



Downstream Users of Chemicals Co-ordination group

**DUCC POSITION ON**  
**Skin sensitisers and their potential**  
**identification as SVHC due to equivalent level of concern to CMRs**  
**(Article 57(f) of REACH)**

29 September 2015

Article 57 (f) of the REACH Regulation No. (EC) 1907/2006 stipulates that substances may be included in Annex XIV *‘for which there is scientific evidence of probable serious effects to human health [...] which give rise to an equivalent level of concern to those of other substances listed in points (a) to (e) [CMR 1A and 1B, PBT, vPvB]*<sup>1</sup>.

However, the REACH Regulation does not further define those aspects which could lead to an *‘equivalent level of concern’*.

In the last months, DUCC has seen increasing regulatory pressure proposing the inclusion of substances with **dermal** sensitising potential in the list of Substances of Very High Concern (SVHC).

DUCC firmly believes that the mere Classification and Labelling of a substance under the CLP Regulation No. (EC) 1272/2008 as a skin sensitiser cannot be a sufficient basis for a substance with dermal sensitisation potential to be considered a SVHC due to “equivalent level of concern”.

In most cases, skin sensitisation manifests itself as **allergic contact dermatitis** (skin lesions or inflammation), which, while undoubtedly disruptive, is treatable, preventable by avoidance of exposure and not life threatening to the same extent as carcinogens, mutagens and reproductive toxicants (CMRs).

We believe that:

- There is no **proportionality** in equating skin sensitising effects with the serious health effects of carcinogenic, mutagenic or reproductive toxicant substances, which can cause severe life threatening health effects and often require radical treatments.
- In spite of the constant debate on this issue, neither the **level of societal concern**, nor the **public funding** to combat the diseases, is the same for allergic contact dermatitis as for CMR related diseases.
- **Allergic contact dermatitis, the skin sensitisation reaction, can be avoided.**  
The effects of a CMR, e.g. tumour genesis, once there has been sufficient exposure to the substance, cannot be simply managed by avoidance of exposure whereas adverse effects of sensitising substances are drastically reduced by limiting the exposure of the person to the skin sensitising source, i.e. reoccurrence of skin effects can be prevented.

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<sup>1</sup> CMR: carcinogens, mutagens and reproductive toxicants; PBT: persistent, bioaccumulative and toxic, vPvB: very persistent, very bioaccumulative.



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- **Dermal sensitisation is a threshold effect.**

For dermal sensitisers, safe use levels for induction can be established and risk assessment conducted. In case a risk has been identified, appropriate risk management measures can be implemented.

For consumers in particular, labelling provides the necessary framework for managing reoccurrence of effects ('elicitation'), allowing exposure to be avoided.

When evaluating skin sensitising substances for potential further regulatory measures, we propose the following criteria to be fulfilled:

- The regulatory approach chosen should be proportionate to the level of concern. Applying Article 57(f) of REACH to skin sensitisers is disproportionate.
- Consider whether risk management measures are already in place within **other product legislation** establishing safe use levels (e.g. Cosmetic and Detergents Regulations).
- Consider the experience gained through **other legislation** (e.g. Chemical Agent Directive, Workers Protection legislation) protecting **workers** from the incidence of sensitisation from exposure.
- Ensure that **information** is made available for **consumers and workers** to be able to choose and limit, and, if necessary, avoid, exposure to allergens via adequate warning statements and/or effective risk management measures (e.g. gloves).

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*DUCG is a joint platform of European associations whose member companies use chemicals to formulate mixtures as finished products for end-users, in particular consumers and professional users (cosmetics, detergents, paints and coatings, inks, adhesives, aerosols, chemical distribution, construction chemicals, fragrances, crop protection chemicals, imaging and printing chemicals).*