UNITED STATES
ENVIRONMENTAL PROTECTION AGENCY

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BEFORE THE ADMINISTRATOR

In the Matter of)
)
Lily Products of Michigan, Inc.,) Docket No. IF&R-V-128-P
)
Respondent)

Federal Insecticide, Fungicide and Rodenticide Act. Sale of pesticide for unregistered use constitutes a violation of Section 12(a)(1)(B), (7 U.S.C. §136j(a)(1)(B)).

Federal Insecticide, Fungicide and Rodenticide Act. The amount of the civil penalty may be mitigated where circumstances so warrant.

Appearances:

Mr. Harold J. Popma
President
Lily Products of Michigan, Inc.
2070 Calvin Ave., S. E.
Grand Rapids, MI 49507

Respondent

John Van Vranken, Esquire
Office of Regional Counsel
U. S. EPA, Region V
230 So. Dearborn St.
Chicago, IL 60604

Counsel for Complainant

ACCELERATED DECISION[1/]

This is a proceeding under the Federal Insecticide, Fungicide and Rodenticide Act, as amended, (FIFRA), Section 14(a)(1), 7 U.S.C. §136 l(a)(1) for assessment of a civil penalty for alleged violations of the Act.[2/]

Complaint was issued against Respondent Lily Products of Michigan, Inc. on March 27, 1984, charging Respondent with the sale of the registered pesticide Oxine for cold sterilization of inhalation therapy equipment, whereas such claim has not been accepted in connection with the registration of Oxine. And further, that Respondent's act of selling Oxine for this purpose constituted a violation of Section 12(a)(1)(B) of FIFRA, (7 U.S.C. §136 j(a)(1)(B)). A penalty of $5,000.00 was proposed and later corrected to $4,250.00.

Respondent answered wherein it admitted the sale of Oxine to Butterworth Hospital, Grand Rapids, Michigan to be used as a cold sterilizing agent on cardiopulmonary equipment.

And further:

> I do not disclaim the sale of OXINE (Liquid Stable ClO_2 to Butterworth Hospital. In fact when we were compelled to pick up their last shipment, they stated that OXINE was the safest and most effective product they had used. Butterworth Hospital decided to try OXINE after reading an article in the Michigan Airway Publication, by B. L. Goddard, A.R.I.T. (copy attached as Appendix A).

1/ An Accelerated Decision constitutes the Initial Decision in this Proceeding. 40 CFR 22.20(b).

2/ FIFRA, Section 14(a)(1) provides as follows:

> Any registrant, commercial applicator, wholesaler, dealer, retailer or other distributor who violates any provision of this Act may be assessed a civil penalty by the Administrator of not more than $5,000 for each offense.

The reason for supplying Mr. Goddard with the OXINE sample, was that the former manufacturer and supplier of OXINE, Control Metal Corporation, informed me as one of their Distributors, that OXINE could be used for all such applications. They later sent me a copy of the letter from Daniel J. Potter, M.D., Medical Director of Good Samaritan Hospital, copy attached as Appendix B. It was with this information I presumed OXINE could be used as such.

Respondent continues:

For the record, I was first introduced to OXINE by the former City Manager of Grand Rapids, Mr. Henry Nabors and Mr. Leon Noel, President of Lily Products Company, Manufacturer and Supplier of OXINE. (I asked their permission to use the name Lily Products of Michigan, Inc., to register in our State). They were interested in having a Distributor in Michigan. Mr. Nabors knowing that I was a Reputable Salesman, thought I could do well in promoting OXINE in Michigan. Since that introduction, the Patent and Manufacturing rights of OXZINE, has passed from Lily Products Company to Control Metals Corporation, to the present Manufacturer, Bio-Cide Chemical.

With the information provided by the Manufacturer, I proceeded to present all this information to the proper Authorities in Lansing Michigan, to register and get their approval to sell OXINE in Michigan. At the same time I was directed to various Doctors and Heads of different departments at Michigan State University, to acquaint them with OXINE. They in turn provided me with more positive results in the use of OXINE, which I sent to the Manufacturer.

Findings Of Fact

1. Respondent is a corporation organized under the laws of the State of Michigan with its principal place of business located in Grand Rapids, Michigan.

