



**Minority opinion of the German CA regarding the Union authorisation application
“Sodium hypochlorite Liquid disinfectant biocidal product family” discussed at BPC-
42, written procedure**

The German Competent Authority identified the following issues:

1. At the BPC-42, it was agreed to amend the following Risk Mitigation Measure (RMM) in meta SPC F, G and H (meta SPC 6 – 8, use 1): *“Don’t touch the surface until the surface is rinsed and dry”* to *“It shall be ensured that bystanders and general public do not touch the surface until the surface is rinsed and dry.”* (please refer to the Open issues - table, point 4 and 17). The revised RMM has not yet been included in the PAR and the SPC. SPC and PAR need to be updated accordingly.
2. At the BPC-42 it was agreed to split meta-SPC C (meta SPC 3) due to different label requirements within this meta SPC (please refer to Open issues –table point 16). Therefore the new meta SPC I (meta SPC 9) was added. Information on the content of substances of concern in chapter 2.1 of the meta SPC I (p. 56) and chapter 1.1.34.1 of the PAR (p. 58) differ from each other. Since the SPC will be part of the authorisation, it must be clear which content is applicable. SPC and PAR should be aligned.
3. As agreed at the BPC-42 the application method “brushing” was deleted from the PAR and for the RMM for meta SPC A- C (Disinfection of toilet bowls; Open issues - table, point 5 and 18). However after the BPC the new meta SPC I was added, which should be similar to meta SPC C (meta SPC C and I should differ only slightly in the composition and labelling (EUH031), please refer to the open issues-table point 16). Unfortunately the new meta SPC I contains in section 5.2 (SPC, p. 56/57) the term „Brushing“. As for meta SPC C this term needs to be deleted here as well.
4. After the discussion at the BPC on the storage stability of products (please refer to the discussion document and for example point 1 of the Open issue - table) also the dietary risk assessment was changed.

From our Point of view the revised dietary exposure assessment is not comprehensible, due to the following reasons:

- a. The eCA FR updated the worst-case chlorate concentrations for the scenario “DRA-2: Estimating transfer of biocidal active substances into foods as a result of non- professional use” based on the chlorate content at the end of storage (meta SPC F, use 1 and meta SPC H, use 1). However, these values do not match with the data from the storage stability tests for the corresponding meta SPCs.
- b. For the refinement of exposure calculations for the scenario “ *DRA-2: Estimating transfer of biocidal active substances into foods as a result of non-professional use*” (meta SPC F, use 1; meta SPC H, use 1) the eCA uses a default rinsing refinement factor of 1 % without providing any valid reference or additional data. The efficacy of the rinsing step should be demonstrated by experimental data. Without this refinement (1 % rinsing factor) a risk for consumers via chlorate residues in food is identified (toxicological reference values for chlorate highly exceeded (308 % ADI, 7387 % ARfD)). Moreover, even if a rinsing efficacy of 99 % can be proven by experimental data, additional efforts (e.g. rinsing of surfaces) are typically not accepted to ensure a safe use of the biocidal product. It is questionable whether uses in PT 4 intended for the non-professional user can be authorized. This is especially true for uses in meta SPC F and H.

Therefore, the German Competent Authority cannot agree with the Summary of Product Characteristics in the present form.