FOR IMMEDIATE RELEASE

A local New Jersey newspaper recently reported an undocumented claim of health-related issues allegedly arising from a Zimek sanitizing and disinfectant dispersal system used by a local ambulance service. This article was written at the apparent behest of a union official currently engaged in an acrimonious contract negotiation with the ambulance service in question.

A few members of the first-responder community have asked about this.

Zimek’s sanitizing/ disinfectant process is the most advanced and effective technology available to control the expansion of community-acquired or healthcare-associated infections. It is used effectively in hundreds of government, public and private sector applications nationwide.

Zimek is dedicated to provide a product that meets or exceeds industry standards for both a safe design, and a problem free operation. Our systems have been tested by multiple agencies that allow us to verify our claims.

The local ambulance service in question recently undertook a voluntary testing procedure by an OSHA recommended, independent and professionally qualified industrial hygiene firm, which yielded a report of no violation or exposure. The preliminary findings of a second OSHA test have yielded the same results. The results showed no detectable health hazards with the Zimek technology.

The ability of Zimek to investigate the allegations reported in the newspaper article has been stifled by the insistence of the one individual alleging those issues to remain anonymous, despite the claimed seriousness of the alleged health effects.

The health and hygiene of our customers and our customers’ community remains our top priority.

###
OVERNIGHT DELIVERY & ELECTRONIC MAIL

Vincent Robbins, President & CEO
Monmouth-Ocean Hospital Service Corporation ("MONOC")
4806 Megill Road
Wall Township
Neptune, NJ 07753

Re: Stop Sale, Use or Removal Order, MONOC
Docket No. FIFRA-02-2011-5101

Dear Mr. Robbins:

Enclosed is a Stop Sale, Use or Removal Order ("Order") from the United States Environmental Protection Agency ("EPA") concerning antimicrobial pesticides sold for the express purpose of application to the interior of ambulances via microparticle disinfecting systems manufactured by Zimek Technologies, LLC ("Zimek"). The Order prohibits the use of any antimicrobial pesticide acquired from Zimek or its representatives in MONOC's ambulances via any system that delivers such pesticides to the interior of the vehicle as microparticles or submicroparticles in a mist or fog. The Order also prohibits the sale or removal of any pesticide acquired from Zimek or its representative(s) as a product intended for use as a disinfectant of the interior of ambulances via a microparticle disinfecting system.

Section 13(a) of FIFRA, 7 U.S.C. § 136k(a), authorizes the Administrator of EPA to issue an order prohibiting the sale, use or removal of any pesticide by any person who owns, controls or has custody of such pesticide whenever there is reason to believe that the pesticide has been distributed or sold in violation of FIFRA. EPA has reason to believe that in distributing the antimicrobial pesticides Sporicidin (EPA Reg. No. 8383-3) and Zimek QD (EPA Reg. No. 70263-6-81632) to MONOC, Zimek and/or its representative(s) made claims for a use not accepted in connection with the registration of either product. Neither Sporicidin (EPA Reg. No. 8383-3) nor Zimek QD (EPA Reg. No. 70263-6-81632) bears directions for fogging the interior of ambulances.

EPA further has reason to believe that MONOC has applied at least these two antimicrobial pesticides to the interior of its ambulances in a manner inconsistent with their labeling and likely to cause harm to humans. Section 12(a)(2)(G) of FIFRA, 7 U.S.C. § 136j(a)(2)(G), provides it shall be unlawful for any person to use any registered pesticide in a manner inconsistent with its labeling. Please be advised that any such application of pesticides in this manner is a violation of FIFRA.
If you have any questions about this matter or wish to request an informal conference to discuss the alleged violation(s), you may contact Dr. Adrian Enache, Manager, Pesticides Program, Pesticides & Toxic Substances Branch, at 732-321-6769 or Enache.Adrian@epa.gov. For any legal matters concerning this Order, please contact Naomi Shapiro, Assistant Regional Counsel, at 212-637-3221 or Shapiro.Naomi@epa.gov.

Sincerely yours,

Dore F. LaPosta
Director, Division of Enforcement and Compliance Assistance

Enclosure

cc: Marcedius Jameson, Administrator
    Pesticide Control & Coastal and Land Use Compliance & Enforcement Program
    New Jersey Department of Environmental Protection
    Mail Code 401-04F
    PO Box 420
    Trenton, NJ 08625-0420

Robert Kulick, Regional Administrator
New York Regional Office
U.S. Dept. of Labor/OSHA
201 Varick St. Rm.670
New York, NY 10014
UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
REGION 2

In The Matter Of:

Monmouth-Ocean Hospital Service Corporation
4806 Megill Road
Wall Township
Neptune, NJ 07753,

Respondent.

STOP SALE, USE, OR REMOVAL ORDER,
Docket No. FIFRA 02-2011-5101

1. AUTHORITY AND BACKGROUND

1. Section 13(a) of the Federal Insecticide, Fungicide, and Rodenticide Act, as amended ("FIFRA"), 7 U.S.C. § 136k(a), authorizes the Administrator of the U.S. Environmental Protection Agency ("EPA") to issue an order prohibiting the sale, use, or removal of any pesticide or device by any person who owns, controls, or has custody of such pesticide or device whenever there is reason to believe that, inter alia, the pesticide or device has been or is intended to be distributed or sold in violation of any provision of FIFRA.

