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Technical Bulletin

Worker Personal Protective Equipment (PPE) Tips for Peracetic Acid Use in Pharmaceutical Manufacturing Industry

Executive Summary

Peracetic Acid (PAA) is a hazardous chemical found in some products often sold with anti-microbial claims (e.g. sanitizer, disinfectant, sporicide, sterilant). PAA can become airborne and has some relatively low exposure limits, but exposure assessment can be difficult due to its chemical nature and lack of simple, inexpensive, and validated sampling methods. In addition to the difficulty in accurately characterizing potential worker exposure, the regulatory framework for anti-microbial products may be useful to understand when performing risk assessments for PAA-containing products to determine appropriate exposure controls. This paper is intended to help health and safety professionals with this type of risk assessment background information and tips on selection of personal protective equipment such as respirators to help control worker exposure to PAA.

Hazards of Peracetic Acid

PAA, also known as peroxyacetic acid, is a strong oxidizer often used as a biocide in disinfectant products. It is always present in an equilibrium mixture with hydrogen peroxide and acetic acid (aka vinegar) due to its chemical nature, which rapidly breaks down in the environment to oxygen, water and acetic acid. PAA is corrosive to eyes and skin with direct contact and has some volatility, so worker exposure can occur to airborne aerosol and vapor. The hazard classification under the Globally Harmonized System (GHS) will vary depending on the chemical concentration and product formulation, but typical disinfectant products as sold may be classified as flammable, oxidizer, toxic, corrosive and hazardous to the environment.

Toxicity data for Peracetic Acid indicates sensory irritation as the suggested endpoint that might be used to derive occupational inhalation exposure limits. In an evaluation of the available data, a combination approach of both an 8-hour Time Weighted Average (TWA) and a Short-Term Exposure Limit (STEL) was recommended for PAA. A range of 0.1-0.2 ppm for the TWA and 0.4-0.5 ppm for the STEL was proposed as a basis for PAA occupational risk management decisions in a 2015 toxicity data review by Pechacek, et. al.

Occupational Exposure Limits (OELs) have been published and proposed for Peracetic Acid (PAA), Hydrogen Peroxide (HP), and Acetic Acid (AA) and are summarized on the table below:

OEL Type	Peracetic Acid	Hydrogen Peroxide	Acetic Acid
CalOSHA PEL	0.2 ppm (TWA Draft)	1 ppm (TWA)	10 ppm (TWA)
ACGIH TLV	0.4 ppm (STEL)	1 ppm (TWA)	10 ppm (TWA)
OSHA PEL	None	1 ppm (TWA)	10 ppm (TWA)

Note the ACGIH Mixture Formula for interpretation of exposure monitoring data, where the sum of the weighted values of all three components of PAA products are used when interpreting monitoring results, is used by NIOSH in a recent publication[8]. The upper end (0.2 ppm TWA) of the proposed OEL range for PAA in the toxicity data review was used in this formula:

[HP]	+	[PAA]	+	[AA]	=	X, where X < 1 or X > 1
1 ppm		0.2 ppm		10 ppm		for exposure risk judgements

The increasing use of PAA, its ability to become airborne, and relatively low OELs have led to an increased need to review company PPE and risk assessments for those applications.

US Regulatory Considerations That Influence PPE

OSHA

Peracetic Acid is a hazardous chemical as defined by the Occupational Safety and Health Administration (OSHA) Hazard Communication Standard so workers are expected to have access to hazard information, such as safety data sheets (SDS) and labels, in addition to training on how to protect themselves. While the precautionary information provided in the SDS can be used as general recommendations, the employer is expected to conduct a workplace-specific assessment to manage the risk of PAA handling. In addition, the OSHA Respiratory Protection Standard applies if respirators are worn in the workplace (see the 3M Administrative Respiratory Program Brochure for more information on this Standard).

