



WORLD LEADERS IN EMERGENCY EYE CARE

**How to Identify Safe and Effective  
Emergency Eyewash — and the  
Hidden Dangers to Avoid**

# How to Identify Safe and Effective Emergency Eyewash — and the Hidden Dangers to Avoid

The human eye is a complex and intricate organ that provides us with the invaluable sense of sight. Commonly referred to as our windows to the world, eyes allow us to take in the majority of information we obtain about the environment around us. In fact, experts agree that the eyes contribute nearly 85 percent of an individual's total knowledge. Because we rely on our eyes for nearly every activity we perform, most individuals value the sense of sight above all others.

The eyes are considered the most complex organs in the human body, second only to the brain. Each eye is made up of more than 2 million working parts and is capable of detecting more than 10 million colors. The human eye can process 36,000 bits of information every hour, and its lens is faster than any existing camera lens. No human inventions, including computer-assisted cameras, rival the human eye in complexity and function.

Measuring about an inch in diameter in adulthood, the eye is made up of three tissue layers. The outer layer is the cornea, a clear covering that helps focus light entering the eye. The middle layer is the iris, whose adjustable circular opening – the pupil – contracts and expands to control the amount of light that travels deeper into the eye. Located at the back of the eye is the retina. Measuring approximately a quarter millimeter thick, the retina is made up of ten distinct layers and contains more than 125 million receptors. It focuses images and sends electric signals to the brain via the optic nerve at a rate of 300 miles per hour. The brain translates these electric signals into the images we see. Because of its direct connection to the brain, the retina is considered part of the central nervous system.

## Protecting the eyes is crucial

Given the eyes' complexity, size and location, it is easy to understand that they are also extremely vulnerable to injury. Eyes are susceptible to hazards encountered every day outside of work such as flying or falling objects in the yard, sand and dust particles, chemicals and vapors from household cleaning products and even ultraviolet light. Likewise, most workplace environments contain potential eye hazards — and in many workplaces eye hazards are abundant.

For this reason, national standards are in place to protect individuals' eyes at work. In the U.S., the Occupational Safety and Health Administration (OSHA) requires employers to provide employees with suitable eye and face protection "whenever necessary to protect against chemical, environmental, radiological or mechanical irritants and hazards." While OSHA publishes the general framework for eye protection and emergency eyewash workplace practices and hazard assessments, it refers to the American National Standards Institute (ANSI) for performance requirements relating to personal protective equipment and eye safety. The Canada Occupational Health and Safety (OHS) regulations are similar in scope for that country to those set by OSHA in the U.S., while the Canadian Standards Association maintains detailed standards in a similar fashion to ANSI.

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According to OSHA, more than 2,000 people injure their eyes at work each day in the U.S. Roughly one in 10 of those individuals requires one or more missed workdays to recover, and 10 percent to 20 percent of all occupational eye injuries result in temporary or permanent vision loss, according to OSHA.

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ANSI Z87.1 compliant eye protection in the form of safety spectacles or goggles is suitable to protect from most common hazards found in the workplace. In identified high-hazard areas, however, face shields or welding helmets may be required to provide additional, secondary protection. Many employers supplement ANSI guidelines by implementing eye safety protocols above and beyond national standards to meet their site's specific needs and safety goals. Together, these national and corporate-level efforts have successfully reduced the number of occupational eye injuries in recent decades.

But still, workplace eye injuries are very common. According to OSHA, more than 2,000 people injure their eyes at work each day in the U.S. Roughly one in 10 of those individuals requires one or more missed workdays to recover, and 10 percent to 20 percent of all occupational eye injuries result in temporary or permanent vision loss, according to OSHA.

The cost of lost vision to an individual is immeasurable, spanning medical expenses, diminished quality of life and the reduced ability to earn a living. Furthermore, workplace eye injuries cost employers more than \$467 million in direct costs per year, according to the U.S. Bureau of Labor Statistics (BLS). Once indirect costs such as legal fees, judgments and training new workers are factored in, that estimated total exceeds \$934 million per year, according to Prevent Blindness America.

## Proper injury response is imperative

When an eye injury occurs, proper and immediate treatment is the best defense for both a positive outcome and minimal financial impact. The ANSI Z358.1-2009 standard for “Emergency Eyewash and Shower Equipment” establishes a universal minimum performance and use requirement for all eyewash and drench shower equipment used for the treatment of the eyes, face, and body of a person who has been exposed to hazardous materials and chemicals. Because there is no Canadian standard for the design or placement of eyewash stations, the ANSI standard is generally used as a guide in that country as well.