2. The Director of the Division of Enforcement and Compliance Assistance ("DECA"), EPA Region 2, has been duly delegated authority to issue such Stop Sale, Use, or Removal Orders.

3. For the purposes of this Stop Sale, Use, or Removal Order ("SSURO" or "Order"), the term "MONOC" herein refers to Monmouth-Ocean Hospital Service Corporation, its agents, officers and employees, all of whom are persons within the meaning of the definition of "person" in Section 2(s) of FIFRA, 7 U.S.C. § 136(s).

4. MONOC's principal place of business is located at 4806 Megill Road, Wall Township, Neptune, NJ 07753.

5. MONOC is a non-profit company comprised of fifteen acute care hospitals throughout New Jersey.
6. MONOC operates a fleet of over 100 ambulances.

7. Section 2(u) of FIFRA, 7 U.S.C. § 136(u), defines the term “pesticide” as, among other things, “(1) any substance or mixture of substances intended for preventing, destroying, repelling or mitigating any pest.”

8. Section 2(mm)(1) of FIFRA, 7 U.S.C. § 136(mm)(1), defines the term “antimicrobial pesticide” as, among other things, “a pesticide that (A) is intended to (i) disinfect, sanitize, reduce, or mitigate growth or development of microbiological organisms.”

9. On or about April 29, 2009, MONOC purchased a microparticle disinfecting system manufactured by Zimek Technologies, LLC for the express purpose of applying a “sub-micron fog of hospital-grade disinfectant” to surface areas inside ambulances, thereby “killing dangerous bacteria, viruses ... toxic mold ... [and] community acquired diseases.”

10. Upon information and belief, in choosing to purchase the microparticle disinfecting system manufactured by Zimek Technologies, LLC, MONOC relied on representations made on Zimek’s website, in Zimek publications, and by a Zimek representative(s) that broad-based hospital disinfectants may be used with the system for applications to the interiors of ambulances.

11. Broad-based hospital disinfectants specifically identified by Zimek and its representative(s) for use in the microparticle disinfecting system manufactured by Zimek Technologies, LLC include the antimicrobial pesticides Sporicidin (EPA Reg. No. 8383-3), Zimek QD (EPA Reg. No. 70263-6-81632), Zimek D & I Plus (EPA Reg. No. 70263-3-81632), Vital Oxide (EPA Reg. No. 82972-1), and Steriplex Ultra (EPA Reg. No. 84545-8).

12. Upon information and belief, the microparticle disinfecting system manufactured by Zimek Technologies, LLC was packaged with antimicrobial pesticides to be used in the system including Sporicidin (EPA Reg. No. 8383-3), Zimek QD (EPA Reg. No. 70263-6-81632), Zimek D & I Plus (EPA Reg. No. 70263-3-81632), Vital Oxide (EPA Reg. No. 82972-1), or Steriplex Ultra (EPA Reg. No. 84545-8).

13. Pursuant to Section 3 of FIFRA, 7 U.S.C. § 136a, all pesticides intended for distribution or sale must be registered with EPA.

14. As part of the registration process, referenced in paragraph 13 above, pesticide registrants must provide inter alia proposed labeling, including application instructions, and data supporting the efficacy of the proposed product if applied according to the label instructions.
15. The EPA-registered antimicrobial pesticides Sporicidin (EPA Reg. No. 8383-3), Zimek QD (EPA Reg. No. 70263-6-81632), Zimek D & I Plus (EPA Reg. No. 70263-3-81632), Vital Oxide (EPA Reg. No. 82972-1), and Steriplex Ultra (EPA Reg. No. 84545-8) have never been accepted for registration bearing directions for application as a microparticle, nanoparticle, or a "sub-micron" fog to the interior of ambulances.

16. The sale or distribution of any of the antimicrobial pesticides identified in paragraph 11. above, with claims for a use not accepted in connection with its registration under Section 3 of FIFRA is a violation of Section 12(a)(1)(B) of FIFRA, 7 U.S.C. § 136j(a)(1)(B).

17. Upon information and belief, antimicrobial pesticides applied to MONOC ambulances include Sporicidin (EPA Reg. No. 8383-3), a Phenol-based broad-spectrum disinfectant.

18. Upon information and belief, MONOC applied Sporicidin to the interior of its ambulances via microparticle disinfecting system on at least September 7, 2010.

19. The EPA-approved label for Sporicidin does not contain directions for use for Sporicidin via a microparticle disinfecting system to the interior of ambulances.

20. Upon information and belief, individuals working in MONOC ambulances in which Sporicidin was applied using the microparticle disinfecting system referenced in paragraph 9, above, have been hospitalized for Phenol poisoning.

21. Upon information and belief, individuals working in MONOC ambulances in which Sporicidin was applied using the microparticle disinfecting system referenced in paragraph 9, above, continue to suffer ill-effects associated with exposure to Phenol.

22. Upon information and belief, antimicrobial pesticides applied to MONOC ambulances include Zimek QD (EPA Reg. No. 70263-6-81632), a broad-spectrum disinfectant.

23. Upon information and belief, MONOC applied Zimek QD to the interior of its ambulances via microparticle disinfecting system on multiple occasions.

