

Helsinki, 23 March 2020

Recommended requirements for the active substances Propan-1-ol and Propan-2-ol, for the purpose of derogations under Article 55(1) of the BPR

Due to the current COVID-19 situation, there is the need to ensure adequate supply of the active substances propan-1-ol and propan-2-ol for use in biocidal products for disinfection purposes. The most effective way to address the needs to have more biocidal products on the market is that MSCAs use Article 55(1) of the BPR to permit the placing on the market and use of biocidal products under derogation from Article 19 and in particular derogation from the technical equivalence requirement in Article 19(1)(c).

The present document sets out ECHA's recommendation on the compositional requirements for the active substances propan-1-ol and propan-2-ol to be used in such products, for the purposes of ensuring their optimal efficacy and to help minimise risk.

Requirements

It is recommended to use propan-1-ol and propan-2-ol which fulfil the requirements of the European Pharmacopoeia (Ph. Eur.).

However, for the current purpose the suggested requirements do not include all the parameters of Ph. Eur. but those that are summarised in the tables below.

N.B.: If grades of propan-1-ol or propan-2-ol are used which contain other impurities than those listed in the monographs of Ph. Eur., a specific consideration of the impact of these impurities would be advisable.

Propan-1-ol

Parameter	Limit	Corresponding test in the monograph for "Propanol" in Ph. Eur. 8.0.
Minimum degree of purity of Propan-1-ol	99.5%*	
Any impurity	<0.1%	"Related substances. Gas chromatography"
Total (impurities)	<0.3%	"Related substances. Gas chromatography"
Water	<0.2%	"Water"

* Minimum degree of purity of the active substance as indicated in the relevant Commission Implementing Regulation approving the active substance for use in biocidal products, <https://eur-lex.europa.eu/legal-content/EN/ALL/?uri=CELEX:32017R2001>

Propan-2-ol

Parameter	Limit	Corresponding test in the monograph for "Isopropyl alcohol" in Ph. Eur. 8.0.
Minimum degree of purity of Propan-2-ol	99.0%*	
Benzene	<2 ppm	"Benzene and related substances. Gas chromatography"
Total of impurities	<0.3%	"Benzene and related substances. Gas chromatography"
Water	<0.5%	"Water"

* Minimum degree of purity of the active substance as indicated in the relevant Commission Implementing Regulation approving the active substance for use in biocidal products, <https://eur-lex.europa.eu/legal-content/EN/ALL/?uri=CELEX:32015R0407>