CONFORMITY OF PREVOR EMERGENCY SOLUTIONS IN THE FACE OF CHEMICAL SPLASHES

EUROPEAN STANDARD OVERVIEW

EN 15154

Published and effective since June 2009

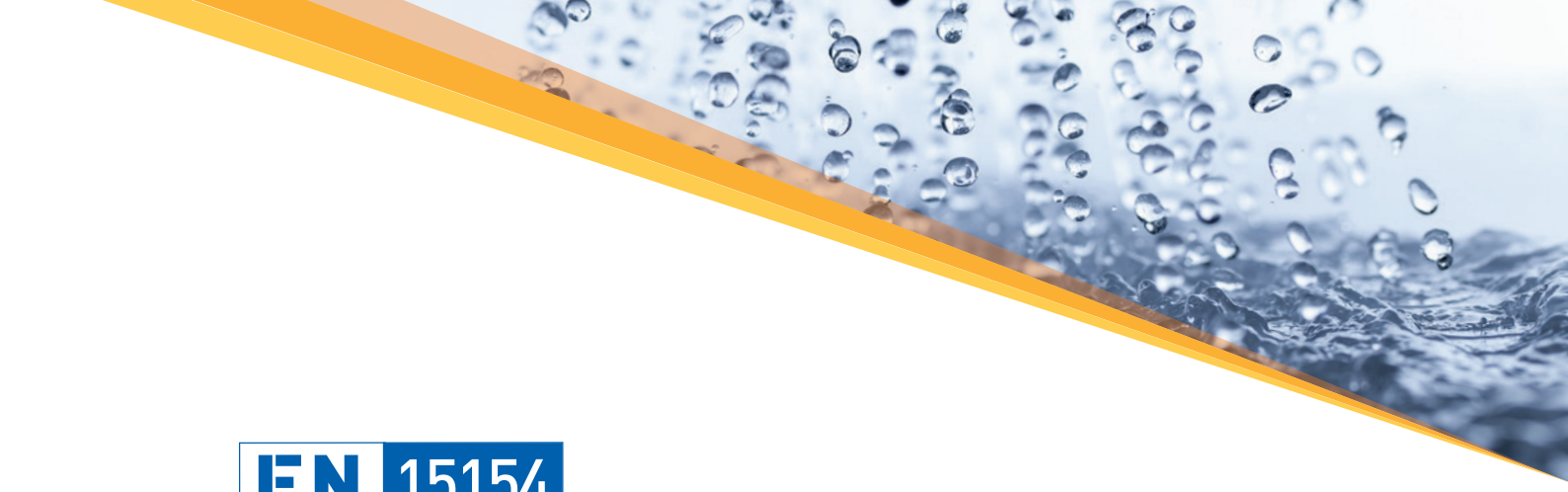
CEN TC 332

PREVOR

ANTICIPATE AND SAVE

Toxicology Laboratory & Chemical Risk Management

So that a chemical accident remains an incident



EN 15154

A safety standard for Europe

The European Committee for Standardization (CEN) is working toward a common standard for safety showers and eyewash units

Faced with the multiplicity of regulatory or normative recommendations in Europe and the existence of an American standard, the majority of European countries gathered together to create **a standard for safety showers and eyewash units.**

The project for European standards began in 2002. It aims to define the minimum requirements of performance for a safety shower and an eye wash unit. The draft standards are sent to the CEN for approval.

The European committee for standardization takes into account the countries and various players;

European standard organisation is based on a dual objective:

- **Bring together all voluntary countries** in an expert working group and maximise the exchange to obtain both quality and consensus. The WG6 (Work Group 6) regroups the following countries: Germany, Belgium, Denmark, Spain, Ireland, Luxembourg (Chair), France (secretariat), the Netherlands, Sweden, Switzerland, the United Kingdom and the United States (observer)
- **Bring together all the players**, regulatory or reference bodies (INRS in France), users, manufacturers, distributors, installers, certification bodies.

