

**Dragon, Karen E. (CDC/NIOSH/EID)**

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**From:** - |  
**Sent:** Sunday, November 23, 2008 6:29 PM  
**To:** NIOSH Docket Office (CDC)  
**Subject:** Re: Peer Review of NIOSH Current Intelligence Bulletin: A Strategy for Assigning the New NIOSH Skin Notations for Chemicals  
**Attachments:** A Strategy for Assigning the New NIOSH Skin Notations for Chemicals -

Please find attached my comments on the above document. Please accept my apologies for the delay in sending these.

Research Director

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## **A Strategy for Assigning the New NIOSH Skin Notations for Chemicals**

Skin notation is assigned in many countries for a wide range of chemicals. There is little evidence of any consistency in the approach adopted, either within or between countries. It is therefore an important development that NIOSH have produced a sound scientific basis for assigning skin notation. In addition, the introduction of a more elaborate skin notation has the potential to improve the clarity and utility of the information communicated. I support the NIOSH proposal for assigning skin notation for chemicals.

I have provided more specific comments under the following list of questions.

### ***1. Are the proposed classes of skin notations appropriate?***

It is proposed to assign skin notation for systemic (SYS), direct (DIR), and sensitizing (SEN) effects. Substances that may be lethal following acute dermal exposures are designated with the systemic sub-notation (FATAL). Irritants and corrosive chemicals are indicated by the direct effects sub-notations (IRR) and (COR), respectively. These notations cover the main adverse health effects that may arise from skin exposure to chemicals. They therefore seem an appropriate set of classes for the skin notation.

My main concern with the proposal is in relation to the intended user base, which is not clearly described in the present document. Mention is made of the NIOSH *Pocket Guide to Chemical Hazards*, which I understand is aimed at providing a "concise source of general industrial hygiene information for workers, employers, and occupational health professionals." The information in the Guide is quite technical and I think more suited to use by health and safety professionals rather than workers or employers.

The proposals for the skin notation sit well with the other information in the Pocket Guide. However, I note that there is already information in the Guide about entry routes into the body and target organs, both including skin. The assignment of skin notation and these other pieces of information in the Guide will need to be done with care. The totality of information may be open to some misinterpretation, e.g. if a chemical is assigned SK-SEN but did not have skin as a target organ.

The simple assignment of skin notation was open to misinterpretation, while this more complex notation may be too difficult for the non-technical user to fully understand.

***2. Are the proposed criteria for assigning each type of skin notation appropriate?***

I believe that the approach adopted to assign skin notation are appropriate. The reliance on a broad range of in vivo, in vitro and modelling data will ensure that the assignments are based on the best available evidence. As noted above the assignment needs to be coordinated with the other information in the NIOSH Pocket Guide.

***3. Is the proposed assignment of multiple skin notations useful for protecting workers from dermal hazards?***

I believe this is an important step forward and I am sure that it will help protect workers from dermal hazards. My two main reservations are points that are recognised in the document: first that this is a designation of hazard rather than risk and second that it is only for the pure chemical and not the mixtures that are likely to be found in articles and preparations used in the workplace.

In my opinion it is necessary for occupational hygiene practice to move beyond the management of dermal exposure on the basis of hazard and to provide tools to facilitate risk-based management strategies. For example, a relatively volatile agent assigned a skin notation is, in my opinion, unlikely to be systemically absorbed via the skin unless the worker has some fairly extreme exposure – e.g. immersion of part of their body in the liquid. However, with a hazard-based warning skin notation the users may be drawn towards the use of chemical protective clothing to protect a negligible risk. Currently we do not have good tools to make assessments of the risk from dermal exposure and this should be a priority for the future.

Substances in mixtures may behave differently from the pure chemical. It is impossible for a regulator to properly deal with the very large number of mixtures on the market. The link between the proposed skin notation and the Globally Harmonized System (GHS) for

labelling chemicals will hopefully ensure that there is correspondence between the skin notation and labelling of chemicals in the marketplace.

***4. Should the SEN notation apply strictly to allergic contact dermatitis or is it appropriate to assign the SEN notation for other immune-mediate responses, such as respiratory sensitization, airway hyperactivity and mucosal inflammation, associated with dermal exposure to a compound?***

Yes, I think it is appropriate to have a relatively wide definition of the potential sensitisation hazard from skin exposure to chemicals. As far as the worker is concerned it is the fact that an adverse effect occurs as a consequence of dermal exposure rather than the final target organ for that effect. The authors make a good argument for the inclusion of respiratory sensitisation from dermal exposure and I believe that this could be one of the more important developments from the changes in skin notation. Certainly in the UK there is some reluctance to recognise that skin contact with some chemicals may be a cause of respiratory sensitisation. In my opinion this may be part of the reason why in the UK we have not seen the reduction in occupational asthma following the introduction of strict risk management measures for respiratory exposure to isocyanates.

***5. Does the proposed harmonization scheme found in Appendix G.2 link the new NIOSH skin notations and the GHS assignments sufficiently?***

I am not an expert in the GHS but from what I have read in the document I am reassured that the proposed approach to assigning skin notation is consistent with GHS.

***6. Should additional information be included within document? If so, what?***

The document should discuss how the new assignment will fit with the information already in the NIOSH Pocket Guide on target organs and exposure route.

***7. Do the data cited support the objectives of the document?***

I believe that the document provides a logical approach to assigning skin notation and is supported by appropriate scientific arguments. I could not find any explicit statement of

the objectives of the document, but if it is to "promote the identification and control of dermal exposures to hazardous agents and conditions in the workplace" then I am certain that this document will have an important impact.

**8. Are the conclusions appropriate in light of the current understanding of the toxicological data?**

Yes, I consider that the conclusions that the authors have arrived at are appropriate in the light of the current toxicological data.

**Other minor comment**

On page 8 it is said "Protocols for testing chemicals developed by the Organization for Economic Cooperation and Development (OECD) and Registration, Evaluation, Authorization and Restriction of Chemical (REACH)." However, REACH is a European Union regulation rather than an organization. The relevant organization in Europe would probably be ECVAM (<http://ecvam.jrc.it/>) or another EU institution.

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