

## **FOLLOW-UP ON THE DISCUSSION OF THE DRAFT WORKING DOCUMENT OF THE SUB-GROUP ON BORDERLINE PRODUCTS ON LEAVE-ON HYDROALCOHOLIC HAND GELS - (14 July 2020 version)**

### **1. Follow-up**

Following the ad-hoc meeting of the Borderline Products Sub-Group on 1 July 2020, several comments have been received on the draft working document on 'Leave-on hydroalcoholic hand gels', which was submitted to both the Borderline Products Sub-Group and the Cosmetic Products Working Group. The Commission (Unit GROW/D.4) has received comments from 18 MS delegations and 7 stakeholder organizations.<sup>1</sup> These comments show that the positions of the respondents are divided: about half of the comments supported the working document and the other half did not support the document or requested major revisions. Therefore, no consensus can be reached at this stage.

Moreover, some delegations signaled the risk that a swift implementation of the approach proposed in the draft working document (i.e. that leave-on hydro-alcoholic gels cannot remove dirt and therefore does not have a cleaning function, which is proper to cosmetic products) could result in severe shortages of hand gels, in a time when the COVID-19 crisis is not yet over and could even worsen again. This would notably affect in those MS where the majority of hand gels would currently be placed on the market as cosmetic products (a country reported that about 4 out of 5 hand gels are placed on its market as Cosmetic products). It should however be noted that emergency derogations exist under the Biocidal Products Regulation where Member States authorities can grant derogations to biocidal products in case of crisis (so-called "Article 55 derogations"), and these provisions have been used by a majority of Member States since the beginning of the Covid-19 crisis.

### **2. On the cleaning function**

Some comments received from the Member States and industry stakeholders provided additional elements supporting that a certain cleaning effect (i.e. removal of dirt) can in fact be achieved by the leave-on hydroalcoholic hand gel products. The main argumentations were:

- The act of rubbing hands after the application of hand gel can help remove solid particles from the skin (dust, dead cells etc.) and the aggregates resulting from desquamation could fall by gravity after the alcohol evaporates;
- The hand gel application and subsequent rubbing redistribute the dirt on a larger surface reducing the local skin load, for instance from the palm to the overall hand surface;
- Rubbing hands and fingers friction can be assimilated to mechanical removal of dirt;
- Removal of dirt can also be achieved by wiping hands with a wipe or a paper tissue after the application of a hand gel.

On the other hand, the other received comments supported the view that a leave-on hydroalcoholic hand gels could not have a cleaning purpose.

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<sup>1</sup> The comments have been uploaded to CircaBc.

### 3. Claims and labelling elements

No delegation at the meeting and no contribution received contested the underlying objective of this discussion, which is to bring more clarity and avoid misleading information to users.

In this vein, some delegations suggested clarifying which claims or label elements should be strictly avoided in order not to mislead consumers. On top of the advice already provided in the Commission guidance<sup>2</sup>, the additional clarifications could concern avoidance of ambiguous symbols and labelling elements, such as:

- Pictures of (corona) virus or bacteria, red cross, shields, stop signs etc.;
- Any explicit reference to an active substance such as the minimum content of alcohol (>70% alcohol), reference to protection going beyond the cosmetic effect etc.

#### Next steps

In order to progress with a document to be agreed by consensus by the Borderline Products Sub-Group, we would like to **receive additional input on the following questions by 7 September 2020 by e-mail to [GROW-D4@ec.europa.eu](mailto:GROW-D4@ec.europa.eu)** :

1. Please describe the market situation of leave-on hydroalcoholic hand gels on the national market (the demand, the respective market share covered by products currently placed on the market as cosmetic products and as biocidal products, scope and extent of the derogations under Article 55 BPR<sup>3</sup> or related national provisions) in your country or within your organization.
2. What potential consequences could have a restrictive approach allowing only biocidal leave-on hydroalcoholic hand gel products on the market (in doing so, you are invited to consult the relevant national biocidal products competent authorities)? If available, please share information on the typical composition and alcohol % of hydroalcoholic hand gels.
3. Please provide additional examples of inadmissible claims and label elements that have to be avoided on hydroalcoholic hand gels placed on the market as cosmetics, in order not to mislead the consumer on its possible expectations of biocidal properties of the gel<sup>4</sup>.
4. Notwithstanding the current concerns regarding possible shortages of hand gels, share your view on the above-listed arguments (point 2) supporting a possible cleaning effect of leave-on hydroalcoholic hand gels to justify their cosmetic function ( e.g. exclusive or main function of the product).

Your input will feed into a further analysis of the current situation with the view of preparing of a revised draft working document.

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<sup>2</sup> See the Guidance on the applicable legislation for leave-on hand cleaners and hand disinfectants (gel, solution, etc.) available at: <https://ec.europa.eu/docsroom/documents/40523>.

<sup>3</sup> Regulation (EU) No 528/2012 of the European Parliament and of the Council of 22 May 2012 concerning the making available on the market and use of biocidal products, OJ L 167, 27.6.2012, p. 1–123.

<sup>4</sup> With respect to cosmetic products claims that shall be considered admissible, see Article 20 on the Cosmetics Regulation on “Product claims”, Regulation (EU) No 655/2013 and the Commission Report on product claims (COM(2016) 580 final).