EPA

When antimicrobial claims are desired for a PAA-containing product, such as for marketing as a surface disinfectant or sanitizer, the product is regulated as a pesticide under the Environmental Protection Agency (EPA) Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA). The types of claims desired will dictate the test methods and subsequent use instructions for the PAA-containing product. Test methods can vary for different claims and product application types such as sprays and wipes. Potential EPA Pesticide Product Label (PPL) statements are derived from the approved Master Label for a tested product formulation which can be identified by its EPA Registration Number. Approved claims and their related use instructions can be reviewed on the EPA PPLS website. Note the EPA Label may also contain precautionary information including PPE, like respiratory protection, and will always state "It is a violation of Federal law to use this product in a manner inconsistent with its labeling."

FDA

When a PAA-containing product is planned to be marketed as a high-level disinfectant or cold sterilant for processing reusable medical devices, the Food and Drug Administration (FDA), rather than the EPA, has jurisdiction. These applications are different from the non-critical surface disinfection or sanitization applications mentioned above and typically fall under the Spaulding Classification of semi-critical (see the CDC Guidelines for Disinfection and Sterilization in Healthcare Facilities for more information). The FDA Label may then also contain precautionary information for handling in the workplace.

Sometimes there may be a potential for conflict in precautionary information, such as PPE, when products are regulated by both the OSHA Hazard Communication (HazCom) Standard and the EPA or FDA. Also, any deviation or “off-label” use of these products that conflicts with their EPA or FDA use instructions for antimicrobial applications is not allowed by Federal law. Therefore, if an application method is prescribed by the label, such as spray-application, the product must by applied in that manner as per EPA regulation. Since the EPA has not adopted GHS, but OSHA has in the 2012 amendment of the HazCom Standard, a Pesticide Registration Notice (PRN) was issued by the EPA in 2012 recommending EPA Label information be included on OSHA SDS’s along with an explanation of the differences.

There may be applications where PAA-containing products are used to reduce or “neutralize” chemical contamination on surfaces, such as hazardous drug residues, rather than for their antimicrobial claims under EPA or FDA regulation. It should be noted that there is no regulatory approval process for products claiming to remove this type of chemical contamination. Employers are encouraged to carefully review both the SDS and Labels for these products and intended applications when conducting their workplace-specific risk assessments to determine worker handling practices and PPE. Note the labels for these products will still reflect only their prescribed EPA or FDA required content and deviation from those use instructions may become problematic even though the desired objective is not disinfection.

Note since PAA is a strong oxidizer and can degrade quickly, it is important to carefully review the shelf life information on the EPA label. Even when not used for its disinfectant claims, the oxidizing potential relied upon for effective decontamination may be affected by a short shelf life.

Understanding the regulatory framework for PAA-containing products can help with understanding the variables and constants for potential risk management measures.

Hazardous Drugs and Pharmaceutical Manufacturing Applications

PAA-containing products can have many applications where pharmaceuticals are manufactured, processed or administered. These activities often are accompanied by cleaning, sanitizing, disinfecting, sterilizing or neutralizing and PAA-containing products may be chosen by facilities for all these tasks. Increased use of PAA may also be expected due to increased public scrutiny and regulatory pressure around contaminated products and worker health.

The nature of these cleaning and disinfecting tasks often means repeatedly using higher PAA concentrations spread over large surface areas, which may result in significant worker exposures. Keep in mind that these EPA-regulated products must be used according to label directions, which can limit opportunities for reducing exposure by changing the way a product is used (such as not spraying when the product label indicates to apply using a sprayer or not maintaining a wet surface for the appropriate contact time).

Worker Exposure Assessment Methods

Exposure assessment is a key component of managing the risk when workers are handling PAA-containing products and a required step in the process of determining the need for respiratory protection. Understanding potential inhalation exposure can be broadly grouped into two types: qualitative and quantitative exposure assessment. Air monitoring accomplishes the latter, as the objective is to quantitate the amount of airborne PAA in the worker’s breathing zone during relevant tasks. Air monitoring methods can be divided into two main types: direct-reading where a device can provide results right away, often in real-time as the work tasks are being conducted; and methods that require laboratory analysis, so results are not available until later and typically only represent an average concentration over the time period sampled (Time-Weighted Average or TWA). Qualitative exposure assessments are those which do not involve actual measurements, but instead may rely on data from studies or judgements about exposure potential based on mathematical modeling, professional experience, or other inputs.

