

Guideline "Requirements regarding rinsing fluids for first aid"

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1. Facts

Immediate rinsing with plenty of water is the first alternative to counteract caustic poisoning, burns, scalding and contamination of all kinds according to current scientific knowledge. This is the most important measure used in first aid and is also the method applied immediately and universally by everybody successfully and without any reservation whatsoever. Apart from their mechanical cleansing features, eye wash stations and emergency showers also achieve the quick reduction of reaction and dilution heat because of their high flow speeds and volume. Experience gained in practical operation confirm the efficiency of rinsing with water if the victim and the first person helping have been instructed sufficiently and the rinsing is carried out without delay. The crucial prognosis factor for an accident victim is thus less the selection of the

rinsing fluid, but immediate, efficient rinsing, for a sufficient length of time with sufficient volumes of fluid! It must be ensured that there is a continuous availability of the fluid at all times; a loss of time before rinsing is begun must be avoided under all circumstances.

Rinsing fluids or solutions packed in other packages can be used

- in addition to available eye wash stations or emergency showers,
- when no drinking water, or water of comparable quality is available, or
- when special decontamination preparations are required
(e. g. for the decontamination of the skin when suffering from carbolic acid burns).

Rinsing must be performed immediately. The procurement of a specific rinsing fluid is not allowed to not delay the start of immediate rinsing. Prompt rinsing of the eyes, skin or mucous membranes is decisive for the immediate dilution or removal of caustic or poisonous substances to keep physical damage as low as possible.

Apart from stationary emergency showers or eye wash stations rinsing fluids can also be used at the place of work. However, there is no standard in Germany that can be called on for the evaluation of rinsing fluids as first aid preparations according to their biological, chemical and/or physical action. Therefore there is no uniform labelling available, regarding which requirements have been complied with.

2. Target groups and purposes

The target group of this guideline are the people responsible within their field of operations, for the implementation and use of rinsing fluids and the people in their respective areas of operations, acting as advisory capacities in regard to first aid questions.

If rinsing fluids are used, this guideline should provide the employers with evaluation criteria and information on the requirements for rinsing fluids as substances for first aid.

This guideline should also help them to compare the various preparations, enabling them to decide which rinsing fluid is suitable for their requirements.

This guideline was prepared by a committee of experts with practical experience and operational knowledge, using the pertinent literature. The guideline also describes application instructions and requirements for the products.

3. Range of application

This guideline applies to first aid measures for accidents with, for example, caustic or poisonous substances at the workplace, particularly when no eye wash stations or emergency showers are available.

They do not apply to secondary emergency treatment by qualified medical personnel, or to specific clinical medical treatment.

4. Definitions

Rinsing fluids in the sense of this guideline are fluids that are manufactured in advance and supplied in packages as first aid preparations to be used to rinse eyes or the skin in emergencies.

Eye rinsing fluids in the sense of this guideline are rinsing fluids especially prepared for application to the eyes.

5. Legal bases

The employer bears the responsibility for accident prevention and must ensure that the necessary first aid material and equipment are at disposal [regulations for the prevention of industrial accidents "Principles of Prevention" (BGV A 1- (Accident Prevention & insurance Association directives))].

The installation of emergency showers and eye wash station is required in the Basic Principles and Guidelines for laboratories (BGI/GUV-I 850-0e) and the technical regulations for hazardous material laboratories (TRGS 526) . Workplaces with similar hazards are also to be equipped with emergency showers and eye wash stations in compliance with the state of the art as described here.

If the installation of an eye wash station or an emergency shower is not possible, they both can be replaced with packaged rinsing fluids in divergence to these regulations.

The packages used for the eye rinsing fluids for acid burns of the eyes must comply with DIN 12930. This standard does not expressly apply to the rinsing fluids stored in these packages.

Rinsing fluids are either, drugs approved pursuant to the drug law by the Federal Institute for Drugs and Medical Devices (BfArM) / German Drug Agency, or Personal hygiene preparations pursuant to the cosmetics directives of the food and feed code, or Medicinal products pursuant to the medicinal product law or equivalent institutes in other European member states.

Further legal bases in national law are the workplace regulations in connection with the workplace ordinance (e.g. A 4.3) - the labour protection law - the hazardous materials directives and the following technical regulations governing the hazardous materials directives in the scope in which they still comply with the currently applicable law (e.g. TRGS 526).

