Alternatives to Isopropyl Alcohol for Biocide Control in Healthcare and Industrial Applications
Phase I Report

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Bay Area Air Quality Management District

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I. Introduction and Background

Many different organizations use isopropyl alcohol (IPA) for wiping down critical surfaces so they can achieve disinfection. California has more than 500 hospitals with an estimated 80,616 beds. Hospitals routinely use IPA for biocide control to reduce infection. Medical device manufacturers produce a range of products designed to diagnose and treat patients in healthcare systems. These manufacturers use IPA routinely in clean rooms and on a variety of surfaces for biocide control. Pharmaceutical manufacturers produce drugs for the healthcare industry and they, too, rely on IPA for routine biocide control. Some of these companies are classified as biotechnology companies whose products or services use biological systems, living organisms or their derivatives to make or modify products or processes for specific use. These companies also use IPA for disinfection in all their processes.

IPA is classified as a Volatile Organic Compound (VOC) and VOCs contribute to smog. In California, many of the local air districts have severe smog problems. Smog has been shown to contribute substantially to lung disease. It is vital to find acceptable alternatives to VOCs in California that are cost effective for businesses to use in their operations. Another issue that has recently come to the forefront concerns the worker exposure to IPA. The Occupational Safety and Health Administration (OSHA) established a worker exposure limit of 400 ppm for IPA several years ago. IPA is a developmental toxin and can cause kidney damage, however, and Cal/OSHA plans to reduce the exposure level of the chemical significantly over the next few years because of the chemical's toxicity. The level may be as low as 35 or 50 ppm.

The Bay Area Air Quality Management District (BAAQMD) regulates stationary sources of air pollution in nine counties that surround San Francisco Bay. The District has developed regulations that focus on reducing VOC emissions and emissions of other materials that pose toxicity problems. Many medical device manufacturers, pharmaceutical manufacturers and biotechnology companies are located in the area covered by the BAAQMD and most of them use IPA as part of their processes.

The Institute for Research and Technical Assistance (IRTA) is a nonprofit technical research organization that identifies, develops, tests and demonstrates safer low-VOC, low toxicity alternatives, primarily in solvent applications. IRTA proposed a project to the BAAQMD to work with companies in the District's jurisdiction to find and test alternatives to IPA for biocide control. The BAAQMD sponsored the research which was to be completed in two phases. The first phase involved recruiting facilities to work on the project, identifying potential alternatives for testing and developing a general protocol for testing the alternatives. The second phase would involve conducting tests of the alternatives with the participating facilities according to the protocol, analyzing the results of the testing and the cost of using the alternatives and writing a final project report. This report is an interim report that summarizes the work of the first phase of the project.

Section II of this report focuses on the companies in the BAAQMD jurisdiction using IPA and the facilities that agreed to participate in the project. In Section III, the potential alternatives to IPA are identified and discussed; some of these alternatives were selected for more detailed investigation. Section IV describes the elements of a protocol that were agreed upon by the participating facilities and IRTA. The general protocol would provide sufficient information on the performance of the alternatives so that the best alternative(s) could be selected. Finally, Section V summarizes the results of the interim report and discusses the approach to the second phase of the project.

II. Participating Facilities

The BAAQMD provided IRTA with a list of the facilities that emit IPA in the Bay Area. The list included forty-three facilities involved primarily in medical device manufacture, pharmaceutical manufacture and biotechnology. IRTA contacted several of the companies to see if they would be interested in participating in the project.

The companies most interested in finding alternatives to IPA were biotechnology companies. These companies rely on IPA extensively for biocide control and wanted to identify viable alternatives that would not contribute to VOC emissions. They were also interested because of the possibility that Cal/OSHA would reduce the allowed worker exposure limit substantially in the future. With the current limit of 400 ppm, only limited worker exposure controls are necessary. If the limit were reduced below 50 ppm, it would be much more difficult to control worker exposure.

IRTA contacted several different companies and three of them wanted to participate in the project. The first company is BioMarin Pharmaceutical, a biotechnology company that focuses on developing therapies for small numbers of patients suffering from serious or rare orphan diseases. The company currently has four products on the market and has plans to investigate gene therapies which have promise for treating Hemophilia A, a genetic disorder.

The second company is Genentech, a leading biotechnology company that discovers, develops, manufactures and commercializes medicines to treat patients with serious or life-threatening medical conditions. The company has several therapeutic focus areas including oncology, immunology, neuroscience, metabolism and infectious diseases. Genentech has developed monoclonal antibodies, small molecules and antibody drug conjugates that address serious unmet medical needs.

Novartis is an international pharmaceutical biotechnology company that discovers, develops and successfully markets innovative products for preventing and curing diseases. The company has a diverse portfolio which includes innovative pharmaceuticals, eye care products, generics, consumer health products and vaccines and diagnostic tools. In the vaccine and diagnostics area, for example, Novartis provides products to fight viral and bacterial diseases and to prevent transfusion related transmission of HIV.

IRTA visited Bay Area locations of all three facilities and discussed and toured the areas where IPA is used for biocide control. The three companies were interested in finding low-VOC, low toxicity alternatives to IPA and wanted to participate in a program that would have that end. Since the problem was a common one among all three companies, IRTA and the three companies decided to collaborate on the project. This was an innovative idea and IRTA and the three companies met to scope out aims, identify tasks for IRTA and each of the participants and identify the important elements of a draft protocol for testing the alternatives.