24. Zimek QD (EPA Reg. No. 70263-6-81632) is a supplemental registration or distributor product of Microban QGC (EPA Reg. No. 70385-6) (hereinafter "the basic product").

25. The label submitted by the registrant of the basic product is the only EPA-approved label for the basic product and any distributor product.

26. Pursuant to 40 C.F.R. § 152.132(d)(5), the supplemental registrant of a distributor product may omit specific claims from the EPA-approved label of the basic product.
27. Both the basic product and Zimek QD are antimicrobial pesticides as defined by FIFRA.

28. The registrant of the basic product has never had a label for the basic product accepted for registration bearing directions for application as a microparticle, nanoparticle, or a “sub-micron” fog to the interior of ambulances.

29. The label of Zimek QD omits ambulances as a site of application for the product and does not contain directions for use for Zimek QD via a microparticle disinfecting system to the interior of ambulances.

30. Upon information and belief, individuals working in MONOC ambulances in which Zimek QD was applied using the microparticle disinfecting system referenced in paragraph 9, above, have been treated for ailments associated with pesticide poisoning.

31. Upon information and belief, individuals working in MONOC ambulances in which Zimek QD was applied using the microparticle disinfecting system referenced in paragraph 9, above, continue to suffer ill-effects associated with pesticide poisoning.

II. ORDER

32. EPA hereby ORDERS MONOC to stop the use (application) of any antimicrobial pesticide acquired from Zimek or its representatives in its ambulances via any system that delivers such pesticides to the interior of a vehicle as microparticles or submicronparticles in a mist or fog.

33. EPA hereby further ORDERS MONOC to stop the use (application) of Zimek QD in its ambulances in any manner.

34. EPA hereby further ORDERS MONOC not to sell or otherwise remove any antimicrobial pesticide acquired from Zimek or its representatives as a product intended for use as a disinfectant of the interiors of ambulances via a microparticle disinfecting system until otherwise instructed by EPA.

35. This Order shall be EFFECTIVE IMMEDIATELY upon receipt by MONOC.

36. MONOC shall, immediately upon receipt of this Order, comply with FIFRA and its implementing regulations, with respect to all pesticides it applies.

37. This Order shall remain in effect until after EPA vacates the Order in writing.

38. Section 12(a)(2)(I) of FIFRA, 7 U.S.C. § 136j(a)(2)(I), states that it shall be unlawful for any person to violate any order issued under Section 13 of FIFRA.
39. Violations of the terms or provisions of this Order may be subject to civil and/or criminal penalties prescribed in Section 14 of FIFRA, 7 U.S.C. § 136j.

40. Within ten (10) days of the effective date of this Order, MONOC shall provide written documentation to EPA that MONOC, or any person or organization on its behalf, has stopped the uses as ordered by paragraphs 32 and 33, above, and maintained the pesticides on hand as ordered by paragraph 34, above.

41. In the event that MONOC needs to clean any of the treated ambulances in any way, within ten (10) days of making such determination, MONOC shall provide EPA with a written description of the efforts made, including, but not limited to, the products used and the disposal of any wastes generated by such efforts.

42. In the event that MONOC elects to use any of the pesticides acquired from Zimek or its representatives, MONOC shall certify that such use will be conducted in strict compliance with the directions for use on the product labeling.

43. Any information provided pursuant to paragraphs 40-42, above, shall contain the following certification:

"I certify that the information contained in or accompanying this statement is true, accurate and complete. As to the identified portion(s) of this statement the truth or accuracy of which I cannot personally verify, as the supervising company official, I certify that person(s) under my supervision has/have verified that this information is true, accurate and complete."

44. The issuance of this Order shall not constitute a waiver by EPA of its remedies, either judicial or administrative, under FIFRA or any other federal environmental law, to address this matter or any other matters or unlawful acts not specified in this Order.

III. BASIS FOR ORDER

45. EPA’s basis for this Order is information provided to the Agency by the New Jersey Department of Environmental Protection (“NJDEP”), the Occupational Safety and Health Administration (“OSHA”), and individuals affected by applications described herein.
IV. OTHER MATTERS

46. Please send any written documentation required by this Order and any other additional information or comments regarding this Stop Sale, Use, or Removal Order, to:

Dr. Adrian J. Enache, Ph.D., M.P.H.
Manager, Pesticides Team
US EPA Region 2, Pesticides and Toxic Substances Branch
2890 Woodbridge Avenue – MS-500
Edison, NJ 08837
(732)-321-6769 (phone)
(732)-321-6771 (fax)
Enache.Adrian@epa.gov

47. For assistance regarding legal matters surrounding this SSURO, your attorney is encouraged to contact:

Naomi Shapiro, Esq.
Assistant Regional Counsel
U.S. EPA, Region 2
Office of Regional Counsel
290 Broadway, 16th Floor
New York, NY 10007-1866
212-637-3221 (phone)
212-637-3199 (fax)

Dore E. LaPosta
Director, Division of Enforcement and Compliance Assistance
U.S. EPA, Region 2
290 Broadway, 21st Floor
New York, NY 10007-1866
CERTIFICATE OF SERVICE

This is to certify that on this day I caused to be mailed, via overnight service, the original of the Stop, Sale, Use and Removal Order bearing Docket Number FIFRA-02-2011-5101, to Vincent Robbins, President and CEO, Monmouth-Ocean Hospital Service Corporation, 4806 Megill Road, Wall Township, Neptune, NJ 07753.

