Do not discharge treated [pool,] [spa,] [hot tub,] or [fountain] water to any location that flows to a gutter, storm drain or natural water body unless discharge is allowed by state and local authorities.”</p> <p>For end-use products, NPDES permit language for pool, spa, hot tub, or fountain use is not required and must be removed if currently on the label associated with these uses.</p>	Directions for Use, on applicable labels
Industrial Processes and Water Systems End Use Products, and All Technical Grade and Manufacturing Use Products ^{4, 5, 6}		
	“Do not discharge effluent containing this product into lakes,	

Description	Labeling Language for Hypochlorites	Placement on Label
<p>For technical and manufacturing use formulations used to formulate swimming pools, hot tubs, spas, and fountains and other approved use sites</p> <p>To clarify Environmental Hazards statements based on product category</p>	<p>streams, ponds, estuaries, oceans or other waters unless in accordance with the requirements of a National Pollutant Discharge Elimination System (NPDES) permit and the permitting authority has been notified in writing prior to discharge. Do not discharge effluent containing this product to sewer systems without previously notifying the local sewage treatment plant authority. For guidance contact your State Water Board or Regional Office of the EPA.”</p>	<p>Environmental Hazards, on applicable labels</p>

¹ If your master label includes uses other than Drinking Water Disinfection, you have the option of using a reader’s note to inform the EPA or state reviewer that the language in this section only applies to end use products with this use. For example: “[The following is for use only on marketplace labels that include the directions Disinfection of Drinking Water (Emergency/ Public/Individual Systems).]”

² If space is limited on the container label, you may include this language in a service bulletin and reference it: “For drinking water uses see additional precautions on [service bulletin, product bulletin, other use label, side [back] panel].”

³ Precise placement must be at the end of the precautionary statements section in “Precautionary Statements for Physical or Chemical Hazards.”

⁴ Note for Pool, Spa, Hot Tub, and Fountain Products: The Agency allows master labels to include multiple uses. Therefore, a label may include uses that would trigger the non-NPDES language (e.g. end use pool) and the NPDES language (e.g. industrial processes such as cooling tower use). For products whose uses trigger multiple discharge direction language, the label should indicate which uses the NPDES language applies to and which uses other discharge instructions apply to. This should be indicated as a note in the Environmental Hazards sections and the related use site’s Directions for Use section.

⁵ See EPA’s Antimicrobial Pesticides Use Site Index for a full description of use sites at <https://www.epa.gov/sites/production/files/2016-10/documents/158w-usi.pdf>

⁶ Clarification on NPDES label language can be found in Pesticide Registration Notice (PRN) 95-1: Effluent Discharge Labeling Statements at <https://www.epa.gov/pesticide-registration/prn-95-1-effluent-discharge-labeling-statements>

Timeline and Instructions

Your sodium hypochlorite, calcium hypochlorite, and/or potassium hypochlorite product label(s) must be amended and submitted to the Agency for review on or before November 20, 2018 which is 60 days from the issuance of this letter. Please submit electronic copies of your amended product label(s), with changes highlighted, as well as an application for a fast-track Agency-initiated label amendment to EPA’s Pesticide Submission Portal (PSP), which can be accessed through EPA’s Central Data Exchange (CDX) using the following link: <https://cdx.epa.gov/>. Once in the CDX system, use the “Registration Review Label” link, found under the “Re-evaluation” column of the Pesticide Submission Portal home page. The Agency encourages registrants to use the CDX system as it greatly expedites the review process. If needed, you may also send paper copies of your amended product labels, with an application for

a fast-track, Agency-initiated non-PRIA label amendment to the Reevaluation Team Leader, PM 36 at one of the following addresses:

By US mail:

Document Processing Desk
Attn: Reevaluation Team Leader, PM 36
US EPA, OPP/Antimicrobials Division (7510P)
1200 Pennsylvania Ave. N.W.
Washington, DC 20460

By express or courier service:

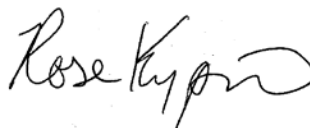
Document Processing Desk
Attn: Reevaluation Team Leader, PM 36
US EPA, OPP/Antimicrobials Division (7510P)
One Potomac Yard (South Building)
2777 S. Crystal Dr.
Arlington, VA 22202

After a preliminary review by the reevaluation team, your label(s) will be provided to the appropriate Antimicrobials Division Product Manager (PM) for final review and stamping by the registration team.

The Agency believes that, in the absence of this revised labeling, sodium hypochlorite, calcium hypochlorite, and potassium hypochlorite products will not have sufficient directions for use and/or precautionary statements to adequately protect human health and the environment. Therefore, failure to submit amended labels implementing the interim registration review decision in a timely and adequate manner may result in regulatory action.

Please contact Chemical Review Manager, Jessica Bailey at (703) 347-0148 or at bailey.jessica@epa.gov, if you have any questions about this letter or the *Interim Registration Review Decision for Sodium Hypochlorite, Calcium Hypochlorite, and Potassium Hypochlorite*.

Sincerely,



Rose Kyprianou, Chief
Regulatory Management Branch II
Antimicrobials Division
Office of Pesticide Programs

Attachments:

- (1) *Interim Registration Review Decision for Sodium Hypochlorite, Calcium Hypochlorite, and Potassium Hypochlorite*
- (2) *List of Sodium Hypochlorite, Calcium Hypochlorite, and/or Potassium Hypochlorite Products*

cc: Demson Fuller, PM 32, Regulatory Management Branch I, Antimicrobials Division