One of the issues that was very important to the three participating companies was a non-disclosure agreement (NDA). This was necessary because it was unusual that three biotechnology companies would move forward to collaborate on a common problem. Novartis offered to develop an NDA that IRTA and the three companies would sign. IRTA's role was to screen potential alternatives and evaluate the cross-media and worker exposure issues that might arise with their use. By the time the meeting was held, IRTA had prescreened the alternatives and selected a few that held promise. The group discussed the list and determined how to move forward. Genentech offered their facility for much of the testing and BioMarin also indicated they would conduct some of the testing. BioMarin offered to develop the draft protocol.

III. Preliminary Alternatives Analysis

The IPA used today by biotechnology/pharmaceutical manufacturers contains 70% IPA and 30% water. This blend is a more effective disinfectant than is 100% IPA. Disinfectants are substances that are applied to non-living objects for the purpose of destroying microorganisms that are living on the objects. Disinfectants do not necessarily kill all microorganisms, especially resistant bacterial spores. It is less effective than sterilization which is a process or material that kills all types of life. Disinfectants operate by destroying the cell walls of microbes or interfering with their metabolism. The presence of the purified water in the IPA blend facilitates the diffusion through the cell membrane. Sanitizers are substances that disinfect but clean as well. IPA, in many cases, functions as a sanitizer since the solvent is effective in removing certain contaminants, generally those that are polar like fingerprints. The major reason companies use the IPA is that it is a disinfectant; a very valuable benefit of the IPA, however, is that it also cleans. An ideal alternative to IPA would not only disinfect, but perform some limited cleaning as well.

Alternative Disinfectants/Sanitizers

There are several different classes of known disinfectants/sanitizers. These include:

- Alcohols
- Phenolic compounds
- Chlorine compounds

- Aldehydes
- Peracetic Acid
- Hydrogen Peroxide
- Quaternary Ammonium Compounds

The IPA that is used by the industry today is classified as an alcohol. These materials are not corrosive and they evaporate fairly quickly leaving no residue. Alcohols are not effective in controlling fungal and bacterial spores. Another alcohol that is used to some extent as a disinfectant is ethanol. Ethanol was not considered as an alternative to IPA since it, like IPA, is a VOC.

Phenolic compounds have good activity against bacteria and fungi but are not generally effective against spores or viruses. They are compatible with most materials. A major disadvantage is that some phenolic compounds may leave residues on surfaces which can negatively impact product quality. Phenol itself is a respiratory irritant and can cause other organ system toxicity. Irritants can cause an asthma attack in someone who already has asthma. For this reason and because they leave a residue, phenolic compounds were not considered to be potential alternatives.

Chlorine compounds have been used for many years as disinfectants, primarily because they are effective against bacteria, fungi, viruses and spores. A disadvantage, however, is that they are very corrosive to many materials including stainless steel. They are also corrosive to the lungs and eyes and can have a strong odor. Examples of chlorine compounds used for disinfection are hypochlorites and chloramine. Chlorine bleach compounds have been found to be irritants, which are materials that can trigger asthma in someone who already has asthma. Chlorine compounds were not considered further as alternatives to IPA for this reason.

Aldehydes like gluteraldehyde and formaldehyde have been used for disinfection. They are capable of controlling bacteria, fungi, viruses and spores. These materials have pungent smells so they are difficult to use. Formaldehyde is a carcinogen and gluteraldehyde has been found to cause asthma. These materials were not considered as alternatives to IPA.

Peracetic acid is a strong oxidizing agent formed from the reaction of hydrogen peroxide and acetic acid. Because of its oxidizing action, it has materials compatibility issues. It does not leave a residue and therefore does not require rinsing. It is effective against bacteria, fungi, viruses and spores. The major disadvantage of peracetic acid is that it has an extremely irritating pungent odor. There are blends of hydrogen peroxide (see below) and peracetic acid that are effective and reduce the effect of the odor. Even so, because of the strong odor, peracetic acid or blends were not further considered as alternatives to IPA.

Hydrogen peroxide has a wide spectrum of activity against bacteria, fungi, viruses and spores. It does not leave a residue and the breakdown products are water and oxygen. Hydrogen peroxide is compatible with all materials. Hydrogen peroxide blends with water were considered as potential alternatives to IPA.

Quaternary ammonium compounds are often referred to as "quat" and they are used in very dilute form in water. They have no activity against mycobacteria, spores and certain types of viruses. They are generally compatible with materials but are severely compromised by the presence of organic soils. Benzalkonium chloride, one of these compounds, is a sensitizer which is a material that causes asthma. One of the participating facilities wanted to test these materials further as potential alternatives to IPA in spite of the fact that one of them is a sensitizer.

Other/Emerging Disinfectants

Various other approaches to commercial disinfecting methods are currently being explored. Electrolyzed water and ozonated water are both being investigated. Specialized equipment for producing and dispensing electrolyzed water are required but users can generate it onsite which reduces materials handling. The water itself does have corrosive properties so there may be materials compatibility issues. No residues are left on surfaces. Ozonated water production also requires special equipment which includes UV or corona discharge generators. Ozone is toxic to workers at low levels and it can be damaging to some materials but no residue is left on surfaces.

IRTA and one of the participating facilities were interested in pursuing acetone as a possible alternative to IPA. Acetone is exempt from VOC regulation and is low in toxicity compared with other organic solvents. Whether or not acetone has disinfecting properties has never been investigated and this investigation could be done as part of this project. It is likely that, if acetone did have disinfection properties, it would be more effective when diluted with water for the same reason the IPA/water blend is effective. The group agreed to do additional work to investigate acetone as a possible replacement for IPA.

