AN EMPLOYEE HAS BEEN SPLASHED WITH A CHEMICAL AND HAS BEEN DECONTAMINATED WITH DIPHOTÉRINE® OR HEXAFLUORINE®

Why use DIPHOTÉRINE® or HEXAFLUORINE®?

- To stop the chemical’s action on the eye or skin and to easily remove it
- To increase effectiveness in comparison with washing with water or saline solution:
  * Improved intervention time for optimal efficacy use within one minute as opposed to 10 seconds for water washing
  * Effective for binding a wide variety of different chemical substances
  * Decreases requirements for care beyond initial decontamination, sequelae and lost work time
  * For hydrofluoric acid: simultaneous action on both its corrosiveness and toxicity
  * In the event of delayed washing:
    - Diphotérine® stops the chemical’s harmful effects,
    - has a positive effect on the healing time, facilitating patient management

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1.1 – FACTORS DETERMINING THE SEVERITY OF CHEMICAL BURNS

Chemical burns are the result of a chemical reaction between a corrosive or irritating molecule and one or more biochemical components of the skin or eye.

The severity of a chemical burn depends mainly on:
- the nature and concentration of the chemical,
- the energy brought into play,
- the duration of contact.

It also depends on physical factors such as the pressure or the temperature, the area and the extent of the affected tissues and whether the tissues are healthy or not. The effectiveness of the emergency decontamination and the first aid care influence the appearance and the development of the chemical burn and consequently, the significance of the sequelae.

1.2 – SPEED AND EFFECTIVENESS OF WASHING CHEMICAL SPLASHES

It is well-known, by all professionals in the field of prevention and safety, that the early washing of a chemical splash makes it possible to decrease the severity of the burn. Historically, water became the obvious universal means of decontamination. This was a great advance in limiting the severity of chemical burn lesions. However, this progress is limited by two factors which are:
- the time it takes to intervene and thus the duration of chemical contact,
- the concentration of the major corrosive agents.

This very short recommended intervention time, about 10 seconds, leads to a situation, which in practice, is difficult to manage at the time of the accident and thus a source of worsening of the lesions in the event of burns due to a corrosive agent.

The study and the comprehension of the mechanism of the chemical burn (Figure 1) has led the PREVOR Laboratory to conceive solutions for “active washing”, which can be considered as improvements on washing with water. An amphoteric molecule with multiple binding sites, capable of reacting with corrosive and irritating agents and preventing or decreasing their action on the tissues was added to the effects of mechanical washing and passive dilution provided by water decontamination. The types of chemicals which result in chemical burns are acids, bases, oxidising agents, reducing agents, chelating agents and certain solvents.

The active washing solution is also hypertonic, in order to stop the penetration of the corrosive or irritating agent from penetrating the tissue. The purpose of active washing, with solutions such as Diphotérine® and Hexafluorine®, is to prevent or decrease the after-effects inherent to chemical burns.
CHEMICAL BURNS
AND AGGRAVATING FACTORS

FACTORS OF SEVERITY

> Type of elementary chemical reaction
- acido-basic
- oxydo-reduction
- solvatation
- alkylation...

> Energetic level of the reaction
Intrinsic, harmful potential of the product
- pKa and pKb
- oxido-reduction potential

> Molar concentration
> 0.2 N

> Area of affected tissue
Expressed in percentage of the body surface or in cm²
(notably for the systemic effects at the time of HF splashes)

> Period of chemical contact
- time period for the start of the active washing
- delay by first washing with water
- non-active washing solution

> Aggravating factors
- temperature
- solid particles (example soda flakes)
- splash under pressure
- viscosity...

ACTION MODES

> DESTRUCTION of cells and tissue
- in the eye
- on healthy skin
- on already damaged skin

SYMPTOMS AND CONSEQUENCES

> Inflammation
Destruction then Healing

> Sequelae
- corneal opacity
- keloids
- retractile sclerosis

> Restitutio ad integrum

ACTION

Figure 1
2.1 – DIPHOTÉRINE®’S MECHANISM OF ACTION

- Diphotérine® is a general-purpose washing solution for ocular and cutaneous chemical splashes. Diphotérine® is a **hypertonic**, **amphoteric** and **multisite** washing solution. It therefore has a double effect:
  - the **mechanical properties of washing with water**
  - the **additional neutralising and chelating properties** which at the same time make it possible to accelerate and to optimise the process of decontamination.

- Because of its hypertonicity, Diphotérine® prevents the chemical from penetrating the tissue and makes it possible to create a reverse flux capable of pulling the chemical away from the tissue.

- Its amphoteric character and its various reactive sites enable it to act on the irritating and corrosive agents which are at the origin of chemical burns. These are products such as acids, bases, oxidising agents and reducing agents, ...

2.2 – WASHING WITH DIPHOTÉRINE®: ADVANTAGES COMPARED TO WATER

- As with water, the purpose of using Diphotérine® rapidly is to attempt to prevent chemical burns. The more rapidly Diphotérine® is used, the shorter the contact with the chemical will be. The risk of a chemical burn occurring will thus be minimised.

Concerning the action performed on the corrosive substance, Diphotérine®, unlike water, more rapidly and effectively neutralises the harmful potential of the chemical with a lesser amount of washing.
Diphotérine®’s effectiveness has been proven on an experimental as well as on a clinical level. The analysis of these data concerning chemical decontamination with Diphotérine® is based on three levels of scientific evidence.

- Convergent clinical data:

In spite of the difficulties of performing studies on first aid in the workplace and the inevitable limitations related to the interpretation of the results, much of the data collected on human subjects provide convergent elements.

Many accounts of Diphotérine® use have been provided by companies (1). Generally transmitted by occupational health doctors, the reports can be criticised one by one, either for a problem of methodology or interpretation, but when all of these several hundred cases of Diphotérine® use are combined, the coherence of the whole reveals some certainties about its effectiveness:

- no noxious effects,
- lessens pain,
- no after-effects,
- absence of or only a small amount of secondary care,
- absence of or few days of work loss.

