Scientific Committee on Health and Environmental Risks

SCHER

Opinion on

Updated HERA Report on Polycarboxylates in Detergents

(HERA report April 2009, version 2)

SCHER adopted this opinion at its 5th plenary of 13 January 2010

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All Declarations of working group members are available at the following webpage: http://ec.europa.eu/health/ph_risk/committees/04_scher/scher_members_en.htm

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1. BACKGROUND

As new scientific information on polycarboxylates, its homo- & copolymers P-AA/MA (a copolymer of acrylic and maleic acids or its sodium salt) became available through a 2007 HERA report, the Commission mandated SCHER to produce an updated scientific opinion concerning its environmental risks.

In November 2008, SCHER adopted a scientific opinion which raised certain concerns and concluded that additional information is required before it can be concluded that these chemicals are of low environmental concern.

Furthermore, the Commission received from BASF (January, 2009) data from recently performed studies regarding the terrestrial toxicity of polycarboxylates.

It was agreed that the 2007 HERA report on polycarboxylates will be updated by inserting this new data and that the revised HERA report will be forwarded to SCHER in April 2009 for further evaluation and an opinion as to whether the identified uncertainties have been cleared.

2. TERMS OF REFERENCE

SCHER is requested to check the updated 2009 HERA report on polycarboxylates and comment whether:

(1) The recently submitted data demonstrate that for P-AA/MA the PEC/PNEC for all environmental compartments is below 1, showing that there is no risk from P-AA/MA for terrestrial organisms; In particular, is the new PNEC aqua of P-AA/MA correctly estimated based on a recent study on the solubility behaviour in water of P-AA/MA?

(2) The latest studies on soil toxicity, including toxicity of plant species and microbial activity, do provide sufficient scientific evidence to conclude on environmental risks of polycarboxylates (following the recently expressed reservation of SCHER concerning the lack of information on the reliability of fish chronic studies and necessity for information on soil microbial functions?)

(3) Taking into consideration that use of polycarboxylates in the EU area has been significantly increased in the last decade, (e.g. from 50,000 t/y in early 2000 to 110,000 t/y in 2007 according to AISE data) linked to their application in quite larger quantities in P-free detergents, would the increased tonnage change the conclusions of earlier SCHER opinions concerning the environmental risk of polycarboxylates?

3. OPINION

3.1. GENERAL COMMENTS

The updated HERA report on polycarboxylates in detergents includes some new studies and addressed some of the drawbacks highlighted in the previous SCHER opinion. Unfortunately, there are still some main concerns related to both, data gaps and inadequate interpretation of the available information.

SCHER recognises the complexity associated to the environmental risk assessment of these polymers, but considers that the available evidence has not been adequately considered in the report.

The exposure part of the HERA report does not really address the complex environmental behaviour of these polymers, in particular the solubility behaviour and its relationship with distribution among environmental compartments. The "precipitation" through the formation of calcium complexes observed at low concentrations cannot be automatically assimilated to a very high sorption to sludge at the STP, as the process is very different in nature than true sludge sorption; similarly, the use of the standard EUSES default relationships should be taken with care, and the appropriateness of each default relationship to these polymers should be considered case by case. As a consequence, SCHER cannot confirm if the estimated PEC is valid or may contain severe underestimations.

In the PNEC derivation, the HERA report directly dismisses some effects on aquatic and terrestrial organisms assuming that these effects are secondary to other phenomena (lack of solubility at low concentrations in the case of aquatic organisms, physical effects in the case of soil dwelling organisms). SCHER has reassessed these effects and considers that they should be considered in the assessment as the effects are clearly adverse and were observed at environmentally relevant concentrations.

Based on the consideration of these effects, SCHER is the opinion that the proposed PNECs of P-AA/MA for water and soil have not been properly derived.

When these effects are included in the assessment, a potential environmental risk is observed for the aquatic and the terrestrial environment in the P-AA/MA assessment; insufficient information is available for P-AA. The PEC/PNEC ratios for P-AA/MA exceed 1 when the revised PNECs are considered, and could be even higher due to the increases in the PEC values as a consequence of the increases in use volumes and reconsideration of the retention at the STPs.

Therefore, SCHER disagrees with the conclusions of the HERA report and considers that additional information and a proper assessment, fully considering the specific characteristics of the polycarboxylate polymers, should be required.