The debates are organised on two levels:

- The national level (mirror committee) which ventures its positions and sends them to all committees for general distribution.
- The European level (WG6) which seeks points of agreement in national positions or which technically resolves divergences. At the end of the discussions, the standards are sent to each country for public inquiry. The final agreements are then taken and the final draft of the standard is sent to the European Committee for Standardization (TC332) to be officially recorded as a standard. Each country then distributes the standard at a national level.

The United States and Europe exchange observers

In order to ensure the compatibility of standards which respects the independence of the two major organisations (European and American), the European and American committees exchange observers who can contribute with their point of view without participating in the decisions.

The European standard is a product standard validating several technologies.

COMPLY WITH EN 15154	Safety shower for the body		Eyewash	
	Plumbed-in	Non-plumbed	Plumbed-in	Non-plumbed
For laboratory use	EN 15154 Part 1	EN 15154 Part 3	EN 15154 Part 2	EN 15154 Part 4
Use other than laboratory: (Production, storage…)	NF X15 - 221 In preparation EN 15154 Part 5 & 6			

When justified, parts 3 and 4 are also relying on reference texts related to medical devices (Directive 93/42), drugs (Directive 2001/83) and sterility standards (EN 556-1&2).

The US standard is a product, installation and maintenance standard advocating installation less than 10 seconds from the hazard zone and weekly checks.

The US standard ANSI/ISEA Z358-2014 whose first version is dated from 1981 was reviewed for the last time in 2014. It is both a product standard like European standards but also an installation and maintenance standard.

The exchange of observers will ensure that the minimum requirements provide the same level of safety. As an installation standard, it recalls that **plumbed-in safety showers and eye wash units must be installed less that 10 seconds from the hazard zones, i.e. approximately 17m on the same floor and with no obstruction on the way**.

The US standard also recalls the importance of the weekly use of showers and eyewashes units in order to prevent the occurrence of sediment in the diffusers as well as microbial contamination. The duration of the test must take into account the length of connection to the installation.

OBJECTIVE: Have a European standard giving minimum requirements to the performance of safety showers and eye washers.

PREVOR OBJECTIVE: Describe the validation criteria of the efficacy in order to enable technical progress. Thanks to the standardization, companies using showers and eye wash units with active solutions conform with the standard are conform with the prevention objectives.

PRINCIPLE OF ACTION OF A CHEMICAL PRODUCT

COMPLY WITH EN 15154

To understand the construction of the standard, small reminder of the gravity of a chemical splash. The gravity of a splash depends on 5 criteria, 3 are related to the agressive product, 2 depend on the first aid given.

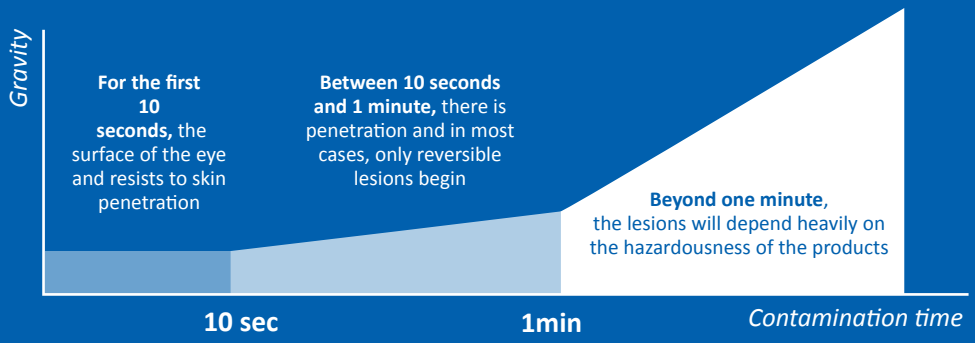
Criteria depending on the agressive product

- **The product:** its corrosive or irritating character.
- **Its concentration** : the higher the concentration, the more dangerous the product is.
- **Its temperature:** the higher the temperature, the more active the product is.

Criteria depending on the washing means

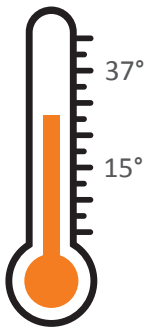
- **The effectiveness of the washing** (external washing and decontamination of the tissues) depends on the nature of the washing solution, its flow rate and the washing time.
- **The intervention time** depends on the installation.