The National Institute of Research and Safety decided to independently verify the effectiveness of various chemicals splash decontamination methods, including Diphotérine®. For that purpose, an investigation (2) was carried out with the help of company medical doctors in France. 73 companies and more than 60 accidents were taken into consideration. This study shows Diphotérine®’s action on a varied sample of chemicals, and indicates that Diphotérine®, when used according to the recommended protocol, is always at least as effective as water. The continuation of this investigation (3) showed that the results, for a total of 145 chemical splash cases studied, seemed superior on concentrated bases. This was confirmed by the study carried out by Martinswerk (1), which made it possible to confirm the superiority of Diphotérine® washing on bases, both in terms of effectiveness and washing safety, despite the small size of the statistical series:

<table>
<thead>
<tr>
<th>Washing Solution</th>
<th>Diphotérine®</th>
<th>Acetic Acid</th>
<th>Water</th>
</tr>
</thead>
<tbody>
<tr>
<td>No secondary care</td>
<td>100 % +/- 15</td>
<td>0 % +/- 15</td>
<td>0 % +/- 15</td>
</tr>
<tr>
<td>Simple secondary care</td>
<td>0 % +/- 15</td>
<td>80 % +/- 15</td>
<td>25 % +/- 15</td>
</tr>
<tr>
<td>Medicalised secondary care</td>
<td>0 % +/- 15</td>
<td>20 % +/- 15</td>
<td>75 % +/- 15</td>
</tr>
<tr>
<td>Number of days of work loss</td>
<td>0.18 % +/- 0.4</td>
<td>2.91 % +/- 4.3</td>
<td>8 % +/- 8.12</td>
</tr>
</tbody>
</table>

For isolated reported cases, the examples are also very significant. Take the case of 2 large cutaneous splashes of concentrated sulphuric acid with equal concentrations (95%): the one washed with water lead to serious after-effects, and six months of work loss, and the other washed with Diphotérine® resulted in neither after-effects nor work loss (4).
**Experimental in vivo data which confirm the clinical results:**

When the chemical burn does occur, its development is determined by two phenomena:

- the detersion phase (inflammation, destruction), which is increased in cases of chemical burns,
- the repairing phase (healing), which is decreased.

The in vivo experimental studies have confirmed that when the development of the chemical burn is stopped, the healing of the injured tissues is carried out in better conditions. Dr. Cavallini (5,6) compared the effectiveness of washing with Diphoterine® to washing with saline solution on a concentrated cutaneous hydrochloric acid burn in rats. Diphoterine® stopped the development of the chemical burn, which led to the following consequences:

- **better healing of the skin** (size of the lesion after 7 days: Diphoterine® 4 mm versus saline solution 6 mm, no washing 12 mm)

- **a significant reduction of pain** (Substance P in the first 48 hours, \( p < 0.05 \); \( \beta \)-endorphin after 7 days, \( p < 0.05 \)),

- **a reduction of inflammation** (IL-6 to 48h, \( p < 0.01 \); after 7 days, \( p < 0.05 \)).

Dr. Gérard studied a 15.3% ammonia ocular burn in rabbits (7). This study has allowed an understanding of the chemical burn mechanism and has showed the relevance of delayed treatment of such a burn. This experimental burn model was then tested in order to compare the effectiveness of Diphoterine® versus saline solution (8). After washing with Diphoterine® there is:

- **an absence of a stromal oedema**, while it has been observed after washing with saline solution or when there is no washing,

- **an inflexion of the pH**, which has not been observed after washing saline solution or when there is no washing.

The presence of a stromal oedema, resulting from inflammation due to the burn and the hypotonic effect of washing, is known to be an aggravating factor in the development of chemical burns (9).
Experimental data ex vivo / in vitro which explain the clinical results:

These studies have allowed us to understand and confirm the clinical results obtained. Dr. Schrage (10) compares the effectiveness of different washing solutions by dosage of 5ml of 0.5 M caustic soda or hydrochloric acid and shows the limitations of water washing on corrosive agents. Despite adding an amount of water which represented 50 times the amount of caustic soda or of hydrochloric acid contamination, water did not bring the pH level back to physiological values:

<table>
<thead>
<tr>
<th>Chemical</th>
<th>Added Water (250 ml)</th>
<th>Added Diphoterine® (Previn®) (100 ml)</th>
</tr>
</thead>
<tbody>
<tr>
<td>0.5M Caustic Soda</td>
<td>pH = 11.8</td>
<td>pH &lt; 9</td>
</tr>
<tr>
<td>0.5M Hydrochloric Acid</td>
<td>pH = 2</td>
<td>pH = 6.3</td>
</tr>
</tbody>
</table>

Physiological zone (no burn): 5.5 < pH < 9

An experiment on enucleated pig eyes measured the effect of washing on the development of the intra-ocular pH according to whether it was early or delayed: only washing with Diphoterine® showed an improvement of the intraocular pH, even if the washing was delayed.

In this same publication, the physical limits of water washing on fibroblast cultures is shown. Water is hypotonic. When there is a chemical burn, the osmotic pressure of the cornea increases up to 1280 mosmoles/kg. Washing with a hypotonic solution (such as water) can cause an osmotic shock and a cytolyis (destruction of cells after swelling). See also the Kompa et al’s publication (11) on the direct effect of a washing solution’s osmolarity on the cornea’s osmolarity.

