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**AkzoNobel**

Tomorrow's Answers Today

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October 11, 2012

US EPA Office of Pollution Prevention and Toxics  
EPA East Building Room 6428  
Attn: Section 8(e)  
1201 Constitution Avenue, NW  
Washington, DC 20004

Cc: Polymer Chemicals bv  
Arkema France  
Pergan GmbH  
United Initiators GmbH & Co. KG



**SUBJECT: TSCA 8(e) Notice**

Dear TSCA Section 8(e) Coordinator:

On behalf of Akzo Nobel Polymer Chemicals LLC we are submitting data on an OECD 487 *in vitro* Mammalian Cell Micronucleus Test with tert-amyl hydroperoxide CAS# 3425-61-4. The study was conducted as part of the REACH (Registration, Evaluation, Authorization and Restriction of Chemicals) program.

The study was conducted to evaluate the potential of the test item, to induce an increase in the frequency of micronucleated cells, in L5178Y TK<sup>+/+</sup> mouse lymphoma cells.

After a preliminary toxicity test, tert-amyl hydroperoxide, was tested in three independent experiments, with and/or without a metabolic activation system, the S9 mix, prepared from a liver microsomal fraction (S9 fraction) of rats induced with Aroclor 1254, as follows:

	First experiment	Second experiment	Third experiment
Without S9 mix	3 h treatment + 24 h recovery	24 h treatment + 20 h recovery	
With S9 mix	3 h treatment + 24 h recovery	3 h treatment + 24 h recovery	3 h treatment + 24 h recovery

Each treatment was coupled to an assessment of cytotoxicity at the same dose-levels. Cytotoxicity was evaluated by determining the PD (Population Doubling) of cells and quality of the cells on the slides has also been taken into account.

The test item was dissolved in dimethylsulfoxide (DMSO).



**CONTAINS NO CBI**

#### Experiments without S9 mix

The dose-levels selected for micronucleus analysis were:

3-hour treatment: 4.7, 9.4 and 18.8 µg/mL (higher dose-levels being too cytotoxic)

24-hour treatment: 10, 20 and 30 µg/mL (higher dose-levels being too cytotoxic)

No significant increase in the frequency of micronucleated cells was noted after the 3-hour treatment. Following the 24-hour treatment, an increase in the frequency of micronucleated cells (exceeding the threshold of 2.5-fold the vehicle control value) was observed at 30 µg/mL. This increase was statistically significant ( $p < 0.05$ ). However, the corresponding micronucleated cells remained within the historical data range of the vehicle control (5 micronucleated cells in 1000 cells *versus* 0-5 for the historical data). Consequently, this increase is considered as equivocal.

#### Experiments with S9 mix

The dose-levels selected for micronucleus analysis were as follows:

First experiment: 9.4, 18.8 and 37.5 µg/mL (the latter inducing a 45% decrease in the PD)

Second experiment: 4.7, 9.4 and 18.8 µg/mL (the latter inducing a 55% decrease in the PD)

Third experiment: 10, 20 and 30 µg/mL (the latter inducing a 57% decrease in the PD)

In all experiments, slight increases in the frequency of micronucleated cells (exceeding the threshold of 2.5-fold the vehicle control value) were observed. These increases reached statistical significance in the first and third experiments and were dose-related. Therefore, these increases being reproducible in independent experiments, they were considered to be biologically significant.

#### Conclusion

Under the experimental conditions of the study, the test item, Tert-amyl hydroperoxide, induced chromosome damage, or damage to the cell division apparatus, in cultured L5178Y TK<sup>+/+</sup> mouse lymphoma cells, in the presence of a rat metabolizing system. In the absence of a rat metabolising system, its potential to induced chromosome damage, or damage to the cell division apparatus, remained equivocal.

Please contact me at (312) 544-7061 if you have any questions regarding this letter.



**AkzoNobel**  
Tomorrow's Answers Today

Sincerely,

*Louette Rausch*

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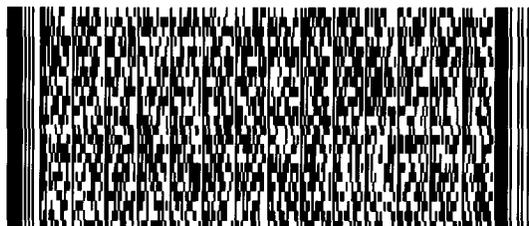


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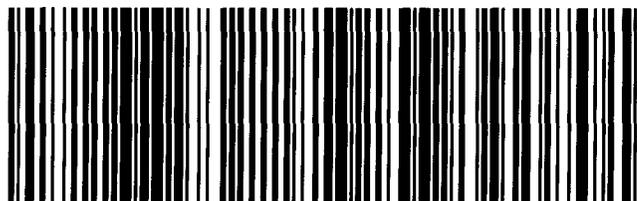
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