Alternatives Selected for Testing

There were four alternatives selected for cleaning tests in the protocol that was being developed. These included 3% hydrogen peroxide, 1% hydrogen peroxide, quats and acetone. The hydrogen peroxide alternatives were the preferred alternatives by all members of the group. The 3% hydrogen peroxide blend is used currently as a disinfectant. Although it is not known whether 1% hydrogen peroxide has adequate disinfecting properties, the group members wanted to test it to make this determination in the research project. If it did have these properties, the more dilute material would certainly be preferred.

Suppliers currently carry sterile hydrogen peroxide dilute solutions in Water For Injection (WFI). Two different concentrations are generally available, including a 3% solution and a 6% solution. An MSDS for both the 3% and 6% formulations from Veltek Associates, called Steri-Perox, is included in Appendix A. The group decided to test the 3% solution. The group decided to make and test a 1% solution using WFI from the testing site. A Veltek representative also agreed to provide the group with testing formulations at the 3% and 1% concentration. The aim was to keep the concentration of the active ingredient, in this case hydrogen peroxide, as low as possible.

Testing the 1% hydrogen peroxide solution would answer the question of whether it has disinfecting capability.

The 3% hydrogen peroxide has advantages over IPA. It can control fungal and bacteria spores which IPA cannot. It is a water-based material with only a small concentration of the active ingredient. It does not leave a residue so additional wiping would not be required for surfaces. IRTA has tested hydrogen peroxide in other applications and it does have some limited cleaning capability; it is probably not as good a cleaner as IPA, however.

One of the group members wanted to test quats in spite of the fact that at least one of the quats is a sensitizer. The reasoning was that high air flows and protective equipment are routinely used at biotechnology facilities and that these measures should adequately protect the workers. This reasoning is not valid, however, since asthmagens do not have a threshold exposure below which it is safe. As a consequence, prescreening of the workers to ensure that asthmagen exposure would not occur would be required. IRTA agreed to do further investigation to see if a suitable formulation for testing could be identified. Part of the investigation would involve identifying any quat compounds that are not asthmagens. If such materials are available, they would be the ones selected for the testing.

The group also agreed to include acetone in the testing protocol. The group as a whole favored the hydrogen peroxide formulations but agreed that acetone might be used in niche applications. Preliminary work would be necessary to determine if acetone and/or acetone blends with water actually has disinfecting properties. The preliminary work would also be needed to determine the most effective dilution concentration. IRTA agreed to investigate other issues that might arise if acetone were used. These included hazardous waste characteristics, wastewater discharge limits and glove compatibility. IRTA completed most of this work as part of the phase I research and the results are discussed below.

The reason the group wanted to further investigate acetone is that it has three advantages over IPA. First, acetone, unlike IPA, is exempt from VOC regulations. Second, acetone is a much stronger cleaner than IPA and can remover oil based contaminants. IPA is not effective in removing oils and greases. Third, acetone is lower in toxicity than IPA and has a high worker exposure limit. One disadvantage of acetone is that it may have compatibility issues with some materials. A second disadvantage is that acetone has a strong odor, although if it could be combined with water, this odor would be much less pronounced.

Investigation of Acetone Issues

If acetone were to be used as an alternative to IPA, three major issues would require resolution. First, acetone is a listed hazardous waste under the federal and state regulations whereas IPA is not. The question that needs to be addressed here is whether or not the spent acetone materials would have to be handled as hazardous waste. If they are classified as hazardous waste, the cost of using acetone would be higher. Second, acetone is treated differently for purposes of water contamination than is IPA by local water agencies. If this is an issue, again, the handling requirements would raise the cost of using acetone. Third, acetone is a more aggressive solvent than IPA so the gloves that are currently used with IPA might not be suitable if acetone were substituted. IRTA analyzed the first two issues but plans to analyze the third issue in the second phase of the project after preliminary testing on an effective acetone concentration in water is completed.

Hazardous Waste Implications Suppliers of the disinfecting solutions generally provide them to users in spray bottles. Users spray the formulation on the surfaces and use wipe cloths In a specific way to wipe the surface. In other cases, users might spray the formulation directly on the wipe cloth. Suppliers also often provide pre-moistened wipes that contain the formulation. In these cases, wipes are always used and they are discarded after use. If the wipes are classified as hazardous waste, the used wipe cloths must be handled as hazardous waste and the storage and disposal requirements raises the cost of using them. In general, if acetone were substituted for IPA in the disinfecting applications, it would be used in the same manner as IPA. That is, it could be used in a spray and would be wiped with wipe cloths or it would be used in pre-moistened wipes.

California companies have to be aware of two different hazardous waste regulations, the federal Resource Conservation and Recovery Act (RCRA) regulations and the state regulations, which are enforced by Cal/EPA's Department of Toxic Substances Control (DTSC). At the local level, the hazardous waste regulations are enforced by the Certified Unified Program Agencies (CUPAs).

In this application, the main issue to resolve is whether or not the wipes would be classified as hazardous waste simply because of the presence of acetone. Solvents in RCRA are classified as hazardous waste if they meet one of two criteria. A waste can be a listed hazardous waste or a waste can exhibit certain characteristics that make it a hazardous waste. The relevant characteristic in this case is whether it exhibits the characteristic of ignitability. Acetone is a listed hazardous waste in F003 of RCRA, whereas IPA is not a listed waste. Both materials have flash points so they could be characteristic wastes depending on the flash point of the "assembly" (like a wipe cloth) they are part of.