Dated: ________________, 2011
EPA orders ambulance company to stop using fogger

By Matt Fair/The Times

Acknowledging that workers have become ill after exposure to disinfectant chemicals, the U.S. Environmental Protection Agency (EPA) this week ordered a New Jersey ambulance company to cease using fogging machines to sanitize its vehicles.

The Monmouth-Ocean Hospital Service Corporation (MONOC), which provides transportation services for Princeton Healthcare System in Mercer County, was ordered to stop using its Zimek Dri-Mist Micro-Particle Generator after more than 100 paramedics allegedly showed signs of exposure to toxic disinfectant chemicals.

"We have a reason to believe that people became sick as a result of MONOC’s actions," John Martin, an EPA spokesman, said in an interview yesterday.

The patented machine, manufactured by Zimek Technologies LLC, a Tampa, Fla.-based company, converts liquid disinfectant into dry atomized particles that cling to exposed surfaces.

The machine, which MONOC purchased from Zimek and first started using in May 2009, blows the fog of particles into ambulances to disinfect areas that normal cleansers wouldn’t be able to reach.

MONOC had been using a Zimek disinfectant called Zimek QD in the machines.
A month after the machine went into use, MONOC paramedics began complaining to union representatives with the Professional Emergency Medical Services Association of New Jersey (PEMSA) that they were becoming ill.

"In June (2009), we started getting complaints from people about odors in the ambulances and people were developing different symptoms: migraines, nausea, asthma, eye irritation, skin irritation. It was a long list of symptoms,” said Debra Ehling, the union’s president.

The EPA’s Stop Sale, Use or Removal Order now backs up those claims.

"Upon information and belief, individuals working in MONOC ambulances in which Zimek QD was applied using the micro-particle disinfecting system ... have been treated for ailments association with pesticide poisoning," the order reads, adding that workers “continue to suffer ill-effects associated with pesticide poisoning.”

For their part, MONOC officials said they stopped using the Zimek machine in June 2010 when PEMSA first filed complaints with the New Jersey Department of Environmental Protection (DEP). After a brief investigation, during which DEP issued a Notice of Violation to MONOC for using Zimek QD in a manner inconsistent with its labeling, the case was passed off to the EPA and the Occupational Safety and Health Administration (OSHA).
Under the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA), all pesticides are approved with strict labeling guidelines dictating how and under what circumstances they can be used.

Officials with MONOC said the company got authorization from Zimek to use the disinfectant liquid Sporicidin in the machines in lieu of Zimek QD.

Sporicidin’s label authorizes it for fogging in a “clean room,” a sealed environment where air quality is strictly controlled and monitored. Clean rooms generally aren’t entered without ventilators and biohazard suits.

However, the EPA order specifically prohibits Sporicidin in the machines as well as Zimek QD.

“We have jurisdiction over all pesticides. The labeling, when these pesticides are registered, needs to include all authorized uses,” Martin, the EPA spokesman added. “If a pesticide doesn’t say on its labeling that it’s authorized to be used in a fogging system then it’s not authorized to be used in a fogging system.”

MONOC officials said Sporicidin was used in only one ambulance as a test in September, but the EPA’s order this week said that paramedics have been hospitalized and continue to suffer effects of poisoning from its active ingredient.

Officials with MONOC said yesterday they hadn’t decided whether or not they would challenge the order in court.

Meanwhile, Martin said that, as far as the EPA is concerned, its investigation is closed.
MONOC maintains that it took all complaints from its workers seriously and that it conducted a number of tests that showed that levels of the active ingredients found inside the ambulances after fogging were well below legally permissible exposure limits.

“When the first complaint arose from the staff we took it seriously and we stopped using the machine and we started doing our investigations,” Peter Dworsky, director of support services for MONOC, said yesterday.

“Our investigation did not reveal anything,” he said. "OSHA has not given us reason to believe harm has occurred. EPA has not given any other documentation other than coming in with this last cease and desist order."

Dworsky said only about 16 paramedics have filed worker’s compensation claims with the company, far below the more than 100 the union claims have been sickened.

“I still think it’s baseless,” he said. “It’s been an ongoing investigation for the better part of six months and there hasn’t been any conclusion either way.”

And while Dworsky claimed that the machine didn’t change the chemical properties of the disinfectants used in the ambulances, EPA officials said that it was the fact that they were broken down into much smaller particles that made them dangerous.

“These disinfectants allow them to be sprayed or applied in other manners, but not like this,” Martin said. "It breaks them down into micro-particals which makes them dangerous.”

http://blog.nj.com/centraljersey_impact/print.html?entry=/2011/01/epa_orders_ambulance_company_t...
According to Eileen Senn, an industrial hygiene consultant with the nonprofit New Jersey Work Environment Council, the smaller particle size makes it easier for them to be absorbed into the body.

"Characterizations that the Zimek equipment renders disinfectants into nano-particles are completely baseless and contradict basic laws of matter," said Noah Lichtman, a spokesman for Zimek, in a statement issued late last night. "All liquids used in Zimek equipment remain a liquid when they exit the equipment."