Air monitoring for PAA can be challenging but improvements are in demand with the increased market use of these products and evolving exposure concerns. Since airborne PAA will always be accompanied by hydrogen peroxide and acetic acid, one challenge is to separate those components. Some methods are not able to accomplish this and so cross-reactivity may be problematic. Because the chemistry is highly reactive, another challenge can be in measuring the PAA concentration before it degrades. If airborne aerosol as well as vapor is being generated, then vaporization from the aerosol as well as reactivity during this process can further complicate exposure characterization. This same reactive and mixed nature of the airborne chemistry makes qualitative exposure assessment using modeling equations very difficult.

Understanding potential exposure variables has historically meant considering all aspects of the worker interface with the contaminant source, such as the task being performed, available ventilation or other engineering controls, and aspects such as the length of time spent in the various exposure scenarios. Concentration of the chemical(s) being used is another important

variable and can be particularly relevant for disinfectant products such as PAA. These products can be used at a variety of concentrations depending on the application, such as sanitizer vs. disinfectant vs. sterilant. Sometimes the products are sold at one concentration considered "ready-to-use" but many are sold in concentrated form which may be diluted to a variety of strengths depending on the intended use. It is important to consider possible dilution error with concentrated products, even with automated proportioner systems, as exposure potential might change significantly without assessor knowledge if correct dilution is always assumed. Contact time is another potential exposure variable relevant for disinfectants because it can influence the amount of chemical available for volatilizing from surfaces being cleaned. This is the amount of time, usually in minutes, that the entire surface must remain visibly wet with product for the corresponding microbial kill claim desired. For example, the same product might have a sanitizing (lower) kill claim at a lower concentration and/or contact time but might be capable of a sporicidal (higher) kill claim when used at a higher concentration or longer contact time.

With air monitoring then being the primary method for understanding PAA exposure, and therefore risk, it is important to understand the limitations of current air sampling methods so exposure is not underestimated when performing a risk assessment.

While OSHA is working on validated methods for PAA air sampling none currently exist, but some research has been done using a variety of methods indicated here. Also, some of these methods are more amenable to area sampling rather than for the personal sampling necessary to better understand worker exposure.

Direct-reading air monitoring methods are available for PAA but both require equipment that can be expensive and require some level of training to use. Electrochemical sensors and Fourier-Transform Infrared Spectroscopy (FTIR) are the technologies currently in use to monitor PAA directly in the workplace and both can provide real-time results. Methods that require laboratory analysis will first collect air samples on some type of media, which might vary depending on the type of analysis and if the intent is to capture airborne aerosol, vapor, or both. The sample media is then sent to the laboratory where the general analytical technique is often High-Performance Liquid Chromatography (HPLC). The use of specific laboratories familiar with this type of industrial hygiene chemistry work and accredited by the American Industrial Hygiene Association (AIHA) is recommended if this type of air sampling is pursued.

Few published studies exist that might be used for understanding potential exposure, but below is a brief summary of their data:

- Field evaluation of five workplace settings where PAA products were used for non-critical surface disinfection tasks tested the feasibility of a new PAA air sampling and analysis method. Results ranged from the detection limit of 0.013 ppm to 0.4 ppm.[4]
- Field evaluation of semi-critical disinfection tasks (endoscope re-processing) using PAA product to evaluate a new PAA air sampling and analysis method indicated short term exposure to PAA could be elevated under some circumstances but the 8 hour TWA exposure was low.[7]
- Data from a graduate student study on non-critical surface disinfectant exposure assessment was given as part of a presentation at APIC 2018 - The Industrial Hygienist's Role in Improving Safety for Patients and Workers. This study compared exposure from several different disinfectant chemistries, including peracetic acid monitored using FTIR. STEL exposure scenario results indicated only PAA exposure exceeded the OEL of 0.4 ppm.[6]
- A NIOSH Health Hazard Evaluation (HHE) where over 40 air samples were collected during use of a PAA product in healthcare non-critical surface disinfection, all below OELs.[8]

PPE for Worker Protection

OSHA's PPE Standard requires an assessment be conducted and documented by certification to determine appropriate PPE for worker tasks where hazards exist (see 29 CFR 1910.132). Risk assessments should consider both the hazard and the potential exposure, where qualitative and/or quantitative exposure assessment such as through air sampling are often done to help evaluate inhalation exposure. In some industries such as pharmaceutical manufacturing, the practice of occupational exposure banding may be used to help establish risk management measures (see 3M OEB Bulletin for more information). While typically

used for potent compound exposure, this approach might be useful for other applications where there are relatively low exposure limits and difficulty in accurately characterizing exposure.

