

IMPLEMENTATION OF THE CLASSIFICATION AND LABELLING  
REQUIREMENTS OF THE DANGEROUS PREPARATIONS  
DIRECTIVES 88/379/EEC AND 1999/45/EC  
WITH RESPECT TO HEALTH EFFECTS

**ATC DOCUMENT 43 - REVISION 3**

**SEPTEMBER 2000**

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I. INTRODUCTION:

This paper is intended to assist both ATC member companies and their customers. It explains the general principles and procedures that ATC member companies will follow in line with the current Dangerous Preparations Directive <sup>1</sup> (DPD) and, post-30th July 2002, in line with the revised Directive adopted on 31st May 1999 <sup>2</sup>. It also explains how information on member companies' products will be provided to enable customers to classify and label their own products.

Neither the 1988 nor the 1999 Directive gives much scope for the use of toxicological read-across in classifying preparations. Normally, preparations are to be classified by the conventional calculation method from the known or estimated properties of their component substances. Under the 1999 Directive, classification by testing will be permitted only where it can be "scientifically demonstrated ...that the toxicological properties cannot correctly be determined" by the calculation method. The 1988 Directive, whilst discouraging testing, is less stringent than this.

A number of important changes were introduced under the 1999 Directive, including:

- \* new requirements regarding the labelling of preparations containing sensitizers, even in cases where the preparation is not classified as sensitizing;
- \* new requirements regarding the provision of data sheets for non-dangerous preparations containing low levels of dangerous substances;
- \* classification and labelling requirements based on environmental properties, with a system for calculating classification which is analogous to that for health effects;
- \* confidentiality for chemical names of dangerous components must be approved in advance of marketing; and
- \* restrictions on advertisements for dangerous preparations.

Some of these changes, e.g. those regarding environmental classification and labelling and the declaration of sensitizers at very low levels, will be difficult to implement because of the paucity of substance data. Absence of data must be considered with caution before deciding that a preparation does not fall within the scope of the 1999 Directive. The advertising restriction is not addressed in this paper, as it is seen by ATC as a matter for individual companies.

II. PRINCIPLES:

This paper should be read in conjunction with a number of broad principles and guidelines, which have been agreed by ATC member companies. Of special importance are the following ATC Documents:

- \* Document 31 - An Internationally Recognized Nomenclature System for Petroleum Additives;
- \* Document 43 - Classification and User Labelling Information Concerning the Health Effects of Major Petroleum Additive Components;

- \* Document 50 - Guidance on Classification and Labelling of Additives with respect to Danger for the Environment; and
- \* ATC Document 54 - Guidance on Safety Data Sheets and Information Disclosure.

Copies of all of these Documents are available from ATC member companies or from the ATC Secretariat.

ATC aims to provide, in a way that meets both the specific requirements and the spirit of the law, any and all information that customers may need for the protection of their work force and to enable them to comply with the laws and regulations pertaining to their own products. Where compositional information is provided, this will be done, whenever possible, by the use of the ATC nomenclature system. (In the case of components listed in Annex I of the Dangerous Substances Directive (DSD) - Directive 67/548/EC - use of ATC nomenclature may not be permitted). The ATC system is internationally recognized and is designed to provide meaningful chemical information whilst at the same time protecting commercially sensitive data. ATC believes that this balance is in the best interests of everyone - product developer, customer, carrier, etc. ATC also recognizes that, in certain circumstances, further product-specific information may be needed. In such cases, ATC believes that any necessary information exchange is best handled directly between the supplier and the customer, if necessary under mutually agreed confidentiality provisions.

Whilst ATC members companies intend at all times to be in compliance with relevant laws and regulations, changes will occur in the transition from application of the 1988 Directive to application of the 1999 Directive. The next two sections of this paper highlight where these changes are likely to be seen.

### III. EFFECTS OF IMPLEMENTING THE CHANGES FROM THE 1988 DPD TO THE 1999 DPD:

(a) General Comments: It will be obvious from a look at ATC Document 43 that, within each nomenclature class, the various discrete chemicals do not have identical classifications. However, the variations are of degree only; they are not fundamental differences. For example, zinc alkyl dithiophosphates (ZADPs) range in toxicity from 'not classified' to 'Xi/R41 (irritant with risk of serious damage to eyes)'. Similarly, some sulphonates are skin sensitizers (Xi/R43) but others are not. However, the same general precautions are appropriate for all members of a class, e.g. avoid skin and eye contact. For these reasons, apparently similar additive packages may be classified somewhat differently and have different compositional disclosures on their labels regarding classified component substances.

Under the 1999 Directive, there is a requirement to give some compositional information about all preparations containing 1% or more of a dangerous substance (0.1% in the case of sensitizers and certain other dangerous substances) - unless a lower level is specified in Annex I of the DSD. Customers should not therefore be surprised to find that some products which are not classified as dangerous appear with disclosures on the labels in anticipation of the implementation date of the 1999 DPD (end-July 2002). This does not represent a change in the classification of the product but merely a change in the law regarding compositional disclosures. Similarly, safety data sheets (SDSs) will be required for many non-dangerous preparations post-July 2002. The exact detail required in the SDSs for these products has not yet been decided. When it has been, it will be spelled out in ATC Document 54, which, again, is available from ATC member companies or the ATC secretariat.