While the order applies strictly to MONOC, prohibiting it from using the machine, Martin said it does not apply to Zimek, the manufacturer, who may continue to market and sell the machines to schools, hospitals, and ambulance companies as it sees fit.

"Zimek has not been contacted by EPA or been served any notification from them," Lichtman said. "Zimek has an impeccable safety record. Hundreds of government, public and private sector facilities worldwide have used Zimek’s disinfectant application process thousands of times without a single documented health incident."

"I’m pleased by EPA’s enforcement action," said Eileen Senn, an industrial hygiene consultant with the nonprofit New Jersey Work Environmental Council. "I don’t know that it’s going to completely solve the problem unless EPA goes after Zimek nationally, because this is not the only place that this is happening."

Officials with the EPA would not confirm whether or not they were broadly investigating Zimek’s operations.

"Zimek is making guinea pigs of many people, not just MONOC employees," Senn added. "(This technology) is really intended for pig and chicken farms or for something like an anthrax attack. This is not your friendly cleaning method that’s very benign and nothing to get worried about. This is a deadly technology using deadly chemicals. It does not belong in normal workplaces under normal circumstances."

Ehling, president of the paramedics’ union, said that national leadership of the International Association of Firefighters, of which PEMSA is a member, had been notified of EPA’s conclusions and would be sending out word to local chapters across the country.

When it came to getting health-care needs met for workers affected by the poisoning, Ehling said PEMSA was talking to representatives from the National Institute for Occupational Safety and Health and was also in the process of collecting medical records from employees.

One paramedic currently employed by MONOC, who declined to be identified for fear of retaliation by the company, said he was hospitalized for respiratory failure after exposure to the disinfectant.

"If we have to, we’ll go through the court system to get our people the medical care that they need," Ehling said. "We have people who are permanently disabled now. These are young people in the prime of their careers."

Contact Matt Fair at mfair@njtimes.com or at (609) 989-5707.

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EPA Wades Into Battle Over Hospital Disinfectant

By ELANA SCHOR of

U.S. EPA is interceding in a New Jersey public-health flap that could have national implications, ordering a hospital services company to stop disinfecting its ambulances with finely misted pesticides after a local union complained of workers falling ill.

In an order last Tuesday to Monmouth-Ocean Hospital Services Corp., or MONOC, EPA's Region 2 office in New York forbade the emergency-medicine company from using a "micro-mist" system that sprays "a sub-micron fog" of antimicrobial chemicals inside its ambulances. The EPA action validated complaints from a local union that as many as 100 MONOC paramedics it represents were sickened by on-the-job exposure to the misted pesticides.

"EPA has reason to believe that in distributing the antimicrobial pesticides Sporicidin and Zimek QD to MONOC" -- the company used both chemicals to sanitize vehicles in its 100-strong fleet -- "Zimek and/or its representatives made claims for a use not accepted in connection with the registration of either product," the Region 2 order states.

"EPA further has reason to believe that MONOC has applied at least these two antimicrobial pesticides to the interior of its ambulances in a manner inconsistent with their labeling and likely to cause harm to humans," the federal order continued.

Zimek and MONOC officials take issue with the charges by the New Jersey union, the Professional Emergency Medical Services Association (PEMSA), that the micro-misting product is behind the skin and eye irritation, asthma, headaches and ulcers reported by paramedics after the fogger was put to use in mid-2009. But while the short-term impact of the order may be local, the dispute may well reverberate in other localities where Zimek's pesticide misting caught on as a high-tech shield against the H1N1 flu virus, hospital "super-bugs" and other recent public health scares.

PEMSA President Deborah Ehling said the push launched by her union, a chapter of the International Association of Fire Fighters, is aimed at strengthening chemical safety regulations as well as protecting workers.

"The problem here is that this machine is a relatively new technology ... there's got to be 100 other companies out there developing technology to administer chemicals," she said. "And before those technologies are going to be allowed to hit the broad market, somebody's got to be sitting down and evaluating what [they're] going to do."
In the case of Zimek's micro-mister, its company literature touts a technological advance that effects a conversion of pesticides into microparticles with a negative charge and a sub-micron size. The chemicals dry "virtually on contact" after fogging inside a vehicle with "no visible or toxic residue," according to Zimek materials.

The labels for the pesticides MONOC used in its ambulances, however, refer specifically to "hard non-porous surfaces." Longtime occupational health official Eileen Senn, who has advised PEMSA on an unpaid basis on its concerns, pointed to the contact of tiny chemical particles with blankets, bandages and other porous items as a pathway to potential poisoning of ambulance workers.

"How do you fog an ambulance without contacting porous surfaces?" Senn said. "I'd love to see their protocol for how ambulances should be fogged. I'll bet it doesn't say to take the seats and carpet out -- on the contrary, they tout the fact that this gets on everything and is therefore more protective."

Zimek spokesman Noah Lichtman, in an e-mailed statement, strongly defended the company's "impeccable safety record" and said it "takes very seriously the nature of these allegations" but has not been contacted by EPA concerning the order to MONOC.

Ehling and Senn raised questions about whether the micro-mister could be generating nanoparticles of pesticides, taking the debate into the controversial and scientifically evolving territory of sub-molecular technology, but Lichtman disputed any such assertions.