Special measures of first aid are dealt with, in EU safety data sheets , the substance data sheets (M series) of the German Social Accident Insurance Institution for the raw materials and chemical industry (BG RCI) and in the GESTIS-, GISBAU- and GisChem data bases and in various specific Accident Prevention & insurance Association information (BGI) sheets.

6. Workplace use of rinsing fluids

Rinsing fluids can, taking the operational general conditions into account, be used as substance for first aid in accidents involving, for instance, caustic or poisonous substances. A sample directive on the use of eye rinsing packages for first aid is contained in Appendix 1.

A rinsing period of at least 10 to 20 minutes is required to achieve sufficient results. Experience has shown that approx. 5 to 10 litres of fluid are required for this time span; it is therefore necessary to keep a corresponding number of rinsing packages in stock.

The further treatment of the accident victim with rinsing fluids is solely the responsibility of the medical experts entrusted with the further treatment.

If the risk at the workplace is solely from acids or caustic solutions it may be advisable to have specific rinsing fluids on stock for first aid. Experiments have shown that rinsing fluids bear varying degrees of suitability for caustic solutions or acid burn. The application of the fluid should not lead to a loss of time.

If rinsing fluids are provided at the workplace for applications that the manufacturer has not specifically determined, the suitability is to be evaluated and documented.

7. General demands made on rinsing fluids for use at the place of work.

Rinsing fluids must fulfil the basic demands regarding quality, safety and their harmlessness to health and their purpose (efficacy) (e.g. acc. to MPG, AMG (EU pharmacopoeia or cosmetic directives).

Safety evaluation of the manufacturer/marketing:

- The evaluation of the irritation and allergy potential should be made taking into account the hazards at the workplace .

- Eye rinsing fluids must be sterile, may not be manufactured oneself and must not be stored once opened.
- With reference to the composition of the eye rinsing package the data of DIN 12930 are to be complied with

All the components must be identified scientifically on the packaging according to type and quantity acc. to INCI (International Nomenclature of Cosmetic Ingredients). In founded exception solely the identification of the substances contained suffices.

8. Recipe requirements

Eye rinsing fluids must be sterile.

Rinsing fluids should not contain particles, must not contain visible particles. Suitable validation directives are drawn up, among others, in the EU pharmacopoeia.

Rinsing fluids should not contain any preservative substances.

Buffered eye rinsing fluids must be isohydric (almost pH-neutral), unbuffered eye rinsing fluids and other rinses should be isohydric, the pH may only diverge from the physiologic range (approx. pH 7.2) in exceptional cases.

All the constituents must be of the required quality, preferably in compliance with the applicable pharmacopoeia.

Rinsing fluids must be approximately isotonic to tear and tissue fluid, all exceptions must be justified.

9. Requirements for validation of efficacy and suitability

If a marketing authorisation is not available (for which the following is a prerequisite anyway), the areas of application must be precisely described. The efficacy and safety when applied (purpose) must be validated in the course of a safety evaluation while taking the toxicological profile of the constituents and the conditions of use at the workplace into account or must be plausible according to approved state of knowledge.

10. Requirements for product information and packaging

Important information must be drawn up on the label of the package. The employers and users who provide rinsing fluids at the workplaces, who use the latter respectively, require a number of information data for the right selection and the best application respectively. The latter are listed as an example in the following.

Relevant product information

- Clear definition as rinsing fluid for first aid application
- Intended use with concrete identification of the area of application (eye, skin etc.) if applicable, further areas of application and information on type of application (first aid substance, emergency measure, medical treatment etc.)
- Mention of contra-indication applications (e. g. “not suitable for...”)
- Data on proof of efficacy
- Legal status (e.g. drug, body hygiene substance, pharmaceutical product, etc.)
- Application form
- Where applicable instructions on applicability to the eye)
- Storage and transportation information (e.g. min. shelf life or application period after opening, exclusion of reusability)
- Package sizes
- Functionality with regard to area of application, type of application, duration of application and quantity

- Information for the user (e.g. "Package insert", application recommendation, indication)
- Identification of composition
- Data on buffering and, if applicable, specific actions
- pH
- Buffering capacity as acid or base equivalent indicating the pH value
- Contact data of the manufacturer [Telephone (where applicable with 24-hour hotline), Email address etc.]

