

6/2/2010

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**Review:** NIOSH Skin Notations Review - Group A

**Profile Number:** 17

**Profile Title:** Sodium hydroxide (NaOH)

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### Summary

Both reviewers found the scientific rationale behind the skin notation assignments of sodium hydroxide to be generally acceptable. Reviewer 1 felt that the document outlined well the systemic health hazards, direct health hazards, and immune-mediated responses associated with skin exposure. Reviewer 1 did, however, note a significant omission of the word "not" in the SK:SEN section. The last sentence reads as though the SK:SEN assignment was made, when it was not, and the reviewer agreed with the rationale for not assigning it. Reviewer 2 found some deficiencies in the description of the systemic health hazards, direct health hazards, and immune-mediated responses. These are given in detail below.

### Recommendations

- Add the need for more acute toxicity data. (Q1, Reviewer 2)
- Provide "NOEL" in man. See elegant data in man - Alf Bjornberg textbook (about 1965 – Sweden) (Q3, Reviewer 2)
- Add the need for experimental guinea pig, etc. sensitization studies. (Q5, Reviewer 2)
- Correct apparent misstatement at end of paragraph entitled, "4.0 Immune-mediated Responses (SK:SEN)," where the word "not" is omitted. Should read, "Therefore, on the basis of the data for this assessment, NAOH is not assigned the SK:SEN notation." (Q6, Reviewer 1)
- NaOH is a penetration enhancer; provide patent reference (Q13, Reviewer 2)

### Suggested additional scientific data to review:

- Alf Bjornberg textbook (about 1965 – Sweden) (Q3, Q12, Reviewer 2)

### Verbatim Reviewer Comments

**1. Does this document clearly outline the sysemic health hazards associated with exposures of the skin to the chemical? If not, what specific information is missing from the document?**

#### Reviewer 1:

This document clearly explains that there is no reliable data showing the absorption of NaOH through the skin or that it could cause any systemic toxic effects following dermal exposure.

#### Reviewer 2:

Partially. Add need for more acute tox data.

**2. If the SYS or SYS (FATAL) notations are assigned, is the rationale and logic behind the assignment clear? If not assigned, is the logic clear why it was not (e.g., insufficient data, no identified health hazard)?**

Reviewer 1:

These notations are not assigned to NaOH by this document.

Reviewer 2:

NA

**3. Does this document clearly outline the direct (localized) health hazards associated with exposures of the skin to the chemical? If not, what specific information is missing from the document?**

Reviewer 1:

Due to its strong alkalinity, it is no surprise that NaOH is corrosive to the skin. Volunteer and animal studies showing corrosivity of this compound are described clearly. In addition, studies of human and animal in vitro systems are presented.

Reviewer 2:

Partially. Provide "NOEL" in man.

See elegant data in man- Alf Bjornberg textbook (about 1965- Sweden).

**4. If the DIR, DIR (IRR), or DIR (COR) notations are assigned, is the rationale and logic behind the assignment clear? If not assigned, is the logic clear why it was not (e.g., insufficient data, no identified health hazard)?**

Reviewer 1:

The rationale and logic for assigning the SK:DIR (COR) to NaOH is clearly presented in this document.

Reviewer 2:

Yes

**5. Does this document clearly outline the immune-mediated responses (allergic response) health hazards associated with exposures of the skin to the chemical? If not, what specific information is missing from the document?**

Reviewer 1:

This document presents the conclusions of several studies dealing with the skin sensitization potential of NaOH in humans. All data indicates that NaOH does not cause an immune-mediated response and it does not act as a skin sensitizer.

Reviewer 2:

Partially. Add the need for experimental guinea pig, etc. sensitization studies.

**6. If the SEN notation is assigned, is the rationale and logic behind the assignment clear? If not assigned, is the logic clear why it was not (e.g., insufficient data, no identified health hazard)?**

Reviewer 1:

The logic and rationale for not assigning the SK:SEN notation to NaOH is clearly presented in this document. Be that as it may, there seems to be a misstatement at the end of the paragraph entitled "4.0 Immune-mediated Responses (SK:SEN)". For some reason, the word "not" is omitted, so the last sentence in this paragraph says that NaOH has been assigned the SK:SEN notation, which is not consistent with all the previous statements in this paragraph and throughout the document. The last sentence should be corrected so it reads as follows: "Therefore, on the basis of the data for this assessment, NAOH is not assigned the SK:SEN notation."

Reviewer 2:

Partially. See #5 (above)

**7. If the ID<sup>(SK)</sup> or SK were assigned, is the rationale and logic outlined within the document?**

Reviewer 1:

These notations were not assigned to NaOH in this document.

Reviewer 2:

NA

**8. Are the conclusions supported by the data?**

Reviewer 1:

All of the conclusions are supported by the data. I agree with the skin notation given in Table 1 and supported by the summary in the last paragraph of the document entitled "5.0 Summary".

Reviewer 2:

Partially. See #3 and #5 above.

**9. Are the tables clear and appropriate?**

Reviewer 1:

The tables are clear and appropriate.

Reviewer 2:

Yes

**10. Is the document organized appropriately? If not, what improvements are needed?**

Reviewer 1:

The document is organized appropriately.

Reviewer 2:

Yes

**11. Is the language of the manuscript acceptable as written? If not, what improvements are needed?**

Reviewer 1:

The language throughout the manuscript is both clear and concise.

Reviewer 2:

Yes

**12. Are you aware of any scientific data reported in governmental publications, databases, peer reviewed journals, or other sources that should be included within this document?**

Reviewer 1:

I am not aware of any additional scientific data that should be included in this document.

Reviewer 2:

Yes. See #3 above.

**13. What is your final recommendation for this manuscript? (Do you agree with the scientific rationale that serves as a basis for the skin notation assignments?)**

Reviewer 1:

After correcting the concluding sentence in the paragraph entitled "4.0 Immune-mediated Responses (SK:SEN)", I recommend that this manuscript be accepted as the final "SK Profile for NaOH".

Reviewer 2:

Acceptable. Above would help reader.

NB NaOH is a penetration enhancer; provide patent reference.

Add statement re data (or lack of) on:

- a) Photoirritation
- b) Photoallergic Contact Dermatitis
- c) "Validity" of penetration algorithm