Exposure controls that reduce inhalation exposure should be considered where an employer's risk assessment indicates that the respiratory hazard may result in unacceptable adverse health effects. Where respiratory protection is chosen as an inhalation exposure control, the NIOSH Respirator Selection Logic is one resource for determining an appropriate respirator. Part of that Logic is consideration of the Assigned Protection Factor (APF) needed, based on the level of exposure. Also, consideration needs to be given to any Immediately Dangerous to Life or Health (IDLH) level that might have been established. Note in 2015 NIOSH published a draft IDLH for PAA of 0.64 ppm; however, numerous comments resulted in a NIOSH re-evaluation of the proposed IDLH with no additional proposals to date. Another thing to keep in mind are the points at the beginning of this paper on the additional chemicals always present with PAA and application of the ACGIH mixture formula when determining exposure.

Respirator manufacturers may also have publications which can help with respirator selection for PAA. Information on the type of respirator (including cartridge and filter if applicable) recommended, along with cartridge service life data should be requested of the supplier to help satisfy requirements of the OSHA Respiratory Protection Standard (29 CFR 1910.134). See the 3M Technical Bulletin "Respiratory Protection for Hydrogen Peroxide, Peracetic Acid, and Acetic Acid" for more information on 3M respirator products for PAA. Respiratory protection that includes suitable eye protection such as a full facepiece respirator or PAPR with appropriate headgear may want to be considered, due to the eye irritation potential of PAA-containing products.

Selection of appropriate PPE should also consider the need for eye and skinprotectiondueto the potentially irritating or corrosive nature of PAA. Tasks that may result in eye or skin contact with liquid require eye and face protection, gloves and body coverings such as coveralls. Vapor or aerosol presence may require goggles or respiratory protection that includes suitable eye protection. Manufacturer-provided selection guides may be helpful in choosing appropriate eye and skin protection. Keep in mind the nature of the task, including chemical concentration and extent of potential eye and skin contact, when selecting PPE. More information on 3M products can be found at www.3M.com/workersafety.

References

1) Pechacek, N. et. al. Evaluation of the toxicity data for peracetic acid in deriving occupational exposure limits: A minireview. Toxicology Letters 233 (2015) 45-47.
2) Casey, M. et. al. Health problems and disinfectant product exposure among staff at a large multispecialty hospital. American Journal of Infection Control 45 (2017) 1133-8.
3) https://www.epa.gov/pesticide-analytical-methods/antimicrobial-testing-methods-procedures-mb-15-04
4) Nordling, J. et. al. Description and evaluation of a peracetic acid air sampling and analysis method. Toxicology and Industrial Health 33 (2017) 922-929.
5) https://www.epa.gov/pesticide-labels/pesticide-labels-and-ghs-comparison-and-samples
6) Thompson, K. et. al. APIC 2018 Education Session 3009 - The Industrial Hygienist's Role in Improving Safety for Patients and Workers, Industrial Hygiene Exposure Assessment: Non-Critical Surface Disinfectants. Minneapolis, MN.
7) Pacenti, M. et. al. Air Monitoring and Assessment of Occupational Exposure to Peracetic Acid in a Hospital Environment. Industrial Health 48 (2010) 217-221.
8) Hawley, B. et. al. Evaluation of exposure to a new cleaning and disinfection product and symptoms in hospital employees, NIOSH HHE Report No. 2015-0053-3269.
9) NIOSH Respirator Selection Logic 2004. DHHS (NIOSH) Publication Number 2005-100.

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