Fish Health News You Can Use - *Miracle Cures*

Brought to you by the Pacific Region Fish Health Program

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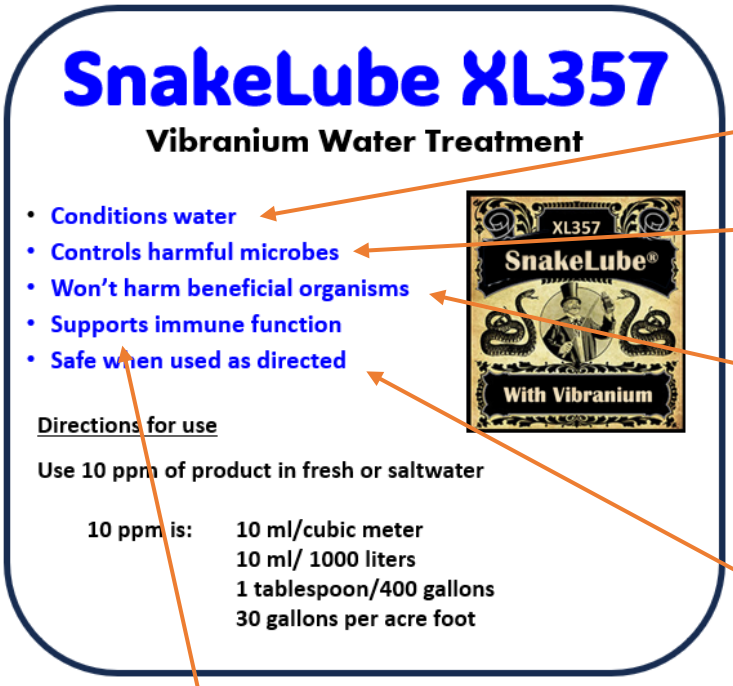
In both human and veterinary medicine, we are often challenged by advertisements for products that offer miracle cures. This problem is nowhere more obvious that in aquaculture. Miracle cures are often ineffective, and time and money spent on them is not available for other measures that would truly benefit the fish. Even worse, some miracle cures are harmful to fish, people, or the environment, and potentially illegal. So how do you make good decisions when faced with a sales pitch for a miraculous new product? Start out with the label. Let's look at an example label (made up of course – but quite similar to many that you'll see) and then look for the red flags that put this product in the "dubious and potentially dangerous" category.



Vague and nebulous claims that sound good but can't be defined or tested. For example:

What does "conditions" mean in this context? It sounds great, but what does it really mean?

What about "controls"? Does it get rid of them, reduce them by 2%, slow down their replication, or do something else?

Who decides what a "beneficial organism" is? Is it reasonable to believe that this will kill disease-causing bacteria but not the bacteria in biofilters, or those that live in partnership with fish in their guts or on their skin?

"Safe" for you, the fish, plants, metal pumps, or the environment?

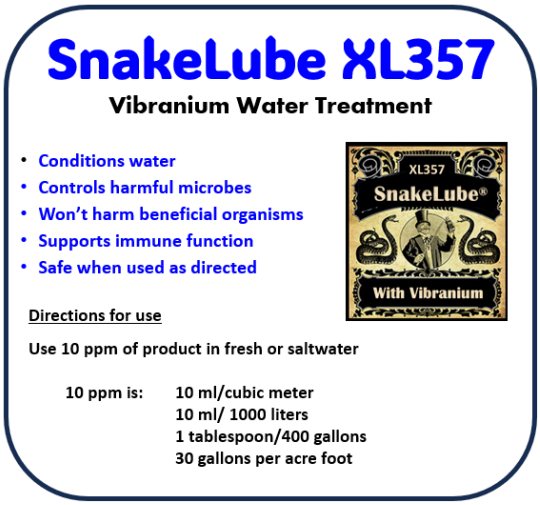
What about "supports"? This is meaningless in this context. We are so used to seeing useless feel-good claims like these that they are getting harder to recognize. The "supports immune function" claim is especially troubling. If they said "increases immune function" that might be a good thing (better disease resistance) or a bad thing (an indication of disease). If the label said "reduces inflammation" that sounds good but some readers will recognize that inflammation is the process that your immune system uses to fight infectious diseases and repair tissue and organ damage. This is why you see vague and meaningless feel-good terms like "supports."

The label should have specific and testable claims. This label has <u>none</u>!

The label should have a claim that directly applies to your intended use.

If Snakelube XL357 works for columnaris or bacterial infections of eggs, why doesn't it say anything like that on the label? The likely answer is that the product isn't effective for these purposes, or that the seller is trying to avoid the difficult and expensive regulatory process needed to demonstrate that a treatment is safe and effective.

