〈原 著〉

油性肛門清浄剤の動物及びヒトに おける皮膚刺激性の検討

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The Comparative Study of Skin Irritancy in Animals and Human Using Oily Anal Cleansing

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Abstract

The skin irritancy of an oily anal cleansing product containing liquid triglyceride, squalane and guaiazulene as antiphlogistic was studied on animals and human.

After the skin irritation test with animals and human, clinical tests were carried out to confirm the final safety and the efficacy of this product on patients.

Single occlusive application of this product produced erythematous irritative effects on the flank of guineapigs, while no irritancy was observed on the back of rabbits and on both site of the nipple and the outer earlap of guinea pigs.

Although the cumulative skin irritancy ranging from slight to moderate was observed by the repeated applications of this product with rabbits and guinea pigs, such effect was not confirmed with hairless rats and hairless mice.

On the anal area of guinea pig, this product produced a very slight irritancy by the repeated applications.

Human examination including single closed patch test and repeated application test did not show any significant skin irritancy. In clinical examination with patient, any significant skin irritancy due to this product was not observed.

Key Words

skin irritancy, safety evaluation, difference of animal species, difference of applied site extrapolation