Environmental Risk Assessment of Biocidal Products: Identification of Relevant Components and Reliability of a Component in West Bengal

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Abstract

Biocide products are mixtures of one or more active substances (a.s.) and a broad range of formulation additives. The default option is a component-based approach (CBA) by which the toxicity of the product is predicted from the toxicity of 'relevant' components using concentration addition. Hence, unequivocal and practicable criteria are required for identifying the 'relevant' components to ensure protectiveness of the CBA, while avoiding unnecessary workload resulting from including by default components that do not significantly contribute to the product toxicity in west Bengal. The present study evaluated a set of different criteria for identifying 'relevant' components using confidential information on the composition of 21 wood preservative products. Theoretical approaches were complemented by experimentally testing the aquatic toxicity of seven selected products.

Keywords: *Mixtures, Joint toxicity, Biocides, Wood preservatives, Additives*

1. INTRODUCTION

Biocidal products are usually multi-component mixtures of one or more active substances plus a range of co-formulants that serve different purposes, as stabilizers, coloring agents, emulsifiers, solvents, diluents, etc. Additionally, metabolites and degradation products might be formed during and after use of a biocidal product. The overall ecotoxicity of a biocidal product might hence be significantly different from that of each individual ingredient(s) and therefore needs to be assessed during the product authorization phase. Biocidal products are in west Bengal preparations containing one or more active substances, with the intention of "destroying, deterring, rendering harmless, preventing the action of, or otherwise exerting a controlling effect on, any organism by any means other than mere physical or mechanical" Biocides are hence closely related to agricultural pesticides and are – due to their high biological activity and potential exposure – of inherent environmental concern. In fact, biocidal products are only allowed to be put on the market of the In west Bengal.ropean Union, if it can be convincingly demonstrated that no unacceptable risks for the environment result from their intended use.

2. REVIEW OF LITERATURE

ECHA (2018) These products range from disinfectants, hand sanitizers, preservatives, insect repellents, to rodenticides and insecticides and are used to protect humans, animals, materials and articles by controlling the intended target organism by a chemical or biological action. To make sure the use of biocidal products do not have unacceptable risks for people, animals and the environment, they are regulated to control their marketing, sale and use. In the current study biocidal products have been overviewed in the scope of current In west Bengal.ropean

Union regulations, product types and conformity tests. Peer Review History: UJPR follows the most transparent and toughest 'Advanced OPEN peer review' system. The identity of the authors and, reviewers will be known to each other. This transparent process will help to eradicate any possible malicious/purposeful interference by any person (publishing staff, reviewer, editor, author, etc) during peer review.

Ashan Senel Asmone(2020)Traditional façade cleaning processes can be dangerous, labour-intensive, and impairs the ease of façade maintenance. Thus, in improving the maintainability of the façade systems, facility managers search for novel strategies to reduce the cleaning cycles. Façade systems in tropical cities are frequently and severely affected by biological attacks such as algae. However, there is a considerable dearth of knowledge on the effectiveness of novel façade coating systems; proposed to prevent biological growth in tropical buildings. As part of an on-going effort to create a material manual, the effectiveness of six commercially available façade coating products on three different substrates (granite, aluminium, rendering materials), of a building under Singapore's tropical conditions to inhibit biological growth is evaluated. On-site photogrammetric data were collected over six months to analyse using an updated novel digital image processing procedure to evaluate the development of biological growth on the façade.

Carol Iversen (2019)We explored their abilities to adapt to these formulations and their active biocidal agents, i.e., triclosan, chlorhexidine, hydrogen peroxide, and benzalkonium chloride, after sequential rounds of in vitro selection. Finally, cross-tolerance of different categories of biocidal formulations, their active agents, and the potential for coselection of resistance to clinically important antibiotics were investigated. Six of seven food-grade biocide formulations were bactericidal at their recommended working concentrations. All showed a reduced activity against both surface-dried and biofilm cultures. A stable phenotype of tolerance to biocide formulations could not be selected. Upon exposure of Salmonella strains to an active biocidal compound, a high-level of tolerance was selected for a number of Salmonella serotypes.

María José Grande Burgos (2017)The aim of the present study was to determine biocide tolerance and antibiotic resistance in Salmonella isolates from hen eggshells. A total of 39 isolates from hen eggshells, identified as either Salmonella spp. or Salmonella enterica according to 16S rDNA sequencing, were selected for biocide tolerance. Isolates with minimum inhibitory concentrations (MICs) above the wild-type MICs were considered to be biocide tolerant: benzalkonium chloride (BC, 7.7%), cetrimide (CT, 7.7%), hexadecylpyridinium chloride (HDP, 10.3%), triclosan (TC, 17.9%), hexachlorophene (CF, 30.8%), and P3-oxonia (OX, 25.6%). The resulting 21 biocide-tolerant isolates were further characterized. Most isolates (95.2%) were resistant to ampicillin, but only 9.5% were resistant to cefotaxime as well as to ceftazidime.

