

LETTER OF EXPLANATION

Chemi-Pharm AS

Subject: Comment on interpretation of alcohol concentration requirement (60–80%)

The bidder's objection is based on an assumption that the alcohol concentration in hydroalcoholic products must always be expressed as % vol and that the tender's 60–80% requirement therefore refers exclusively to % vol. This assumption does not reflect the regulatory framework applicable to biocidal hand rubs in the EU.

Under Regulation (EU) No 528/2012 on biocidal products (BPR), the composition of a biocidal product must be reported as a "complete quantitative (g/kg, g/l or % w/w (v/v)) composition of the biocidal product" (Annex III, point 2.3).

<https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32012R0528>

This explicitly allows the use of mass-based units (% w/w) as well as volume-based units where appropriate. In addition, composition information in safety data sheets and classification under CLP/REACH is routinely expressed in % w/w.

The standard cited by the bidder, GOST 3639–79, and corresponding OIML/ISO alcoholometry tables, relate to the metrological control of alcoholic beverages, not to biocidal products. They are not the legal basis for the authorisation or labelling of biocidal handrubs under BPR. Consequently, their use to reinterpret the tender criterion is not justified.

For our product, Chemisept Med, the ethanol/isopropanol content is specified in the regulatory dossier and SDS as % w/w, fully compliant with BPR Annex III. Interpreting the tender requirement of "alcohol, concentration 60–80%" in this commonly used and legally accepted unit, Chemisept Med falls within the required range.

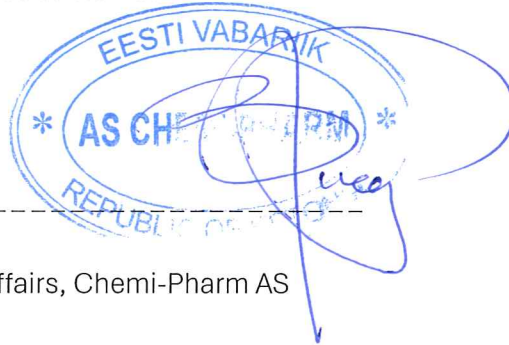
The bidder's subsequent statement that 80% as a mass fraction would be "physically impossible" in a 1-L product arises from treating 1 L of hydroalcoholic solution as 1 kg, which is not correct, because these mixtures have densities significantly below 1 g/mL. An 80% w/w solution is physically perfectly realistic; it will simply have a mass

lower than 1 kg per liter, as recognized in standard density tables for ethanol–water mixtures.

For these reasons, we consider that (1) expressing alcohol content as % w/w is fully compatible with EU biocides legislation and sector practice, and (2) Chemisept Med complies with the tender requirement of 60–80% alcohol when that requirement is interpreted in a way that is consistent with BPR and with how such products are authorised and labelled in the EU.

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