IRTA discussed the issue with a CUPA representative in the San Francisco area. She indicated the same issue arose in a similar investigation. She has been working with a coalition of people looking at nail salons nationwide. One of the issues is that a significant amount of acetone is used in nail polish remover, thinner and other products in nail salons. Nail salons use cotton balls to apply the acetone. The question the group was addressing is whether or not the saturated cotton balls would be classified as hazardous waste because of the presence of acetone. EPA and the state hazardous waste people are involved in the project so there was input from the federal and state agencies. The group arranged for testing of the cotton balls to determine whether they exhibited the characteristic of ignitability and, as might be expected, some did and some did not. This would depend on how saturated the cotton balls are and how they are kept before analysis. She said that EPA and the state hazardous waste people all agreed that the only issue was whether or not the ignitability characteristic applied and not the fact that acetone is a listed waste.

IRTA contacted another CUPA representative in California who had previously worked at DTSC and handled hazardous waste classification interpretations from industry and the public. He indicated that the waste would be hazardous waste only if the "assembly" exhibited the characteristic of ignitability. He provided the code in RCRA where this is explicitly covered. This section of the code is shown in Appendix B.

As RCRA code indicates, the reason for listing acetone (and the other chemicals) in F003 is ignitability. Thus, if the waste in question (the spent wipe) doesn't exhibit ignitability, then the waste is not classified as hazardous waste. This is actually the same situation we have today with the IPA contaminated wipes. The only way an IPA wipe would be classified as hazardous waste is if it exhibited the characteristic of ignitability. Since the IPA laden wipes are not currently being handled as hazardous waste, it is not likely the acetone laden wipes would have to be handled as hazardous waste unless the wipes are more likely to exhibit the ignitibility characteristic.

On the one hand, acetone has a lower flash point than IPA which suggests it might exhibit the characteristic more easily than IPA. On the other hand, acetone evaporates much more quickly than IPA so there is likely to be much less acetone on the wipe than there is IPA on the wipe. The cotton balls from the nail salons would seem to be more likely to exhibit the characteristic of ignitability than the acetone wipes from biotechnology companies. Cotton balls have less surface area and may retain more solvent as a result. The cotton balls are also saturated with pure acetone whereas, in the biotechnology application, they would be saturated with an acetone/water combination which would dampan the ignitibility. It would be necessary to analyze some of the discarded wipes to determine whether they could be handled as non-hazardous waste to be sure they are handled properly.

Water Contamination Implications It is unlikely that the wipes and spray bottle use by companies would result in contamination of the water. Because a solvent is present, however, there is a possibility that a transfer to water might occur. It was important to examine this issue for acetone to see if acetone should be treated differently than IPA.

Several years ago, IRTA conducted an EPA project to find alternative low-VOC, low toxicity alternatives to mineral spirits parts cleaners used by auto repair and industrial facilities to clean parts. IRTA demonstrated that water-based cleaners were a viable and cost effective alternative. The South Coast Air Quality Management District (SCAQMD) and, later, the other air districts in California, regulated the VOC content of the cleaning agents in parts cleaners as a result of the research.

As part of the implementation, a task force that included IRTA, SCAQMD, several Publicly Owned Treatment Works (POTWs), including Los Angeles County Sanitation Districts (LACSD), worked with the wastewater people to ensure that the auto repair facilities did not dispose of the spent water-based cleaners in the sewer. There is a list of Total Toxic Organics (TTOs) in the Clean Water Act and IPA and acetone are not on that list so neither of the chemicals is of concern at the federal level. LACSD analyzed the spent water cleaners and found many chlorinated and non-chlorinated solvents in them. The solvents came from brake cleaners, engine degreasers and carburetor and fuel injection cleaners that the technicians would spray over the water cleaning tanks. LACSD did not want the components of the chlorinated solvents to go into the water because they can cause downstream pollution.

In a later research project, IRTA developed and demonstrated low-VOC alternatives for aerosol automotive cleaners. Some of the alternative formulations contained acetone so it was possible they would have a pathway to the water through the water-based parts cleaners.

In their testing and analysis, LACSD determined that the only problem with acetone is that it should not enter the sewer if the concentration is at flammable levels. In other words, acetone poses a threat of flammability. There would be a similar concern with IPA exceeding flammable limits but, since IPA's flash point is much higher than the flash point of acetone, it would be of less concern for IPA than for acetone. In either case, however, it is unlikely that enough of either chemical would enter the water to signal a problem. Acetone and IPA are both biodegradable so the biodegradation processes used in wastewater treatment facilities will easily degrade the two chemicals.

Some POTWs list acetone as a chemical of concern and it is reasonable to do so if there is a concern about the operations leading to flammable levels. It is not reasonable to worry about acetone for any other reason. IRTA contacted an LACSD representative again recently to discuss the current issue. The LACSD representative indicated that POTW people concerned about acetone could contact LACSD to discuss the issue if they assume that acetone is a problem for any other reason.

Glove Material Compatibility Biotechnology employees using spray bottles and wipes containing IPA wear gloves. Latex gloves can be used with IPA and these gloves are fairly low in cost. Some people have an allergy to latex and companies also offer nitrile gloves which are also low cost and also compatible with IPA.

Acetone is a more aggressive solvent than IPA and it may not be compatible with latex or nitrile gloves. It is compatible with butyl rubber gloves but these are much more expensive. It is worth noting that, if acetone does have disinfecting properties, it is likely that it would be used in dilute form. IRTA has tested acetone extensively over the years in many applications and adding even a small amount of water inhibits its aggression. It may be that acetone in diluted form could be used with the less costly latex or nitrile gloves.

IRTA did not complete the analysis of the glove issue and plans to complete it during the second phase of the project. It may be necessary to conduct testing with the acetone in dilute form to determine which gloves would be suitable for use with the material.