The penetration and appearance of the symptoms depend on the hazardousness of the product, but we can draw some EMPIRICAL RULES:



WASHING TEMPERATURE AND HYPOTHERMIA

COMPLY WITH EN 15154



The washing duration greatly affects the influence of the cooling of the water on the body.

Water of safety showers usually come from underground pipes with a temperature between 10 and 12°C. A 15 min washing at 60 l / min (900 l) may cause hypothermia requiring to stop the decontamination.

This is why all standards (European and American) recommend a washing temperature between 15° and 37°C. The use of active solutions enabling a reduction in the washing volume avoids this constraint.

Plumbed-in devices remove the chemicals to enable potential treatment

The purpose of plumbed-in safety shower (Part 1) and eye wash units (Part 2) is to **immediately deliver a large volume of water** to **extinguish flames** and/or sufficiently **rinse or dilute the contaminants** to render them harmless. Once this has been accomplished, the injured person may receive medical care.

KEY REQUIREMENTS	SAFETY SHOWER	EYEWASH
Flow rate	- if no legislation: **60 l/min** - Operation: **15 min** **- 95% flow rate in diameter of 40 cm** **- Low enough velocity to be non-hazardous**	- **6l/min** - Operation: **15 min** **- Jet/nozzle height between 100 mm and 300 mm** **- Low enough velocity to be non-hazardous**
Water quality	- Potable water or of similar quality - No "contamination" from the installation	
Temperature	**- Temperature between 15° and 37°C to avoid stopping decontamination**	
Design requirement	- Height 2.2 m +/- 0.1 - Clearance> Radius 0.4 m - Single action opening in less than 1 sec	- Height 1 m +/- 0.1 - Nozzles must be protected - Single action opening in less than 1 sec
Information to be provided by the manufacturer	- Installation, operation and maintenance rules **- Method and frequency of routine testing**	
Marking	- Installation, operation and maintenance rules - Method and frequency of routine testing	

Autonomous devices are intended for immediate first aid interventions.

The first few seconds after accidental exposure of the body or parts of the body to hazardous substances or to heat, are crucial to minimise the damages caused. Non-plumbed safety showers (part 3) and safety eye wash units (part 4) are designed and intended to be located in the immediate vicinity of persons working in a potentially hazardous area. **These devices are mainly intended for immediate first aid interventions.**

These devices can also be used to carry out continuous washing during transport to the hospital.

A STANDARD TO IMPROVE PREVENTION

EN 15154

Active decontamination solutions permit to have safe and efficient first aid products at the workplace, if they comply with the standard. **Compliance with the standard means the manufacturer has an information obligation**. Thanks to this information, the informed choice of type of device and volume makes it possible to improve the intervention time and efficacy. This provides numerous possibilities for the organisation of prevention.

<table>
<tr><th>KEY REQUIREMENTS</th><th> 
SAFETY SHOWER</th><th> 
EYEWASH</th></tr>
<tr><td>Quality of solutions</td><td colspan="2">Water or saline solution, buffer or of similar such as chelating amphoteric solutions
- If water, it must be potable water or of similar quality and antiseptic
- If not, it must be sterile and non-hazardous (safety according to medical device directive)</td></tr>
<tr><td rowspan="2">Volume & efficacy</td><td colspan="2">If the solution is water, the following table gives the minima according to type of device
If not, the volume is chosen by the manufacturer, its efficacy must be demonstrated as equivalent to the minima.
The manufacturer shall provide a simple procedure for use of the product to dilute the hazardous substances and subsequent procedures for diluting a product until it is rendered harmless.</td></tr>
<tr><td>The procedures should be at least equivalent to the efficacy of a 15/minute water safety shower and a 60 l/min flow rate</td><td>The procedures should be at least equivalent to the efficacy of a 15/minute water eyewash unit and a 6 l/min flow rate</td></tr>
<tr><td>Classification of solutions</td><td colspan="2">Attention is drawn to the fact that the devices are medical devices (conform with EC Directive 93/42) or drugs (EC 2001/83)</td></tr>
<tr><td>Key mandatory information</td><td colspan="2">• Intended use
• Simple procedure for the use of the product to dilute hazardous substances and subsequent procedures for diluting a product until it is rendered harmless
• All chemical groups or specific chemicals that the unit permits to decontaminate
• Possible contraindications</td></tr>
</table>

Compliance with "medical device" or "drugs" directives ensures that the manufacturer has conducted all validations with documented evidence (innocuousness test, clinical study ...) in their preliminary file for marketing authorisation.