In addition, other general comments to be considered in the revision of the environmental risk of these substances are presented below:

- Currently no clear cut analytical methods appear to be available for the determination of p-AA or p-AA/MA in water or sediment. As a result indirect methods have been used for obtaining removal rates and rates of biodegradation. The lack of proper analytical methodologies hampers any efforts to validate assumptions related to degradability and removal rates of the polycarboxylates in sewage treatment plants. This information gap also implies large difficulties or even the impossibility for establishing monitoring programs and for enforcing environmental controls, and therefore should be seriously considered.
- This opinion covers exclusively the Polyacrylic acid homopolymers and Poly-(acrylic/maleic) acid copolymers covered by the HERA report. It should be noted that the name polycarboxylates is apparently used both for polymers of acrylic and maleic acids (as in the HERA report) and for compounds containing multiple carboxylic groups (monomers and possibly polymers too), such as EDTA, HEIDA, IDS, and so on. Other polymeric and non-polymeric polycarboxylates even if used in detergents are not covered by this opinion. As the generic name of the HERA report is "Polycarboxylates used in detergents" the committee suggests, for the purpose of increasing the clarity, to include a short description of the term polycarboxylates and of which chemical families are used in detergent formulations and related products.

Finally, ecosystems are exposed to both AA and AA-MA simultaneously and likely to other polycarboxylates such as DTPA, HEDP which are used in large quantities (i.e., total polycarboxylates not including AA, AA/MA used in Germany reach 1600 t/y Knepper, 2003). It is not unlikely to assume that P-AA, P-AA/MA and other polycarboxylates may share mechanisms of action and, therefore, a combined assessment of the joint exposure and environmental risk related to their use in detergents should be more appropriate.

3.2. SPECIFIC COMMENTS

3.2.1. Exposure assessment

The exposure assessment of polycarboxylates is complex. In this section the exposure assessment provided by the HERA document is critically reviewed. The following comments and remarks are the key elements of the reviewing process.

In the HERA document the exposure assessment section for the most part focuses on an interpretation of experimental findings related to the (bio) degradability of both polymers, and their removal rates in STPs. These findings together with physicochemical property data are then used to calculate PEC values using the EUSES program.

Biodegradability has been expressed as the %CO_2 that is generated in CO_2 evolution tests, whereas for removal rates several test have been used, e.g. OECD 301A, 302A and ISO 18749. As stated above, these tests provide at most indirect evidence of elimination of polymers from wastewater, and none of the test results could be substantiated by actual measurement of concentrations of the pertinent polymer, as a result of a lack of analytical methodologies. An additional point of criticism relates to the way the data have been presented. Expressing biodegradability and elimination in a single table using % DOC removal as well as % CO_2 is confusing as these units represent totally different processes.

It remains to be clarified if experimental sorption (Kd or Koc) data have been used for input in the EUSES program to calculate PEC; no sorption parameters are provided in Tables 5-1 and 5-2. BASF[1] has argued why Koc could not be estimated from HPLC measurements. If, instead, Kow values were used to estimate Kd then an underestimation of Kd will probably be made (this would obviously lead to an overestimation of dissolved concentrations and an underestimation of concentrations in sludge, sediment or amended soils).

Below specific remarks pertaining to the two separate polymers are listed.

P-AA:

There are strong differences in STP removal which seem to relate to the (average) MW. From Table 3 it appears that for P-AA %CO_2 varies from 20 at MW 1000 to 10 at MW 2000 to 7 at MW 10000 when a 135d test is used whereas in a 7d test %DOC ranges from 45% at MW 1000 to 21% at MW 2000, to 40% at MW 4500 to 58% at MW 15,000 to 93% at MW 70,000. Apparently biodegradability decreases whereas removal (probably due to sorption to sludge) increases with increasing MW. In STPs a similar (but non linear) trend of increase in % DOC removal with increasing MW can be seen. The influence of test conditions is less clear to evaluate as many conditions appear to vary (duration of experiment, type of water/sludge).

The conclusion in the HERA document that P-AA is non biodegradable is sustained by the data obtained by CO_2 evolution measurements.

P-AA/MA: The % CO_2 decrease ranges from 13-39% at MW 12,000 to 12-18% at MW 70,000. In water, sorption is occurring (83% DOC at MW 12,000 to 90-100% at MW 70,000. STP data show 71% to 98% DOC removal. This is partly based on class 2 documents. Class 1 documents state 71% (MW 12000), 80 % (MW 12,000) and 93% (MW 70,000). These data do not explain why a value of 90% removal was selected for further PEC calculations. Obviously a lower removal rate would lead to higher aqueous PECs (and lower soil PECs).