The following table clearly shows the advantages of using Diphoterine®.
<table>
<thead>
<tr>
<th>WATER</th>
<th>DIPHOTÉRINE®</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Advantages</strong></td>
<td><strong>Limitations</strong></td>
</tr>
<tr>
<td>Chemical agent at the surface of the affected tissues are carried away</td>
<td></td>
</tr>
<tr>
<td>Dilution</td>
<td></td>
</tr>
<tr>
<td>Polyvalent</td>
<td>Polyvalent</td>
</tr>
<tr>
<td><strong>Hypotonic</strong></td>
<td><strong>Hypertonic</strong></td>
</tr>
<tr>
<td>Favours a part of the chemical agent’s penetration of the tissue, especially in the eyes</td>
<td>Stops the chemical agent’s penetration of the tissue and carries the chemical away from the interior to the exterior of the tissue</td>
</tr>
<tr>
<td>No action on corrosive or irritating agents Development of the chemical burn</td>
<td>“Neutralising” action on the potentially irritating or corrosive nature of the chemical agent <strong>Stops the development of the burn</strong></td>
</tr>
<tr>
<td>Intervention time: the first 10 seconds Possibility of serious physical after-effects, which may have lethal consequences</td>
<td>Intervention time: the first minute Decrease or absence of after-effects Prevents chemical burns</td>
</tr>
<tr>
<td>In certain cases, complex secondary treatment with reconstructive surgery</td>
<td>Decrease or absence of secondary treatments Prevents after-effects Decrease in work loss</td>
</tr>
<tr>
<td>Non-toxic</td>
<td>Non-toxic, sterile</td>
</tr>
</tbody>
</table>
The recent study published by Dr. Merle (12) shows the importance of using Diphoterine® even in cases of delayed washing, within the first hours following an accident. The study compares, for the equivalent grades of burns, the differences which occur after washing with Diphoterine® versus washing with saline solution before treatment of a basic burn. This study shows a significant reduction in the amount of time needed for the reepithelialisation of the cornea:

<table>
<thead>
<tr>
<th>Reepithelialisation time in days</th>
<th>Diphoterine®</th>
<th>Saline Solution</th>
<th>Value of p</th>
</tr>
</thead>
<tbody>
<tr>
<td>Grade I</td>
<td>1.9 +/- 1</td>
<td>11.1 +/- 1.4</td>
<td>p &lt; 10^-7</td>
</tr>
<tr>
<td>Grade II</td>
<td>5.6 +/- 4.9</td>
<td>10 +/- 9.2</td>
<td>p &lt; 0.02</td>
</tr>
<tr>
<td>Grade III</td>
<td>20 +/- 14.1</td>
<td>45.2 +/- 23</td>
<td>p = 0.21 NS</td>
</tr>
</tbody>
</table>

Absence of ocular Grade IV with Diphotérine®

Dr. Gérard (13) has published a case of a severe ocular chemical burn (Grade IV) which shows the advantages of delayed washing with Diphoterine® and describes the associated secondary treatment, principally aimed at reducing inflammation, as well as infection and pain. The case evolved towards a progressive reepithelialisation in less than 21 days, and complete, stable healing in 180 days. No surgical act was necessary in this case.

Resume of the advantages of using Diphotérine® versus water or saline solution

<table>
<thead>
<tr>
<th>Results with Diphotérine®</th>
<th>Ocular (ammonia in rabbits (7,8))</th>
<th>Cutaneous (hydrochloric acid in rats (5,6))</th>
</tr>
</thead>
<tbody>
<tr>
<td>in vivo versus saline solution</td>
<td>- Decrease in corneal oedema</td>
<td>- Reduction of pain</td>
</tr>
<tr>
<td></td>
<td>- Reduction of the extraocular pH</td>
<td>- Reduction of inflammation</td>
</tr>
<tr>
<td></td>
<td>- Reduction of the intraocular pH</td>
<td>- Reduction in the time needed for tissue healing</td>
</tr>
<tr>
<td>Clinical tests in industry (1) versus water</td>
<td>- Decrease in requirement for care beyond initial decontamination,</td>
<td>- Decrease in lost work time,</td>
</tr>
<tr>
<td></td>
<td>- Decrease in after-effects.</td>
<td></td>
</tr>
<tr>
<td>Clinical tests in hospitals (12,13) versus saline solution</td>
<td>- Decrease in the time needed for healing</td>
<td></td>
</tr>
</tbody>
</table>

The advantage of Diphotérine® is that it acts directly on the corrosive or the irritating agents. This action results in the prevention or minimisation of the inflammatory phenomena which are established very early in response to a cutaneous or ocular chemical splash. Hence the necessity, in order to achieve optimal effectiveness, of an immediate intervention at the site of the accident and of the presence of Diphotérine® as a first aid treatment at work stations.
DIPHOTÉRINE®

2.3 – WHEN AND HOW SHOULD DIPHOTÉRINE® BE USED?

> Diphotérine® is indicated in first aid washing of any type of ocular and cutaneous chemical splashes. It has a limited effect on hydrofluoric acid splashes because of both the corrosive and toxic mechanisms of this acid. It is preferable in these cases to wash with Hexafluorine®, which specifically meets these two requirements. Carried out within the first minute and using the entire amount in the appropriate product container, the purpose of external washing with Diphotérine® is to prevent or minimise the appearance of lesions and thus the risks of sequelae.

WASHING PROTOCOL

Wash with Diphotérine® as rapidly as possible within the first minute for optimal efficacy and remove clothing and/or contact lenses. Continue washing, being sure to use the entire contents of the Diphotérine® container. Consult a specialist.

OCULAR WASHING:

> Less than one minute of chemical contact requires 3 minutes of washing, that is to say all the contents of a 500 ml bottle or a portable eyewash. There is a minimal time period of about 10 seconds before the beginning of the chemical’s penetration. For that reason, water can sometimes be effective, in particular with weak corrosive agents. However, water, because of its hypotonicity, creates a flow into the tissue from the surface to the deep structures of the cornea. That makes it possible, in practice, for the corrosive agent to penetrate the anterior chamber more easily and more deeply. (10)

> Particular case of the SIEW (Sterilised Individual Eyewash): Washing within the first 10 seconds requires decontamination with a SIEW, in other words with 50 ml of Diphotérine®. In cases where washing has not begun within the first 10 seconds, it must be supplemented with a 500 ml bottle or a portable eyewash.

> Contact lenses: wearing contact lenses at work stations with exposure to chemical risk is very strongly discouraged. This adds to the problem of clothing contaminated during a chemical splash by favouring an over-concentration of the chemical which will hinder the effectiveness of washing within the first seconds.
2.4 – MANAGEMENT OF A CHEMICAL SPLASH WASHED WITH DIPHOTÉRINE®

2.4.1 – Medical findings

Three types of cases are possible during the examination:

1st case: absence of lesions
This happens frequently, because the Diphotérine® protocol has been applied correctly. Usually, no damage is observed and no secondary treatment is necessary. There is no lost work time.