ANSI requires that the first step following chemical contact of any kind with the eye(s) – including caustics, acids, solvents and other hazardous materials – is immediate flushing of the eyes with water. According to the standard, such water may be any potable (drinking) water, preserved water, preserved buffered saline solution or other medically acceptable solution.

The first 10 to 15 seconds after exposure to a hazardous substance, especially a corrosive substance, are critical. Delaying treatment, even for a few seconds, may cause serious injury. For this reason, ANSI calls for eyewash stations to be located within a 10-second walk from the hazard. To ensure easy access to a station within ten seconds, it must be located on the same level as the hazard with no steps, stairs or obstructions. In the case of strong caustics and strong acids, eyewash must be located immediately adjacent to the hazard. The area surrounding the station should be well lit and marked with a sign that is highly visible to everyone served by it.

Once an injured worker reaches the station, ANSI calls for the eyes to be flushed continuously for a full 15 minutes with fluid flowing at a rate of 0.4 gallons per minute for portable and plumbed eyewash stations. This fluid must be delivered at a tepid temperature, defined as ranging between 60°F and 100°F, in order to safely treat eyes without causing further injury or discomfort. Fluid that is too cold may prevent the worker from flushing for the full 15 minutes, and fluid exceeding 100 degrees can harm the eyes and even exacerbate chemical reaction with the eyes and skin.

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## Primary eyewash delivery options

ANSI calls for eyewash to be present at the site of any hazardous material that can cause adverse effects on an individual's health and safety. Because such hazards exist in nearly every workplace, primary eyewash stations are also required in nearly every workplace. The options available for eyewash delivery systems and the fluids they deliver are vast — but not all flushing fluids are equal in content, manufacture, safety or even intended use. Making informed selections can significantly affect the outcome of an injury to an individual and its impact on an employer.

### ***Plumbed units***

Primary eyewash can be delivered by either a plumbed or a portable unit.

Plumbed eyewash stations have been a long-standing solution because they deliver tap water in plentiful amounts. However, they are expensive to install, impractical to move and require weekly maintenance. Furthermore, tap water has been proven detrimental in treating injured eyes. Because its temperature is not easily regulated, plumbed water is often too hot or too cold to carry out ANSI's required 15-minute flush. Since it does not match the eye's natural pH, flushing with it can cause further irritation. Similarly, harmful microorganisms and other contaminants commonly found in tap water can cause serious long-term effects.

A 2008 study by the Associated Press found that public drinking water for at least 41 million Americans was polluted with chemical contaminants. A study conducted by the Environmental Working Group found that water utilities nationwide detected more than 300 pollutants between 2004 and 2009. Many of the microorganisms and contaminants found in tap water can cause secondary injury and even vision loss when used in treating an already compromised eye.

### ***Portable units***

Portable eyewash stations are available in a variety of styles and sizes to meet nearly any facility's needs. As their name implies, portable units can easily be moved and are compact enough to fit into nearly any workspace. Units with features such as alarms, view-through windows for easy maintenance and heated coverings for cold-weather applications make portable units easier than ever to install, use and maintain.

Because they are self-contained, portable eyewash units store and deliver preserved and/or pH-balanced water, saline solution or 100% sterile saline at room temperature for safe and comfortable flushing.

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The fluid in sealed-cartridge stations provides the longest shelf life – up to 24 months – and therefore such stations require the least frequent maintenance, involving monthly visual checks. Portable units containing buffered saline solution closely match the natural pH of the eye to protect it during flushing. Portable stations that deliver pH-balanced, buffered, 100% sterile saline offer unrivaled flushing safety.

### ***Secondary or supplemental eyewash***

Secondary, or supplemental, eyewash can be delivered in bottles or smaller portable stations. Secondary eyewash does not have the fluid capacity to flush both eyes at the rate of primary eyewash. Rather, ANSI states that supplemental eyewash “supports primary plumbed units, self-contained units or both by delivering immediate flushing fluid.” Secondary bottles or stations are required at the site of nuisance particles such as pollen, dust, sawdust and smoke as well as places where very caustic substances exist. In the case of electric storage battery handling, charging and maintenance areas where the extent of possible employee exposure to electrolytes is small, an eyewash device that contains no less than one gallon of water is an acceptable alternative to a primary station.

Secondary bottles and stations are well-suited for use in confined spaces that can’t accommodate a full-sized primary unit. Furthermore, secondary eyewash systems can be as critical for the treatment of an injured eye as their primary counterparts. In the case of chemical or caustic eye injury, eyewash bottles provide immediate treatment en route to a primary eyewash unit. They also provide continuous irrigation on the way to medical care. Available in a variety of sizes, personal eyewash bottles are small and highly portable, and can be made readily available at the site of any hazard.

