

THE SCIENTIFIC COMMITTEE ON COSMETIC PRODUCTS AND NON-FOOD PRODUCTS
INTENDED FOR CONSUMERS

POSITION STATEMENT
ON THE

CALCULATION OF THE MARGIN OF SAFETY OF INGREDIENTS
INCORPORATED IN COSMETICS WHICH MAY BE APPLIED TO THE SKIN OF
CHILDREN

adopted by the SCCNFP during the 19th Plenary meeting
of 27 February 2002

Position Statement on the Calculation of the Margin of Safety of ingredients incorporated in cosmetics which may be applied to the skin of children

The stratum corneum barrier of human skin matures in the first days to weeks after birth, i.e. is as protective against percutaneous absorption of xenobiotics as adult skin. Thus the potential of percutaneous toxicity of any chemical is directly proportional to the respective surface area of skin contact.

The skin surface of infants and children relative to their body weight is larger : about three times higher skin-surface-area/body weight (SA/BW) ratio as compared with that in adults is often cited, mostly with reference to data collected by the US Environment Protection Agency EPA. The tables in EPA documentation do not differentiate between the ratios of new-borns and children of 2 years of age. An interpolation to the age of one year results in a ratio of about two.

The critical age of children possibly exposed to these products is one year or older (any exposure to direct sun for infants under the age of one should be strongly discouraged).

Furthermore it is commonly recognised that 80% of skin cancers are due to sun exposure under the age of 18 (American Academy of Dermatology). Thus there is a strong benefit in protecting children against UV-light exposure, amongst other measures by sun protection products, UV-photons being amongst the most toxic, carcinogenic, mutagenic and immunosuppressive agents in daily life.

Sun protection products are among the most extensively used cosmetic preparations as well as to the concentrations of incorporated UV filter substances as to the surface area of application, i.e. they have the greatest potential for percutaneous absorption.

Thus the question is raised whether it would be advisable to adjust the uncertainty factor of 100 commonly used in the calculation of margins of safety, for children accordingly, that is by multiplying this factor by the difference between the SA/BW ratio of adults to that of children. Renwick et al. recently summarised the outcome of a symposium on toxicokinetics in children.(1) He presented more precise tables of the SA/BW ratio for children than those of the EPA and addressed the problem of a potential need for an additional uncertainty of children. He comes to the conclusion that as to the intake of toxicants there is no such need.

From the cited tables it shows that in fact the difference between the SA/BW ration of children of one to two years of age, and that of adults is of 1.7.

This inter individual variation is already taken into account by the uncertainty factor of 100, which is composed of 10 for interspecies variations (animal to man) and 10 for inter individual variations, of which according to Renwick et al.(2), the factor of 4 accounts for variations in toxicokinetics (that is in the case of cosmetics in percutaneous absorption.).

Taking into account the cited facts it is considered that as for sunscreens and cosmetics, there is no general scientific justification for adding an extra uncertainty factor due to a larger exposure surface area in children over the age of one year.

References

1. Renwick AG, Toxicokinetics in infants and children in relation to the ADI and TDI. Food Addit Contam. Suppl. 15:17-35, 1998
2. Renwick AG, Dorne JL, Walton K., An analysis of the need for an additional uncertainty factor for infants and children. Regul Toxicol Pharmacol 31:286-96, 2000