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Statement of the

German Contact Dermatitis Research Group

(Deutsche Kontaktallergie-Gruppe; DKG)

concerning concentration limits for labelling of 2-methylisothiazol-3(2H)-one (MIT) in cosmetics and consumer products.

The DKG is the German speaking scientific society dedicated to clinical research in contact allergy. The IVDK is a network of currently 56 departments of dermatology in Germany, Switzerland, and Austria dedicated to clinical epidemiology of contact allergy. All IVDK members are also member of the DKG and perform and read patch tests according to DKG guidelines.

The DKG preservative series is patch tested in about 60% of all IVDK patients, summing up to about 7,000 patients per year. During routine patch testing the DKG preservative series in the departments of dermatology joining the IVDK, a continuous increase of sensitization to MI, being patch tested at 500 ppm in Aqua, was noted, from 2.0% positive reactions in 2009 to 7.2% in 2013 and 2014. This increase was accompanied by an increase in positive reactions to the mixture methylchloroisothiazolinone / MI (ratio 3:1; tested at 100 ppm aq.), in most cases probably due to cross-reactions. In depth IVDK data analyses revealed that very probably cosmetics and body care products, but also paints are the most important allergen sources leading to MI sensitization. Currently, the maximum allowed concentration of MI in cosmetics is 100 ppm. From our epidemiological data, it is obvious that this concentration is high enough to sensitize many individuals.

Reactions frequencies to all other preservatives tested in the preservative series remained stable during the years 2009 to 2014, underlining that the current problem is a specific problem caused by MI, not generally by all preservatives.

MI elicitation thresholds have been determined in 40 patients with a positive patch test reaction to MCI/MI in the DKG / IVDK (data not published yet). A repeated open application test (ROAT), using MI concentrations of 50 to 200 ppm, was performed.
21 patients (52.5%) reacted to any of the ROAT preparations containing MI and 19 were ROAT negative. The vast majority (19/21) reacted already to the 50ppm or 100 ppm ROAT.

Conclusion:

The impact of sensitization to MI and subsequent clinically manifest disease (allergic contact dermatitis) after contact to MI containing products is even extended to patients sensitized to the mixture MCI/MI, a preservative often used in industrial applications. Hence, there is an impact also in the field of occupational medicine.

Against the background of our above mentioned data, hereby, we would like to inform the European chemicals agency that the MI threshold concentration of 0.06% (600 ppm) as proposed concentration

limit for labelling is not evidence based and does not reflect the state of current scientific knowledge. It is definitely not low enough to protect consumers neither from skin sensitization nor elicitation of allergic contact dermatitis and derails necessary exposure assessment. In our opinion, the concentration limit for labelling must be markedly below 0.005% (50 ppm).

With best regards,

for the presidium of the German Contact Dermatitis Research Group (DKG)

Prof. Dr. Vera Mahler, Erlangen, President of the DKG

Prof. Dr. Johannes Geier, Göttingen, Vice-president of the DKG

Prof. Dr. Axel Schnuch, Göttingen, President of the IVDK, member of the DKG-presidium

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