"Characterizations that the Zimek equipment renders disinfectants into nanoparticles are completely baseless and contradict basic laws of matter," he said. "All liquids used in Zimek equipment remain a liquid when they exit the equipment."

**Labeling clash?**

For MONOC, the EPA order represents a simple disagreement over the wording of the labels for the pesticides misted inside its ambulances. MONOC support services director Peter Dworsky described the New Jersey case as "a red herring" in an interview, saying he has found no evidence of any other Zimek clients experiencing negative health consequences.

"We believe it is a good system, we believe it works as intended, and we believe that once people's issues are resolved, we'll be able to start using it again," Dworsky said of the Zimek product.

Responding to Ehling's estimate that 100 out of the union's 600 MONOC-affiliated workers have reported adverse symptoms linked to the pesticides, Dworsky said he had "not been provided with documentation" of any specific number of complaints but that workers' compensation officials were investigating, as well as the Occupational Safety and Health Administration (OSHA). MONOC and OSHA also have screened samples from misted ambulances and not reported chemical levels above permitted limits, according to Dworsky.

Ehling said she is beginning to receive reports that indicate PEMSA workers may not be the only ones experiencing symptoms, but declined to elaborate given the still-early nature of the data. EPA's order to ...
MONOC states only that exposed workers "continue to suffer ill effects" consistent with pesticide poisoning.

Material safety data sheets for Sporicidin and Zimek QD, the two chemicals used at various times by MONOC inside ambulances, note that respiratory protection should be used whenever ventilation cannot be relied upon to remove mists of the substances from an area.

"We look forward to an opportunity to speak with the EPA and learn more details about the allegations so we can either address this isolated incident -- if it is related to the Zimek equipment -- or else fully clear our name from these spurious claims," said Lichtman, spokesman for the company.

Well-connected company

Zimek has forged high-profile alliances in Washington during its rise in a biotechnology sector that experienced major growth in the wake of the anthrax and "bird flu" scares in the early 2000s.

The company counts James Lee Witt, Clinton-era chief of the Federal Emergency Management Association and an adviser to BP PLC's Gulf of Mexico cleanup work, as a senior adviser. Its lobbying team at International Government Relations Group, an affiliate of Mercury Public Affairs, is led by former Rep. Max Sandlin (D-Texas), according to disclosures, and Mercury counselor Emil Jones Jr. -- a mentor of President Obama's during their time in the Illinois state Legislature -- sits on the company's advisory board.

"We were concerned from day one, looking at their advisory board, that there would be a lot of political pressure to suppress any investigation," Ehling said.

But at the moment, PEMSA members are counting the EPA order as a victory that vindicates their health concerns, while Zimek and MONOC vow to counter any suggestion that the chemicals were improperly used. "Hundreds of government, public and private sector facilities worldwide have used Zimek's disinfectant application process thousands of times without a single documented health incident," Lichtman said in his statement.

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FOR IMMEDIATE RELEASE

Date: January 11, 2011

ZIMEK TECHNOLOGIES STATEMENT TO THE PRESS

Tampa, FLA (January 11, 2011) – Zimek Technologies, the industry leader in infection control and biohazard remediation, has not been contacted by the EPA or been served any notification from them. The EPA’s actions stem from reports of undocumented health-related claims allegedly arising from a Zimek's Micro-Mist® Disinfectant and Sanitizer Application System used by a local New Jersey ambulance service. The EPA Region 2 issued an order directly to the local New Jersey ambulance service to stop using its Zimek System until further notice while the health-related claims are further investigated to determine if they are legitimate. By its terms, the order did not affect any other Zimek user.

Zimek takes very seriously the safe and proper use of its system. The company is contacting the EPA to learn more details about the allegations in New Jersey to either address this isolated incident – if it is related to the Zimek equipment – or else confirm the efficacy of the Zimek System to control the expansion of community-acquired or healthcare-associated infections.

Zimek has an impeccable safety record. Hundreds of government, public and private sector facilities worldwide have used Zimek’s disinfectant application process thousands of times without a single documented health incident.

Zimek’s products and processes serve the urgent need to defend against the array of ever-present threats to public health that are posed by pathogenic infection. The health and hygiene of our customers and our customers’ communities remain our top priority.

Read our “Frequently Asked Questions” for more information.

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EPA: United States Environmental Protection Agency

News Releases from Region 2

EPA Issues Order to NJ Hospital Group

Release date: 01/12/2011

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(New York, NY) The U.S. Environmental Protection Agency (EPA) has ordered the Monmouth-Ocean Hospital Corporation (MONOC) to stop applying disinfectants using a fogging system in ambulances.

The disinfection process identified in the order is not an approved use for any of the EPA-registered pesticides used by MONOC. This process breaks disinfectants down into micro particles and can potentially make people ill. EPA has reason to believe that some ambulance workers have already become ill as the result of MONOC’s actions. The Agency is taking this action to prevent any further misuse of disinfectants by this company.

"MONOC has been put on notice that what they were doing is not consistent with federal law," said Judith Enck, EPA Regional Administrator. "A ride to a hospital should not include over exposure to pesticides. EPA has ordered the hospital to stop this practice immediately."