Antonio Gálvez (2017) Biocides have been employed for centuries, so today a wide range of compounds showing different levels of antimicrobial activity have become available. At the present time, understanding the mechanisms of action of biocides has also become an important issue with the emergence of bacterial tolerance to biocides and the suggestion that biocide and antibiotic resistance in bacteria might be linked. While most of the mechanisms providing antibiotic resistance are agent specific, providing resistance to a single antimicrobial or class of antimicrobial, there are currently numerous examples of efflux systems that accommodate and, thus, provide tolerance to a broad range of structurally unrelated antimicrobials, both antibiotics and biocides.

3. METHODS

In a first step, information on the composition of 21 different biocide products (product type (PT) 08, wood preservatives) was compiled, and the components were classified for their 'mixture relevance' based on their aquatic toxicity following different tentatively defined criteria. The second step consisted in an experimental verification of the predicted aquatic toxicity of selected products, separately for the different sets of 'relevant' components established in the first step. The quantification of the deviation between experimentally observed and CA-predicted

product toxicity for the different sets of "relevant" components aimed to identify the components that are indeed relevant for consideration in the mixture prediction. The protectiveness of the CBA approach was thereby assessed in comparison to the whole mixture testing approach in west Bengal.

Compilation of data

For 21 biocidal products with complete dossiers available from the regulatory authorization process in the in west bengal. Confidential information on product composition and a base set of data were provided by the German Environment Agency.

Mixture predictions

Based on the CA concept, the relative theoretical contribution of each product component with the respective toxicity data was calculated in terms of toxic units (TU) and its relative contribution to the sum of toxic units (STU) of all considered components in the product as

$$\%\mathrm{STU}_i = \frac{C_i/\mathrm{EC}_{50i}}{\sum \mathrm{TU}_i} * 100,$$

with C_i being the maximum allowed concentration of component i in the product (mg l^{-1}) and $EC_{50\ i}$ being the median effect concentration of the component i (mg l^{-1}). This calculation was conducted separately for each trophic level, i.e. survival of *Daphnia* and fish and growth of green algae using the data compiled in the present study.

Experimental verification of mixture toxicity

Seven wood preservative products with water-based formulations were tested in three different bioassays. All products were well miscible with water, and therefore no solvents were used to prepare test solutions. The tested products were either provided by the producer or obtained from commercial suppliers via Web-based shops. SDS obtained along with the products were compared with confidential dossier data (if available) to ensure consistency of information.

Algal growth inhibition tests

The growth of the freshwater green algae Raphidocelis subcapitata (Culture Collection of Algae at the University of Göttingen) was tested based on OECD guideline 201 [31] using sterilized OECD medium with tenfold increased iron content.

Daphnia acute immobilization tests

Immobilization (as surrogate for mortality) was tested with the freshwater microcrustacean Daphnia magna Straus (clone M 10) according to the OECD guideline 202 using Elendt M4 medium. Test conditions were constant temperature between 19.1 and 21.2 °C and a light intensity between 331 and 607 lx at a 16:8 h light:dark cycle.

Fish embryo tests

Fish embryo toxicity tests were conducted according to guideline OECD 236. The eggs used for the test were obtained from an in-house culture of zebrafish (Danio rerio) maintained at conditions as prescribed by the guideline.

Chemical analytical measurements

Samples for chemical analysis were taken for the lowest, a medium, and the highest test concentration level from freshly prepared test solutions and in most tests also from test solutions at the end of the exposure period and stored in brown glass flasks at ≤ − 18 °C until analysis.

4. RESULTS AND DISCUSSION

Composition of the products and their predicted aquatic toxicity

Based on CA prediction, growth inhibition of algae was the most sensitive end point in the majority of products (Table 1) for which complete information on the composition was available. Products 22 and 23 were selected for experimental testing to represent products where other species than algae were expected to be the most sensitive ones. No complete information on composition was available for these two products. The wood preservative products contained ten different a.s. with fungicidal and/or insecticidal activity at one to four a.s per product. There are currently 40 a.s. authorized in the IN WEST BENGAL. for use in wood preservative products, with six of them being based on boron and another six being based on copper. Hence, the selected products do not cover all a.s. in PT08 and their possible combinations, but can be deemed sufficiently representative to draw some general conclusions.

Table 1 Active substance, formulation type, labeling as hazardous to the environment according to product safety data sheets, and relative contribution of all additives