2. Respondent is a person as defined in Section 2(s) of FIFRA (7 U.S.C. §136(s)).

3. The product here in question, Oxine, is a pesticide registered with the U. S. EPA under Section 3 of FIFRA, (7 U.S.C. §136(a) and is assigned registration number 9804-1.

4. Respondent made a claim for using Oxine for cold sterilization of cardiopulmonary therapy equipment; whereas such claim has not been accepted in connection with the registration of Oxine.

5. On or about December 6, 1983, Respondent sold three cases of Oxine to Butterworth Hospital, Grand Rapids, Michigan.

6. On February 27, 1984, a sample of Oxine from said sale was collected at Butterworth Hospital by the Food and Drug Administration.

7. Respondent's gross business revenues for the year 1983 were between $700,000 and $1,000,000, resulting in an assignment of Category IV of the Guidelines For Assessing Civil Penalties.

Conclusion

Since there is no dispute as to the facts of the violation, the only remaining matter to be resolved is whether a civil penalty is warranted and, if so, the amount thereof. The amount of the proposed penalty, $4,250.00 is taken from the Guidelines matrix E17 A.I. "Directions Unacceptable -- Likely to Result in Mishandling or Misuse."

Complainant's view of the gravity of the violation is set forth in the prehearing exchange, as follows:

> Complainant has no evidence that the alleged violation caused any actual harm to people or to the environment. However, Complainant believes that there is the possibility of harm when a product such as this is sold for an unregistered use, especially when that use is disinfection of hospital equipment. U.S. EPA requires much more proof of the effect and absence of danger to approve such a use than it does for many other uses.
>
> Complainant believes that the violations are agrevated [sic] because the company has been in this business for many years and is familiar with U.S. EPA's registration process. Complainant does not believe the company has any justification for relying on "testimonials" to promote the sale of this product for unregistered use.

There is certainly no reason to dispute these statements. But by the same token, there is no support in the record to indicate any likelihood of mishandling or misuse, when in fact, the "testimonials" appear to be good faith evaluations of the product. Respondent should have known about the requirements for registration of a use for the product. The penalty proposed is hereby reduced to $2,380.00 for the reason stated. It is further reduced to $1,500.00 based upon the mitigating factors of cooperation and good faith efforts to correct the situation resulting in monetary loss.

O R D E R [3/]

Pursuant to the Federal Insecticide, Fungicide and Rodenticide Act, Section 14(a)(1), 7 U.S.C. 136 l(a)(1), a civil penalty of $1,500.00 is assessed against Lily Products of Michigan, Inc., for violation of the Act found herein.

3/ Unless an appeal is taken pursuant to the rules of practice, 40 CFR 22.30, or the Administrator elects to review this decision on his own motion, the Accelerated Decision shall become the final order of the Administrator. See 40 CFR 22.20(b).

Payment of the full amount of the civil penalty assessed shall be made within sixty (60) days of the service of the Final Order upon Respondent by forwarding to the Regional Hearing Clerk, U. S. EPA, Region 5, P. O. Box 70753, Chicago, IL 60673, a cashier's check or certified check payable to the Treasurer, United States of America.

Edward B. Finch
Chief Administrative Law Judge

Dated: August 14, 1985
Washington, D. C.

EXHIBIT #1a
Butterworth Hospital 2-15-84 JVD

EDITOR'S NOTE:

Mr. Barry S. Anderson was nominated by the MSIT for the AAIT Board of Directors. It is very unusual for a chapter to nominnte someone outside of their own chapter, and I feel that we, as members of the MSIT, can feel justly proud of this move. Mr. Anderson's response follows:

January 20, 1972

Mr. George West, Member
Michigan Society for Inhalation Therapy
c/o Inhalation Therapy Department
Harper Hospital
3825 Brush Street
Detroit, Michigan 48201

Dear George:

I cannot find the words to adequately express my surprise, gratitude and humility for being an individual so honored by such an august body as the Michigan Society.

I have long admired your organization from an organizational point of view as well as from a professional view. There is no group to equal yours, in the American Association for Inhalation Therapy.

I pose a problem, the real reason for my late reply, to you. I have been nominated by my own chapter also. I could not refuse your unprecedented action by refusing to accept your nomination. Therefore, I will let you make the decision for me, should my nnme be submitted by two chapters or should you select another person instead of me?

I fully trust your julgment in this confusing situation.

Again, may I try to express my gratitude for the symbol of your trust in my ability to ask me to consider the nominntion for the AAIT Board of Directors, through the nomination process of the Michigan Society.