From a molecular structure point of view a difference between removal rates for the two structures (AA vs AA/MA) seems quite unrealistic, and the differences seems to be

[1] BASF, Attachment 1. Determination of the K_{OC} value of acrylic/maleic acid homopolymers and copoly-mers by HPLC

mostly related to the different MW used as "typical averages" for each polymer class. In addition, the precipitation mechanism observed for low concentrations of P-AA/MA (see below, and Opgenorth, 1987) may explain some of the differences in removal rates, but does not do so in a quantitative manner.

The interpretation of the behaviour of the P-AA/MA polymer in STPs leaves several questions. According to the additional information provided by BASF, at low concentrations the polymer largely (>80%, see Opgenorth, 1987) precipitates from aqueous solutions in the presence of divalent cations (only Ca^{2+} tested)[2], whereas at higher concentrations (> 500 mg/L) the entire polymer is dissolved. This was explained by Opgenorth (1987): as long as Ca^{2+}-ions are present in excess the polymer salt precipitates; however if there are too few divalent cations to saturate all carboxylate groups of the polymer then the polymer remains in solution. 'Precipitation' is used here to describe a complexation of the polymer with the divalent cations. Whether or not the resulting complexes remain in solution as a dispersed emulsion, or precipitate as a result of gravity is not clear.

The high removal rate of P-AA/MA in STPs, where concentrations are usually (far) below 25 mg/L and Ca^{2+} is abundant, is ascribed to the "sorption" of the precipitates to sewage sludge. The precise mechanism of this sorption process has not been clarified, but is very likely different from classical sorption that would involve hydrophobic and/or electrostatic interactions with the sorbent, because a precipitate (or solid?) is involved rather than a dissolved compound. As a result the binding to the sludge may be entirely different. Hence, the availability of the sorbed polymer for uptake by plants or soil organisms after land application of the sludge could be different than in the case of classically sorbed compounds, and may be erroneously represented in the EUSES parametrization by classical partitioning constants for the same reason.

3.2.2. Effect assessment

3.2.2.1. Aquatic and sediment compartment

P-AA: The data set of acute aquatic toxicity on fish and *Daphnia* is very consistent and shows E(L)C50s all above the concentration limit in the tests (> 200 mg/l).

Two toxicity tests on algae are available and show similar results (EC50 values of 40 and 44 mg/l). These tests were conducted with polymers with mean MW of 8,000 and 78,000, instead of 4,500, which is stated as the most frequent one. Nevertheless, the results show that algae are the most sensitive trophic level in short- term exposure.

A data set of 10 chronic NOEC is presented in the HERA report. The lowest NOEC (a 21d NOEC for reproduction in *Daphnia magna* of 5.6 mg/l) has been considered in the HERA report as not valid (Klimisch 4, no possibility to check). Therefore the next lowest NOEC (in *Daphnia magna*) has been retained to derive the $PNEC_{water}$. Although the approach may be accepted, the report does not meet the requirement of the opinion of SCHER (2008): the inter-sample variability should be further investigated. This requirement is important to explain the observed variability (over an order of magnitude for the same MW), and in order to predict conditions where P-AA could induce even lower NOECs.

Possible causes for variability could be differences in test medium, or differences in the actual composition of the tested polymers such as chain length or small MW residues. So the assessment requires reviewing the experimental conditions of the tests and analytical

[2] According to presentation by BASF on 23.06.09 and document 'Attachment 2: solubility of polycarboxylate P-AA/MA' this is an empirical finding, reported in the open literature (Opgenorth 1987).
BASF concludes that at concentrations < 25 mg/L "all P-AA/MA is precipitated"; however the figure shown in this document suggests that at the lowest concentration tested (11 mg/L) a significant amount is still in dissolved form. In the original paper by Opgenorth a value of 80 % precipitation is shown for solutions of 0.05, 0.1, 1, 10 and 100 mg/L of P-AA/MA, and dissolution at 1000 mg/L.

profiles of the tested polymers. The 5 study reports on chronic toxicity to *Daphnia magna* for P-AA are not available to the Committee and could not be checked. SCHER considers that the variability has not been sufficiently considered in the revised report.

The derivation of $PNEC_{STP}$ presented in the new HERA report is acceptable.

P-AA/MA: The data set of acute aquatic toxicity data in aquatic species is very consistent and shows E(L)C50 all above the concentration limit in the tests (> 100 mg/l).

A data set of 8 chronic NOECs is presented in the HERA report.

