

6/2/2010

Review: NIOSH Skin Notations Review - Group A

Profile Number: 22

Profile Title: p-Phenylene diamine (PPD)

Summary

Both reviewers generally agreed that the systemic health hazards associated with exposures of the skin to p-Phenylene diamine were clearly outlined in the document. They found the scientific rationale behind the skin notation assignments to be acceptable. Reviewer 1 did have suggestions for improvement of the direct health hazards and immune-mediated responses sections (see Recommendations).

Recommendations

- Add best estimate of acute and cumulative "NOEL" in man. (Q3, Reviewer 1)
- Add for all types of observations the "NOELS." (Q5, Reviewer 1)
- Add – does PPD elicit ICU (immunologic contact urticaria) – as potentially fatal. (Q5, Reviewer 1)
- Add clearer statement regarding possible human carcinogenicity – especially occupational. (Q13, Reviewer 1)

Verbatim Reviewer Comments

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

Reviewer 1:

Yes

Reviewer 2:

This clearly prepared document outlines the systemic health hazards associated with exposures of the skin to p-Phenylene diamine. All areas are covered and no specific information is missing.

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:

NA. See ICU below.

Reviewer 2:

p-Phenylene diamine has not been assigned SYS or SYS (FATAL) notation. The logic behind not assigning the notation is very clearly explained by summarizing available data.

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:

Partially. Add best estimate of acute and cumulative "NOEL" in man.

Reviewer 2:

This document clearly outlined the direct (localized) health hazards associated with exposures of the skin to p-phenylene diamine and assigned the notation SK: DIR (IRR) notation. This is very well explained and documented.

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:

NA

Reviewer 2:

The rationale and logic behind assigning DIR (IRR) notation is clearly explained in the document.

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:

Partially. Add – for all types of observations the "NOELS"

Add – does PPD elicit ICU (immunologic contact urticaria) – as potentially fatal

Reviewer 2:

This document clearly outlined the immune-mediated responses health hazards associated with exposures of the skin to p-Phenylene diamine and assigns SEN notation.

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:

Partially. See above

Reviewer 2:

The rationale behind assigning SEN notation for p-Phenylene diamine is well explained in the document.

7. If the ID^(SK) or SK were assigned, is the rationale and logic outlined within the document?

Reviewer 1:

NA

Reviewer 2:

No such notations were assigned.

8. Are the conclusions supported by the data?

Reviewer 1:

Partially. See above

Reviewer 2:

Conclusions reached in the document are well supported by the data provided.

9. Are the tables clear and appropriate?

Reviewer 1:

Yes

Reviewer 2:

All tables are appropriate and clear.

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

Reviewer 1:

Yes

Reviewer 2:

The document is appropriately organized. No improvements are required.

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

Reviewer 1:

Yes

Reviewer 2:

The language of the manuscript as written is acceptable.

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:

Yes

Reviewer 2:

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

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:

Acceptable. See above especially ICU, above would aid reader.

Add clearer statement re possible human carcinogenicity– especially occupational

NB Add statement re data (or lack of) on:

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

Reviewer 2:

I recommend that this document should be accepted as presented.