

New Federal Regulations for Iodine...



Has Gram Staining Without a License Become a Criminal Act?



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Jay Hardy is the founder and president of Hardy Diagnostics. He began his career in microbiology as a Medical Technologist in Santa Barbara, California.

In 1980, he began manufacturing culture media for a few local hospitals that had a need for a reliable source of media.

Today, Hardy Diagnostics is the third largest media manufacturer in the U.S.

To ensure rapid and reliable turn around time, Hardy Diagnostics maintains six distribution centers, and produces over 2,800 products used in clinical and industrial microbiology laboratories throughout the world.

Iodine, commonly used in microbiology staining procedures, is also used in illegal drug labs to produce methamphetamine. This dual use for iodine puts microbiologists in the awkward position of utilizing a substance that is tightly controlled by the federal and some state governments.

New Regulations

Many microbiologists may be unaware of the new regulations regarding iodine that were passed by Congress and became effective on August 1, 2007 (see 21 CFR Parts 1309 and 1310). These new laws still allow the use of iodine in staining, but now require registration and an onerous quantity of red tape to acquire this now highly regulated chemical.



Excessive dental decay, known as “meth mouth” is just one of the many devastating effects of the abuse of the highly addictive drug methamphetamine.

First, let's look at why iodine became a substance controlled by the Drug Enforcement Administration (DEA).

Methamphetamine, a growing problem in the U.S., can be manufactured relatively easily in a crude laboratory. Ephedrine or pseudoephedrine, contained in such over-the-counter preparations as “Sudafed” and other cold and allergy remedies, can be purchased from any local drug store. When it is exposed to hydriotic acid, a high quality d-methamphetamine can be produced.



A typical clandestine lab for the production of methamphetamine in which iodine is used for one of the steps in the conversion of pseudoephedrine into the illegal drug.

Hydriotic acid is made from the combination of iodine and a form of phosphorus. Detailed instructions for this home-made process abound on the internet.

What is being regulated?

Iodine crystals became a DEA regulated substance in 1996, and in 2007 the law was expanded to include alcoholic tinctures and aqueous solutions of iodine. Currently the federal DEA controls any concentration of iodine that exceeds 2.2%. In California, the regulations are even tighter, in that it controls all iodine solutions unless the concentration is less than or equal to 1% and is in a container of eight ounces or less.



The federal DEA now strictly regulates all iodine that exceeds concentrations of 2.2%. Povidone iodine is exempt.

What does this mean to microbiologists?

Under federal regulations, iodine solutions for Tetrathionate Broth (30%) and Lugols Iodine (5%) would fall into the new laws. Under California law, it also includes non-stabilized Grams Iodine, (1%) in containers over eight ounces. This would also include iodine alcohol that is used in the Trichrome Stain procedure.

Note: some formulations for Gram Staining include iodine in the stabilized form. This form has a longer shelf life and is less light sensitive than the non-stabilized form. The stabilized form contains povidone iodine, which is expressly **exempt** from the federal regulations. Federal law regulates only tinctures and aqueous solutions made from iodine crystals.

How does this affect the ordering of iodine products?

The new regulations, enforced by the DEA, require that every manufacturer and distributor of iodine products be registered. They also require that all customers of the distributor be registered. In addition, the distributor must maintain detailed transaction records and report them to the DEA.



Grams Iodine in containers of 8oz or less is exempt from California regulation. However, Non-stabilized Grams Iodine in the gallon size is regulated by the new state law, since the concentration is over 1% and is over 8 ounces.

Hardy Diagnostics now complies with the new iodine state and federal regulations by requiring that all customers purchasing regulated iodine products must fill out a form which includes their laboratory license number. Each end user must be approved by the California Department of Justice before the transaction can take place. Unfortunately, the state approval process takes 21 days, so it is best to plan ahead and register as early as possible.

The following iodine products require registration at Hardy Diagnostics and customer approval from the California Department of Justice prior to purchase:

Iodine Alcohol for Trichrome, 1 gallon, #VXI128

Iodine Alcohol for Trichrome, 16 ounces, #VXI016

Iodine Solution, D'Antoni, 4 ounces, #628A4

Iodine, Grams, Non-Stabilized, 1gallon, #I128N

Lugol's Iodine, 16 ounces, #652A16

Lugol's Iodine, 250ml, #VIG008

Trichrome Starter Kit, 8 bottles for stain, #VXR010

Trichrome Starter Kit, 8 bottles, w/Coplin jars, #VXF019

Iodine-Iodide Solution, for Tetrathionate, 50ml, #Z129

Hardy's new [Gram Stain Advanced](#) contains stabilized iodine (povidone), which is exempted from the federal iodine regulations. This

enhanced formula for gram stain produces [brighter, more distinct colors](#) and prevents organisms from being mis-identified. It especially intensifies the “difficult to stain” organisms, such as *Bacillus*, and anaerobes.

Right or wrong, these new laws remind us of the highly regulated society in which we now live. Consider the following...

- Pythagorean Theorem: 24 words
- The Lord's Prayer: 66 words
- Archimedes' Principle: 67 words

- The 10 Commandments: 179 words
- The Gettysburg address: 286 words
- The Declaration of Independence: 1,300 words
- The US Government regulations for the sale of iodine: 18,968 words

If you have any questions about these new iodine requirements, please contact our [Customer Service](#) department. We would be glad to assist you!

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