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Press Release:

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SECOND PUBLIC CONSULTATION ON HARMONISED CLASSIFICATION AND LABELLING

ECHA has published on its website the second public consultation on a proposal to harmonise the classification and labelling of four chemical substances. Comments are welcome on the proposal within the next 45 days. All comments will be taken into account in the subsequent decision-making process.

The substances and their proposed classification, as submitted by two Member States (France and the Netherlands) are:

- **Di-tert-butyl-peroxide** (FR), which is used for example to bond together polymer chains in polymer synthesis (a cross-linking agent) or to start a polymerisation reaction (a free radical polymerisation initiator), is proposed to be classified as a Category 3 mutagen (see below for an explanation of the Categories).
- **Gallium arsenide** (FR), which is used for example in integrated circuit manufacture in the microelectronics industry, is proposed to be classified as toxic to reproduction Category 2, carcinogen Category 3, and as toxic because of the danger of serious damage to health by prolonged exposure.
- **Indium phosphide** (FR), which is used for example as a semiconducting compound in electronics, is proposed to be classified as toxic to reproduction Category 3, carcinogen Category 2, and as toxic because of the danger of serious damage to health by prolonged exposure.
- **Trixylyl phosphate** (NL), which is used for example as hydraulic fluid in industrial power generators, is proposed to be classified as toxic to reproduction category 2.

The Dutch and French authorities have submitted to ECHA comprehensive dossiers on these substances and asked for their classification and labelling to be harmonised across the European Union.

Explanation of Categories

The rules for the classification of dangerous substances according to the degree of hazard are contained in Council Directive 67/548/EEC. Here are the general principles of the classifications:

Category 1: There is sufficient evidence to establish a causal association between human exposure to a substance and ill health (cancer for example in the case of carcinogens).

Category 2: There is sufficient evidence to provide a strong presumption that human exposure to a substance may result in the development of ill health, generally on the basis of:

- appropriate long-term animal studies
- other relevant information.

Category 3: Substances which cause concern for man but in respect of which the available information is not adequate for making a satisfactory assessment. There is some evidence from appropriate animal studies, but this is insufficient to place the substance in Category 2.

Further Information

The public consultation on the proposals for harmonised classification & labelling can be accessed at:

http://echa.europa.eu/consultations/harmonised_cl_en.asp

Information about the new EU regulation on classification, labelling and packaging of substances and mixtures, the so called CLP Regulation is available at:

http://echa.europa.eu/classification_en.asp

Notes to Editors

ECHA

The European Chemicals Agency in Helsinki, Finland, manages the REACH Regulation and the Classification, Labelling and Packaging Regulation. Together, they form the foundation for ECHA – with the aim of protecting human health and the environment, and ensuring the competitiveness of European industry. An important means to achieving this goal is to provide information which ensures the safe use of chemicals.

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Why harmonise?

Suppliers of chemicals (substances and mixtures) across Europe have a legal obligation to evaluate the hazards of chemicals and to classify and label them in an appropriate way before placing them on the market.

However, individual EU Member States (via their competent authorities) or industry may ask for the classification and labelling of a substance to be harmonised across Europe. This may happen in three situations:

- Where the substance is either:
 - carcinogenic;
 - mutagenic;
 - toxic for reproduction; and/or
 - a respiratory sensitizer.
- When the substance is a biocide or pesticide (designed to control harmful organisms) or
- When there is a need to harmonise the classification at the EU level, other hazard classes than those listed above may be proposed, for example when the suppliers classify the same substance in a different or an incorrect way.

Procedure

The proposal for harmonisation is submitted to ECHA along with a dossier which outlines the scientific reasons for making the request. ECHA receives these proposals and, together with its Committee for Risk Assessment, ensures that the dossier is complete and consistent. It then organises a public consultation. You will find details of all the current proposals for consultation on our website.

The consultation period lasts for 45 days, and, at the end of it, ECHA forwards all comments received to the Member State or industry who had submitted the proposal, so that they can provide their responses.

The proposal, the comments and the responses will then be forwarded to ECHA's Committee for Risk Assessment which consists of scientific experts from all the EU and EEA Member States and observers from stakeholder organisations. The Committee will issue a scientific opinion on the proposal which ECHA will forward to the European Commission. The Commission then decides, on the basis of the advice from a regulatory committee of the EU Member States, on the classification and labelling of the substance concerned.

Publication of result

If the proposal to harmonise is accepted, the substance will be added to the list of harmonised classifications in Annex VI, part 3 of the CLP Regulation.

The harmonised classifications will also be made available on ECHA's website.

Thereafter, all manufacturers, importers and users of the substance in the EU will need to abide by the new harmonised classification and labelling, enabling the ultimate users to be better informed about the substance, its potential effects and how best to make use of it safely.

For media questions, please contact press@echa.europa.eu

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