My nomination form is in your hands, do with it as you require.

With sincerest admiration,
I remain,

Barry S. Anderson
Ventilation Associates, Inc.
2001 Kirby Drive
Houston, Texas 77019

A "NEW" COLD STERILIZING AGENT

By

BENJAMIN L. GODDARD, A.R.I.T.

The following is a report on a product we are using for cold sterilizing of inhalntion therapy equipment that is not really new, – but yet relatively unheard of in the medical field. The product is Oxine, marketed by Lily products of Michigan,* 1911 Martindale S.W., Grand Rapids, Michigan and distributed by their representative Harold J. Popma.

Oxine is chlorine dioxide (clo_2) in a stabilized liquid form. Chlorine dioxide, as a gas, has been used for over 60 years in water purification and for bleaching cloth and wheat flour. In 1955 a patent was issued on the process of stabilizing the gas in a solution form and commercial production began in 1963. Since then it has been enjoying a continually increasing market as a commercial bactericide and disinfectant.

We were introduced to this product, by Mr. Popma, in the Spring of 1970 and, to be honest, were very skeptical. We had been using another, very well known, cold sterilizing product and felt secure with it even though we had encountered some problems such as minor skin irritations and the necessity of rinsing off the residual with sterile distilled water. However, Mr. Popma is a good evangelist, – thoroughly sold on his product, and eventually persunded us to give it a try.

Now, we were on unknown territory to start because the product had not been utilized for sterilizing hospital equipment before and there was no documentation of how to use it, – let alone how effective it would be.

So, one day, Harold brought a sample of Oxine, a titration Kit to analyze solution strengths, and various articles of information to Mason General Hospital. Together he, my Associate Jerry Shoup, and I worked out a preliminary bath solution that we tested for effectiveness. We ran a routine "batch" of respirator accessories and, after drying and packaging, took a sample to the Laboratory for culturing. The sample came back, after 48 hours, completely negative and we were delighted.

Needless to say, Harold was pleased that his enthusiasm for his product had been vindicated and we were happy because we actually liked

* A Subsidiary of Control Metal Corporation of Glendale, Arizona.

ATTACHMENT A

of the stuff better than what we had ...sing. (The bath looks almost like clear ...with little odor and, more important, no necessity of rinsing soaked items prior to drying.

We proceeded, then, to run a controlled study comparing Oxine to the old product and using all sorts of materials and equipment items. We set up two separate baths and identified two separate sets of respirator accessories. For the next week we proceeded to use both sets in patient contact, clean the items and place them in their respective bath solutions for disinfection. At the end of one week we had samples of both sets tested. You guessed it, the old standby came back negative but the Oxine soaked items showed some organisms. True, they weren't numerous or too serious but for us the world had dropped in, – any bacteria was more than we wanted or would accept.

We immediately stopped using the Oxine and tried to find out why it had failed. We knew it should have been strong enough to destroy all bacteria with the solution we started with but we increased it, varied the immersion times, tried additives, did everything; – and finally did the right thing, – read the literature that Harold had left with us.

We had known that Oxine was influenced by the pH of the solution. What we found by reading was that the lower the pH, the more rapid the destruction time. This was the key. We tested the pH of our solution and found it to be above 7.0. Our Laboratory people gave us some acid to acidify the solution and, immediately, we began getting negative cultures again. Through a process of experimentation (during which we ruined some metal products through too much acid) we found that the ideal pH was around 6.0.

Ironically enough, we later found out something that none of us was aware of; that distilled water, as commonly produced in hospital distilling operations, is definitely on the acid side with a pH range (from 5 hospitals tested) of 5.5 to 6.5. We found this out after the still was reconditioned at Mason and we began getting some deterioration of metal items again. As a result, we quit using the acid completely and have never needed it since. (We later surmised that our initial test bath had been made with properly distilled water and that by the time the controlled study was set up we were on water that was coming from the defective still.)

Today, and for the past, almost, two years, we have used Oxine exclusively for cold sterilization and find the following formula effective for us: two (2) ounces of Oxine per gallon of distilled water. We use the solution until it begins to look contaminated and then discard it, - usually a couple of times each week. We can afford to be lavish in its use as, based on a two gallon bath, in the above proportions, one gallon of Oxine concentrate will last 32 weeks! (which isn't bad at less than $8.00 per gallon.)