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Not all flushing fluids are created equal. Treating an injured eye with sub-standard fluid increases risk of irritation, allergic reaction or infection; can prolong the length of recovery; and can even lead to permanent vision loss for the affected individual. Such negative results can significantly impact an employer’s bottom line as well.

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## **Not all flushing fluids are created equal**

It is important to understand that — no matter how they are delivered — flushing fluids vary in many ways. They may be derived from tap, potable, purified or sterile water and they are offered in various end products ranging from concentrates or additives, which are added to water, to purified or sterile solutions that are premixed. Differences in ingredients and manufacturing processes also exist.

For these reasons, not all flushing fluids are created equal. Treating an injured eye with sub-standard fluid increases risk of irritation, allergic reaction or infection; can prolong the length of recovery; and can even lead to permanent vision loss for the affected individual. Such negative results can significantly impact an employer’s bottom line as well.



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When manufactured using poor-quality ingredients or large amounts of additives, non-sterile fluid can in fact be detrimental. For example, chemicals such as boric acid, benzalkonium chloride and benzethonium chloride are commonly used to kill bacteria or prevent its growth in non-sterile fluids or fluids that are not sterile from inception. These and other additives and preservatives have the potential to introduce harmful impurities, cause an allergic reaction, lengthen recovery and increase the chance of infection and disability.

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## Eyewash regulation

Flushing fluid enters the body through an open orifice and can potentially introduce harmful elements; for this reason eyewash is regulated as an over-the-counter ophthalmic drug by the U.S. Food and Drug Administration (FDA). In Canada, emergency eyewash is regulated by Health Canada and is classified as a Medical Device and/or Natural Health Product. In most other countries emergency eyewash is also regulated by equivalent organizations. Aside from tap water, which is regulated by the Environmental Protection Agency in the U.S., all forms of eyewash fluid must be registered with the FDA as an OTC ophthalmic drug.

Entities wishing to market eyewash in the U.S. may be manufacturers, distributors, repackagers, relabelers and foreign firms. In order to gain permission to do so, each entity must meet minimum requirements set forth by the FDA. The FDA requires that current good manufacturing practices are followed, and that the manufacture of fluids is conducted in accordance with that agency's Quality Systems Regulation. Drug facts must be listed in a standardized fashion on the product's label, and brand names and manufacturing information must be confirmed accurate.

Eyewash marketers and manufacturers are required to have a National Drug Code, or NDC, which is then listed on the FDA Web site. Entities wishing to change the brand name or the label must re-register with the FDA. This process ensures that purchasers and end-users can easily look up a drug's compliance with FDA standards by searching for its NDC number, brand or product name, manufacturer name or by active ingredient on the FDA Web site.

## Hidden dangers of flushing fluids

### *Non-sterile solution*

Despite government controls and oversight, there is a lot to look out for when selecting emergency eyewash. The most commonly used flushing fluids are not sterile and include concentrate, additive and purified water as well as saline. Yet the use of such fluids does not guarantee safe treatment, as most of these are left to the consumer to ensure proper mixing and measuring.

Furthermore, when manufactured using poor-quality ingredients or large amounts of additives, non-sterile fluid can in fact be detrimental. For example, chemicals such as boric acid, benzalkonium chloride and benzethonium chloride are commonly used to kill bacteria or prevent its growth in non-sterile fluids or fluids that are not sterile from inception. These and other additives and preservatives have the potential to introduce harmful impurities, cause an allergic reaction, lengthen recovery and increase the chance of infection and disability.

Regarding ophthalmic drug products, the U.S. Code of Federal Regulations (21 CFR 200.50) states, “The Food and Drug Administration concludes that all such preparations (offered or intended for ophthalmic use), if they are not sterile, fall below their professed standard of purity or quality and may be unsafe.”

### ***Sterile solution***

The 21 CFR 200.50 regulation goes on to state: “Informed medical opinion is in agreement that all preparations offered or intended for ophthalmic use, including preparation for cleansing the eyes, should be sterile. It is further evident that such preparations purport to be of such purity and quality as to be suitable for safe use in the eyes.”

Buffered, sterile saline is the safest ophthalmic flushing fluid for two reasons: first, because its properties are physiologically compatible with human tears and second, because it is devoid of impurities. These attributes minimize the likelihood of irritation, infection or allergic reaction and maximize the chance for a positive outcome.

The manufacture of sterile, buffered saline through aseptic production is rigorous and requires compliance with process controls, inspections and testing. Aseptically filled sterile eyewash is conducted in a clean room using filtration and demanding controls. The result is the type of eyewash that assures 100% purity as well as pH and isotonic qualities that match those of the human eye.

