

6/1/2010

Review: NIOSH Skin Notations Review - Group A

Profile Number: 11

Profile Title: Bisphenol A (BPA)

Summary

Both reviewers generally agreed that the document clearly outlines the systemic health hazards, direct health hazards, and immune-mediated responses associated with skin exposure to Bisphenol A. However, Reviewer 1 questions the SK:DIR (IRR) notation as assigned. One of the two studies cited, Shumskaya [1961], concludes that BPA had an insignificant effect on skin, whereas, the NIOSH document under review states that, "a limited number of studies" and "available evidence indicates that mild skin irritation following prolonged dermal exposure may exist." It is recommended that the findings of the Shumskaya study be more clearly described to support justification of the SK:DIR (IRR) notation for BPA.

Recommendations

- Further justify SK:DIR (IRR) notation assignment by describing the findings of the Shumskaya [1961] more clearly. Reconcile Shumskaya concluding that BPA had an insignificant effect on skin with the conclusions of the NIOSH document. (Q4, Q13, Reviewer 1)
- Appendix showing the calculation of the SI ratio is missing, although it is listed in the Table of Contents. (Q10, 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:

This document points out that there are no human or in vivo studies and no epidemiological studies involving the dermal uptake of BPA that could result in systemic toxic effects. The fact that insufficient data exists is clearly explained.

Reviewer 2:

This document clearly outlined the systemic health hazards associated with exposures of the skin to Bisphenol A. No specific information is missing from the document.

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:

The fact that SK:SYS notation is not assigned is clearly explained due to insufficient data.

Reviewer 2:

Based on the information available bisphenol A was not assigned the SYS or SYS (FATAL) notation. The rationale and logic behind this is clear in the document.

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:

This document does describe several studies dealing with skin irritation and clearly outlines the results of each study with the exception of Shumskaya [1961].

Reviewer 2:

This document clearly outlined the direct health hazards associated with exposures of the skin to bisphenol A. Bisphenol A was not assigned the SYS notation. This is clear and no specific information was found to be missing.

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:

Although the SK:DIR (IRR) notation is assigned, there seems to be insufficient justification for this assignment based upon the studies described. One of the two studies cited as rationale, Shumskaya [1961], actually concludes that the BPA had an insignificant effect on skin. Although the author of this document concludes that there are "a limited number of studies" and the "available evidence indicates that mild skin irritation following prolonged dermal exposure may exist", additional rationale or justification for making the IRR notation needs to be provided.

Reviewer 2:

Bisphenol A is assigned DIR (IRR) notation. The rationale and logic behind this notation is clear.

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 clearly describes skin sensitization and photo allergenic potential associated with exposures of human skin to BPA.

Reviewer 2:

This document clearly outlined the immune-mediated responses to bisphenol A and a notation of SEN is assigned. This is clear and no specific information is missing from the document.

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:

This document clearly describes human experience and a predictive test in animals that justify the

assignment of the SK:SEN notation.

Reviewer 2:

The logic and rationale for SEN notation to bisphenol is clear in the document.

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

Reviewer 1:

These assignments were not made.

Reviewer 2:

No such notation were assigned.

8. Are the conclusions supported by the data?

Reviewer 1:

Other than the SK:DIR (IRR) notation assignment, all conclusions made in the document are supported by the data presented.

Reviewer 2:

The conclusions in the document are supported by the data provided.

9. Are the tables clear and appropriate?

Reviewer 1:

The tables are clear and appropriate.

Reviewer 2:

Tables are clear and appropriate.

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

Reviewer 1:

The document is well organized. Where is the appendix showing the calculation of the SI ratio? It is listed in the Table of Contents.

Reviewer 2:

The document is organized appropriately.

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

Reviewer 1:

The document is written in a clear and concise language.

Reviewer 2:

The language of the manuscript as written is acceptable. No improvements are necessary.

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 in this document.

Reviewer 2:

I am unaware of any information that should be included in the 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:

I recommend that the findings of the Shumskaya [1961] study be more clearly described, so it is evident why they support justification for the assignment of the SK:DIR (IRR) notation to BPA.

Reviewer 2:

I recommend that the document be accepted as presented.