



November 18, 2008

Via E-Mail

NIOSH Docket Officer
Robert A. Taft Laboratories
4676 Columbia Parkway
M/S C-34
Cincinnati, OH 45226

Re: Comments of The Dow Chemical Company on Draft Document (D26) – Current Intelligence Bulletin (CIB): A Strategy for Assigning the New NIOSH Skin Notations for Chemicals

The Dow Chemical Company ("Dow") is pleased to submit these comments in response to the September 23, 2008 Federal Register Notice Docket Number NIOSH-109 request for public review and comments to the CIB: A Strategy for Assigning the New NIOSH Skin Notations for Chemicals."

Dow believes that employers and employees will benefit from an improved skin notation system that provides more specific and useful information about the specific risks from skin exposure. This system will correct some deficiencies in the current NIOSH Pocket Guide and provide useful information for the anticipation of health hazard risks and appropriate protective measures for workers, albeit with an additional level of complexity.

The proposed classes of skin notations are appropriate for hazard awareness and communication, and appear to be clearer for workers, as well as OEHS professionals, when for a clear determination of effect from dermal exposure can be made. However, it is not clear what the notation would be if the studies are inconclusive or if there is inadequate data to put a specific notation on a substance. Clearly, if a chemical has been evaluated and does not warrant notations, the **SK** notation is appropriate versus a full compliment of notations when deemed appropriate.

Data Sufficiency Important

To assure the credibility of the notation used, care should be taken to make sure that the determination of "sufficient data" for a skin notation is robust and provides real likelihood of a skin effect in humans. While the criteria are stated in the proposed strategy, there is room for interpretation and judgment in a "weight of evidence" methodology, particularly if the "scientific data" used for assigning skin notation are based upon "mathematical modeling and predictive algorithms." Although the document seems to address this, there could be an overly conservative interpretation of certain data (e.g., Quantitative structure-activity relationship (QSAR), dermal absorption, physical and chemical properties) which might not *demonstrate* adverse effects using experimental data. For example, in Dow's experience, initial investigations using three of the most prominent QSAR programs for dermal sensitization have about 60% accuracy against previous human and animal test results. While the document suggests a combination of absorption estimates with a positive QSAR might result in a skin notation, discussion with Scott Dotson during the public hearing indicated otherwise. This at least reinforces the need for clear description of the criteria and methodology. These decisions are neither simple, nor black and white and the process and criteria for such decisions need to include toxicologists and dermal experts when further clarification is needed. There needs to be

consensus regarding the interpretation of such data, as well as the process for doing so. Again, using a QSAR example, programs typically provide results with reliability or domain estimates. These confidence estimates should be recognized, but the literature is replete with many investigators providing 'definitive' interpretations under unreliable circumstances. Dow recommends that NIOSH include a summary of how it will utilize a QSAR approach to lend insight into whether a notation applies by analogy and indicate the degree to which QSAR outcomes can "drive" the notation.

If the calculations and decisions are overly conservative when data appear somewhat limited, then the result would be that far too many chemicals would be given the SK notation. This will result in a skin notation for many chemicals with little or no actual risk, while the same notation will be used for chemicals which are truly dangerous, diluting the value of the skin notation. The dilemma with an "overwarning" situation such as this is that employers and workers can tune out and ignore the risk when it seems everything is labeled as equally hazardous. This situation is exemplified by California's Proposition 65, leading one author to state, "It can be postulated that by failing to focus on the known risk factors associated with specific health effects (e.g., cancer) in humans, [California's] Proposition 65 has diminished the ability and effectiveness of public health efforts to address those known risks."¹

Left unstated in NIOSH's scheme is clear indication of what should be done when the studies are inconclusive or if there are inadequate data or QSAR correlations to confirm or refute systemic toxicity and yet various parameters (e.g. octanol-water partition) indicate that dermal absorption is likely. Dow believes that there should be some indication of the "unknown" status of dermal absorption in the resulting NIOSH notation. Would there be a scenario proposed whereby a substance in this situation would not have any indication? Or rather, would NIOSH perhaps put an asterisk and a footnote regarding the expected absorption but lack of definitive data? Dow considers the failure to address this situation clearly as a key gap in an otherwise complete and detailed classification scheme.

GHS and MSDS Considerations

The proposal indicates that the strategy for assigning skin notations has been developed to correspond with the classification strategy adopted in the Globally Harmonized System of Classification and Labeling of Chemicals (GHS). This is commendable and recommended that both the strategy and the actual skin notation results match the GHS classifications. Many manufacturers sell their products globally and it is likely that NIOSH's skin notation scheme will not be recognized worldwide. It would create problems to have different skin notations in different countries for the same chemical, if the organizations interpret data differently. It would be useful to know specifically how NIOSH plans to apply the skin notation classification of GHS. Dow strongly recommends that NIOSH provide a table (perhaps in an appendix) that compares and contrasts the scientific criteria for skin notations to clearly communicate the similarities and highlight any differences in classification in both systems.

For those entities (such as manufacturers or distributors of substances) that must develop Material Safety Data Sheets (MSDSs), consideration must be given to the financial and resource impacts of updating these skin notations for materials with RELs if reported on their MSDSs. Dow suggests that NIOSH take the steps below to minimize the practical MSDS creation impacts:

¹ **Juberg, Daland R., Ph.D.;** "Burning fireplace or wood stove fuels such as natural firewood results in emission of carbon monoxide, soot, and other combustion by-products which are known by the State of California to cause cancer, birth defects, or reproductive harm". California's Proposition 65 and Its Impact on Public Health. Abstract posted on December 1, 2000. http://www.acsh.org/publications/pubID.146/pub_detail.asp

- Consider the symbols and the space to report them on an MSDS or in a table. At a minimum, the format for "Notations" and the space allocated to them will need to be altered. Select only characters which any word processor, database or internet program can use, as some automated systems do not currently have the capability to utilize complex symbols beyond character strikeouts (use **SK** instead of **Ⓚ**). At a later date, if the GHS and resulting MSDS structure are adopted in the US, additional graphic capabilities may be available at that time.
- Consider contacting the Society of Chemical Hazard Communication (SCHC) regarding their OSHA Alliance Program on GHS and MSDSs to ensure they have considered inclusion of an expanded Section 8 inclusion of skin notations.
- Because these skin notations are new and more complex, provide a concise sentence or definition for MSDS preparers to include as brief footnoted explanations of the NIOSH skin notations just below the RELs in Section 8 of the MSDSs, particularly where they deviate from the traditional "Skin" notations.
- Plan to communicate the new skin notations and definitions to the various database providers used by manufacturers for creating MSDSs (e.g. Thomson Micromedex[®], ARIEL[®] by 3E Corporation or the United States National Library of Medicine).

NIOSH's proposed skin notation process could be leveraged globally, for instance, for inclusion in the European REACH Derived No Effect Levels (DNELs) for workers by the route of dermal exposure, and could potentially be adopted by other OEL-setting bodies. In the interest of applying the proposed skin notation scheme more broadly so that there are not multiple 'skin notation' schemes potentially based on different criteria, Dow would suggest requesting technical reviews from the ACGIH TLV[®] Committee and the AIHA WEEL Committee requesting a harmonized approach to setting and communicating skin notations.

The Dow Chemical Company appreciates this opportunity to offer its comments, and urges NIOSH to revisit the points discussed above.

Sincerely,

Susan D. Ripple, MS, CIH

Industrial Hygiene Leader
The Dow Chemical Company
Midland, MI 48674

Cc: Scott Dotson, NIOSH (via e-mail)
Charles Geraci, NIOSH (via email)