



Your Specialties, Our Expertise

Use of general terms for application frequency



December, 2022

In the recent meeting of Coordination Group (CG-54), a proposal of the Austrian Member State was discussed which has been raised in a CG e-consultation, concerning information on the use frequency of products (“Number and timing of application”) for use in PT 1, PT2 and PT4 given by the applicants in SPC and PAR for BPR product authorization.

Austrian authorities are experiencing that applicants often use quite general terms for application frequency for professional and non-professional use, such as “as required” or “daily use”, etc.



Your Specialties, Our Expertise

It has been proposed that these general terms must not be accepted any longer by the Member States, as the application frequency, e.g., expressed in number of applications per day, determines how often the product is applied and is a crucial input parameter especially for human exposure assessment. The maximum or typical number of applications per day must be stated in SPC and DRA/PAR authorised use to reflect realistic worst-case assumptions.

This proposal has been agreed at CG-54 meeting in November 2022 by consensus:

For product authorisation, the use frequency must be given in SPC and PAR according to the guidance and Annex VI, point (33) of the BPR and the term 'as required' (or similar terms, e.g. 'daily use') for determination of application frequency shall be no more accepted by the member states for the application frequency without further justification. Details of application frequency are relevant input parameters for human and environmental exposure and risk assessment. Therefore, the (maximum or typical) number of applications per day must be stated in SPC and DRA/PAR authorised use.



Your Specialties, Our Expertise

Examples are given as follows:

Example 1, hand disinfectants used in the medical sector: Nurses or hospital/medical staff should use hand disinfectants as often as necessary. However, in the case of hand disinfectants, a “maximal or typical” number of applications per day should be indicated in SPC and PAR authorised uses. This number should correspond to the safe number of applications determined by the exposure scenario (reverse reference scenario).

Example 2, surface disinfection products: no clear use frequency can be set. Therefore, a “maximal or typical” number of applications per day should be indicated in SPC and PAR authorised uses. This number should correspond to the safe number of applications determined by the exposure scenario (reverse reference scenario, chapter 3.2.5.5).



Your Specialties, Our Expertise

Example 3, automated dosing: In certain situations, “as required” can mean “adding the product intermittently to the system, in order to maintain a system concentration within certain defined limits”. In such cases, the term “as required” might be acceptable. However, typical and/or maximal amount of product needed for application should be given.

This conclusion might generally be applied to all PTs.

Sources

CG-54 e-c Use of the term as required for the application frequency vf.pdf

ECHA Guidance on the Biocidal Products Regulation Volume III Human Health - Assessment & Evaluation (Parts B+C), Version 4.0, December 2017, chapter 3.2.5.5 Reverse reference scenarios

Interested to read more publications from CEHTRA?
www.cehtra.com/publications