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**Via Federal Express**

Attention: TSCA Declassification Coordinator

United States Environmental Protection Agency  
Office of Pollution Prevention and Toxics  
Confidential Business Information Center (CBIC)  
EPA East Building, Room 6428  
1201 Constitution Avenue  
Washington, DC 20004



**Subject: Declassification Activity, Health and Safety Filing  
DCN: 8EHQ-08-17320**

Dear TSCA Declassification Coordinator:

In response to Mr. Sherlock's electronic mail request of March 16, 2011 regarding confidentiality claims for the identity of the chemical substance that was reported under TSCA Section 8(e) by Ciba, dated November 12, 2008, BASF Corporation (successor to Ciba) hereby withdraws all claims of confidentiality made with respect to the Section 8(e) report in question.

Please note that this withdrawal of confidentiality is intended only to allow EPA to reveal to the public the information that was claimed confidential at the time of the report in question. BASF Corporation is not relinquishing any property rights in the study in question.

Attached is a public version of the document (copy of the original submission), with the declassified data circled and document control number (DCN) identified.

If you have any questions regarding this letter, please contact Janet Cerra at (973) 245-6693.

Sincerely,

*Janet Cerra*  
Janet Cerra

Enclosures

Irganox L135\_Ciba\_8EHQ-08-17320\_CBI DeclassLetter.doc



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**Ciba**



**Declassification Activity, Health and Safety Filing  
DCN: 8EHQ-08-17320**

November 12, 2008

*Via Courier*

TSCA Confidential Business Information Center (7407M)  
EPA East - Room 6428 Attn: Section 8(e)  
U.S. Environmental Protection Agency  
1201 Constitution Avenue NW  
Washington, DC 20004-3302

Phone: (202)564-8940

Subject: TSCA 8(e) Notice - Irganox L 135/1135 (TK 11014)

Dear Section 8(e) Coordinator:

In accordance with EPA's March 16, 1978, Policy Statement on Section 8(e) reporting under the Toxic Substances Control Act (TSCA), and the EPA's June, 1991 TSCA Section 8(e) Reporting Guide, Ciba Corporation wishes to bring to the attention of the Environmental Protection Agency the results observed for Irganox L 135/1135 (TK 11014) in a Prenatal Developmental Toxicity Study in the Himalayan Rabbit (OECD 414). The chemical name is Benzenepropanoic acid, 3,5-bis(1,1-dimethylethyl)-4-hydroxy-, C7-9-branched alkyl esters and the CAS number is 125643-61-0. The study is being conducted by RCC Ltd in Füllinsdorf, Switzerland.

In this study, four groups of female rabbits (20 per treatment group) were treated by gavage with Irganox L 135/1135 (TK 11014) once daily from day 6 post coitum (implantation) to day 27 post coitum (the day prior to Caesarean section) at dose levels of:

Group 1	0 mg/kg body weight/day (control group)
Group 2:	20 mg/kg body weight/day
Group 3:	40 mg/kg body weight/day
Group 4:	80 mg/kg body weight/day

In group 4, mean food consumption was reduced, at times statistically significantly, throughout the treatment period. Mean body weight gain and body weight were also reduced. Post-implantation loss was statistically significantly increased and as a result, the total number of fetuses was statistically significantly reduced. One dam aborted. During macroscopic

**Declassification Activity, Health and Safety Filing  
DCN: 8EHQ-08-17320**

examination, a higher number of findings were noted in group 4 than in the other dose groups, especially in the stomach, kidneys and gall bladder. The weight of the thyroid and adrenal glands was increased on both sides. This increase was not statistically significant and was not considered to be adverse. Mean fetal weights in group 4 were statistically significantly reduced. There were also more visceral abnormalities in the fetuses than in the control group. There was reduced cranial ossification, as well as reduced digit/limb ossification. The findings from the skeletal and cartilage examinations suggest a possible minor disturbance in the development of the axial skeletons of the fetuses. These findings in the dams and fetuses were considered to be attributable to maternal toxicity.

In group 3, there was no indication of maternal toxicity. There was reduced cranial ossification and reduced ossification of the digits in the fetuses, which was considered to be a minor fetal effect that is transient and with no adverse impact on further development or health of the offspring.

In group 2, there was no indication of maternal toxicity. The hint of reduced ossification of the digits in the fetuses was within the historical control data.

Based on these interim results of this study, the maternal NOEL was considered to be 40 mg/kg body weight/day. The NOAEL for fetal organisms was considered to be 40 mg/kg body weight/day.

Irganox L135 is a hindered-phenol antioxidant with effects similar to phenobarbital-like liver inducers that interfere with rodent thyroid hormone metabolism. Ciba reported toxicity test results on this effect for Irganox L135 in a previous 8(e) report (April 16, 1991). This effect, which we believe is largely responsible for the maternal toxicity in the present study, is considered a rodent-specific phenomenon and of minor relevance to man.

A study report is expected in 4-6 weeks which will be provided immediately to the EPA. A sanitized copy of this notice and a Confidential Business Information Substantiation form is also submitted pursuant to TSCA 8(e) requirements. If you have questions or require additional information, please contact me.

Sincerely yours,

Marie Paquette  
Manager EPA Compliance  
914-785-4288

From: (973) 245-6693  
 Janet Cerra  
 BASF  
 100 Campus Drive  
 Florham Park, NJ 07932

Origin ID: LKKA



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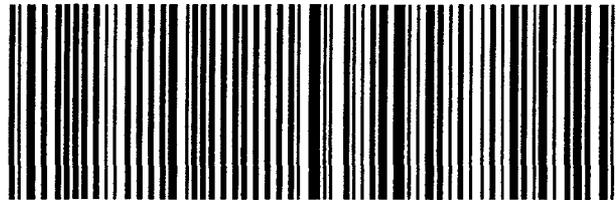
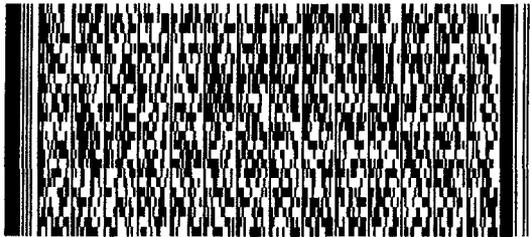
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