IV. Draft Protocol

Before the testing defined in the protocol would be conducted, an initial set of screening tests would be conducted to determine whether acetone had disinfectant properties. This initial testing would also be useful to determine the concentration of acetone and water that might be most effective.

The group held a meeting and summarized the components that would be necessary for the protocol for conducting testing of the alternatives. A representative from BioMarin volunteered to draft the protocol. The elements of the draft protocol are summarized here.

The protocol would consist of three basic components. The first component is to test and compare the disinfectant/sanitizer performance of the currently used IPA/water formulation with the alternative formulations which would be 1% and 3% hydrogen peroxide in water, an acetone formulation in water and the selected quat compound(s). The IPA formulation would serve as the baseline. It is worth noting that the IPA formulation has disinfectant properties but it is not effective against bacterial spores. The 3% hydrogen peroxide formulation is effective against bacterial spores. Use of this alternative would be advantageous as a result.

The test protocol would involve inoculating plates with four bacteria organisms, including pseudomonas, staphylococcus, E Coli and yeast, at 10 to the fifth cfu per ml. Colony-forming unit, or cfu, is an estimate of viable bacterial or fungal numbers. Bacillis and fungi would not be tested since IPA is not effective against spores. The IPA formulation and each of the potential alternatives would be applied to the organisms and would be sampled at zero, five, 10 and 15 minute intervals to determine their effectiveness in controlling the organisms. The viable alternatives would control the organisms as well as or better than IPA. The acceptance criterion would be a three log reduction with an allowed variation of 20 or 30%.

The second component of the protocol would be to test the alternatives that perform well on the bacteria organisms on various substrates. Substrates that are commonly encountered on process surfaces are stainless steel, epoxy, glass and polyvinyl chloride. Coupons with dimensions of about two inches by four inches would be made from the four candidate substrates. The four organisms would be applied to the coupons together with a neutralizer. The IPA formulation and each of the potential alternatives would be applied to the coupons and the level of control would be determined. This set of tests would be conducted in triplicate.

The third component of the protocol, which may or may not be needed, is to determine if the potential alternatives leave a residue. This test could be a Total Organic Carbon (TOC) or other residue analysis test if it were deemed necessary.

BioMarin has completed the draft testing protocol. The three companies decided that the four parties (IRTA and the three companies) would need to sign Non-Disclosure Agreements (NDA) to ensure that proprietary information would not be divulged. Novartis has prepared the draft NDA and the legal departments of the other two companies are reviewing it.

V. Results, Conclusions and Future Phase II Work

The first phase of the two phase project to identify, test and demonstrate alternatives to IPA for disinfecting surfaces has been completed. IPA is classified as a VOC and it contributes to smog. Emissions of IPA for biocide use are high and low-VOC alternatives would help to reduce overall VOC emissions. Cal/OSHA is likely to reduce the allowed worker exposure limit for IPA in the future based on toxicity. This would make it much more difficult to use the chemical safely.

IRTA recruited three biotechnology pharmaceutical manufacturers to work on the project designed to find viable alternatives to IPA for disinfection and sanitizing uses. The three biotechnology companies agreed to collaborate with one another on the project since they all have a common interest in finding alternatives. There is also more widespread interest in alternatives since many other organizations, like hospitals, medical device manufacturers and other pharmaceutical companies have come to rely on IPA extensively.

IRTA conducted an investigation of alternatives that would be candidates for the alternatives testing. The best alternative from an overall health and environmental standpoint is hydrogen peroxide. This chemical is used in either a 3% or 6% concentration in water today and, in contrast to IPA, it is capable of controlling spores in addition to bacteria. IRTA and the group decided to select 3% hydrogen peroxide as a candidate for testing and wanted to also test 1% hydrogen peroxide to determine if it had disinfecting capability. The aim was to use as dilute a concentration as possible.

The group also decided to conduct some preliminary tests to determine if acetone had disinfecting capability. Acetone is a stronger cleaner than IPA so it would likely be a better sanitizer if it could control bacteria. The chemical is exempt from VOC regulation and is lower in toxicity than nearly all other organic solvents. If acetone were suitable as a candidate alternative, it would likely be more useful in dilute form as is IPA. If the preliminary testing were successful, an appropriate acetone formulation would be tested as part of the protocol.

Regulatory constraints that could prevent the use of acetone were identified by the group. IRTA investigated the two constraints and found that acetone would not be considered differently from IPA for purposes of wipecloth disposal and wastewater limits. IRTA also agreed to investigate glove compatibility of acetone once the preliminary testing to determine if acetone had disinfecting capability had been completed.

One of the group members wanted to test quats. The disadvantage of quats is that they are asthmagens. There may be quats that are not asthmagens and IRTA agreed to study this issue to determine if certain quats could be identified that did not cause asthma. If this were successful, then quats would also be tested as part of the protocol.

One of the group members, Bio Marin, volunteered to develop a draft protocol for the testing. That draft protocol has been prepared and, once the members and IRTA sign an NDA, the protocol can be finalized.

The second phase of the project will involve the testing of the alternatives according to the protocol. Once the results of the testing are available, IRTA will conduct a cost analysis to compare the cost of using the best performing alternative(s) to the cost of using IPA.

