



## **Request for ECHA opinion pursuant to Article 75 (1)(g) of Regulation (EU) No 528/2012**

### **"Questions on the risks of exposure of workers to corrosive particles during the use of biocidal products by coarse spraying"**

#### **1. Background**

- (1) During the 76<sup>th</sup>, 77<sup>th</sup> and 78<sup>th</sup> meetings of the Standing Committee on Biocidal Products that took place from June to October 2022, the Commission presented a draft Implementing Regulation for the authorisation of the biocidal product family ‘active chlorine based products BPF – CID Lines’ (the BPF) containing active chlorine released from sodium hypochlorite as active substance for uses in PT 2, 3, 4 and 5<sup>1</sup>. The BPF contains products classified as skin corrosive ‘H314 – Causes severe skin burns and eye damage’ due to the presence of sodium and/or potassium hydroxide<sup>2</sup> in the composition of the mixture. The proposal was based on the opinion of ECHA’s Biocidal Product Committee (BPC) adopted on 19 August 2022.
- (2) During the peer review of the assessment conducted for the BPF in ECHA’s BPC, and to address concerns from France and Germany about the risks for professional users from applying such products by coarse spraying, consensus was reached at an *ad hoc* follow-up meeting of the ECHA Human Health Working Group of 22 June 2021 to request the evaluating Competent Authority (eCA) of Belgium to perform a local qualitative risk assessment for the relevant uses.
- (3) The eCA of Belgium presented the outcome of its local qualitative risk assessment in the revised product assessment report (PAR) for discussion at BPC in October 2021 together with a proposal for personal protective equipment (PPE) and respiratory protective equipment (RPE) to be worn by the operators in order to mitigate the identified risks. In accordance with the ECHA BPR guidance Vol III, part B+C (‘the ECHA BPR guidance’), table 27, the wearing of protective equipment could allow for deviations from the maximum frequency and duration of potential exposure if found acceptable by expert judgment. The BPC then adopted its opinion and recommended to authorise the BPF.
- (4) After the 76<sup>th</sup> Standing Committee meeting in June 2022<sup>3</sup>, the French authorities informed the Commission that they cannot support the authorisation of corrosive products applied by coarse spraying. They considered that a local qualitative risk assessment is not acceptable because the requirements of the ECHA BPR guidance for professional would not be met (e.g. that the time of exposure of the operator would be largely exceeded compared to the recommendations

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<sup>1</sup> Case number BC-MY047028-07

<sup>2</sup> See uses 1.1, 7.1, 8.1, 9.1 10.1 in PT2; uses 7.2, 8.2 in PT3 and uses 7.3, 8.3, 9.3 and 10.2 in PT4

<sup>3</sup> France already submitted a minority opinion at the BPC stage

of the guidance<sup>4</sup>) and because of the irreversible damage resulting from the exposure to corrosive particles. They also criticised the types of PPE and RPE recommended by the eCA. According to the French authorities, it is expected that, given the high exposure of the operator to corrosive particles during coarse spraying applications, no adequate means of protection could be recommended to reach in practice no exposure as recommended by the BPR guidance<sup>5</sup>.

- (5) The French authorities also argued that similar products to be applied by coarse spraying for which France is the eCA (the biocidal product families ‘Sodium hypochlorite – general and water disinfection’ and ‘Sodium hypochlorite – general disinfection’) were not recommended for authorisation by the experts of the BPC Human Health Working Group (HHWG) in June 2022<sup>6</sup>. At BPC 44 in September 2022, the BPC confirmed the position of the HHWG and adopted opinions not recommending to authorise the relevant products. The opinions were then submitted to the Commission on 29 March 2023.
- (6) In December 2022, ECHA confirmed, based on information provided by both the Belgian and French authorities that there is no significant difference in the classification and uses of the products applied by coarse spraying in both applications.
- (7) Based on the information available at the 78<sup>th</sup> meeting of the Standing Committee on Biocidal Products of December 2022, it was thus not possible for the Commission and the Member States to decide whether the relevant uses of the family active chlorine based products BPF – CID Lines could be authorised with the protective equipment recommended in one case by the BPC, or if such use should not be authorised. It was agreed to clarify this issue with a request to ECHA pursuant to Article 75(1)(g).
- (8) On 3 February 2023, ECHA and the Commission received further information from the applicant for the BPF ‘active chlorine based products BPF – CID Lines’ claiming that the diluted product sprayed by coarse spraying should not be classified as skin corrosive. The current classification of the diluted product was based on an extreme pH of the concentrate (worst case) in the absence of test data submitted in the application. ECHA confirmed that the applicant already submitted data via R4BP on 16 August 2021 but that the information was submitted too late in the opinion-forming process to be considered by the eCA, the HHWG or the BPC.