Further important information:

Source of supply for the products

Labelling on the container:

- Clear definition as rinsing fluid for the application as first aid substance
- Intended use and application areas
- Mention of contra-indication application
- Application form
- Where applicable, instructions on applicability to the eye
- Storage and transportation information (e.g. min. shelf life or application period after opening, exclusion of reusability)
- Package sizes
- Contact data of the manufacturer [Telephone (where applicable with 24-hour hotline), Email address etc.]

Packaging:

Rinsing fluids for application to the eye must be sterile.

Rinsing fluids may only be marketed in single dose containers with originality lock.

The product must be clearly assigned for the intended application. It must be recognised at first glance that the rinsing fluid is a substance for application in first aid. The same also applies for the respective area of implementation. Pictographs (Rescue symbols E06) are recommended in this connection.

11. Literature

The following quotations reflect the state as in 06/2013. It goes without saying that the latest laws and ordinances are always to be applied:

- 1 Regulations for the prevention of industrial accidents “Principles of Prevention” (BGV A1)
- 2 Directive of the Accident Prevention & insurance Association "Working Safely in Laboratories - Basic Principles and Guidelines (BGI/GUV-I 850-0e)
- 3 DIN 12930 "Eye rinsing flasks"
- 4 Regulations governing place of work (German regulations on work place – ArbStättV)
- 5 Law on the implementation of measures of safety to improve the safety and health protection of the employees at work (Article 1 of the law on the implementation of the EC Frame Directive and of other safety guidelines; e.g. German labour protection law -ArbSchG)
- 6 Regulations on the protection against hazardous substances (Regulation on hazardous substances – (GefStoffV))
- 7 TRGS 526 "Laboratories"

- 8 Data leaflets “hazardous Substances” of the German Social Accident Insurance Institution for the raw materials and chemical industry (BG RCI) (e.g. BGI 595)
- 9 Hazardous substance information system specific for the industry of the German Social Accident Insurance Institution for the raw materials and chemical industry (BG RCI) <http://www.gischem.de/>
- 10 Law governing medical devices (Medical device law – MPG)
- 11 National and EU pharmacopoeia; e.g. AMG
- 12 Cosmetics regulations
- 13 Nasterlack,M. et al.: Zur Effektivität der Spülung mit fließendem Wasser als Erste-Hilfe Maßnahme nach chemischer Augenkontamination, Zbl Arbeitsmed 63 (2013) 94-100

a. Appendix 1 Sample Directives

SAMPLE OPERATING DIRECTIVES on the use of eye rinsing fluids for first aid



- **Work area:** _____
(to be supplemented by the company)

- **Data on rinsing fluid/identification:**

- Rinsing fluid is used to rinse eyes when the eye has come into contact with hazardous substances

- _____
(Product and company definition of the rinsing fluid)

- _____
(Application areas and prohibitions of application)

- _____
(to be supplemented by the company)

- **Instructions on practical implementation of the wash:**

- Open eye rinsing package, force the lids of the injured eye open and rinse pointing towards of the outside angle of the eye for at least 10 minutes
- While protecting the uninjured eye, rinse with weak jet
- Have further rinsing flasks procured in time

or

- Bring the injured victim to an eye wash station connected to the drinking water supplies and flush for at least 10 minutes
- Continue to rinse without interruption on the way to the emergency shower and during transport to the ophthalmologist

- _____
(to be supplemented by the company)

- **Further procedure:**

- Immediate presentation to the ophthalmologist¹
- Enter in the first aid record book

- **Storage and care:**

- _____
(Inspection date / Inspection interval)

- _____
(Person in charge of the inspection – Name /Tel. No.)

- _____
In charge of procuring replacement – Name /Tel. No.)

- _____
(to be supplemented by the company)

- Eye rinsing fluids must be readily available and easily accessible and stored in suitable packages, must be protected against damaging influences (for example including extreme heat and cold), and must be provided in sufficient quantities.
- Eye rinse packages must be checked regularly, e.g. for damage, condition, shelf life and loss.
- If damage is detected or impairment of serviceability, replacement is procured.
- Opened rinsing flasks are to be replaced immediately after use

- **Employee instruction:**

- Employees are to be instructed before beginning work and then regularly, at least once a year

- _____
(to be supplemented by the company)

Date / Signature Management/Officer in charge

¹ May, acc. to the company doctor's/works doctor's judgement, not be necessary.

