Reviewer’s report

Title: In vitro and in vivo safety evaluation of Dipteryx alata Vogel extract

Version: 1 Date: 21 September 2011

Reviewer: Alvaro Augusto da Costa Leitão

Reviewer’s report:

The question is well defined by the authors.

The methodology is appropriate and has been well described for testing the quality and toxicity of the extract, however, the description of the mutagenicity tests needs some corrections:

Second paragraph of “Biological Tests”

1 - In the composition of the top agar, histidine and biotin (0.5 mM each) must be added
2 - Define minimal agar and explain why you used this technique (double layer), which is not described in the work of Ames.

Other general methodological issues:

1 - Why the lyophilized preparation that was used in vivo was not used for mutagenicity?
2 - Why was DMSO used as a negative control? A water-alcohol solution should have been used.

The results are relevant and the manuscript is clear and fairly well describes the results. However, in the “Results and Discussion” section the authors need to correct the following:

Shortening the second paragraph,

Delete the third paragraph (the explanations are not necessary)

The discussion and conclusions are well addressed, except:

Fifth paragraph: The results only allow to state that the extracts are not mutagenic. The authors cannot state that they are not carcinogenic.

General comment

The toxicological tests were well conducted and the authors should have mentioned his work “Implementation of the three Rs in the human hazard assessment of Brazilian medicinal plants: An evaluation of the genotoxic potentials of cititoxic and Dipteryxalata Vogel in ATLA Alternatives to Laboratory Animals, 33:189-196 2011.”