INTRODUCTION

BAT have expanded their product portfolio to meet the needs of the modern consumer. This has resulted in innovation in the arena of smokeless tobacco products (snus). With this expansion, BAT’s risk assessment approach needed to adapt to account for the differences in consumer exposure and resulting potential toxicological endpoints between pouched snus and traditional combustible products.

Pouched snus is pre-packaged moist tobacco in small teabag-like sachets. The product is used by placing the pouch under the upper lip for extended periods of time, meaning the consumer exposure is prolonged contact with the buccal vestibular mucosa. As with other tobacco products, pouched snus contains added ingredients. These ingredients in prolonged contact with the buccal mucosa could result in contact sensitisation if the ingredient is associated with this endpoint. Therefore, in order to conduct the risk assessment for contact sensitisation an appropriate exposure scenario taking into account product use (see Table 1) needed to be developed.

STEPWISE APPROACH

Whilst there was a need for a new approach, our basic principles of risk assessment remained the same and were translated into a new paradigm. A stepwise approach (see Figure 1) was developed to address the following key questions:

1. Is the level of ingredient(s) proposed above a sensitisation threshold of no concern of 10ppm (EU Cosmetics Directive labelling limit for ‘leave on’ products)?
2. Do any ingredient(s) above the threshold have any hazard alerts for contact sensitisation?
3. If yes, does the calculated Consumer Exposure Level (CEL) exceed the derived Acceptable Exposure Level (AEL)?

CASE STUDY 1 – Isoeugenol applied at 2.4ppm: Demonstrating the use of the sensitisation threshold of no concern

1. Is the presence of Isoeugenol within snus above the sensitisation threshold of concern? No
2. Does Isoeugenol have a harmonised classification for contact sensitisation?

a. Source used is the ECHA CLP database looking for formal classification of H317
b. No hazard alert identified for Menthol as a contact sensitisation

Conclusion: Isoeugenol is not a cause for concern regarding contact sensitisation at the intended level of inclusion

CASE STUDY 2 – Menthol applied at 2000ppm: Demonstrating the Weight of Evidence (WoE) approach applied to hazard screening

1. Is the presence of Menthol within the snus above the sensitisation threshold of concern? Yes
2. Does Menthol have a harmonised classification for contact sensitisation?

a. Source used is the ECHA CLP database looking for formal classification of H317
b. No sources checked include; ingredient MSDS, ECHA CLP database, EU Cosmetics directive 76/768/EEC and IFRA Guidelines

Conclusion: Menthol is not a cause for concern regarding contact sensitisation

CASE STUDY 3 – Hydroxycitronellal applied at 600ppm: Demonstrating the full risk assessment process

1. Is the presence of Hydroxycitronellal within the snus above the sensitisation threshold of concern? Yes
2. Does Hydroxycitronellal have a harmonised classification for contact sensitisation?

a. Source used is the ECHA CLP database looking for formal classification of H317
b. No sources checked include; ingredient MSDS, ECHA CLP database, EU Cosmetics directive 76/768/EEC and IFRA Guidelines

Conclusion: Hydroxycitronellal is not a cause for concern regarding contact sensitisation at the intended level of inclusion

FUTURE REFINEMENTS TO THE ASSESSMENT PROCESS

• Evolution of the sensitisation threshold of concern
  o Inclusion of dilution factor to account for some salivary clearance
  o Deeper understanding of the transfer of different chemical compounds from the snus to the consumer
  o Refinement of sensitisation assessment factors
  o Further determining the relative susceptibility to sensitisation of the oral mucosa vs. the skin
• Extrapolation from other industry approaches as the field of sensitisation develops

CONCLUSION

The assessment process provides a means to evaluate contact sensitisation potential of ingredients within BAT’s pouched snus products. The process developed is a base line that can be adapted to other product categories where contact sensitisation might be a concern.

REFERENCES


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