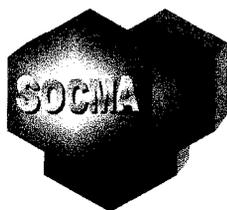


201-14625



Urea Resins Group

**SOCMA
Urea Resins Group**

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July 21, 2003

Administrator
U.S. Environmental Protection Agency
P.O. Box 1473
Merrifield, VA 22116

2003 JUL 29 AM 9:34

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Re: SOCMA Urea Resins Group (EPA Log # 201-11814, 201-13060, 201-13551)
Submission of a Revised HPV Test Plan and Robust Summaries under the
Chemical Right-to-Know Program

Dear Administrator:

The SOCMA Urea Resins Group (SURG) is responding to the EPA Comments on the robust summaries and test plan for 2-Imidazolidinone, 4,5-dihydroxy-1,3-bis(hydroxymethyl)-methylated (CAS No. 68411-81-4).

The responses below are in order corresponding to the key issues in the EPA comments.

General

In response to the Agency's question on whether the final aqueous products are produced by adding water to an anhydrous product, SURG is providing additional information. Commercial products containing CAS# 68411-81-4 are manufactured in an aqueous media. CAS# 68411-81-4 is never isolated in anhydrous form. For this reason, the aqueous form is the most appropriate test material. It is neither practical nor feasible to isolate an anhydrous sample for test purposes. The physicochemical results that were obtained with the commercial materials provide the most relevant and useful data. Also, the use of the commercial product is consistent with current guidelines in the OECD/SIDS manual Section 2.3.3 that discusses what material should be tested. Therefore, for all additional testing noted below SURG will use the commercial product with the highest level of CAS# 68411-81-4 that is available.

Test Plan

Physicochemical properties

For the reason stated above melting point, boiling point and water solubility studies were conducted using the commercial material containing 13% water. Since the test substance is not isolated or marketed in an anhydrous form, these data on the aqueous products were determined to be the most relevant for hazard and risk assessment. The studies were conducted under OECD guidelines and are adequate for purposes of the EPA HPV Challenge Program.

Environmental Fate

The agency suggested that any new measured physicochemical property or environmental fate data should be used as inputs to the environmental fate and fugacity models. The SURG agrees that when conducting such modeling, available measured values should normally be inputted to the extent possible. In this case, however, the SURG believes that it is inappropriate to input measured values for the following reason.

As explained in Sections 2 and 4 of the test plan, SURG modeled two substances for this submission using EPIWIN. These are 2-imidazolidinone, 4,5-dihydroxy-1,3-bis(hydroxymethyl)- (CAS No. 1854-26-8) and 2-imidazolidinone, 4,5-dihydroxy-1,3-bis(methoxymethyl)- (CAS No. 3001-61-4). The first substance is a "non-methylated analog and the second substance is a "dimethylated" analog. Both of these substances have defined molecular structures that can be inputted to the EPIWIN program. The data obtained from these two modeled substances serve to bracket and therefore predict the environmental fate values expected for the test substance 2-imidazolidinone, 4,5-dihydroxy-1,3-bis(hydroxymethyl)-, methylated (CAS No. 68411-81-4). This test substance cannot be modeled. The extent of methylation and positions of methylation are not known. Therefore, because it cannot be represented by a single specific molecular structure is not available to create a SMILES code for entry into the EPIWIN model. As stated in the test plan, the substance may have one or more positions that are methylated, and indeed several different molecular variations may be present in the test substance.

Measured data on the commercial product cannot be used to model environmental fate parameters for CAS No. 68411-81-4. The commercial material contains 13% water and, as noted above, cannot be modeled because it is not a single defined molecular structure. For CAS No. 1854-26-8 measured data exist only for the commercial grade of CAS No. 1854-26-8 that contains ca 25% water. Therefore, the measured data on the commercial products containing water are not relevant or appropriate for modeling a 100%, anhydrous material. Also, there are no measured data for CAS No. 3001-61-4.

Information on why additional data were not entered was added in a remark in the robust summary for fugacity.

Biodegradation

SURG believes that the existing data presented in the robust summaries and test plan are sufficient to predict that the test substance is inherently biodegradable although it is likely to biodegrade somewhat more slowly than the non-methylated material (CAS No.

likely to biodegrade somewhat more slowly than the non-methylated material (CAS No. 1854-26-8). However, recognizing the limitations of EPIWIN BIOWIN in estimating the biodegradability of the test substance (only the surrogates could be modeled), the SURG agrees to conduct an OECD 301 biodegradation study on the commercial material. The test plan matrices and summaries at the end and front of the test plan are changed accordingly.

Acute toxicity

Two new inhalation toxicity studies were located. Robust summaries for these studies were written (see IUCLID document) and the results were added to Table 5 of the test plan.

Ecological Effects

In response to the EPA's comments, the test plan has been changed to indicate that an OECD Guideline 201 study will be conducted because the modeling data suggest that the algal toxicity of the methylated material may be lower than the unmethylated analog. The test plan matrices and summaries at the end and front of the test plan have been changed accordingly.

Robust Summaries

In response to the Agency's comments, additional study information for the acute oral, 14-day and 91-day tests in mice and rats was obtained from the manufacturer of CAS# 1854-26-8. All pertinent information (including strain and sex of animals, study design, incidence of mortality, analytical and statistical methods, purity of test material, and organs that were examined, and the fact that the doses were based on 100% neat material) were added to the summaries. In addition, 2 new acute inhalation studies were found. Summaries for these studies were written.

SURG's responses to specific comments by EPA on the test plan are as follows:

1. 95 % confidence intervals for the acute oral toxicity studies. Confidence intervals are not relevant, since the LD50 values were greater than the highest dose given.
2. Hematological, clinical chemistry and urinalysis parameters. These were not measured in the repeat dose studies. Therefore, no information is listed about these parameters. The initial summaries for the 91-day studies listed them as being conducted according to an OECD guideline. However, the studies themselves listed the studies as being conducted according to an NTP Protocol. Accordingly, the test method listed in the IUCLID document for these studies has been changed.
3. Ames test. The units have been changed to micrograms/ml.
4. Reproductive toxicity. The summary for the rats has been edited to contain data about the one high dose male that had testicular toxicity. The fact that doses in the rat study were based on 100% neat material has been added.

SURG plans to initiate the studies described above in accordance with the commitment of SURG and its member companies to the EPA HPV Challenge Program. Once these are complete, we will revise the robust summaries to include the new data and will submit this to the Agency. Please contact me if you have any comments or questions.

Sincerely,

William H Smock
Executive Director

CC: SOCMA Urea Resins Group