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Hand disinfectants (PT 1) to be used with dispensers and refilled containers (risk assessment, labelling information)

March, 2022

Introduction

In April 2021, the NO CA initiated an e-consultation in the Coordination Group, concerning packaging and labelling on dispensers and refilled containers used for hand disinfection.

The aim of the e-consultation was to have a harmonized agreement on the applicability of larger packaging volumes and labelling/information requirements on the dispensers and/or refilled in containers (i.e., dispensers or bottles) to ensure safe and efficient use of hand disinfectant products.

CG-members agreed that hand disinfectants provided in large packaging volumes should be used with a dispensing pump or systems, and to facilitate proper use of the product, information should be available for the user, also for products used in dispensers and refilled containers.

As agreement was not reached on all topics in the CG, it was decided to address them further in the 94th CA meeting in December 2021. After a discussion at the 94th CA meeting, a newsgroup was initiated. Five MSs and AISE provided written comments. The document was agreed by MSs at the 95th CA meeting.

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General agreement and conclusions

Member States agreed that for all use foreseen (i.e., intended use) hand disinfection products should be evaluated in the risk assessment, and addressed in the SPC, in order to facilitate safe and efficient use of the biocidal product.

Q1; A common maximum pack size for hand disinfectant products not to be used with a dispensing pump or in system.

Conclusion:

The decision on the appropriate pack size for hand disinfections to be used without a dispensing pump or system, should be considered as a part of the risk assessment of the product. During the product evaluation, the eCA should take into account all relevant aspects (e.g., suitable design, viscosity of the liquid, strength of the active substance, the orifice of the bottle opening) when concluding on an appropriate pack size that would ensure safe and efficacious use of the product.

Q2 and Q3; Labelling of dispensers and refilled containers to ensure information down the supply chain.

Conclusion:

Hand disinfectant products to be used in dispensers and/or refilled in containers (i.e., dispensers or bottles) should be assessed as a separate use in the risk assessment, and if found acceptable, included in the product authorization.

In this way, the use will be part of the authorization and specified in the SPC. When authorizing the biocidal product, one must ensure that the SPC provides instruction for all intended uses (e.g., filling of the dispensers, applying the product on the hands) as well as a thorough specification of the packaging and the dispensing pump or system to be used, all in accordance with the assessment.

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By this, it would be clear what labelling information the authorization holder (and distributers) should provide to the downstream user chain. This will further ensure that the user is provided with the information needed to facilitate safe and efficient use of the product.

Clear SPC information is also useful for enforcement when checking whether the product is placed on the market in accordance with the authorized use.

It was agreed that minimum labelling information to be provided on the dispensers and/or refilled in containers should be:

- the authorization number,
- the trade name of the biocidal product,
- the identity and amount of every active substance,
- the directions for use, including the period of time needed for the biocidal effect,
- the CLP triggered information (when relevant)

In addition, in cases where refilling is not part of the approval, it is useful to include a sentence in the use instructions in SPC to address this. The following sentence was agreed: “Use original packaging only. Do not refill or transfer to other containers/devices.”

Sources

CA-March22-Doc.4.4 – PT1 hand disinfectants