If a sales pitch tries to sell you a treatment for a purpose that isn't on the product label, it is likely to be ineffective or dangerous and might even be illegal if you are using it in a manner not described on the label.



There should be solid peer-reviewed science showing that the product is effective for your purpose.

Going back to our example of columnaris or bacterial infections of eggs, there should be papers that clearly show that pure and chemically defined Vibranium, at a specific dose and frequency, is safe and efficacious for these purposes. Studies performed by the manufacturer, or that have not been peer-reviewed in a reputable journal, should always be evaluated with a very critical eye. Was the study conducted with the appropriate controls and replication? What about the statistics? Is it likely that funding from the manufacturer may have influenced the results? Are they just showing me the studies that are positive and not sharing results that cast doubt on the safety and efficacy of the product? What about side effects and water quality impacts? Is there just anecdotal evidence and no real science?

The label should accurately describe the ingredients of the product.

The SnakeLube XL357 label says that it contains Vibranium. How much? In what form? Does the word "Vibranium" describe a single well-defined chemical? What else is in there? The label doesn't make any useful claims about what is in the jug. It could be a jug of water with some coloring and a useless trace amount of Vibranium. It could also contain other substances that are not safe or legal in some situations. You have no way of knowing.

There are other reasons to be very concerned about a vague label. If there is good peer-reviewed science showing that Vibranium trichloride at 3 ppm is an effective treatment of columnaris, does that mean that you should give SnakeLube XL357 a try? ***No!*** You have no way of knowing how much Vibranium is in the product, if it is in the effective Vibranium trichloride form, and what interactions it may have with other substances present in SnakeLube. In fact, this commercial product may have nothing in common with the peer-reviewed research that shows that Vibranium trichloride is effective for your purpose.

Another big concern with the lack of label details is that the actual composition of SnakeLube XL357 may change between manufacturing lots. The manufacturer might find that the original formula was too expensive and reduce the active ingredient, there might be problems with ingredient availability, other forms of the ingredient might be substituted, or quality control might be so poor that there is huge variability between lots. This means that it might have worked last year, but not work this year. Even worse, if a study was done to look at the efficacy of the SnakeLube X357 product and it worked really well, there is no way to know if the Snakelube that you are buying today has any similarity to the SnakeLube used in that product-testing.

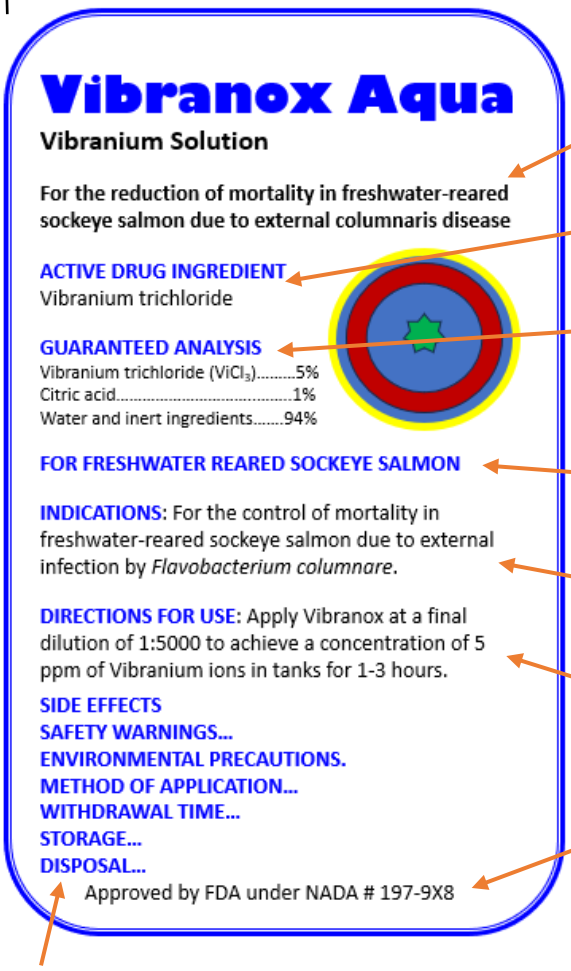
The vague label means that there is no way to have any confidence that your jug of SnakeLube will work like the one used even in a peer-reviewed product-testing publication, and there is no way to know if peer-reviewed science that used purified Vibranium chloride has anything to do with your jug of SnakeLube XL357.

The label should accurately describe which fish species can be treated.

The SnakeLube XL357 label does not say which fish species can be treated. This is critical information because 1) sensitivity to drugs and chemicals varies widely among aquatic animals, 2) because there may be human food safety risks and 3) there may be significant risks other animals in the food chain.