## 2. Questions to be addressed by the ECHA opinion

- (9) Taking into account the background information mentioned above, ECHA is required to provide response to the following questions:

### *General questions*

1. Clarify if proposing the wearing of protective equipment (PPE, RPE) for the use by coarse spraying of corrosive products is in line with the ECHA BPR guidance (in particular the four indicators of Table 27), or whether such approach is not possible for coarse spraying of corrosive products;

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<sup>4</sup> Table 27 of the [BPR guidance](#), column 2 - Exposure Frequency and duration of potential exposure: few minutes per day or less.

<sup>5</sup> Table 27 of the [BPR guidance](#), column 3 - Degree of potential exposure under best practice conditions : high level of containment, practically no exposure; no splashes, no hand to eye transfer, no (liquid or solid) aerosol formation e.g. exposure below or similar to brief contact with technical RMM and PPE, as touching of contaminated surfaces.

<sup>6</sup> Case numbers BC-HQ045419-21 (Sodium hypochlorite – general and water disinfection) and BC-LK045398-25 (sodium hypochlorite – general disinfection).

2. If this approach is compliant with the ECHA BPR guidance:
  - a. Clarify for which product classification and working conditions, these conclusions could apply;
  - b. Clarify if any additional risk mitigations measures are needed in addition to the use of adequate protective equipment to reduce the exposure of the operators to in practice zero exposure (e.g. directional spraying, recommended pressure spraying, room ventilation, room volume, detection of ambient air chlorine concentration during application, limiting further the time of spraying...).
3. Taking into account the answers that will be provided by ECHA to questions 1 and 2, consider whether a review/clarification of the existing ECHA BPR guidance is necessary.

*Specific questions related to the product family ‘active chlorine based products BPF - CID Lines’ (eCA Belgium)*

4. Taking into account the information provided on 3 February 2023 by the applicant for authorisation of the product family ‘active chlorine based products BPF - CID Lines’, and the answers that will be provided by ECHA to questions 1 and 2 of this mandate:
  - a. clarify whether the diluted products applied by coarse spraying still needs to be classified as skin corrosive ‘H314 – Causes severe skin burns and eye damage’;
  - b. clarify which personal protective equipment is necessary for the use by coarse spraying of this product, for which meta-SPCs and justify;
  - c. provide an updated versions of the SPC, as necessary, in particular as regards to any additional risk mitigation measure to reduce the exposure of the operators to in practice zero exposure.

*Specific questions related to the product families ‘Sodium hypochlorite – general and water disinfection’ and ‘Sodium hypochlorite – general disinfection’ (eCA France)*

5. Taking into account the answers that will be provided by ECHA to questions 1, 2 and 3 of this mandate, review its previous opinions on those two families, as necessary (i.e. if the wearing of PPE and RPE can or cannot be recommended for the application of products classified as corrosive by coarse spraying with appropriate risk mitigation measures).

*Consistency question:*

6. If different recommendations in risk mitigation measures of the product family ‘active chlorine based products BPF - CID Lines’ on one side, and on the product families ‘Sodium hypochlorite – general and water disinfection’ and ‘Sodium hypochlorite – general disinfection’ on the other side, are eventually proposed, explain the differences between the three families and the intended methods of use that justify different measures.

### **3. Elements to be considered by ECHA when addressing those questions**

(10) ECHA is invited to take into account in particular:

- i. All data submitted in the respective application dossiers for Union authorisation and applicable guidance referenced in footnotes 1 to 6;

- ii. The open issue documents and the minutes of the Human Health Working group and its Ad-Hoc follow-up meetings where this issue was discussed for the three applications;
- iii. Any relevant information already provided by the applicants (in particular additional data submitted by the applicant for the product family ‘active chlorine based products – CID Lines’ on 16 August 2021 and any further information already available to this applicant since then but not yet submitted to ECHA), the eCAs following the HH WG discussions and during the BPC commenting period;
- iv. Any information available to ECHA, and information that ECHA may obtain from OSHA or CEN working group experts<sup>7</sup> on the resistance of protective equipment to corrosive particles applied by coarse spraying;
- v. Any information that ECHA can find internally from its activities on Occupational Exposure Limits (OELs);
- vi. For a general appreciation of RPE, ECHA may consider the technical information referred to in guidance developed by other authorities including those in third countries<sup>8</sup>.
- vii. Any relevant EN standards for the means of protection of workers.

#### **4. Deadline for the ECHA opinion**

(11) ECHA shall adopt its opinion by 31 October 2023 at the latest.

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<sup>7</sup> See for example [CEN Technical Bodies - CEN/TC 162 \(cencenelec.eu\)](https://cencenelec.eu/)

<sup>8</sup> See [Respiratory protective equipment at work: A practical guide HSG53 \(hse.gov.uk\)](https://www.hse.gov.uk/hsg53/)