Appendix A: Material Safety Data Sheet for Hydrogen Peroxide

MATERIAL SAFETY DATA SHEET

1. Product and Company Identification

Material name	**STERI-PEROX**
Revision date	12-15-2011
Version #	01
CAS #	Mixture
MSDS Number	SP-98-01
Product use	Cleaner.
Manufacturer/Supplier	Veltek Associates, Inc. 15 Lee Blvd MALVERN, PA 19355 USA vai@sterile.com Contact Person: All questions regarding chemical content should be directed to CARECHEM 24
Telephone:	610-644-8335
Emergency	CARECHEM 24: 1-866-928-0789

2. Hazards Identification

Physical state	Liquid.
Appearance	Clear, colorless liquid.
Emergency overview	WARNING Causes eye irritation.
OSHA regulatory status	This product is considered hazardous under 29 CFR 1910.1200 (Hazard Communication).
Potential health effects	
Routes of exposure	Eye contact. Ingestion. Skin contact.
Eyes	Causes eye irritation.
Skin	Prolonged contact may cause dryness of the skin.
Inhalation	No inhalation hazard under normal conditions.
Ingestion	May cause abdominal pain, swelling and mild diarrhea. However, ingestion is not likely to be a primary route of occupational exposure.
Target organs	Eyes.
Chronic effects	Frequent or prolonged contact may defat and dry the skin, leading to discomfort and dermatitis.
Signs and symptoms	Eye contact: Symptoms can include irritation, redness, scratching of the cornea, and tearing. Ingestion: May cause abdominal pain, burning sensation, nausea.
Potential environmental effects	The product is not classified as environmentally hazardous. However, this does not exclude the possibility that large or frequent spills can have a harmful or damaging effect on the environment.

3. Composition / Information on Ingredients

Components	CAS #	Percent
Hydrogen peroxide	7722-84-1	3 - 6

Composition comments All concentrations are in percent by weight unless ingredient is a gas. Gas concentrations are in percent by volume.

4. First Aid Measures

First aid procedures	
Eye contact	Immediately flush eyes with plenty of water for at least 15 minutes. Remove contact lenses, if *present and easy to do. Continue rinsing. Get medical attention if irritation develops and persists.*
Skin contact	Immediately flush skin with plenty of water. Get medical attention if irritation develops and persists.
Inhalation	Move to fresh air. For breathing difficulties, oxygen may be necessary. Get medical attention if symptoms persist.
Ingestion	Immediately rinse mouth and drink plenty of water. Get medical attention.

Notes to physician	Provide general supportive measures and treat symptomatically.
General advice	Ensure that medical personnel are aware of the material(s) involved, and take precautions to protect themselves.

5. Fire Fighting Measures

Flammable properties	The product is not flammable.
Extinguishing media	
Suitable extinguishing media	Use extinguishing agent suitable for type of surrounding fire.
Unsuitable extinguishing media	None.
Protection of firefighters	
Specific hazards arising from the chemical	During fire, gases hazardous to health may be formed.
Protective equipment and precautions for firefighters	Selection of respiratory protection for firefighting: follow the general fire precautions indicated in the workplace. Self-contained breathing apparatus and full protective clothing must be worn in case of fire.
Fire fighting equipment/instructions	Stop leak if you can do so without risk.
Specific methods	Use standard firefighting procedures and consider the hazards of other involved materials.
Hazardous combustion products	Fire will generate toxic and irritating gases.

6. Accidental Release Measures

Personal precautions	Provide adequate ventilation. Follow precautions for safe handling described in this safety data sheet.
Environmental precautions	Prevent further leakage or spillage if safe to do so. Do not contaminate water.
Methods for containment	Stop leak if you can do so without risk. Dike the spilled material, where this is possible. Collect spillage. Prevent entry into waterways, sewer, basements or confined areas.
Methods for cleaning up	Stop the flow of material, if this is without risk. Wipe up with absorbent material (e.g. cloth, fleece). Clean surface thoroughly to remove residual contamination. Never return spills in original containers for re-use. For waste disposal, see section 13 of the MSDS.
Other information	Clean up in accordance with all applicable regulations.

7. Handling and Storage

Handling	Avoid contact with eyes and prolonged or repeated contact with skin. Handle in accordance with good industrial hygiene and safety practice. Wear protective clothing as described in Section 8 of this safety data sheet. Wash hands thoroughly after handling.
Storage	Store away from incompatible materials. To maintain product quality, do not store in heat or direct sunlight.

8. Exposure Controls / Personal Protection

Occupational exposure limits

US. ACGIH Threshold Limit Values

Components	Type	Value
Hydrogen peroxide (7722-84-1)	TWA	1 ppm

US. OSHA Table Z-1 Limits for Air Contaminants (29 CFR 1910.1000)

Components	Type	Value
Hydrogen peroxide (7722-84-1)	PEL	1.4 mg/m3
		1 ppm

Canada. Alberta OELs (Occupational Health & Safety Code, Schedule 1, Table 2)

Components	Type	Value
Hydrogen peroxide (7722-84-1)	TWA	1.4 mg/m3
		1 ppm

Canada. British Columbia OELs. (Occupational Exposure Limits for Chemical Substances, Occupational Health and Safety Regulation 296/97, as amended)

Components	Type	Value
Hydrogen peroxide (7722-84-1)	TWA	1 ppm

Canada. Ontario OELs. (Control of Exposure to Biological or Chemical Agents)

Components	Type	Value
Hydrogen peroxide (7722-84-1)	TWA	1 ppm

Canada. Quebec OELS. (Ministry of Labor - Regulation Respecting the Quality of the Work Environment)

Components	Type	Value
Hydrogen peroxide (7722-84-1)	TWA	1.4 mg/m3
		1 ppm

Mexico. Occupational Exposure Limit Values

Components	Type	Value
Hydrogen peroxide (7722-84-1)	STEL	3 mg/m3
		2 ppm
	TWA	1.5 mg/m3
		1 ppm

Exposure guidelines Follow standard monitoring procedures.