The other process used in creating sterile eyewash is gamma irradiation, which also requires manufacture in a clean room. In this case, a non-sterile eyewash bag or bottle is filled with non-sterile fluid; the package is then irradiated as a whole to achieve sterilization. When gamma irradiation is employed on these types of products, the end product may still contain traces of chlorine, boric acid and other harmful chemicals used in manufacturing the fluid. The presence of such residual elements leads to harsher flushing conditions that can cause reddening or burning sensations in the eyes and make a continuous flush extremely uncomfortable.

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## How to qualify safe, effective eyewash manufacturers and distributors

- Check for a NDC, which ensures the product is approved by the FDA.
  - Next, review the list of ingredients. Look for sterile saline that is produced from 100% sterile water from the inception
  - Confirm that the fluid is intended for use in the eyes. Ask your distributor, contact the manufacturer directly or visit [www.FDA.gov/drugs](http://www.FDA.gov/drugs) to search the National Drug Code directory for registered products.
  - If the fluid has a New Product Application (NPA), be wary.
  - Consider buying products made in the U.S.A.
  - Heed expiration dates.
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## Sterile saline intended for other uses

Significant differences exist even among sterile flushing fluids, and not all are suitable for treating injured eyes. Just because a fluid is FDA approved and carries a NDC does not ensure that it is safe for ophthalmic use. Sterile saline products are registered by the FDA for specific applications.

For example, sterile saline registered as a surgery product may be intended for flushing tissue during surgery. While it is labeled as a medical-grade product, the fluid's ingredients are not approved for safe use in the eyes. Only sterile saline labeled for ophthalmic use is appropriate to use as emergency eyewash. Other sterile saline solutions may not be pH balanced to match the human eye and can contain elements that are harmful to the eyes' delicate tissue.

## How to qualify safe, effective eyewash manufacturers and distributors

Employers need a reliable source for safe, effective eyewash. Given the multitude of variables involved, making a selection can prove challenging. Here are the top considerations for qualifying a reliable eyewash supplier.

- The first step to qualifying a source is to check for a NDC, which ensures the product is approved by the FDA. Visit [www.FDA.gov/drugs](http://www.FDA.gov/drugs) to search the national drug code directory for registered products. Products are listed and are searchable by NDC number, label, brand and manufacturer. In addition, drug recall information and alerts are available here. Be sure to review a product's recall history. If the manufacturer's product has been recalled, it signifies that its manufacturing process may not meet FDA requirements and the product may be considered unsafe.
- Next, review the list of ingredients. Look for sterile saline that is produced from 100% sterile water from the inception and uses sodium chlorides (salt) only for the purpose of matching the pH to that of the human eye. Beware of solutions containing numerous additives or chemicals which may introduce irritants, allergens or worse. Tamper resistant packaging is the best option to ensure safety and purity.
- It is extremely important to confirm that the fluid is intended for use in the eyes. Ask your distributor, contact the manufacturer directly or visit [www.FDA.gov/drugs](http://www.FDA.gov/drugs) to search the National Drug Code directory for registered products. Look for the 21 CFR 200.50, which denotes an ophthalmic-grade product.

- If the fluid has a New Product Application (NPA), be wary. This means it has been approved as a new product based on paperwork but has not yet undergone and passed thorough audits and testing by the FDA. Products with a NPA have not yet been granted a NDC and the manufacturer or supplier may not be a reliable source.
- Consider buying products made in the U.S.A. Domestic manufacturing regulations and inspections are more stringent than those in some overseas markets.
- Heed expiration dates. Products are tested and approved to maintain efficacy for a measured length of time and are approved by the FDA according to those parameters. After time, compounds can change form, packaging can degrade and drugs may lose their ability to perform at safe standards. Be sure to renew eyewash solution according to the manufacturer's guidelines to ensure its sterility and stability.

Despite a decline in eye injuries, such occurrences are still very common in the workplace. National standards and private safety programs alike continue to evolve to provide workers with greater levels of protection. But when accidents happen, an employer's best defense is to immediately administer the safest and most effective treatment possible.

While the FDA states that ophthalmic drug products should be sterile, ANSI does not require that emergency eyewash solution or its delivery mechanism be sterile. Yet the dangers of administering non-sterile eyewash can have profoundly negative impacts on injured individuals, as well as their employers.

By selecting a reputable manufacturer that supplies FDA-approved, sterile, ophthalmic-grade eyewash, employers benefit from uninterrupted access to a product with superior integrity. That translates into the highest level of care for workers in the event of an eye injury. When workers recover quickly, companies recover quickly, and the safety benefits of exceptional eyewash are clear for everyone to see.

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