2nd case: observation of a benign lesion
(for eyes: grade I and II of the Roper-Hall classification).
They can be due:
• to the nature of the chemical agent
  - product in solid form, responsible for mechanical erosion of the cornea with inflammation,
  - sensitising character (for example, chromium solution),
  - chemical splash under pressure...
• to the non respect of the initial washing protocol
  - delayed washing,
  - insufficient washing,
  - initial washing with water (almost non existent osmotic pressure. In these cases, the penetration of the corrosive agent towards the interior of the tissue is facilitated leading to deeper, more serious lesions).
2.4.1 – Medical findings

• Possible side effects of the medical treatment (for example reaction to certain components of topical ocular medications).

The benign symptoms observed in these various situations more often concern the eye than the skin. They are possibly delayed by 24 or 48h. They are common place inflammatory signs (simple ocular redness and slight pain).

They require the application by a specialist of a therapeutic protocol, generally involving antibiotic and/or anti-inflammatory medications. It has been proven, in particular for ocular cases (9) that a good command of the inflammatory phenomena is essential to a rapid and favourable development of the healing process.

3rd case: Serious lesions  (Ocular: grade III or IV of the Roper-Hall classification)

They are generally due to delayed washing observed after accidents in the home or, more rarely, at the time of criminal attacks where chemicals are used. According to the severity of the burn and its development, a complementary treatment (more or less complex and long) is essential. These cases require a very specialised and complex approach in a hospital setting.

Clinical Exam : Signs of seriousness of an ocular chemical burn (14)

Conjunctival limbal ischaemia (whitish zone): is due to the interruption of blood circulation at the level of the conjunctivo-limbic vessels. The extent of this ischaemia is the principal sign of the severity of the burn. An ischaemia greater than one half of the limbic circumference is a factor in a a negative prognosis. This ischaemia is often associated with chemosis (conjunctival oedema which is an elevated ring), often hemorrhagic (red spots).

On the other hand, conjunctival hyperhemia, ocular redness diffused by simple vasodilatation of the conjunctival vessels is a sign which is not serious, evidence of simple conjunctival irritation.

The corneal oedema will be at the origin of a decrease in transparency, and the iris can just be made out or not seen at all (porcelain cornea). The result is then a decrease in visual acuity.

An ulcer of the cornea which is complete (affecting all of the corneal surface) and deep (affecting the epithelium and the corneal stroma) is a sign of severity. Paradoxically, in these cases, visual acuity can be preserved.
Clinical Exam : Signs of seriousness of an ocular chemical burn (14) continued...

Whereas in **tiny corneal injuries**, such as superficial punctual keratitis, visual acuity is often decreased.

Associated lesions :
- Burns on the eyelids: 1st, 2nd or 3rd degree
- Burns on the face or other parts of the body, the significance of which can influence the potential for patient survival

2.4.2 – Patient management in the company medical department

Washing with Diphotérine®, immediately carried out according to PREVOR’s recommendations and using the entire contents of the container, prevents the burn from occurring or considerably decreases its severity.

> **IN THE EVENT OF AN OCULAR SPLASH**

Make sure that Diphotérine® washing has begun:
- with a SIEW (50 ml) within the first 10 seconds following the splash
- or with an Eyewash (500 ml) within the first minute

If not, for a contact time greater than 1 minute, continue washing with Diphotérine® and if needed, continue washing for 3 to 5 times the duration of contact time. A chemical burn constitutes a biological aggression with an inflammatory reaction of the ocular tissues. Diphotérine® acts by stopping this aggression. Then use the Washing Solution®, which is isotonic with human tears, to facilitate the return to a physiological state.

> **IN THE EVENT OF A CUTANEOUS SPLASH**

Make sure that Diphotérine® washing has begun within the first minute. If not, for a contact time greater than 1 minute, continue washing with Diphotérine® and if needed, continue washing for 3 to 5 times the duration of contact.

Then, in all cases, the patient should be referred to a specialist who will decide more precisely on the action to be taken according to the initial lesions observed.
2.4.3 – Treatment by a specialist or at the hospital

**OCULAR CHEMICAL BURN CLASSIFICATION (ROPER-HALL), prognosis and therapeutic protocol**
according to a comparative clinical study (12) Diphotérine® versus normal saline solution

<table>
<thead>
<tr>
<th>Grade</th>
<th>Initial clinical exam</th>
<th>Prognosis</th>
<th>Therapeutic protocol after washing with 500 ml</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Epithelial ulcer, no limbal ischaemia</td>
<td>Favourable</td>
<td>Verification of the anti-tetanus vaccination, rifamicyne 6 times/day, 2% ascorbic acid 6 times/day, tropicamide 6 times/day</td>
</tr>
<tr>
<td>2</td>
<td>Corneal oedema Ischaemia &lt; 1/3 of the limbal circumference</td>
<td></td>
<td>Verification of the anti-tetanus vaccination, rifamicyne 6 times/day, 2% ascorbic acid 6 times/day, dexamethasone combined with neomycine 6 times/day for 7 days, 1% atropine 3 times/day, 1 g ascorbic acid orally 3 times/day and installation of symblepharon rings. The treatment is maintained until complete reepithelialisation of the cornea.</td>
</tr>
<tr>
<td>3</td>
<td>Complete corneal ulcer &gt; 1/3 and Ischaemia &gt; 1/2 of the limbal circumference</td>
<td>Unfavourable</td>
<td></td>
</tr>
<tr>
<td>4</td>
<td>Opaque cornea with non visible iris Ischaemia &gt; 1/2 of the limbal circumference</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

A recently published case of an ocular grade IV burn, showed the advantages of using Diphotérine® under these conditions (13). The patient was treated approximately one hour after the chemical assault and an ocular washing with one litre of Diphotérine® was carried out. The treatment described in the above table was used for this patient. The emergency number of PREVOR (+33 1 30 34 76 76) is placed at your disposal during business hours (time zone, France, GMT +1) for further information.