The variability observed in the different NOECs obtained in *Daphnia* chronic tests (3.75 to 350 mg/l) is tentatively explained in the HERA report by differences in P-AA/MA solubility. The 3 lowest NOECs were not been used in the HERA report for the PNEC derivation because of solubility/precipitation issues. According to the HERA report, it was shown that in the M4 medium used for the chronic *Daphnia* tests, P-AA/MA was completely soluble at concentrations higher than 500 mg/L. However, at concentrations below 500 mg/L the precipitation process started and under 25 mg/L almost all P-AA/MA was present as an insoluble calcium complex. Detailed microscopic observations showed that at concentrations below 10 mg/L, the observed chronic effects on *Daphnia magna* of P-AA/MA are likely due to precipitated polycarboxylates products, as under conditions with low exposure concentration of P-AA/MA, the colour of the gastro-enteric tract of *Daphnia magna* changed from green, i.e. the typical colour resulting from the algae feed, to grey, i.e. the colour of the precipitated polycarboxylates (BASF AG, 1990a).

It is concluded in the HERA report that the effects observed in these experiments at low concentrations might not be caused by intrinsic toxic properties of the polymer, but by secondary effects of the uptake of precipitates. This argument was the basis for not taking into account in the PNEC derivation the 3 lowest NOEC which are below 10 mg/l, assuming that the observed effects were related to precipitate ingestion.

SCHER has reassessed the reports of the three key studies (BASF studies 1985e, 1985f and 1986n). The Procter & Gamble 1989a study giving a NOEC of 350 mg/l for *Daphnia* reproduction could not be checked, so no conclusion could be given by SCHER about its validity as compared with the 3 BASF studies.

The BASF studies were not conducted under GLP, and the lack of analytical control during the tests, leading to the use of nominal concentrations, creates additional uncertainty. The study conclusions are presented as EC0 >= 3.75 mg/l (BASF 1985e), EC0 >= 7.5 mg/l (BASF 1985f) and EC0 = 15.6 mg/l (BASF 1986n). In the last study BASF (1986n) SCHER has observed that the new HERA report presents a figure of 6.2 mg/l as NOEC value for this study, instead of the study conclusion of 15.6 mg/l. A clarification is therefore required. It should be noted that according to the rationale presented in the HERA report, the substance should remain in solution, as the nominal concentration 15.6 mg/l is higher than 10 mg/l, and the NOEC should be considered fully valid.

Regarding the BASF 1985e and 1985f studies, a brood size decrease was observed in the concentration range of 0.5 - 2 mg/l substance; even considering that the effects could be a result of substance particle ingestion at this range of concentration, as suggested by the new HERA report, SCHER is of the opinion that these observed effects cannot be simply dismissed.

To summarize the observed evidence, there seems to be two different chronic toxicity mechanisms on *Daphnia*, due to two different chemical species (calcium complex and free molecules). SCHER considers that the effects associated to the calcium complex should be properly interpreted, in particular as the effects are clearly of adverse nature, reproduction reduction, and observed at realistic relevant environmental concentrations. Additional information, e.g. specific calcium complexation and soluble substance concentration analysis under environmentally relevant conditions may be required for fully understanding the expected environmental consequences of the observed effects.

A precautionary NOEC could be retained at 0.23 mg/l, leading to a precautionary

PNECaqua = 0.023 mg/l, in order to take into account the potential toxicity associated to the calcium complex ingestion.

The most reliable (42 days) chronic study in fish is now correctly reported, there were no effect observed at 10, 31.6 and 100 mg/l.

The derivation of the $PNEC_{STP}$ presented in the new HERA report is acceptable.

3.2.2.2. Terrestrial (soil) compartment

P-AA: No information on soil microbial functions is available; thus only a tentative PNECsoil can be derived. It should be noted that the equilibrium partitioning method has been used for the derivation of the PNECsediment (resulting in a lower PNEC value) but not for the derivation of a PNECsoil. No improvements on the data availability have been conducted. Thus, the previous SCHER comments still remains.

P-AA/MA: New information on the potential effects of P-AA/MA to soil functions is available; however, there are several issues associated to the studies and how the information provided by the studies has been included in the HERA report. First, the studies only present an EC50 value, which has been improperly reported as an EC10 value in the HERA report, an additional caveat is the identity of the tested substance, as the MW included in the HERA reports is not mentioned in the studies. Second, the studies do not included any statistical analysis, which is essential even for demonstrating the absence of effects. Finally, a dose related increase in soil nitrogen concentration is observed in the nitrification assay. This effect is not even mentioned in the HERA report.

The SCHER considers that the relevance of this finding should be mentioned. It should be noted that a possible explanation for this apparent induction of nitrogen mineralization could be a physical effect leading to the modification of the water holding capacity, mentioned in the HERA report for justifying the effects on plants; if this is confirmed, the test should be considered as non valid, as any potential inhibition in nitrogen mineralization could be masked by the reduction in the water holding capacity of the tested soil sample. As a consequence, the suggestion of low sensitivity for these endpoints indicated in the HERA report cannot be confirmed.

