

## ANNEXE 5

# Évaluations des dangers

## Évaluation par le NTP

Le *National Toxicology Program* (NTP)<sup>17</sup> est un programme qui fait appel aux différentes agences américaines et qui a pour mission : d'évaluer les risques présentés par des substances qui concernent la santé publique ; de développer et de valider des méthodes d'analyse ; de développer des approches et fournir des données afin de valider les bases scientifiques de l'évaluation de risque ; de communiquer avec tous les partenaires tels que le gouvernement, l'industrie, les établissements scientifiques, la communauté environnementale et le public. Le NTP a conduit deux longues études (sur 2 ans) de toxicité et de carcinogénicité sur deux éthers de glycol : l'EGBE et le 2PGtBE.

### EGBE – CAS N° 111-76-2

***Rapport du NTP - 2000 -Toxicology and carcinogenesis studies of 2-butoxyethanol (CAS N°. 111-76-2) in F344/N rats and B6C3F1 mice (inhalation studies)***

Under the conditions of these 2-year inhalation studies, there was no evidence of carcinogenic activity<sup>18</sup> of 2-butoxyethanol in male F344/N rats exposed to 31.2, 62.5, or 125 ppm. There was equivocal evidence of carcinogenic activity of 2-butoxyethanol in female F344/N rats based on the increased combined incidences of benign or malignant pheochromocytoma (mainly benign) of the adrenal medulla. There was some evidence of carcinogenic activity of 2-butoxyethanol in male B6C3F1 mice based on increased incidences of hemangiosarcoma of the liver. A marginal increase in the incidences of forestomach squamous cell papilloma and an increase in the incidences of hepatocellular carcinoma may have been exposure related. There was some evidence of carcinogenic activity of 2-butoxyethanol in female B6C3F1 mice based on increased incidences of forestomach squamous cell papilloma or carcinoma (mainly papilloma). Increased incidences of forestomach neoplasms in male and female mice occurred in groups in which ulceration and hyperplasia were also present. Exposure to 2-butoxyethanol caused a mild regenerative anemia and effects secondary to the anemia.

17. <http://ntp-server.niehs.nih.gov/>

18. *No evidence of carcinogenic activity* is demonstrated by studies that are interpreted as showing no chemical-related increases in malignant or benign neoplasms.

## 2PGtBE - CAS N° 57018-52-7

### ***Rapport du NTP – 2004 - Toxicology and carcinogenesis studies of propylene glycol mono-t-butyl ether (cas no. 57018-52-7) in F344/N rats and B6C3F1 mice and a toxicology study of propylene glycol mono-t-butyl ether in male NBR rats (inhalation studies)***

Under the conditions of this 2-year inhalation study, there was equivocal evidence of carcinogenic activity of propylene glycol mono-t-butyl ether in male F344/N rats based on marginally increased incidences of renal tubule and liver neoplasms. There was no evidence of carcinogenic activity of propylene glycol mono-t-butyl ether in female F344/N rats exposed to 75, 300, or 1.200 ppm. There was clear evidence of carcinogenic activity of propylene glycol mono-t-butyl ether in male and female B6C3F1 mice based on increased incidences of liver neoplasms. Exposure of male rats to propylene glycol mono-t-butyl ether resulted in nonneoplastic lesions of the kidney characteristic of  $\alpha$ 2u-globulin accumulation. Exposure to propylene glycol mono-t-butyl ether resulted in nonneoplastic lesions of the liver and nose in male and female rats, the liver in male and female mice, and the eyes in female rats and mice. Kinetic and biomarker studies indicated that clearance was saturated at the 1.200 ppm exposure for both rats and mice.

## Évaluations par le CIRC

Le Centre international de recherche sur le cancer (CIRC) fait partie de l'Organisation mondiale pour la santé (OMS) et a pour mission la coordination et la conduite de recherche sur les causes de cancer chez l'homme, les mécanismes de la carcinogénicité, et de développer des stratégies scientifiques pour contrôler la progression du cancer. Les monographies du CIRC<sup>19</sup> sur l'Évaluation des risques de cancérogénicité pour l'homme sont des évaluations indépendantes, réalisées par des experts internationaux, des risques cancérogènes qu'un grand nombre de différents agents font courir à l'homme. Depuis son lancement en 1972, cette série a permis de faire le point sur plus de 895 agents. Le CIRC vient de réaliser une évaluation de la cancérogénicité de deux éthers de glycol : l'EGBE et le 2PGtBE.

## EGBE – CAS N° 111-76-2

### ***Résumé du rapport de l'évaluation – Vol. 88, 2-9 juin 2004***

2-butoxyethanol is widely used as a solvent in paints and paint thinners, glass and surface cleaners, personal-care products, and as a chemical intermediate.

An inhalation study in male and female rats and mice found increased incidence of liver haemangiosarcoma in male mice, of forestomach squamous-cell papilloma and carcinoma in female mice, and equivocal results in female rats. A link between haemolysis and mouse liver neoplasia has been proposed, but the Working Group noted that other potential mechanisms have not been investigated.

The Working Group concluded that 2-butoxyethanol is not classifiable as to its carcinogenicity to humans (Group 3) on the basis of limited evidence in experimental animals and inadequate evidence in humans.

## **2PGtBE - CAS N° 57018-52-7**

### ***Résumé du rapport de l'évaluation – Vol. 88, 2-9 juin 2004***

1-tert-butoxy-2-propanol is used increasingly as a solvent in coatings, glass and surface cleaners, inks, adhesives, and nailpolish lacquers. An inhalation study in male and female rats and mice found increased incidence of liver tumours, including hepatoblastoma, in male and female mice and equivocal results in male rats. There was a discussion about whether to regard hepatoblastoma as a rare tumour or a variant of hepatocellular carcinoma.

The Working Group concluded that 1-tert-butoxy-2-propanol is not classifiable as to its carcinogenicity to humans (Group 3) on the basis of limited evidence in experimental animals and inadequate evidence in humans.