We have found the titration kit (used to measure the parts per million of the Oxine solution no longer necessary as by starting out with this concentration (which titrates out to about 320 ppm), and by discarding it this often we never get close to depleting its potency. We do, however, periodically check the pH to make sure that our still is working properly.

In practice, the Oxine solution is used just about like any other cold sterilizing product. All items are disassembled and washed, after use, and immersed in the bath solution for a minimum of 15-20 minutes. (Longer immersion doesn't hurt a thing, in fact, we periodically allow items to soak overnight to build up the bacteriostatic potential.) After the items are soaked they are removed from the bath and placed on a clean towel, under a drying light,

until dry. Then they are assembled and packaged in plastic bags.

The product is non volatile with no discoloration of items, no offensive odor or taste and, very important, no toxic residual to rinse off. There is no apparent deterioration to metal, plastic or rubber. (In fact we appear to be getting longer rubber life than we use to.)

As to toxicity, Lily has some data on the subject dealing with elaborate blood studies that is very impressive and porports the product to be very safe. The Food and Drug Administration has tested chlorine dioxide treatment of wheat flour and other related products for human ingestion and report, " – No symptoms of any toxicity have been detected in the several other species, including man, that have been studied." And, in our use, we have noted no adverse reaction, of any kind, to the product.

Just how effective is Oxine? Well, I'm no specialist in bacteria, believe me, – I have trouble pronouncing most of the words, let alone understanding them, – so I have to rely on expert opinion. Therefore, we routinely analyze our equipment items with cultures being run, at least, monthly. Furthermore, we have had five hospitals and the state health lab run these independent cultures and, we are pleased to report that, with only a couple of exceptions (where poor technique was later found to be at fault) all cultures have been consistantly negative.

As to the types of bacteria affected, again I'm no expert, but the product has been tested be several independent authorities with documented results which report as follows: January, 1955. Dr. W.S. Mueller, Associate Professor, University of Massachusetts, found that at a pH of 5.95, and a five minute contact time, chlorine dioxide had a near 100% kill of the following bacteria; p. aeruginosa, e. coli, s. aureus and b. mitens. April, 1960 Raymond Gomski, Bacteriologist, Woonsocket Hospital, Woonsocket, R.I., reported on a test of assorted hospital linens, where 500 ppm clo_2 was utilized in the laundry process, that the following bacteria had been initially destroyed and subsequent new growth inhibited; b. subtilus, streptoccoccus, staphylycoccus, hemolytic staph and molds and yeasts. January 1969. Bolin Laboratories of Glendale, Arizona, tested Oxine specifically against escherichia coli and staphyloccus aureus and found it to be 100% effective, at 200ppm and a pH of 6.0, on both bacteria types, within two minutes!

And, finally, Lab people we have discussed it with are very impressed with its effectiveness and feel that it does the job against anything we need be concerned about.

We are finding other uses for the product as well. We now, routinely, add Oxine to the distilled water used in bedside cold steamers. We find it keeps the bacteria growth under control in the unit as well as helping to deodorize the room air. We have experimented with low concentrations in oxygen humidifiers and find these are maintained absolutely bacteria free with no apparent toxic results. (Units have been tested for as long as six weeks without changing or cleaning, – just replenishing the water as necessary, and have been found to culture out completely negative.) We have also added Oxine to the water of ultrasonic nebulizers and respirator humidification systems and have found no bacteria buildup or harmful effects. We wish to caution that these uses are experimental and that we do not recommend them, – only suggest possibilities. I am confident that with further testing by users throughout the country results will be validated and many, many, more uses of the product found.

Now, the obvious question at this point is, – if this stuff is so great why haven't we heard about it before? The answer I have come to is, – simply, economics. When you stop to think that the average hospital's useage of this product for an entire year can be measured in a few gallons, and that their profit on a single gallon must be quite small, it is easy to see that we're not talking about a large volume, high profit, market. The market for this product has been users that order by the 50 gallon drum, – and those in fairly large quantities.

For instance, it has large application in industry in such areas as potable water treatment (to remove tastes and odors from water caused by phenols, sulphides and algae), to treat chemicals such as oil or fuel, coolants etc. (to control disagreeable odors and bacterial growth), in manufacturing of fibers and plastics (to prevent fungus and eliminate many odor problems), in waste disposal operations (to control spoilage over retention period) and so on. The list is almost limitless.

