

# NaOH

## In Vivo Digestive Burns

### Contamination and Decontamination of Caustic Soda

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**Introduction:** Approximately 15 000 cases of caustic ingestion are registered in France. Even though 75 % of these cases are mild, vital and functional risks in severe cases exist. Oesophageal excision is thus often performed, in order to limit the spread of lesions. For less severe injuries, there is no recognized treatment. Amphoteric concept and hypertonicity have previously been used for active decontamination of cutaneous and/or ocular chemical burns. The purpose of this study is to evaluate decontamination with an amphoteric gel, Diphogel, on oesophageal lesions depending on times of exposure to an alkaline agent.

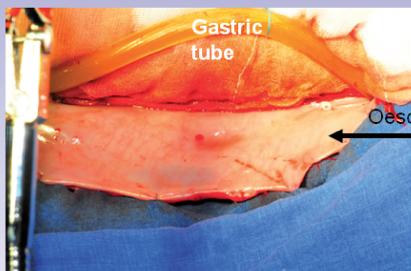


Figure 1

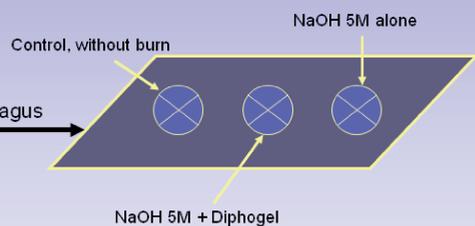
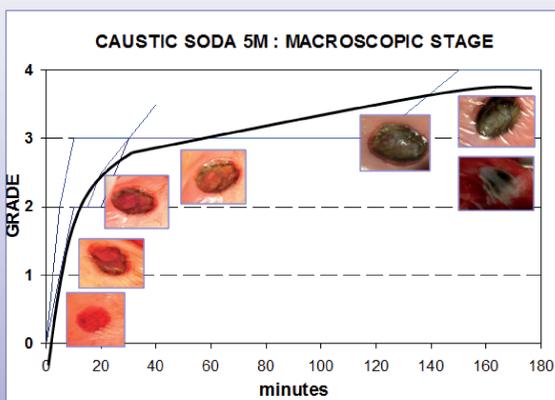


Figure 2

**Methods:** All applicable animal use guidelines were followed. The experiment was performed on two groups of 5 anesthetized goats each. In the first, acute toxicity was studied with a high gel excess. In the other, gel efficacy was evaluated. After surgical cervicotomy, the oesophagus was opened and laid out flat for a 10 cm length (fig.1). 50 µL of sodium hydroxide (5M) were deposited by spots, at different times, alone or followed by gel application (fig.2). Macroscopic lesions on mucous membranes and the muscularis, and their pH (during 30 min with gel exposure) were evaluated. Anatomopathologic analysis supplemented the study.

**Results:** In less than 3 min, mucous membrane lesions appeared. Sodium hydroxide diffuses and reaches the muscularis after 12-13 min. Severe injury (grade III) appeared macroscopically after approximately 30 minutes. Regarding acute toxicity assay, administration of an excessive dose of gel orally was consistently associated with diarrhoea. Administered early after 5 and 10 minutes, the gel prevented the diffusion of sodium hydroxide into the muscularis and integrally preserved it. Beyond 20 minutes, the muscularis was already damaged. The gel blocked the extent of tissue destruction on macroscopic, pH-metric, and histological assessments.

### Macroscopic Stage



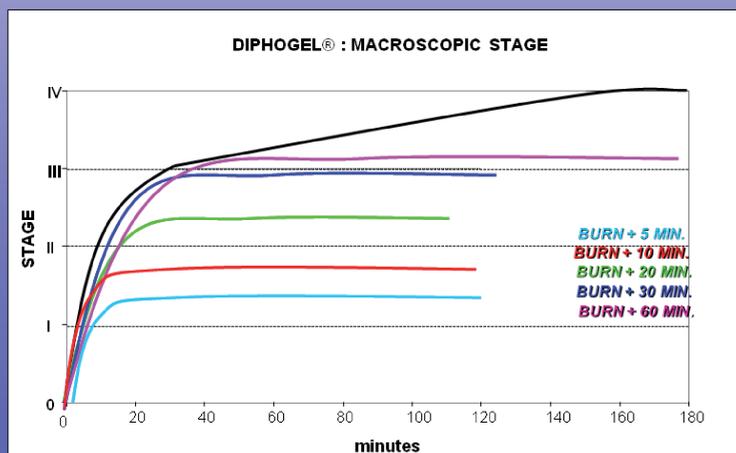
Burn development kinetic - macroscopic evaluation

Exposure times:

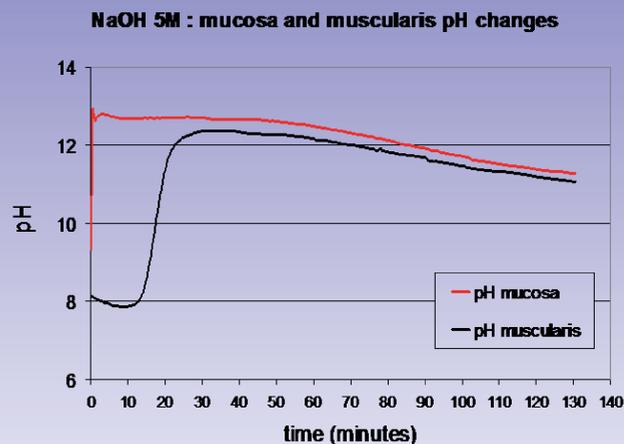
5 min, 20 min, 30 min, 40 min, 60 min, 180 min

Diphogel® application duration	Grade
5 min	I
10 min	II
20 min	II - III
30 min	III
60 min	> III

No macroscopic changes after Diphogel application compared to before application. No progression in the lesion observation was observed.



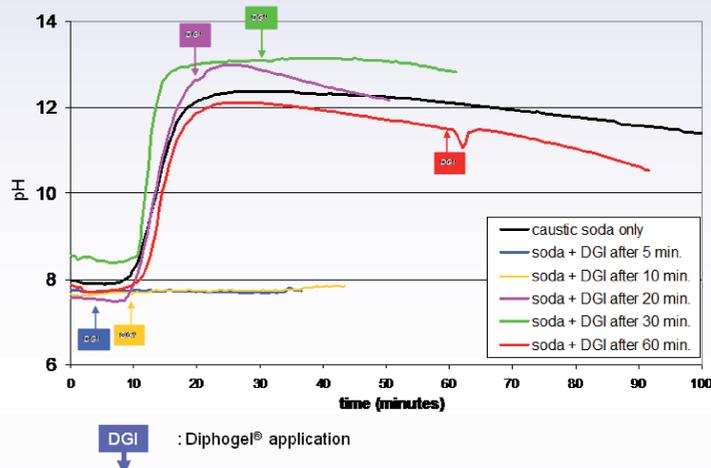
### pHmetry Assessment



The surgical approach of the oesophagus allowed measuring both mucosal and muscularis pH. The ion's diffusion through the entire oesophagus wall was indicated by the muscularis pH value.

Immediate increase of the mucosal pH within the first minute, and full penetration between 12 and 13 min.

### muscularis propria : pHmetric assessment

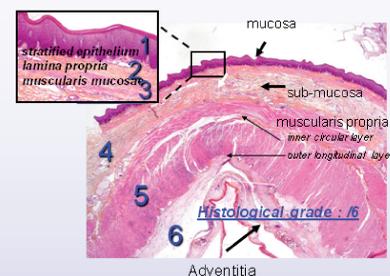
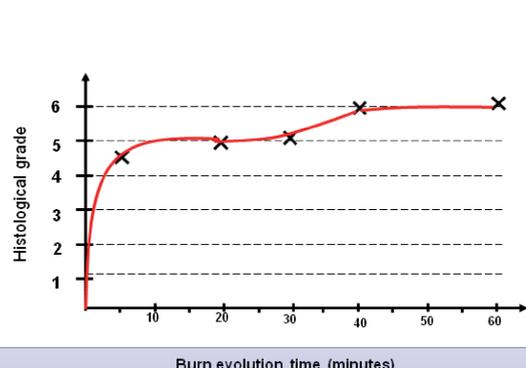


Full penetration of sodium hydroxide applied in these experimental conditions is avoided when Diphogel is applied in the first 10 minutes: muscularis propria is preserved.

In the 3 other cases where Diphogel was applied after full sodium hydroxide penetration, pH remained high.

### Histological Stage

NaOH 5N : histological grade according to the burn evolution time



Histological classification of lesions

Histological grade expected before Diphogel application	Diphogel® application time	Diphogel evolution time before removal for histological study	Histological Grade	
			Observed	Expected
4,5	DIPHOGEL® at 5 min	47 mn	4,5	6
5	DIPHOGEL® at 10 min	125 mn	5	6
5	DIPHOGEL® at 20 min	97 mn	5,2	6
5,5	DIPHOGEL® at 30 min	250 mn	6	6
6	DIPHOGEL® at 60 min	152 mn	6	6

Half of the muscularis propria is already severely altered after 5 min of caustic contact. According to histological results, Diphogel helps to reduce the burn grade, if applied before 20 min.

**Conclusion:** The amphoteric and hypertonic gel appears advantageous for decontamination of oesophageal caustic burns. Administered very early, it prevented the development of serious lesions in this animal model; beyond 20 min, its effectiveness was lessened. This is in agreement with a previous study performed in a pig model. Based on these data, the gel is promising for further evaluation. Human studies could be proposed once the innocuousness of the gel by this administration route is completely evaluated.