2.5 – Formulation, innocuousness and classification of Diphotérine®

- Composition and properties of Diphotérine®
  - Aqueous saline solution containing Diphotérine®, does not contain phosphates
  - Limpid and colourless liquid
  - pH ranging between 7.2 and 7.7
  - Density : 1.034
  - Osmotic pressure : 820 mosmoles/kg
  - Sterile solution (by autoclave)
### Toxicological data concerning Diphotérine®

The tests of innocuousness carried out on Diphotérine® are summarised below:

<table>
<thead>
<tr>
<th>Test</th>
<th>Results</th>
<th>References</th>
</tr>
</thead>
<tbody>
<tr>
<td>Ocular irritation</td>
<td>Non irritant</td>
<td>Test n°133/4, on rabbits, Safepharm Laboratories Limited, UK, 1987</td>
</tr>
<tr>
<td>In vitro Evaluation of the eye</td>
<td>No cytotoxic or irritant potential to the eye after a short (10 minutes) or prolonged (24 hours) time of contact</td>
<td>Test n°REL/032/05/IRRO/ELB, on human fibroblast cultures, test Integra, Italy, 2005</td>
</tr>
<tr>
<td>Cutaneous irritation</td>
<td>Non irritant</td>
<td>Test n°2005-024, in vitro, Dermal Irritection®, test method, Integra, Italy, 2005</td>
</tr>
<tr>
<td>Ocular irritation of a residue of a</td>
<td>Non irritant</td>
<td>Test n°6463 TAL, on rabbits, hydrochloric acid, Centre International de Toxicologie, France, 1990</td>
</tr>
<tr>
<td>washing of an acid with Diphotérine®</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Ocular irritation of a residue of a</td>
<td>Non irritant</td>
<td>Test n°6462 TAL, on rabbits, sodium hydroxide, Centre International de Toxicologie, France, 1990</td>
</tr>
<tr>
<td>washing of a base Diphotérine®</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Oral toxicity</td>
<td>Oral LD₅₀ &gt; 2000 mg/kg; non toxic, no death, normal evolution of weight, no abnormality at necropsy</td>
<td>Test n°6564 TAR, on rats, Centre International de Toxicologie, France, 1990</td>
</tr>
<tr>
<td>Acute dermal Toxicity</td>
<td>Acute dermal LD₅₀ &gt; 2000 mg/kg; non toxic, no death, no sign of systemic toxicity or dermal irritation, normal evolution of weight, no abnormality at necropsy</td>
<td>Test n°133/9, on rats, Safepharm Laboratories Limited, UK, 1988</td>
</tr>
<tr>
<td>Sensitisation</td>
<td>Non sensitising</td>
<td>Test n°20030418ST, Magnusson and Kligman method, on Guinea pigs, OECD 406, CERB, France, 2003 (15)</td>
</tr>
<tr>
<td>Mutagenesis</td>
<td>Non mutagenic ; negative Ames test</td>
<td>Test n°29023 MMT, Bacterial reverse mutation Test on Salmonella typhimurium TA 1535, TA 1537, TA98, TA 100et TA 102, Escherichia Coli WP2 uvrA, Centre International de Toxicologie, France, 2005</td>
</tr>
<tr>
<td>Cytotoxicity</td>
<td>Non cytotoxic</td>
<td>Test n°REL/003/06/IRRC/ELB, ISO 10993-5 standard, Integra, Italy, 2006</td>
</tr>
<tr>
<td>Anti-inflammatory potential</td>
<td>Non anti-inflammatory ; no cytotoxic or irritant effect observed on a 3D human epidermidis model</td>
<td>Test n°REL/011/06/FUNZ/ELB, MTT in vitro tests + pro-irritation potential IL-1α, Integra, Italy, 2006</td>
</tr>
</tbody>
</table>
NO SIDE-EFFECTS HAVE BEEN OBSERVED SINCE DIPHOTÉRINE® HAS BEEN PUT ON THE MARKET.
THE USE OF DIPHOTÉRINE® DOES NOT PRESENT ANY CONTRAINDICATIONS.

> PRECAUTIONS FOR USE

To avoid any microbial contamination, keep containers closed. Opened containers in eyewash stations should only be kept for six months. Do not use after the expiration date written on the containers.

> ADVERSE EFFECTS

Chemical burns damage living tissues. Diphotérine®, because of its hypertonicity prevents the penetration of the tissue (10) and also extracts the chemical. For 1 minute of contact with the chemical, washing with 500ml of Diphotérine® prevents or minimises the appearance of the burn. If the contact time is greater than 1 minute, the chemical burn will appear.

Ocular washing with Diphotérine® can lead to a slight feeling of ocular dryness. The secondary use, for greater comfort, of the Washing Solution®, isotonic to human tears, will lead to a more rapid return to a physiological state. The return to a physiological state will make it possible to carry out secondary care under optimal conditions.

> WHEN DIPHOTÉRINE® SHOULD NOT BE USED

Diphotérine®’s effectiveness is limited on hydrofluoric acid splashes because of the double corrosive and toxic mechanisms of this acid. Hexafluorine® has been specifically developed to address these two requirements.

Do not use in the event of splashes of white phosphorus. In the event of these types of splashes, it is better to use first-aid thermal burn treatment (a water-based gel for example) on the skin. Diphotérine® has not been certified for the treatment of burns due to ingestion. Studies are currently in progress. However, it has already been tested and classified as non-toxic orally.

> CLASSIFICATION OF DIPHOTÉRINE®

- Washing solution,
- Medical device,
- Class Ila, sterile,
- CE 0459, initial CE certificate obtained: September 1996, renewed February 23, 2006 after audit
3.1 – HEXAFLUORINE® ’S MECHANISM OF ACTION

Hexafluorine® is a specific washing solution for ocular and cutaneous hydrofluoric acid (HF) splashes (Figure 3) and fluorides in a medium (e.g.: boron trifluoride). Hexafluorine® is a washing solution with hypertonic and chelating properties.

