

## Navigating country regulations

We are frequently asked whether our Hypo machine is registered or licensed with national authorities. A simple way to think about this is to compare a coffee maker with a cup of coffee. If you manufacture or sell coffee makers, you should have some certification that ensures the machine is safe and won't shock the user. But as a machine manufacturer, you can't be responsible for the quality of coffee that the user makes! As manufacturers/suppliers of a machine that can make hypochlorous acid, we are similar to a coffee machine manufacturer.





In the United States, if you made hypochlorous acid and offered it for sale, you would need an EPA "N" number approving and authorizing you to sell the liquid. But if you make hypochlorous acid and use it for yourself or in your own business, you don't need any licenses or permits. It is the same as serving coffee to your own family or workmates versus selling coffee to the public.

This important difference is one of the great advantages of on-site generation. The owner of the machine can control the quality of the disinfectant, and they are normally exempt from regulation as long as they're the only ones operating it and using the resulting solution. Similarly, when we sell a machine, we do not make "kill claims" about the resulting hypochlorous acid like a registered pharmaceutical might. The effectiveness of hypochlorous is well-documented over many years and that information is available in the public domain. We offer a machine that creates hypochlorous and we invite the user to make their own determinations about how to use the end product.

Our Hypo machine is undergoing ETL approval to UL standards. This assures users that the machine is safe and that they won't be harmed while operating it. Importing countries are likely to accept the ETL/UL listing or a similar third-party test to assure the machine complies with their own safety standards.

In summary, as long as you are only selling the hypochlorous acid machine or using it in your own business, you normally do not need to register with the EPA or equivalent agency in your own country. If you plan to sell and bottle the solution produced by the machine, then it will be your responsibility to have that solution registered and approved by the appropriate regulatory officials in your country.

## **List of US Government Approvals for HOCI**

FDA Approval for Direct Food Contact

USDA Approval of HOCI as a Synthetic Substance for Organic Foods

US Coast Guard Approved Marine Sanitation Device

Registered under EPA Federal Insecticide, Fungicide, and Rodenticide Act

EPA List N Registered Disinfectant

Hypo Source Hypo 7.5 EPA establishment number 082229-GA-001