Prior to asking EPA to take over the case, the New Jersey Department of Environmental Protection issued a notice to Monmouth-Ocean Hospital Corporation informing them that they were in violation of pesticide law. According to information that EPA obtained through inspections and through the corporation itself, MONOC misapplied the disinfectant Zimek QD in ambulances using a fogger about 125 times, and misapplied the disinfectant Sporicidin in a similar manner at least 1 time.

EPA’s order, issued to MONOC on January 4, 2011, directed the company to stop applying any pesticide acquired from the manufacturer of the disinfection system in a manner inconsistent with its labeling. Disinfectants are considered pesticides because they are designed to kill microbiological organisms, known more widely as microbes. EPA registers all pesticides and as part of that process, any product containing pesticides must have an EPA-approved label that contains detailed application instructions.

The Monmouth Ocean Hospital Service Corporation is a non-profit company comprised of fifteen hospitals throughout New Jersey. The company operates more than 100 ambulances.

For more information about pesticides regulations, visit www.epa.gov/pesticides.


11-003
EPA Notice Unnecessary; MONOC Not Using Device

In May of 2009, MONOC, a non-profit hospital-based ambulance company in New Jersey, started using an ultra low volume sprayer to apply disinfectant inside its ambulances. Sometimes called “fogging” or “misting,” this long established application method uses less of the disinfectant or pesticide to treat the room or ambulance than a trigger sprayer familiar to us for home use. Although many manufacturers sell such sprayers, MONOC chose Zimek as its vendor and purchased from Zimek both the vehicle micro-mist device and the disinfectant solutions to use with it.

The impetus was to protect employees and patients from acquiring potentially deadly infectious diseases while in the back of a MONOC ambulance. Every year there is another near-pandemic event or threat. Just in the past few years the major threats facing the world included the H1N1 virus, avian flu, and community acquired MRSA. It is also well documented through research studies that even with routine cleaning, ambulances do not get cleaned as well as they should. A recent study in *Emergency Medicine Journal* revealed that 57% of the equipment cleaned by EMS crews remained contaminated, allowing the potential spread of organisms from equipment or surfaces to patients or emergency workers.

“We had read enough articles about how ambulances contain infectious materials dangerous to patients and crew even after regular manual cleaning, and we wanted to reduce the chances that our employees and patients would be exposed,” says Peter Dworsky, MONOC’s Corporate Director of Special Services. Before purchasing the system, Dworsky, who treats patients in the vehicles himself, contacted other users of the device, who had no complaints of employee illness and experienced no problems with the device.

“When we heard that a few employees thought the disinfection treatment was making them sick, we stopped using it while we investigated,” Dworsky explained. This was over a year after the system was introduced. “OSHA was brought in, and asked us to treat another vehicle so we could take samples after the misting process. We did this and sent the test samples to the laboratory as instructed by OSHA. All the results were within permissible limits, and OSHA closed the case.” Continued employee complaints to OSHA prompted the agency to open another investigation.

Months after routine use had been discontinued OSHA and EPA asked MONOC to confirm that they were not still spraying the ambulances, because employees were still
complaining to federal agencies. MONOC confirmed this, but EPA still published the Stop Order, even after inspecting the machine and confirming it had not been used.

“It was concerns about employee health that prompted us to start using the Zimek system,” explains MONOC President and CEO Vince Robbins. “That’s why we stopped regular use of the device when the complaints were made. Even though we have seen no evidence that any employee is sick because of our disinfectant program, we decided to wait until the government agencies make a decision before starting to use it again.”

Robbins also pointed out the following factual inconsistencies and inaccuracies in some coverage of the investigation:

1) MONOC has always used these products consistent with each manufacturer’s recommendations and guidelines.

2) MONOC completely disagrees with the EPA’s declaration that we have used these products in a manner inconsistent with their labeling. In fact, Sporicidin’s® EPA approved label specifically states it may be used in **ambulances** and it may be **fogged**. MONOC has consistently followed the directions of EPA Bulletin 301 regarding fogging, as well as all manufacturers’ guidelines and recommendations.

3) Claims that the fogging of Sporicidin® is only permitted in “clean rooms” and one must use a respirator to enter the room afterward, are false. The EPA label does not restrict fogging to clean rooms only, and their own bulletin regarding fogging of clean rooms (#301) states that persons are only restricted from entering the room during and up to two hours afterward. It makes no requirement what-so-ever that persons entering the room after two hours must, or even should, wear a respirator. MONOC has always complied with this direction. MONOC seals the ambulance during fogging, then vent the unit to the outside atmosphere for four hours before placing it back in service.

4) There is no link between the Zimek® fogging system, the chemicals used with it, and alleged illness of staff. Although the labor union representing a large portion of MONOC’s employees continues to claim over 100 employees are ill from the Zimek® disinfectant system, only 16 have made complaint of illness to MONOC. All of these reports were investigated and found to be unrelated to contact with the treated ambulances by MONOC’s Worker’s Compensation company. In fact, among these 16 individuals, some never worked in a vehicle that was ever treated by one of the chemicals that they claim to have been affected by. All tests revealed negligible to no residual chemicals existed in any of the ambulances fogged using the Zimek® system. All of the 16 employees who filed claims did so months after MONOC stopped using the Zimek® system and only after the union bombarded staff with e-mails and phone calls erroneously alleging
MONOC was poisoning them. The union went so far as to instruct staff to copy language they had written for physicians, and ask their personal doctors to issue notes stating their patients (MONOC’s employees) were suffering from phenol poisoning. The fact is, both MONOC’s and OSHA’s testing revealed little to no residual phenol present in our vehicles. When it was present, it was many times below the federal government’s permissible exposure limits.