Engineering controls Observe occupational exposure limits and minimize the risk of exposure. Provide easy access to water supply or an emergency shower.

Personal protective equipment

Eye / face protection Wear approved safety goggles.

Skin protection Wear protective gloves. Be aware that the liquid may penetrate the gloves. Frequent change is advisable. Suitable gloves can be recommended by the glove supplier. Wear appropriate clothing to prevent repeated or prolonged skin contact.

Respiratory protection No protection is ordinarily required under normal conditions of use and with adequate ventilation. In case of inadequate ventilation or risk of inhalation of vapors, use suitable respiratory equipment. If ventilation is not sufficient to effectively prevent buildup of aerosols or vapors, appropriate NIOSH/MSHA respiratory protection must be provided.

General hygiene considerations Handle in accordance with good industrial hygiene and safety practices. Wash hands before breaks and immediately after handling the product. Launder contaminated clothing before reuse. Remove and isolate contaminated clothing and shoes.

9. Physical & Chemical Properties

Appearance	Clear, colorless liquid.
Color	Clear. Colorless.
Odor	Odorless.
Odor threshold	Not available.
Physical state	Liquid.
Form	Liquid.
pH	Not available.
Melting point	32 °F (0 °C)
Freezing point	32 °F (0 °C)
Boiling point	212 °F (100 °C)
Flash point	Not applicable.
Evaporation rate	Not available.
Flammability limits in air, upper, % by volume	Not relevant.
Flammability limits in air, lower, % by volume	Not relevant.
Vapor pressure	Not available.
Vapor density	Not available.

Specific gravity	1
Solubility (water)	Not relevant.
Partition coefficient (n-octanol/water)	Not available.
Auto-ignition temperature	Not applicable.
Decomposition temperature	Not available.

10. Chemical Stability & Reactivity Information

Chemical stability	Material is stable under normal conditions.
Conditions to avoid	High temperatures. Protect against direct sunlight. Contact with incompatible materials.
Incompatible materials	Alkalies. Powdered metals. Metal salts. Reducing agents. Strong reducing agents.
Hazardous decomposition products	Oxygen.
Possibility of hazardous reactions	Hazardous polymerization does not occur.

11. Toxicological Information

Toxicological data

Components	**Test Results**
Hydrogen peroxide (7722-84-1)	Acute Dermal LD50 Rabbit: 4076 mg/kg
	Acute Inhalation LC50 Rat: 2 mg/l 4 Hours Acute Oral LD50 Rat: 376 mg/kg

Toxicological information	The information in this section is for the individual ingredients that are expected to contribute to the potential health effects of this product.
Acute effects	Causes eye irritation.
Local effects	Irritating to eyes.
Sensitization	Not a skin sensitizer.
Chronic effects	Frequent or prolonged contact may defat and dry the skin, leading to discomfort and dermatitis.
Carcinogenicity	Not classified.

ACGIH Carcinogens

Hydrogen peroxide (CAS 7722-84-1)	A3 Confirmed animal carcinogen with unknown relevance to humans.

IARC Monographs. Overall Evaluation of Carcinogenicity

Hydrogen peroxide (CAS 7722-84-1)	3 Not classifiable as to carcinogenicity to humans.

Epidemiology	No epidemiological data is available for this product.
Mutagenicity	No data available to indicate product or any components present at greater than 0.1% are mutagenic or genotoxic.
Neurological effects	No data available.
Reproductive effects	Not classified.
Symptoms and target organs	Eye contact: Symptoms include itching, burning, redness and tearing. Ingestion: May cause abdominal pain with vomiting, nausea, diarrhea, or dizziness.
Further information	No other specific acute or chronic health impact noted.

12. Ecological Information

Ecotoxicological data

Components	**Test Results**
Hydrogen peroxide (7722-84-1)	LC50 Bluegill (Lepomis macrochirus): 26.7 mg/l 96 Hours
	LC50 Chameleon goby (Tridentiger trigonocephalus): 155 mg/l 24 Hours
	LC50 Daphnia: 24 mg/l 48 hours
	LC50 Jack Mackerel (Trachurus japonicus): 89 mg/l 24 Hours
	LC50 Rainbow trout,donaldson trout (Oncorhynchus mykiss): 22 mg/l 96 Hours

Ecotoxicity	The product is not classified as environmentally hazardous. However, this does not exclude the possibility that large or frequent spills can have a harmful or damaging effect on the environment.
Environmental effects	An environmental hazard cannot be excluded in the event of unprofessional handling or disposal.
Persistence and degradability	No data available.
Bioaccumulation / Accumulation	No data available.
Partition coefficient (n-octanol/water)	Not available.
Mobility in environmental media	No data available.

13. Disposal Considerations

Waste codes	Not regulated.
Disposal instructions	Dispose of waste and residues in accordance with local authority requirements.
Waste from residues / unused products	Dispose in accordance with all applicable regulations.
Contaminated packaging	Since emptied containers retain product residue, follow label warnings even after container is emptied.

14. Transport Information

DOT

Not regulated as dangerous goods.

IATA

Not regulated as dangerous goods.

IMDG

Not regulated as dangerous goods.

TDG

Not regulated as dangerous goods.

15. Regulatory Information

US federal regulations

This product is a "Hazardous Chemical" as defined by the OSHA Hazard Communication Standard, 29 CFR 1910.1200.
All components are on the U.S. EPA TSCA Inventory List.

CERCLA/SARA Hazardous Substances - Not applicable.