It has been used for years in dairying where it is extremely important that the large quantity of milk processing equipment be constantly maintained in an aseptic state. It is used in bars and restaurants for sanitizing. It is used in commercial laundries where it has been found that treatment with Oxine will give linens a bacteria free shelf life of well over 90 days. It is used in shipping where treatment of grains

other perishables, prior to loading in the hulls, has reduced transit spoilage by 20% or more. I understand that produce markets are now beginning to spray such items as head lettuce etc. and have reduced spoilage considerably. And so on, the list giving a clear indication that the volume market for Oxine has been, definitely, a non medical one.

And, as for as I'm concerned, this is a benefit to us. We are able to take advantage of a product that is not solely dependent on the medical field for support, therefore, one that can be, and is, substantially cheaper. The fact that it is also better than many of the products for cold sterilization, now available, is a bonus

In summary, we feel confident that Oxine is doing the job for us; – and highly recommend it to the therapy field. (Try it! – You'll like it!)

CHANGES IN THE AIRWAY

1. Mr. Bill Lowery has left the staff of the Airway and his responsibilities as Associate Editor have been placed in the very capable hands of Miss Carol Vick, B.S., a graduate of the Washtenaw Community College program in Inhalation Therapy and also a graduate of the University of Michigan.

2. Denise Dawson, a student at Washtenaw Community College, has been added to the staff and is responsible for handling Abstracts submitted to the Journal.

3. Craig Dunham, B.S., a graduate of the Inhalation Therapy program at Washtenaw Community College and also a graduate of Eastern Michigan University has taken on the responsibilities as Business Manager of the Airway.

Mr. James W. Rawlinson
Editor, Michigan Airway
P.O. Box 808
Royal Oak, Michigan 48067

Mr. Rawlinson,

I just finished reading the December issue of the Airway and feel that the membership was misled by some comments made in the Analyzer column.

Mr. Conquest stated that a splinter group (RTDHA) has been organized. The group has organized, but this group of people is working with other organizations such as the MSIT, and Greater Detroit Area Hospital Council in order to promote Inhalation Therapy and to give extra knowledge and abilities in management to supervisory personnel.

I am a member of this group and I assure you that the members and officers of this group do more than shoot off their mouths. If Mr. Conquest would have attended some of the sessions held by this group, I'm sure he would have been able to see this for himself. However, Mr. Conquest has exhibited his usual pessimistic attitude once again and undoubtedly cast unwarranted suspicions on this group as well as the MSIT.

Having served in several capacities as a board member, state office, and representative of the house of representatives in the past, I assure you that much is left to do in the MSIT but great strides have been made in the past five years.

I also assure you that most of the progress is not because of Mr. Conquest as he usually was opposed to the majority of the decisions made in the past.

I'm sure that the MSIT will continue to progress in the future, even without Mr. Conquest.

Karl O. Baer, C.I.T.T.

CERTIFICATE OF SERVICE

I hereby certify that the original of this Accelerated Decision was hand-delivered to the Hearing Clerk, U. S. EPA, Headquarters, and three copies were mailed by certified mail, return receipt requested, to the Regional Hearing Clerk, U. S. EPA, Region V, for distribution pursuant to 40 CFR 22.27(a).

Leanne B. Boisvert
Legal Staff Assistant

Dated: August 14, 1985

Buttwood Hospital 2-1564 JVD

GOOD SAMARITAN HOSPITAL

February 18, 1972

Mr. Roy Ellis, Sr.
Central Metals Corporation
Box 67
Glendale, Arizona 85301

Dear Mr. Ellis:

We have been using Oxine in sterilizing our artificial kidney machines and dialyzers for over two years.

Periodically we run cultures to determine the effectiveness of Oxine. All cultures have been negative.

Recently the U. S. Public Health Service conducted bacterial studies in our center. They were satisfied with the effectiveness of Oxine as a sterilizing agent. In fact they suggested that we begin to use Oxine to sterilize additional items on which we had not previously used the product.

We are very pleased with this product and, for our purposes, find it superior to formaldehyde, which we had previously used.

Thank you for introducing us to Oxine.

Sincerely,

Daniel J. Potter, M. D.
Medical Director
Kidney Center

DJP:m

ATTACHMENT B