5) Of special note, the labor union that has spearheaded the accusations against MONOC concerning, and have claimed so many anonymous sick employees, was elected three and a half years ago to represent the company’s operational staff. In that time they have failed to secure a collective bargaining agreement, so MONOC’s employees continue to work without a contract. On its three year anniversary, June 2010, this union began to aggressively attack MONOC regarding our use of the Zimek disinfectant system. They have made outrageous allegations against MONOC, claiming at one point we were intentionally poisoning our staff. And yet, in a stunning proposal yesterday during the most recent contract negotiation session, the union, in the person of Deb Ehling, surprisingly offered to “stand by MONOC on the Zimek issue”, to acknowledge “MONOC had done its due diligence” before purchasing Zimek, that “MONOC was not responsible” for any ill effects staff may be suffering, that “MONOC was duped by Zimek and taken advantage of”, and that the union would not pursue, nor support any civil law suits against MONOC regarding the use of Zimek! This offer was contingent upon MONOC agreeing to economic terms (wages and benefits) that were acceptable to the union and that MONOC would move quickly to conclude negotiations. One must ask then, has the union either determined at some time in the past that its allegations against MONOC are completely false, or is it simply willing to lie in order to gain a contract?

6) The claim that the Zimek® system changes the chemicals into a dry form, thereby highly concentrating the chemical into a deadly form, is false. While Zimek® calls there process Dri-Mist®, this is a trade mark not a description of its physical properties. The Zimek® system use an Ultra Low Volume process to introduce the chemical into the air of the target (in MONOC’s case the interior of an ambulance), as very fine droplets which settle on and wet all accessible surfaces. The droplets are between 5 and 0.3 microns, well above the “nano” size which has been claimed to be so dangerous. Even at 0.3 microns, the particles are not small enough to change the toxicity of the chemical or how they affect the human body.

7) The claim that the repeated use of the Zimek® system and how it electrically charges the disinfectants’ particles, causing them to cling to surfaces much longer than other ways of application, results in high concentrations of the chemicals to the point of making them hazardous, is completely false. Both MONOC’s tests and those of OSHA showed definitively that the residual amounts of both
disinfectants were far below the “permissible exposure limits” established by the federal government. As an example, an EPA risk assessment of fogging with Sporicidin® noted that phenol evaporates very quickly, 90% in 5.2 hours at room temperature.

8) The claim that the Zimek® system changes the chemical structure of the disinfectant chemicals in a way that makes them more harmful is ludicrous. Chemical experts have extensively reviewed Zimek’s® process and no such change takes place. Zimek’s Micro-Mist® Generator introduces a stream of air which is added to a mist of disinfectants and sanitizers generated by ultrasonic vibration. Unlike thermal foggers or hydrogen peroxide vapor treatments, Zimek’s Micro-Mist® is not generated through a thermal reaction where the active ingredient could be degraded or altered. In fact, Zimek’s ultrasonic generated Micro-Mist® is created in a manner virtually identical to the mist created by ultrasonic humidifiers, like those sold by Vicks for use with its, “vapo rub” products which are used on a daily basis in the homes of Americans. The Zimek® process very efficiently wets surfaces with disinfectants and sanitizers for the contact time mandated by their EPA label, and as a result, less active ingredient is used; once the water evaporates, residues are lower than if less efficient means of distribution, i.e., wipes or coarse sprays (applied while personnel are present) had been used.

9) The EPA has ordered MONOC to stop using Zimek® because they say it is likely to cause harm to human beings. They did this knowing MONOC had already stopped using Zimek® more than seven months earlier. Since stopping its routine use, the Zimek® machine was only used 4 additional times. Twice for OSHA testing and twice after transport of a patient with a potentially communicable infectious disease. In no case did MONOC ever violate any agency’s directive, order or advise to cease use of Zimek®.

10) It is our understanding that the EPA has specifically not ordered any other agency that uses Zimek® to stop. The EPA is well aware of who many of these other agencies are throughout the country. In addition, the EPA has specifically not ordered Zimek® to stop selling their product or to stop providing its use guidelines that the EPA finds so dangerous.

11) In an incredible error on January 11th, 2011, the EPA compounded its missteps by inadvertently posting a draft press release on its web site that falsely accused MONOC of ignoring its order. The press release was known by the EPA to contain false statements and it has not been appropriately reviewed. Once contacted by the company, the EPA realized its mistake, apologized to MONOC and withdrew the erroneous posting immediately. But, the damage had been done. Many individuals and entities subscribe to the EPA’s automatic notification
system that e-mails them new postings. So, an untold number of people now believe the EPA has accused MONOC of refusing to honor its directive. In fact, at least one media source issued a story claiming exactly that!

MONOC hopes that this factual information dispels the misinformation being spread regarding this topic, which has damaged MONOC’s reputation and falsely called into question our integrity. MONOC intends to appeal the EPA’s order and is considering its legal options.

Please contact Mr. Scott Matin, spokesperson for MONOC, at 732-919-3045, extension 1168, with any questions or further information.