



Regulatory Statement

ALLERGY POTENTIAL OF PROXITANE

To determine the potential of a chemical to cause allergenic contact dermatitis, skin sensitisation tests can be done with animals. The available skin sensitisation tests have been reviewed by the European Centre for Ecotoxicology and Toxicology and Chemicals (ECETOC, 2000). Historically the species of choice for the assessment of skin sensitising activity has been the guinea pig.

Recently the producers of peracetic acid have prepared a critical evaluation of the physicochemical, ecotoxicity and toxicity data of peracetic acid (PAA) solutions (ECETOC, 2001). This report concluded:

No evidence for skin sensitisation was observed in two Böhler tests in guinea pigs with different solutions of PAA. In one guinea pig maximisation test a positive result was claimed, but the report does not allow a critical evaluation of the results. Despite the use of PAA in hand and surface disinfection no cases of skin sensitisation have been reported in humans. Taken together, there seems to be no indication for a skin sensitisation potential of PAA solutions in humans.

Based on Council Directive 67/548/EEC substances can be classified in the European Union (EU) as sensitising and assigned the risk phrase R42 (May cause sensitisation by inhalation) or R43 (May cause sensitisation by skin contact). Peracetic acid has neither been classified as R42 nor as R43.

Based on the previous information, our product Proxitane is considered non-sensitising and non-allergenic.

References

ECETOC (2000). Skin Sensitisation Testing for the Purpose of Hazard Identification and Risk Assessment

ECETOC (2001). Peracetic acid (Cas No. 79-21-0) and its Equilibrium Solutions. JACC report No. 40. European Centre for Ecotoxicology and Toxicology of Chemicals, Brussels, Belgium.

July 2019

Disclaimer:

To our present knowledge, the information contained herein is accurate as of the date of this document. However, neither Solvay nor any of its affiliates makes any warranty, express or implied, or accepts any liability in connection with this information or its use. This information is for use by technically skilled persons at their own discretion and risk and does not relate to the use of this product in combination with any other substance or any other process. This is not a license under any patent or other proprietary right. The user alone must finally determine suitability of any information or material for any contemplated use, the manner of use in compliance with relevant legislations and whether any patents are infringed. Solvay reserves its right to make additions, deletions, or modifications to the information at any time without prior notification.