It thus has two mechanisms of action:
- the mechanical properties of water washing
- additional neutralising and chelating properties which accelerate and optimise the decontamination process

- Hexafluorine®’s hypertonicity prevents the chemical from penetrating (10) the tissue and creates an inverse flow to pull the chemical to the tissue surface
- Its neutralising and chelating properties enable it to act both on the corrosive (H+) and toxic (F−) components which are responsible for the particular severity of burns due to this acid.

Figure 3: Hydrofluoric acid mechanism
3.2 - WASHING WITH HEXAFLUORINE®:
ADVANTAGES COMPARED TO WATER

> As with water, the rapidity with which Hexafluorine® is used prevents the development of HF chemical burns. The more rapidly that Hexafluorine® is used, the shorter the hydrofluoric acid contact, and the risk of a chemical burn resulting will be minimised.

> The pF indicates the measure of F⁻ ions such as H⁺ ions. The greater the pF, the lesser the residual quantity of free F⁻ ions. For a pH value greater than 5, the product is not considered to be dangerous (physiological pF).

---

**Figure 4**: Efficacy of Hexafluorine® on free radical fluoride ions compared to water and a calcium gluconate solution.

**Figure 5**: Efficacy of Hexafluorine® on H⁺ corrosive ions compared to water and a calcium gluconate solution.
Hexafluorine® use permits a rapid neutralisation of the corrosive and toxic potential of HF with a low volume of washing, whereas a progressive addition of water only dilutes the hydrofluoric acid solution. The residual mixture of HF and water remains very aggressive.

Two in vivo experiments were performed (16):
- The first study was carried out on a cutaneous burn due to 70% HF lasting 20 seconds, in order to observe the comparative histological effects between washing with water, washing with water followed by the topical application of a 2.5% calcium gluconate gel, and washing with Hexafluorine®. The intensity of the reaction was established according to a modified Draize scale.

The main observations of the burn grade after washing were summarised as shown below:

Washing with water, which does not trap hydrofluoric acid, is not sufficient to stop the evolution of the burn, which quickly becomes a serious burn.

The use of calcium gluconate blocks the appearance of the burn, at least during the first 24 hours, but a single application is not sufficient to eliminate all fluoride ions. When the treatment is stopped, the burn re-appears, because the residual rate of free fluorides is still above the toxicity limit.

The immediate use of a powerful chelating agent like Hexafluorine® suppresses the action of hydrofluoric acid and does not let any possibility for F⁻ ions to get linked to the calcium into the tissues. The observation of the animals during 6 days does not show any after-effects after a single washing with Hexafluorine® whereas water requires a secondary treatment and calcium gluconate requires multiple applications or injections.
In a second in vivo study, the evolution of the calcium level (Figure 7) during 5 days in rats contaminated by 70% hydrofluoric acid.

The analysis of the data shows that the washing with water, water + CaCl₂ or water and calcium gluconate have similar results. Statistically, the measures of the plasma calcium level done between 10 minutes and 1 hour are the same, already showing an hypocalcaemia, then after 4 hours (for the methods with water or water + CaCl₂). We notice a very pronounced decrease of the calcium level, and an improvement after 24 hours and finally a stabilisation.

The results clearly showed that the calcium level remains constant after a washing with Hexafluorine®.

32 cases of ocular or cutaneous hydrofluoric acid splashes (HF by itself or in combination with other acids, 70% concentration or diluted) washed with Hexafluorine® have been published in the scientific literature. Each patient treated noted rapid pain relief, facilitating the decontamination process.

No after-effects were reported in any of the cases. The loss of work was minimal, one day on average (16,17,18)
5L TO WASH AN ENTIRE BODY WITHIN THE FIRST MINUTE.

HEXAFLUORINE®

5 case studies of emergency decontamination with Hexafluorine®

<table>
<thead>
<tr>
<th>Number of cases</th>
<th>Splashed by</th>
<th>Affected body surface</th>
<th>Type of washing</th>
<th>Consequences/Results</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>HF/HCl* Bath</td>
<td>Total immersion</td>
<td>*Hexafluorine® on the body, **Ocular washing with water</td>
<td>*Slight burns on the abdomen and the back **Serious burn on the left eye</td>
</tr>
<tr>
<td>1</td>
<td>70% HF vapour</td>
<td>Right cheek</td>
<td>Hexafluorine®</td>
<td>Slight painless erythema. Application the next day with calcium gluconate gel, no lost work time</td>
</tr>
<tr>
<td>1</td>
<td>38% HF</td>
<td>One eye</td>
<td>Hexafluorine®</td>
<td>No burns, no lost work time</td>
</tr>
<tr>
<td>2</td>
<td>5% HF</td>
<td>body</td>
<td>Hexafluorine®</td>
<td>No burns, no lost work time</td>
</tr>
</tbody>
</table>

SERIES OF 16 CASES AT OUTOKUMPU (AVESTA, various sites, Sweden)

Decontamination with Hexafluorine®

<table>
<thead>
<tr>
<th>Number of Cases</th>
<th>Splashed with</th>
<th>Affected body surface</th>
<th>Duration of contact</th>
<th>Work loss</th>
</tr>
</thead>
<tbody>
<tr>
<td>2</td>
<td>70% HF</td>
<td>Left forearm– oral cavity</td>
<td>&lt; 1 min</td>
<td>0 - 1</td>
</tr>
<tr>
<td>1</td>
<td>HF (concentration unknown)</td>
<td>One eye</td>
<td>&lt; 1 min</td>
<td>0</td>
</tr>
<tr>
<td>2</td>
<td>HF/HNO₃ pH=1</td>
<td>One eye</td>
<td>&lt; 1 min</td>
<td>0 - 0</td>
</tr>
<tr>
<td>1</td>
<td>HF/HNO₃ pH=1*</td>
<td>One eye</td>
<td>3 - 5 min</td>
<td>3</td>
</tr>
<tr>
<td>1</td>
<td>HF/HNO₃ pH=1</td>
<td>Two eyes</td>
<td>&lt; 1 min</td>
<td>0</td>
</tr>
<tr>
<td>1</td>
<td>HF/HNO₃ pH=1</td>
<td>One thigh</td>
<td>&lt; 1 min</td>
<td>0</td>
</tr>
<tr>
<td>2</td>
<td>HF/HNO₃ pH=1</td>
<td>Two thighs</td>
<td>1h - 1h30</td>
<td>2 - 2</td>
</tr>
<tr>
<td>1</td>
<td>HF/HNO₃ pH=1*</td>
<td>Face</td>
<td>3 - 5 min</td>
<td>3</td>
</tr>
<tr>
<td>2</td>
<td>HF/HNO₃ pH=1</td>
<td>Face + oral cavity – Forehead</td>
<td>&lt; 1 min</td>
<td>1 - 1</td>
</tr>
<tr>
<td>3</td>
<td>HF/HNO₃ pH=1</td>
<td>Forearm – arm + hand – Two elbows</td>
<td>&lt; 1 min</td>
<td>0 - 0 - 1</td>
</tr>
<tr>
<td>1</td>
<td>HF/HNO₃ pH=1</td>
<td>Wrists</td>
<td>2 h</td>
<td>0</td>
</tr>
</tbody>
</table>

