

Super Oxidized Water Registered By EPA As A Hard-Surface Disinfectant

The new registrant, Oculus Innovative Sciences, claims that its novel technology promises to give traditional antimicrobial chemistries a stiff challenge for hospital and food-contact uses.

Setting the stage for a showdown with traditional chemistries, EPA last month approved an Oculus Innovative Sciences application for the use of super oxidized water as a disinfectant. The registration covers hard surfaces in hospitals and food-contact areas in homes and commercial settings.

The Agency's Antimicrobials Division stamped a Master Label for Microcyn technology on Oct. 21 (Registration Number 81206-1). Already registered for various uses in other countries, Microcyn is a proprietary solution produced by the electrolysis of pure water and brine.

The first of the Microcyn hard-surface disinfectants to reach the U.S. market will be marketed under the name Cidalcyn, which is intended for hospital applications. Oculus officials claim that Cidalcyn could pose a significant challenge to current chemistries because it is effective against a full range of pathogens without the drawbacks associated with some other active ingredients.

They also say that the attributes of Microcyn should enable the Petaluma, Calif.-based company to successfully market its Puracyn disinfectant, which will be offered for distribution to commercial and consumer markets next year – probably in the first quarter.

THE PRODUCT IS 'INERT'

"Besides efficacy," Joel Derrico, Oculus Director of Sales and Marketing for Disinfectant Products, told *Insider*, "the feature we're really promoting for Cidalcyn and eventually Puracyn will be safety. It's essentially an inert product, so we don't have to worry about combustibility, and there's essentially no health risk in using the product in environments where it can come in contact with skin – which is one of the main driving forces for the commercial marketplace. Many other products have a strong odor or cause skin irritation. Or they're harmful if ingested. Or the surface has to be rinsed after the product is used."

TOXICITY CLASSIFICATION

Currently, Cidalcyn is classified in EPA Toxicity Category 3, meaning "mildly" or "slightly" irritating to the skin and eyes. Keith Morel, Oculus Manager of Research and Development, says "we expect approval for Category 4 [meaning "non-" or "minimally" toxic] in December. EPA still hasn't reviewed our skin and eye toxicity testing, but this testing has concluded that Cidalcyn is 'rated as non-irritating.'"

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EFFICACIES

While benign to the skin and eyes, Cidalcyn has demonstrated the following efficacies, among others, in lab tests: 10-minute kill-times for *Staphylococcus aureus*, *Salmonella choleraesuis*, and Vancomycin-resistant *Enterococcus faecalis*; a 1-minute kill-time against *Escherichia coli* 0157/H7; and a 10-minute kill-time for HIV-1.

Morel said that, "While we only claim a 10-minute kill time for HIV, that's just because we wanted to ensure that, when we did our testing, we would pass and not hold up registration. But the HIV virus is a fairly easy one to kill, and most of the competing antimicrobials kill in a minute. Our strong belief is that we'd do likewise because we tested similar viruses, and other target organisms, that we kill in that timeframe, so while I can't give you definitive proof, there are good scientific reasons that we believe we would be competitive with HIV kill times for other products."

Morel added that, according to the results of Tuberculocidal Quantitative Suspension Protocol tests, Cidalcyn kills tuberculosis (*Mycobacterium*) in five minutes.

HOW IT WORKS

Some of the efficacy of Microcyn may be attributable to the presence of various oxygen and chlorine species generated by the electrolysis process, says Morel. The salt is added to the water, he points out, "for two reasons. Firstly, because it adds different chemical species to the product and, secondly, because it has electrical properties necessary for the correct function of the electrolytic cell."

Microcyn, Kelderman said, primarily acts as a destructive free ion against microbes. Electrons are "pulled" from the outer valences (or shells) of water molecules, which become "unstable molecules that want their electrons back," Kelderman said. "They'll steal from anything, and once these molecules contact the protein on a unicellular organism, they'll pull electrons out from all sides [of the microbial protein], which denatures the proteins on the cellular membranes, and the microbes basically fall apart due to osmolarity differences."

Despite its potential to destroy microbes, Microcyn is safe to skin and eyes because, says Morel, their "Eukaryotic cells are not as prone to changes in osmolarity as simple bacteria [or Prokaryotic cells], and secondly because there's enough organic material around to neutralize the electrolyzed water before there's any damage."

The basic technology to quickly kill unicellular organisms with electrolyzed water, Kelderman notes, was developed by a Japanese physicist who "was trying to eliminate bacteria growing in the cooling water pipes at a nuclear power plant." Oculus obtained a global license

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for the technology, and “we improved it to increase the stability of the electrolyzed water,” Kelderman adds.

SHELF LIFE

Oculus achieved the stability improvements, says Morel, by creating a dynamic equilibrium in the water. The equilibrium is maintained as ions “hop” from one unpaired valence to another – but the equilibrium doesn’t last forever. Currently, says Anna Christensen – Regulatory, Clinical and Quality Assurance Vice President for Oculus – “our shelf life claim for the United States is one year.”

However, “since we’re doing real-time testing for shelf life,” says Derrico, “and since it’s hard to do accelerated testing, we’re basing that claim on the one year of real-time testing we’ve done so far. But, we expect that [shelf life claim] to increase, so when we come to market with the final product, we’ll be updating our labels to show the increased shelf life. We expect the number to more than double.”

PRICING

When Cidalcyn comes to market, Derrico adds, “its pricing will be more than competitive with other products. But the driving force for Cidalcyn and, down the road, Puracyn, won’t necessarily be pricing as much as it will be efficacy and ease of use.”

OTHER REGISTRATIONS

Oculus has filed an application for Microcyn technology with FDA for additional uses, and the technology is also being commercialized as Vetericyn, which is a wound-spray for animals. Last year, Microcyn was granted a Conformance European Mark in Europe, while – also in 2003 – the Mexican Ministry of Health issued certifications for various uses of Microcyn.

Kelderman says “most of the feedback from Mexico has come from the medical community, which is to be expected because there hasn’t been anything around with which to sterilize wounds without toxicity [from the sterilizing agent].”

MEXICAN RESPONSE

Andres Gutierrez, director of the Cell Therapy Unit of Mexico’s National Institute of Rehabilitation, provided some feedback for *Insider*. Gutierrez, whose work requires him to produce viral vectors, stresses that, “I am not a microbiologist.” However, he adds, “I was asked to advise the Congress here in Mexico if this new antiseptic we have really works or not. What we have learned in laboratory tests is that, in the absence of organic material, Microcyn basically kills bacteria in 30 seconds. In the presence of organic materials, as in AOAC [testing] norms, then the times increase.

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“We have repeated these challenges in many different laboratories and the results have been the same,” Gutierrez continued. “We also have tested Microcyn in at least 600 patients with different doctors, and in all cases, the activity against infection, whether the infection is in muscle tissue or in skin, the activity has been outstanding. In places where you would prefer not to use a toxic antiseptic, super oxidized water would be a good choice. I think this is going to change completely the way we treat wounds. We have not seen something like this before.”

THE FUTURE

While the promise of Microcyn for medical use appears strong, Kelderman says that the hard-surface market will continue to figure prominently in the Oculus business plan. “We see great possibilities in the [commercial and consumer] market, and an important reason for our optimism is a beautiful characteristic of Microcyn – which is environmental safety. Consumers and commercial users will never have to worry about throwing something toxic into the sink.”

Oculus is now entertaining overtures to distribute or commercialize Cidalcyn. 

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