So, what should a good label look like?

It should look like this!



Makes a specific claim as to the purpose of the product.

Gives you the exact active ingredient.

Tells you exactly how much of the active ingredient is present and what else is in the jug.

Tells you which fish to use it on.

Tells you when to use it.

Tells you how to use it and gives the final dose of active ingredient that will result.

Provides an FDA registration number (for disease treatments) or an EPA registration number for other aquaculture chemicals.

Includes details in these important areas (*not shown in detail on this hypothetical label*).

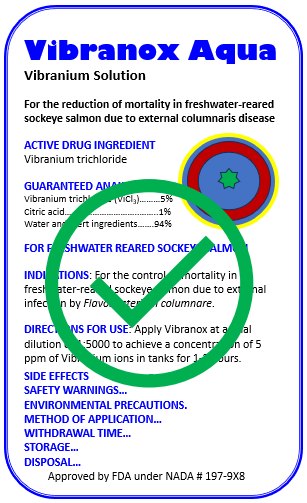
- Side Effects: Understanding side effects is a critical part of treatment decisions.
- Safety Warnings: There maybe hazards to humans or animals exposed to the chemical.
- Environmental Precautions: There may be hazards to other non-target plants and animals.
- Method Of Application: You need details on how to safely use the chemical.
- Withdrawal Time: Can the animals ever re-enter the human food chain? When?
- Storage: What conditions prevent the product from degrading and becoming ineffective or more toxic?
- Disposal: How can you safely dispose of unused product?

How Do You Prevent a *Miracle Cure* Disaster?

The aquaculture drug and chemical research and regulatory situation is always frustrating, especially when animals are dying and the products that you want are not available, not labelled for your use, or are too expensive to be practical. This can make *Miracle Cures* seem very attractive, but it is important to keep in mind that a lot could go wrong including loss of fish because the treatment wasn't effective, loss of fish because the treatments was toxic, wasted time and money that could have been used to do something that was beneficial for the fish, environmental damage, legal jeopardy, bad press, and human health impacts. Also keep in mind that "just trying it to see what happens" is no replacement for peer-reviewed science investigating the properties of the active ingredient. Quick trials can, and often do, produce misleading results because of lack of replication, bias, insufficient controls, and poor (or no) statistics. They also don't provide most of the critical information that is missing from the SnakeLube XL356 label.

To protect your fish, your budget, your agency, people, and the environment from a *Miracle Cure* disaster:

- Study the label. Does it have all the critical information that is included on the "Vibranox Aqua" label? Does the label allow the product to be used for your purpose and situation?
- Read the peer-reviewed science in reputable journals. Make sure that you have the full story on the safety and efficacy of the active ingredient.
- Don't trust anecdotal evidence and be suspicious of unpublished science presented in a sales pitch.
- Don't trust the results of a quick informal trial. They can be very misleading and don't provide information that is critical to a safe and effective treatment.
- Consult your aquatic animal veterinarian. They know what treatments work and they are highly trained in the regulatory and safety aspects of aquaculture drugs and chemicals.
- If you don't have access to an Aquatic Veterinarian, contact the US-FWS Aquatic Animal Drug Approval Program (AADAP) to check on your proposed treatment. [beatriz_silva@fws.gov]


Vibranox Aqua

Vibranium Solution

For the reduction of mortality in freshwater-reared sockeye salmon due to external columnaris disease

ACTIVE DRUG INGREDIENT
Vibranium trichloride

GUARANTEED ANA
Vibranium trich ($VICl_3$).....5%
Citric acid.....1%
Water an rt ingredients.....94%

FOR F SHWATER REARED SOCKEY ALM

INDI TIONS: For the control mortality in fres ater-re sockeye mon due to ext nal infec n by *Flavo terium columnare*.

DIREC NS FOR USE: Apply Vibranox at a al dilution 5000 to achieve a concentr n of 5 ppm of Vib um ions in tanks for 1 ours.

SIDE EFFECTS
SAFETY WARNINGS...
ENVIRONMENTAL PRECAUTIONS.
METHOD OF APPLICATION...
WITHDRAWAL TIME...
STORAGE...
DISPOSAL...

Approved by FDA under NADA # 197-9X8

- Check with the FDA Center for Veterinary Medicine by emailing them at [askCVM@Fda.hhs.gov] or reviewing the list of approved aquaculture drugs found at: Approved Aquaculture Drugs | FDA
- Check with the EPA or your state environmental quality agency.

Dubious *Miracle Cures* are a waste of time and money that should instead be invested in other measures that provide a real benefit to fish health and welfare.