RESULTS

Immediate analgesic effect, no sequelae. In 75% of cases including two splashes with 70% HF, no additional care was required and the average lost work time was less than 1 day (σ = 1.1)

*HF/HNO₃/H₂SO₄ pH = 1 represents the same ocular and cutaneous splash
3.3 - WHEN AND HOW SHOULD HEXAFLUORINE® BE USED?

Hexafluorine® use is appropriate in the event of emergency decontamination of splashes with hydrofluoric acid and fluorides in an acid solution. Carried out within the first minute after the splash and using the entire amount of the appropriate product container, the purpose of external washing with Hexafluorine® is to prevent or minimise the appearance of lesions and thus the risks of sequelae.

### WASHING PROTOCOL

Wash with Hexafluorine® as rapidly as possible within the first minute for optimal efficacy and remove clothing and/or contact lenses. Continue washing, being sure to use the entire contents of the Hexafluorine® container.

Consult a specialist.
OCULAR WASHING:

> Less than one minute of contact with the chemical requires 3 minutes of washing, in other words a 500 ml bottle or a portable eyewash bag. There is a minimal time period of about 10 seconds before the chemical begins to penetrate the cornea. For that reason, water can sometimes be effective, in particular with weak corrosive agents. However water, because of its hypotonicity, creates a flux of the chemical from the exterior towards the interior of the cornea. That makes it possible for the corrosive substance to penetrate more deeply and easily the anterior chamber (10).

> **contact lenses:** wearing contact lenses at work stations with exposure to chemical risk is very strongly discouraged. This adds to the problem of clothing contaminated during a chemical splash by favouring an over-concentration of the chemical which will hinder the efficacy of immediate washing within the first seconds.

IN THE EVENT OF A CUTANEOUS SPLASH

> For a chemical splash on the body, use a 5 litre DAP (Autonomous Portable Shower)

IN THE EVENT OF CHEMICAL CONTACT WITH ORAL MUCOUS MEMBRANES WITHIN THE FIRST MINUTE:

> Possibility of washing with Hexafluorine® and then expectorating it.

Never delay washing
For optimal effectiveness use an active solution such as Hexafluorine® available at the site of the accident
If Hexafluorine® is not available, use water

3.4 - MANAGEMENT OF A CHEMICAL SPLASH WASHED WITH HEXAFLUORINE®

Washing with Hexafluorine® performed according to PREVOR's recommendations, immediately and using the entire contents of the appropriate container, prevents the appearance of burns or considerably decreases their severity.
> IN THE EVENT OF AN OCULAR SPLASH

Ensure that the Hexafluorine® washing has begun within the first minute with a wall-mounted or portable eyewash (500 ml).
If not, for a contact time greater than 1 minute, continue washing with Hexafluorine® and if needed, continue the washing for 3 to 5 times the duration of contact time. HF causes an acid burn from the H+ ion and tissue damage and potential systemic toxicity from the F− ion, leading to frequently observed severe eye injuries. Hexafluorine® stops both of these actions. Then use the Washing Solution®, isotonic with human tears, to facilitate the return to the physiological osmotic pressure of the cornea.

> IN THE EVENT OF A CUTANEOUS SPLASH

Ensure that washing with Hexafluorine® begun within the first minute.
If not, for a contact time greater than 1 minute, continue washing with Hexafluorine® and if needed, continue washing for 3 to 5 times the duration of contact time.
Then, in all cases, the patient should be referred to a specialist who will make a more precise decision about the action to be taken according to the initial lesions observed.

- Effects of hydrofluoric acid (19):

<table>
<thead>
<tr>
<th>Concentration &gt; 50%</th>
<th>immediate pain and necrosis</th>
</tr>
</thead>
<tbody>
<tr>
<td>Concentration 20% - 50%</td>
<td>burn delayed from 1 to 8 hours</td>
</tr>
<tr>
<td>Concentration &lt; 20%</td>
<td>pain and necrosis delayed by up to 24h</td>
</tr>
</tbody>
</table>

- Lethal systemic risk with hydrofluoric acid burns (20)

<table>
<thead>
<tr>
<th>Type of burn</th>
<th>Affected surface</th>
<th>Concentration HF</th>
</tr>
</thead>
<tbody>
<tr>
<td>Burn by contact</td>
<td>1 %</td>
<td>anhydrous</td>
</tr>
<tr>
<td></td>
<td>5 %</td>
<td>&gt; 70 %</td>
</tr>
<tr>
<td></td>
<td>7 %</td>
<td>50 - 70 %</td>
</tr>
<tr>
<td></td>
<td>10 %</td>
<td>20 - 50 %</td>
</tr>
<tr>
<td></td>
<td>20 %</td>
<td>&lt; 20 %</td>
</tr>
<tr>
<td>Ingestion of HF</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Inhalation of HF</td>
<td></td>
<td>&gt; 5 %</td>
</tr>
</tbody>
</table>
> OCULAR BURNS

Every hydrofluoric acid ocular burn must be initially and subsequently handled medically because of the frequent disparity between initial appearance and the severity of the sequelae. The treatment of ocular HF burns is similar to the treatment of other chemical burns; specific antidotes can be used according to the company medical protocol and during pre-hospital and hospital management of the injured person.