TSCA Section 12(b) Export Notification(40 CFR 707, Subpt. D)

Not regulated.

US EPCRA (SARA Title III) Section 302 - Extremely Hazardous Spill: Reportable quantity

Hydrogen peroxide (CAS 7722-84-1)	1000 LBS

US EPCRA (SARA Title III) Section 302 - Extremely Hazardous Substance: Threshold Planning Quantity

Hydrogen peroxide (CAS 7722-84-1)	1000 LBS

CERCLA (Superfund) reportable quantity (lbs) (40 CFR 302.4)

None

Superfund Amendments and Reauthorization Act of 1986 (SARA)

Hazard categories	Immediate Hazard - Yes Delayed Hazard - No Fire Hazard - No Pressure Hazard - No Reactivity Hazard - No
Section 302 extremely hazardous substance (40 CRF 355, Appendix A)	No
Section 311/312 (40 CFR 370)	Yes
Drug Enforcement Administration (DEA) (21 CFR 1308.11-15)	Not controlled

Canadian regulations This product has been classified in accordance with the hazard criteria of the CPR and the MSDS contains all the information required by the CPR.

WHMIS status Controlled

WHMIS classification D2B - Other Toxic Effects-TOXIC

WHMIS labeling

Inventory status

Country(s) or region	Inventory name	On inventory (yes/no)*
Australia	Australian Inventory of Chemical Substances (AICS)	Yes
Canada	Domestic Substances List (DSL)	Yes
Canada	Non-Domestic Substances List (NDSL)	No
China	Inventory of Existing Chemical Substances in China (IECSC)	Yes
Europe	European Inventory of Existing Commercial Chemical Substances (EINECS)	Yes
Europe	European List of Notified Chemical Substances (ELINCS)	No
Japan	Inventory of Existing and New Chemical Substances (ENCS)	Yes
Korea	Existing Chemicals List (ECL)	Yes
New Zealand	New Zealand Inventory	Yes
Philippines	Philippine Inventory of Chemicals and Chemical Substances (PICCS)	Yes
United States & Puerto Rico	Toxic Substances Control Act (TSCA) Inventory	Yes

*A "Yes" indicates that all components of this product comply with the inventory requirements administered by the governing country(s)

State regulations This product does not contain a chemical known to the State of California to cause cancer, birth defects or other reproductive harm.

US - California Hazardous Substances (Director's): Listed substance

Hydrogen peroxide (CAS 7722-84-1) Listed.

US - Massachusetts RTK - Substance: Listed substance

Hydrogen peroxide (CAS 7722-84-1) Listed.

US - New Jersey Community RTK (EHS Survey): Reportable threshold

Hydrogen peroxide (CAS 7722-84-1) 500 LBS

US - Pennsylvania RTK - Hazardous Substances: Listed substance

Hydrogen peroxide (CAS 7722-84-1) Listed.

Mexico regulations This safety data sheet was prepared in accordance with the Official Mexican Standard (NOM-018-STPS-2000).

16. Other Information

Further information HMIS® is a registered trade and service mark of the NPCA.
B - Safety Glasses, Gloves

HMIS® ratings Health: 2
Flammability: 0
Physical hazard: 1
Personal protection: B

NFPA ratings Health: 2
Flammability: 0
Instability: 1

Disclaimer This information is provided without warranty. The information is believed to be correct. This information should be used to make an independent determination of the methods to safeguard workers and the environment.

Issue date 12-15-2011

Appendix B: RCRA Language on Solvent Handling

Title 40: Protection of Environment

PART 261—IDENTIFICATION AND LISTING OF HAZARDOUS WASTE

Subpart D—Lists of Hazardous Wastes

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§ 261.31 Hazardous wastes from non-specific sources.

(a) The following solid wastes are listed hazardous wastes from non-specific sources unless they are excluded under §§ 260.20 and 260.22 and listed in appendix IX.

Industry and EPA hazardous waste No.	Hazardous waste	Hazard code
F003	The following spent non-halogenated solvents: Xylene**, acetone,** ethyl acetate, ethyl benzene, ethyl ether, methyl isobutyl ketone, n-butyl alcohol, cyclohexanone, and methanol; all spent solvent mixtures/blends containing, before use, only the above spent non-halogenated solvents; and all spent solvent mixtures/blends containing, before use, one or more of the above non-halogenated solvents, and, a total of ten percent or more (by volume) of one or more of those solvents listed in F001, F002, F004, and F005; and still bottoms from the recovery of these spent solvents and spent solvent mixtures	**(I)***

*(I,T) should be used to specify mixtures that are ignitable and contain toxic constituents.

The "I" asterisk means that it's listed due to the "ignitability" characteristic. Now look at the definition of hazardous waste under 261.3, you can see that it excludes non-toxic ignitables (as well as corrosives and reactives) if they no longer exhibit the characteristic hazard (according to Subpart C)

§ 261.3 Definition of hazardous waste

(g)(1**) A hazardous waste that is listed in subpart D** of this part **solely because it exhibits one or more characteristics of ignitability** as defined under § 261.21, corrosivity as defined under § 261.22, or reactivity as defined under § 261.23 **is not a hazardous waste, if the waste no longer exhibits any characteristic of hazardous waste** identified in subpart C of this part.

(2) The exclusion described in paragraph (g)(1) of this section also pertains to:

(i) Any mixture of a solid waste and a hazardous waste listed in subpart D of this part solely because it exhibits the characteristics of ignitability, corrosivity, or reactivity as regulated under paragraph (a)(2)(iv) of this section ***(this would include the acetone contaminated wipes)***