

Definitions and Interpretations of Skin Notations and the Use of Biological Monitoring to Assess Total Exposure

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What does a skin notation
mean to you as a practicing
industrial hygienist?



Topics for discussion

- What does “skin” mean around the world?
- Inconsistencies in the use of “skin” notation
- Implications of “skin” notation
 - Potential for systemic toxicity
 - Warning of significant dermal absorption
- The role of biological monitoring in assessing dermal exposure

The ACGIH® TLV® Skin Notation

All of the following apply

- Potential significant contribution of **overall exposure by cutaneous route**, including mucous membranes and eyes, from airborne exposure to gases, vapor, or liquid *OR* by **direct skin contact**
- Dermal application studies show significant absorption or **systemic effects**
- Acute animal toxicity studies show **low dermal LD₅₀** (<1000 mg/kg)

The ACGIH® TLV® Skin Notation (2)

- Ability to cause irritation, dermatitis, or sensitization is not considered relevant
- Excludes irritant or corrosive effects in the absence of systemic toxicity
- Integrates data from acute and repeat-dose animal and human studies with the chemical's ability to be absorbed

The AIHA WEEL Committee

“The word skin indicates that the material might be absorbed in **toxicologically significant amounts** through the skin. Therefore, skin contact can contribute to the overall exposure and invalidate the TWA exposure evaluations”

The Quebec Occupational Safety and Health Regulation

#7) Pc: SKIN (percutaneous): The designation "Pc" in the designation and remarks column refers to the potentially **significant contribution to the overall exposure** by the cutaneous route. Exposure is by contact with vapours or, of probable greater significance, by direct skin contact with the substance. The cutaneous route includes mucus membranes and the eyes"

The UK "Sk"

EH40/2002 Occupational Exposure limits 2002, part 3/29

The "Sk" notation is assigned ... where the available data or experience (or predictions) suggest that exposure via the dermal route may:

- Make a substantial contribution to **body burden**, and
- Cause **systemic effects**, so that conclusions about exposure and health effects based solely on airborne concentration limits may be incomplete

The "Sk" EH40/2002, part 3/30

- Absorption through the skin ... may result in a substantial **body burden** ...so that serious effects may result with little or no **warning**.
- Where the "Sk" notation has been assigned and ...there is a potential exposure route via skin absorption these factors should be taken into account in determining the **adequacy of the control measures**.

The MAK: A substance is designated with an „H“ when one of the criteria below are met.

- Based on workplace studies:
 - Percutaneous absorption is significant ; the percutaneous absorption is responsible for part of the **systemic exposure** and can contribute to **toxic effects**
- Based on animal studies:
 - Percutaneous absorption can be demonstrated in animal studies and the exposure can **contribute to toxic effects**

German „H“ (2)

- Based on in vitro studies:
 - Percutaneous absorption has been measured, the **flux and permeability** constants through the skin calculated or the percent of dose absorbed is calculated
- Based on theoretical models
 - On the basis of data for analogous substances or calculations with mathematical models, a relevant **level of percutaneous absorption** may be expected

The Japan Society for Occupational Health

“S” marks ... show that a **significant dose** of the substance concerned may be **absorbed through the skin** when the liquid or solution of the substance is in contact with the skin. Even the gas, vapor or solid of some substances may cause substantial skin absorption. OELs are set at conditions under which no skin absorption will take place

Comparison of skin designation MAK vs. TLV[®]

	MAK 2002	TLV [©] 2003
No in both	117	117
MAK+/TLV [®] -	50	--
MAK-/TLV [®] +	--	27
MAK+/no TLV [®]	52	--
no MAK/TLV [®] +	--	48
Total	219	192

Comparisons of TLVs[®] and EH 40 guidelines

	2003 TLVs[®]	2003 EH 40
Substances where both TLV [®] and EH 40 have a skin notation	72	72
Substances with a skin notation in EH 40 but no match in the TLV [®] book	-	31
Substances without a skin notation in the TLV [®] book but with one in EH 40	-	21
Substances with a skin notation in the TLV [®] book but not in EH 40	14	-

Examples of discrepancies

- 2-Butoxyethanol
 - No skin notation: TLV[®]
 - Skin notation: EH 40, MAK
- Chloroform
 - No skin notation: TLV[®], OEL
 - Skin notation: EH 40, MAK
- Hexane
 - No skin notation: EH 40, MAK
 - Skin notation: TLV[®], OEL
- Ethylamine
 - No skin notation: EH 40, OEL, MAK
 - Skin notation: TLV[®]

What does a skin notation warning mean to the IH?

- **Use PPE** - significant amounts of substance can be absorbed through the skin.
- Dermal absorption may result in significant **systemic toxicity** over that from inhalation only exposure
- **Biological monitoring** should be considered to assess exposure

Rationale for biological monitoring

- Airborne monitoring: does not assess skin absorption and may underestimate health risks
- There is a potential for absorption of a liquid or vapor through the skin
- There is a potential for significant absorption of the substance through the skin and potential systemic toxicity

Biological monitoring (2)

- To evaluate the effectiveness of PPE or engineering controls to control exposure by all routes.
- To provide meaningful “biofeedback” to workers on the needs to use appropriate PPE.
- BEIs[®] and their *Documentations* can be useful in the assessment of worker exposure by all routes, especially the dermal route.

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