> CUTANEOUS BURNS

1) Medical Treatment

Generally, after emergency decontamination, protocols recommend the use of specific antidotes: topical, sub-cutaneous, intravenous (Beir block technique or systemic), or intra-arterial (for finger and hand burns) such as calcium gluconate or Zéphiran® salts (20). Analgesic treatment may also be prescribed. Medical surveillance of cardiovascular functions may be justified due to the systemic diffusion of HF in relation to the concentration and the total affected body surface area.

2) Additional examinations

Blood tests to be ordered especially if the burn involves more than 1% of the total body surface area (TBSA):
- calcium
- potassium
- magnesium
- phosphorus

Case study of a hydrofluoric acid burn (7)

A 45 year old worker, was splashed with a cutaneous 70% HF projection (face, neck, an arm and the abdomen, with a systemic effect which could be lethal, see table, paragraph 3.4), while he was checking a valve. Immediate washing was carried out with water at the accident site for 15 minutes, then with saline solution while being transported to the hospital. The patient received intravenous injections of Ca²⁺ and Mg²⁺ as well as local applications of calcium gluconate gel.

▶ 1 YEAR OF LOST WORK TIME
Case study of decontamination with Hexafluorine® (18)

A 40 year old worker, was splashed while decanting 40% HF. This was an ocular and cutaneous splash and corresponds to 16.5% of the body surface (eyes, face, neck, thorax, with a risk of lethal systemic effect, to see table, paragraph 3.4). Washing was immediately carried out with Hexafluorine® on the eyes and the body at the site of the accident. The injured worker was washed a second time with Hexafluorine, at the company’s infirmary by medical personnel. At the hospital, an absence of after-effects was noted, and there was no need for secondary care.

NO LOST WORK TIME

3.5 – FORMULATION, INNOCUOUSNESS AND CLASSIFICATION OF HEXAFLUORINE®

> FORMULATION AND PROPERTIES OF HEXAFLUORINE®

- Aqueous saline solution containing Hexafluorine®, does not contain phosphates
- Limpid and colourless liquid
- pH ranging between 7.2 and 7.7
- Density : 1.047
- Osmotic pressure : 1030 mosmoles/kg
- Sterile solution (by autoclave)

> INNOCUOUSNESS OF HEXAFLUORINE®

Tests of innocuousness performed on Hexafluorine® are summarised below:

- Ocular irritation:  Non-irritating (test n°133/8, on rabbits, Safepharm Laboratories Limited, UK, 1987)
- Cutaneous irritation:  Non- irritating (test n°133/7, on rabbits, Safepharm Laboratories Limited, UK, 1987)
- Oral LD₅₀ (rat):  > 2000 mg/kg;  Non-toxic (test n°990533ST, on rats, CERB, France 2000)
- Classified Non-allergic (test n°20040231STC, Magnusson and Klingman method on guinea pigs, CERB, France, 2004)
- No side effects since first marketed.
- Contraindications: none
> PRECAUTIONS FOR USE

To avoid any microbial contamination, keep containers closed.Opened containers in eyewash stations should only be kept for six months. Do not use after the expiration date written on the containers.

> ADVERSE EFFECTS

HF ocular burns can lead to significant injuries. Hexafluorine®, because of its hypertonicity, stops the penetration and extracts the HF. For 1 minute of contact with hydrofluoric acid, washing with 500ml of Hexafluorine® prevents or minimises the chemical burn. If the duration of contact is more than 1 minute, the chemical burn appears. Ocular washing with Hexafluorine® can lead to a feeling of dryness. The use of Washing Solution®, a comfort washing solution isotonic to tears, leads to a more rapid return to a physiological state. Further medical care, if needed, will then be carried out in optimal conditions.

> WHEN HEXAFLUORINE® SHOULD NOT BE USED

Hexafluorine® is less effective on alkaline solutions. The use of Diphotérine® is much better adapted to such cases. Hexafluorine® has not been certified for use in burns resulting from HF ingestion, but it has been tested and classified as non-toxic by ingestion in rats.

> - CLASSIFICATION OF HEXAFLUORINE®

- Washing solution,
- Medical device
- Class IIa, sterile
- CE 0549, initial CE certificate September 30, 1996, renewed February 23, 2006 after audit
Diphotérine® brings a general-purpose response to aggressive chemicals. It improves the management of ocular and cutaneous chemical splashes by pushing back the time of intervention in emergency situations to 1 minute after the splash for optimal effectiveness. When the intervention time is greater than 1 minute, the chemical burn will have already appeared. The delayed use of Diphotérine® will make it possible to stop the chemical’s action on the tissues and to minimise the evolution of the burn, as well as associated pain and inflammation. By limiting the burn, Diphotérine® allows, under better conditions, the application of therapeutic protocols according to the severity of the burn.

Hexafluorine® improves the management of ocular and cutaneous splashes of hydrofluoric acid or fluorides in an acid medium. Used within the first minute, its effectiveness is optimal. If the contact time is longer than one minute, in addition to Hexafluorine®, apply a treatment based on a chelating fluoride antidote such as calcium gluconate.

2. Falcy M, Blomet J. Premiers soins en cas de projections oculaires, premiers résultats d'enquête [First aid in cases of ocular splashes, preliminary results]. DMT 1993, 53, 1st trimester, 33-41

3. Falcy M, Blomet J. Evaluation de l'efficacité des premiers soins lors de projections de produits chimiques [Evaluation of the efficacy of first aid in cases of chemical splashes]. DMT 1997, 70, 2nd trimester, 137-146

4. Testimonial letters, to be consulted on www.prevor.com


15. Mathieu L, Burgher F, Hall AH. Diphoterine® chemical splash decontamination solution: skin sensitisation study in the guinea pig. Accepted for publication in Cutaneous and Ocular Toxicology


Emergency washing of chemical splashes

Management of accidental chemical spills

Training sessions and technical manuals for chemical risk comprehension, management and prevention.

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