

## Improved Classification for 2-Butoxyethanol

During the summer of 1999, the French authorities proposed that the classification of butoxyethanol (BGE, EGBE) was reviewed under the European Commission process.

Progress has recently been made on this issue, since the Commission Working Group on the Classification and Labelling of Dangerous Substances has now agreed on a revised, and improved classification, following consultation and new research. The Group agreed that the classification should be changed as follows:

Old classification	Xn, R 20/21/22; Xi, R 37	New classification	Xn, R 20/21/22; Xi, R 36/38
Special Concentration limits:	<12.5%: None	Concentration limits:	<20%: None
	≥12.5% and <20%: Xn, R 20/21/22		≥20% and <25%: Xi, R 36/38
	≥20%: Xn, R 20/21/22-37		≥25%: Xn, R 20/21/22-36/38

### Consequences for formulators

The revision is important for those users who will wish to make use of the higher level of butoxyethanol permitted in unclassified preparations. Under the new classification, formulations containing butoxyethanol at levels between 12.5% and 20% which were previously labelled harmful, Xn, will no longer be classified (unless other components cause this to occur). Similarly, formulations containing levels between 20% and 25% will only be classified as 'irritants' as opposed to being 'harmful'. Naturally, changes to product classification and labelling must await formal ratification of the working group decision and subsequent completion of the ATP process and translation to national legislation.

### Background to the re-classification

Towards the latter part of 1998, the US National Toxicology Program (NTP) completed a carcinogenicity study on 2-butoxyethanol. The report of the work, states that although there were no significant findings in the rat, there was 'some evidence' of liver cancer in male mice and forestomach cancer in female mice at the highest dose level used (250ppm by inhalation). France suggested the committee consider whether these findings required re-classification as a category 3 carcinogen under the EU Dangerous Substances Directive. Industry were consulted and supplied new research work which demonstrated that the results seen in mice had no relevance to humans. The committee concluded that there was

no justification for a category 3 classification, and took the opportunity to pass an updated view on the other parts of butoxyethanol classification.

### Forward process

It is anticipated that formal ratification will take place at a technical progress committee meeting in early 2001. Once formally agreed, the classification change will appear in an Adaptation to Technical Progress for translation into national legislation. Translation into national legislation will take a further 1-2 years. To ensure compliance with legislation, no changes in the classifications of formulated products should be made until the transposition into national legislation.