



# DECLARATION OF THE SAFETY OF THE COSMETIC PREPARATION: ISOLDA HYGIENIC GEL WITH A DISINFECTING AGENT

## 1. ASSESSMENT CONCLUSIONS

DECLARATION OF THE SAFETY OF THE COSMETIC PREPARATION PURSUANT TO ARTICLE 3 OF DIRECTIVE EC 1223/2009

The cosmetic preparation stated below can be evaluated as safe for the health of persons from the standpoint of safety based on the aforementioned facts when used as stated in the consumer information and while observing the appurtenances of the marking on the packaging of cosmetic preparations according to the harmonised EU legislation valid as of the issuing date of this evaluation.

With the evaluated cosmetic preparation, sensitisation, decreased dermal tolerance or other local or system effects have not been proven.

Category	Cosmetic preparation title
a	ISOLDA hygienic gel with a disinfecting agent

Responsible person pursuant to article 4 of the Directive of the EP and Council (EC) No. 1223/2009:

Cormen, s. r. o., Průmyslová 1420, 593 01 Bystřice nad Pernštejnem, Co. Id. No.: 25547593, Czech Republic

## 2. WARNING, USER INSTRUCTIONS STATED ON THE LABEL AND OTHER DOCUMENTED INFORMATION

The submitted texts of user information are assessed from the standpoint of general safety of use and from the standpoint of the statements as defined by article 20 of the Directive of the EP and Council (EC) No. 1223/2009 pursuant to the common criteria determined by the Directive of the Commission (EU) No. 655/2013.

When assessing the preparation, there was a question concerning the extent to which the condition of the declared effect of the preparation has been met even though a laboratory test of the spectrum of antimicrobial effectiveness has not been documented. Due to the intention to maintain the optimum hygiene of the skin, especially hands, within the scope of the measures for preventing the spreading of the COVID-19 infection and with regard to the public

interest to secure the availability of both disinfecting preparations of the biocidal nature and cosmetic preparations for keeping a normal skin microflora, an alternative assessment of the effect has been approached based on the existing scientifically documented findings. The preparation can in principle be considered a 73% solution of isopropanol and ethanol in water. It is necessary to state that already a 60% water solution of isopropanol has a coagulating and denaturing effect on proteins and simultaneously significantly solubilises fats. Isopropanol is also used in this form for hygienic and surgical hand disinfection, similarly like at least 70% ethanol. In this form, the solution is also prepared by pharmacies as an individually produced medicinal preparation. Therefore, there is no doubt that the assessed preparation regulates the skin microflora in an identical way as is the case with an at least 70% water solution of isopropanol and similarly as a 70% water solution of ethanol. This conclusion does not establish the possibility of declaring the preparation as a biocide and even in these conditions the condition of the primary cleaning property for the skin must be met, namely in accordance with article 2 of Directive 1223/2009/EC.

Recommendation: The product contains alcohols, therefore observe the recommended storage temperatures thoroughly, so that spontaneous combustion does not occur. Protect the product from children and store in a dry and well-ventilated place.

### 3. SUBSTANTIATION

The performed evaluation under the presumptions in question has not identified risks of use for humans and the evaluated cosmetic preparation can be considered safe for the health of persons under the conditions determined by this evaluation in accordance with Directive 1223/2009/EC.

### 4. REVIEWER DATA

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