Regarding the acute earthworm study deviations have also been observed between the study report and its description in the HERA report.

Therefore, the SCHER considers that the PNECsoil proposed in the HERA report is not acceptable and a proper interpretation of the available studies and the potential environmental consequences of the presence of P-AA/MA in the sludge to be applied to agricultural soils.

3.2.2.3. Secondary poisoning

No information on the bioconcentration potential is available. In addition, no data on mammalian toxicokinetics have been presented in the HERA report.

The report authors assume no concern due to the high molecular weight, and no assessment of secondary poisoning is presented.

In the SCHER opinion, the argument is contradictory with the observation of high relative amount of precipitated polycarboxylates in the gastro-enteric tract of *Daphnia magna*. According to the HERA report, these toxicity studies indicate that exposure at low (environmentally relevant) concentrations is expected to be mostly associated to the ingestion of the precipitated calcium complexes, accumulated at large amount in the gastro-intestinal track of the exposed organisms. The potential relevance of this phenomenon should be investigated in relation to secondary poisoning.

Nevertheless, the SCHER considers that secondary poisoning is likely to be of low relevance due to the low toxicity of these polycarboxylates to mammals, as reported in the Human Health part of the report. The Committee suggests to include a section on secondary poisoning indicating that bioconcentration via gills uptake is unlikely, but that ingestion of precipitated particles has been observed in toxicity tests at low concentrations; a quantitative assessment, if possible, or a qualitative assessment based on the low mammalian toxicity of these chemicals should be incorporated.

3.2.3. Risk characterization

3.2.3.1. Aquatic compartment

The revision of the PNEC for P-AA/MA would raise the $PEC/PNEC_{local,\ water}$ to slightly above 1, showing a local risk for the aquatic environment. The $PEC/PNEC_{regional,\ water}$ would be raised to 0.83 based on the PEC reported in the HERA report. As the tonnage placed on the market has increased, and as additional uncertainties have been observed in the PEC estimation presented in the revised HERA report, this PEC/PNEC could be even higher, therefore, a potential regional risk for the aquatic environment cannot be disregarded.

The PEC/PNEC comparisons invalidates the argument used in the report, that the effect observed at low concentrations and associated to complexation is probably not occurring under realistic environmental conditions, as the effects were specifically observed at the concentrations predicted downstream the emissions. It should be noted that exposure levels can only be based on predicted concentrations due to the lack of suitable analytical methods for these substances in environmental samples.

3.2.3.2. Terrestrial (including soil) compartment

SCHER considers that the proposed PNECs cannot be accepted, due to caveats and misinterpretations of the studies and the lack of information on soil microbial functions (no data on P-AA, insufficiently assessed data and/or invalid studies for P-AA/MA). A PEC/PNEC ratio well above 1 could be estimated at least for P-AA/MA based on preliminary information, thus the Committee considers that a potential environmental risk for the soil compartment could be associated to the use of polycarboxylates in detergent formulations.

Low concern for secondary poisoning is expected due to the low mammalian oral toxicity of these polycarboxylates.

Therefore SCHER considers that based on the available information, a potential environmental risk has been identified. A refined risk assessment should be required before it can be concluded that these chemicals are of low environmental concern.

4. LIST OF ABBREVIATIONS

AA	acrylic acid
AA-MA	acrylic/maleic acid
AISE	International Association for Soaps, Detergents and Maintenance Products
DOC	dissolved organic carbon
DTPA	Diethylenetriamene pentaacetate
EC50	Median effect concentration
NOEC	No Observed Effect Concentration
EDTA	ethylenediaminetetraacetic acid
EUSES	European Union System for the Evaluation of Substances
GLP	Good laboratory practice
HEDP	1-Hydroxy Ethylidene-1,1-Diphosphonic Acid
HEIDA	2-hydroxyl ethyleneiminodia- cetic acid
HERA	Human & Environmental Risk Assessment on ingredients of European household cleaning products

IDS	iminodisuccinate
Kd	distribution coefficient
Koc	organic carbon normalized sorption coefficient
MW	molecular weight
OECD	Organisation for Economic Co-operation and Development
P-AA	homopolymers of acrylic acid
P-AA/MA	copolymers of acrylic/maleic acid
PEC	Predicted Environmental Concentration
PNEC	Predicted No Effect Environmental Concentration
STP	sewage treatment plants
TOC	total organic carbon

5. REFERENCES

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