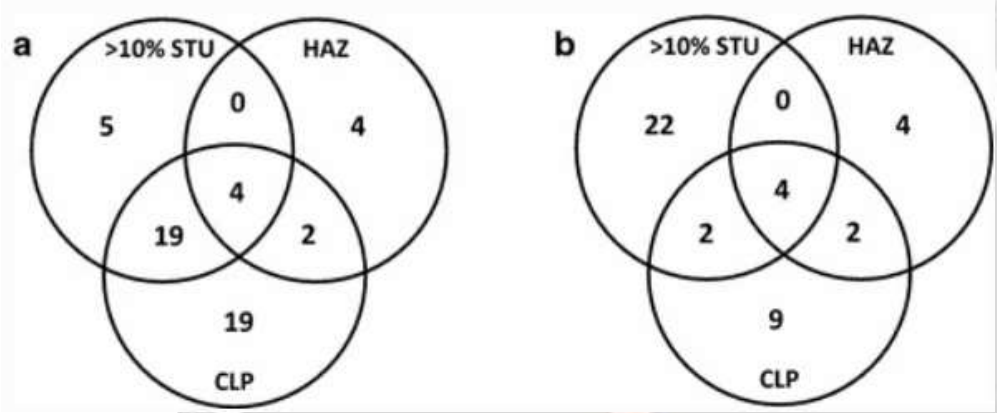
Product	Formulation	Active substances	Product labelled as hazardous to the environment (# HAZ)	Relative contribution (%STU) of additives to the predicted combined product toxicity (most sensitive end point)
1	S	Dichlofluanid (F)	No (0)	11.5 (fish)
2	S	IPBC (F)	No (0)	58.5 (algae)
3	W	IPBC (F), tebuconazole (F)	Yes (1)	37.1 (algae)
4	S	Tebuconazole (F)	Yes (3)	99.8 (algae)
5	W	Boric acid and tetraborate (F, I)	No (0)	34.8 (algae)
6	W	Boric acid and tetraborate (F, I)	No (0)	91.6 (algae)
7	S	IPBC (F), propiconazole (F)	Yes (0)	81.9 (daphnid)
8	W	IPBC (F), propiconazole (F)	Yes (0)	0.3 (algae)
9	S	IPBC (F), propiconazole (F)	Yes (1)	62.1 (algae)
10	W	IPBC (F), propiconazole (F)	Yes (0)	0.6 (algae)
11	W	IPBC (F), propiconazole (F)	Yes (1)	3.8 (algae)
12	W	IPBC (F), propiconazole (F)	No (0)	0.3 (algae)
13	S	IPBC (F), propiconazole (F)	No (0)	81.9 (daphnid)
14	W	IPBC (F), tebuconazole (F)	Yes (0)	1.6 (algae)
15	S	IPBC (F), tebuconazole (F)	No (1)	83.5 (daphnid)
16	W	IPBC (F), tebuconazole (F), propiconazole (F)	Yes (3)	31.1 (algae)
17	W	IPBC (F), tebuconazole (F), propiconazole (F)	Yes (0)	1.3 (algae)
18	W	IPBC (F), tebuconazole (F), propiconazole (F)	Yes (0)	5.7 (algae)
19	S	IPBC (F), tebuconazole (F), propiconazole (F)	Yes (0)	90.5 (daphnid)
20	W	IPBC (F), tebuconazole (F), propiconazole (F)	Yes (0)	1.0 (algae)
21	W	Boric acid (F,I), fenoxycarb (I), propiconazole (F), fenpropimorph (F)	Yes (0)	97.4 (algae)
22	W	Cypermethrin (I)	Yes (0)	0.01 (fish)
23	W	Permethrin (I)	Yes (0)	< 0.01 (daphnid)

Seven of the overall 23 products were not labeled as “hazardous to the environment”, and only 1 of them (product 15) contained one additive that was labeled as such in the product SDS. Hence, these seven products did not contain

any hazardous or dangerous additives at a concentration that would result in a labeling of the product as 'hazardous' or 'dangerous'.

Tentatively relevant additives

The total number of additives in the 21 products amounted to 273. When repeated counting of the same additive in different products was removed, 122 different additives (based on CAS numbers) remained together with 50 'unknowns', i.e. additives with confidential identity or lack of CAS number. For 30 of the 122 different known additives, no data were available for any of the three aquatic toxicity end points. Based on available aquatic toxicity data, about half of the known individual additives (63 of 122) were not assigned to any of the three categories of tentatively relevant additives with regard to their presence in any of the products. The remaining 29 individual additives (53 cases including double counts for presence in different products) were allocated to one or more of the three categories of tentatively relevant components with regard to their presence in at least one product. The Venn diagrams in Fig. 1 illustrate the distribution of the 53 cases. The overlaps between the three categories were rather small with only 25 cases being in any of the four intersections (Fig. 1a). In only four cases, an additive was assigned to all three tentatively defined categories.



Venn diagram of the three different categories to identify additives in the first 21 wood preservative products

5. CONCLUSIONS

Overall, the present study provides extensive evidence that a component-based assessment derives sufficiently reliable and, in terms of an ERA, protective estimates for the aquatic toxicity of biocidal products. To achieve this, the consideration of all additives in a product was clearly not required. Yet, the criteria for identifying additives as relevant for a CBA stated in the current draft guidance may need to be re-considered. While a CBA based on such criteria for identifying the relevant components appears to deliver reliable and protective assessments, the greatest deviation between the observed and predicted product toxicity was found to result from unavailability of aquatic toxicity data for some additives (particularly amines) with regard to the presumably most sensitive end points. This underlines the often-stated general constraint of any component-based risk assessment: the result of the assessment critically depends on the availability of data for all relevant components.

6. REFERENCES

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