SAFETY SHOWER Single use / Multi-use / Refillable		EYEWASH UNIT Single use / Multi-use disposable / Multi-use reconditionable	
Fixed	100 L	**Transportable**	Mass > 15 kg wheel Mass > 20 kg handle
Portable	15 L	**Portable**	Mass < 2 Kg Volume > 400ml
Transportable	Mass < 15 Kg Volume > 10ml	**Individual**	150 ml

Specific case of portable water showers.

Portable thermal and chemical water showers shall have a minimum 10 litre volume and shall be accompanied by a simple procedure for use of the device allowing to dilute hazardous substances and subsequent procedures allowing to dilute the chemicals until they are rendered harmless.
The volume of showers reserved solely for the cooling of thermal burns may be less than 10 litres provided they have special marking and a heat reducing procedure.

CONFORMITY OF PREVOR® WASHING SOLUTIONS

All PREVOR®washing solutions (**DIPHOTERINE®**, **HEXAFLUORINE®**, Afterwash II®, NaCl by Prevor®) are Class IIa medical devices.

Class IIa medical devices are designed to be used on eye or injured skin. Given its use in the context of chemical accidents, the French and German governments have asked us to design our solutions in order to comply with this class. Since the safety and effectiveness of PREVOR solutions have been tested in this setting, there are no restrictions for use.

ADVANTAGE FOR THE USER:

1.

Our solutions can be used at the work station **without prior checking** of the condition of the eye or skin

2.

Our solutions can be used **on wounds contaminated** by chemicals in the event of associated shock

3.

Our solutions can be used **at a late stage**, even when lesions have appeared to stop the action of the chemical product

DIPHOTERINE® SOLUTION:

AN EXAMPLE OF THE CONFORMITY OF PREVOR SOLUTIONS

COMPLY WITH EN 15154

Autonomous portable shower (DAP)

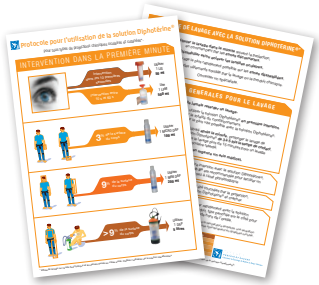
Sterilized Individual Eyewash (SIEW)

Portable Eyewash (LPM)

EFFICACY EQUIVALENCE

The washing efficacy of the **DIPHOTERINE®** solution enables the following protocols

	BODY		EYE		
Solution	Shower water	**DIPHOTERINE®** DAP	Eyewash water	**DIPHOTERINE®** LIS	**DIPHOTERINE®** LPM
Intervention time	10 sec	1 min	10 sec	10 sec	1 min
Rinse time	15 min	5 min	15 min	30 sec	3 min
Flow or volume	60L/min	5L	6L/min	50 ml	500 ml



All the information required under the standards EN 15154 is available on the product labels or their instruction manuals. The chemical groups and chemicals tested are available at www.prevor.com. Clear protocols are available on our web-site or on request as a poster.

SPECTRUM OF ACTIVITY

DIPHOTERINE® solution was designed to decontaminate corrosives, irritants and most chemicals. A complete list of tested products is available on-line at www.prevor.com. On request, an assessment of the effectiveness of the decontamination is conducted in our laboratories and with a written certification.

DIPHOTERINE® solution has limited efficacy on hydrofluoric acid.
It should be replaced by **HEXAFLUORINE®** solution.

DIPHOTERINE® solution is contraindicated on white phosphorus (incendiary bombs).

All information on standard conformity is available at EN 15154 www.prevor.com

PREVOR
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