ATC member companies have issued SDSs for all products for many years now. However, customers will see changes to the detail of these sheets as the 1999 Directive takes effect. Again, this does not represent any change in the classification of the product concerned.

(b) Sensitizers: A few sensitizers are to be found among the additive components used and

marketed by ATC member companies. The most common are certain calcium sulphonates and some amine derivatives. The 1999 DPD is ambiguous concerning the number of names required on the label of sensitizers. Thus Article 10.2.3.3 states: "the name of the substances which have given rise to the classification of the preparation in one or more of the following danger categories: ...sensitizing ... shall be mentioned on the label". According to the rules set out in Annex II, Part A, section 6.1, which is to be read in conjunction with Table V of the Annex, unless the sensitizer is listed in Annex I of the Directive 67/548/EC, as amended, it requires 1% of a sensitizing substance to trigger classification of the preparation as a sensitizer. However, Annex V, Part B, section 9 indicates under the heading "Preparations not classified as sensitizing but containing at least one sensitizing substance" that "The packaging of preparations containing at least one substance classified as sensitizing and being present in a concentration equal to or greater than 0.1% must bear the inscription: 'Contains (name of sensitizing substance). May produce an allergic reaction'." It is not clear what this means with respect to preparations which are classified as sensitizing but contain several sensitizers, only one of which is responsible for the classification as a sensitizer. It is up to individual companies to decide on appropriate naming of names according to individual circumstances and products.

In the past, packages containing sensitizing components have commonly been tested. If found not to be sensitizing, they have not required classification, even where the possible sensitizing component is present at greater than 1.0% (the limit value in the calculation method). Testing may not always be possible under the 1999 DPD so, as a generality, customers may in future see disclosures on labels that have not hitherto been made or required. Again, this does not mean that the product itself has changed.

c) Environmental Classification and Labelling: The methods for evaluation of the environmental hazards of preparations are described in detail in Annex III of the 1999 DPD. They cover danger to both the aquatic and the non-aquatic environment. The methodology of the calculation procedure is analogous to that used for calculating human health effects. However, greater difficulties arise in that there is far less information available on the ecotoxic effects than the health effects of the component substances. Testing is permitted as an alternative to calculation only for the determination of acute aquatic toxicity, but it then overrides a calculated assessment. Although ATC member companies have established a considerable body of aquatic toxicity data on additive components, it will be necessary to make judgemental assessments/read-across as to the toxicity of other, related components. As new data are developed, classification and labelling may need to be amended. ATC member companies will not, in any circumstances, assume that the absence of data means that a component is not classified.

(d) Irritants: Irritants are not required to be named on labels under either the 1988 or 1999 DPD. However, they are required to be recorded in an appropriate way in the safety data sheet (SDS), certainly for classified preparations (see next section).

#### IV. INFORMATION FOR CUSTOMERS:

(a) Safety Data Sheets: ATC member companies were providing SDSs for both classified and unclassified products for many years prior to there being a legal requirement to do so. Significant changes resulting from new findings have always triggered the revision and reissue of these sheets. These practices will continue, as, even under the 1999 DPD, not all preparations will require an SDS. Information about the requirements of the SDS and how ATC member companies will satisfy these will be found in ATC Document 54. At the time of adoption of the 1999 DPD, it was merely noted in the Directive that the SDS Directive<sup>3</sup> will be amended to take account of the changes in SDS requirements introduced by the new DPD. When such changes have been adopted, ATC Document 54 will be updated. The version dated September 1995 deals only with the requirements as known at that date.

(b) Labels: ATC member companies will, of course, apply the labelling requirements of the 1988 and 1999 DPDs as required. For preparations not covered by the DPD, labelling will be

consistent with best industry practice and at the very least, sufficient to ensure that those handling ATC member companies' products may do so with a high degree of safety.

Together, the SDSs and labels prepared by ATC member companies should provide sufficient information to permit customers to perform risk assessments for the use of the additives and to classify their own products blended from them. If cases should arise in which a customer believes additional information is needed for any reason, then direct dialogue with the supplier is recommended. Such dialogue may need to be subject to a confidentiality agreement between the parties. V. INFORMATION TO POISONS CENTRES:

The 1988 and 1999 DPDs both require that Member States shall appoint national bodies responsible for receiving information on dangerous preparations. Although these bodies, commonly known as poisons centres, have not yet defined their needs, ATC has authorized the inclusion in the TOMES Plus INFOTEXT Information System published by MICROMEDEX Inc. of ATC Document 31 - 'An Internationally Recognized Nomenclature System for Petroleum Additives'. This is a key information source used by poisons centres around the world. Further guidance and explanation on this matter may be found in an independent review paper entitled 'Composition and toxicity of petroleum products and their additives', by Professor John A. Henry<sup>4</sup>. Copies of this paper are available through ATC member companies or the ATC secretariat.

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Bibliography:

<sup>1</sup> Directive 88/379/EEC: OJ L187. 16.7.1988, p.14.

<sup>2</sup> Directive 1999/45/EC: OJ L200. 30.7.1999, p.1.

<sup>3</sup> Directive 91/155/EEC: OJ L76. 22.3.1991,p.35

<sup>4</sup> Human & Experimental Toxicology (1998), 17, 111-123).