Abstract

Title: Carcinogenic, Mutagenic, or toxic for Reproduction (CMR substances) Safety Statements for CMR substances present in ingredients to be used in cosmetic and personal care products.

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I. Abstract Body

CMR substances are chemical ingredients that cause carcinogenicity and mutagenicity in humans when exposed for long time or regular uses. The present review investigated the CMRs listed by European Union that are either banned or should be restricted for use in cosmetics as per Cosmetic Ingredient Database (CosIng). Among the CMRs, included were residual solvent s of Class I, II, and III; allergens that are part of flavours and fragrances like safrole; Prop65 (The Safe Drinking Water and Toxic Enforcement Act of 1986) elements listed by OEHHA. All the ingredients were identified that are used in preparation of cosmetics, their toxicity profile pertaining to carcinogenicity was identified from list of studies as reported by National Toxicological program in Report on Carcinogens (RoC) and effect of target organs and tumour index was assessed from reports from weight of evidence basis. TD_{50} (carcinogenicity potency dose/9 value was obtained from CPDB (The Carcinogenic Potency Project- ToxNet) database and Active Intake (AI) was calculated by help of ICH M7 Guideline on the Assessment and Control of DNA Reactive (Mutagenic) Impurities in Pharmaceuticals. The value obtained was compared with NSRL (No Significant Risk Levels) and MADL (Maximum Allowable Dose Levels) value given by OEHHA in Prop65 table for each ingredient to conclude that an exposure of less than or equal to value obtained as AI from use of a finished cosmetic product is not considered to pose a significant toxicological risk and does not represent any undue hazard with respect to human health.

II. Reference:

1 National toxicological Program, 14th Report on Carcinogens. Available at: https://ntp.niehs.nih.gov/pubhealth/roc/index-1.html

2 Proposition 65, Current Proposition 65 No Significant Risk Levels (NSRLs) Maximum Allowable Dose Levels (MADLs). Available at: https://oehha.ca.gov/proposition-65/general-info/current-proposition-65-no-significant-risk-levels-nsrls-maximum

3 Addendum To ICH M7: Assessment And Control Of Dna Reactive (Mutagenic) Impurities In Pharmaceuticals To Limit Potential Carcinogenic Risk, Application Of The Principles Of The Ich M7 Guideline To Calculation Of Compound-Specific Acceptable Intakes M7(R1), 9 June, 2015. Available at: http://www.ich.org/fileadmin/Public_Web_Site/ICH_Products/Guidelines/Multidisciplinary/M7/M7_Addendum_Step_2.pdf

III. Biography:

Jaideep Sarkar is doing his Ph.D. in Pharmacology from K. R. Mangalam University, Gurgaon, Haryana, India. He is also working as Toxicologist in WNS Global Services, Gurgaon, India. He has completed his Masters in Pharmacology at age of 25. He has worked in various highly reputed Pre-Clinical toxicology labs and highly esteemed regulatory toxicology labs in India too. He is also the editorial board member of Bio-Core group research journal publishing house in field of Toxicology. He has presented and also published few research articles in conferences of national and International levels in conference journals.

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