

# **Toxicological Information- und Data Network - A European Challenge?**

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## ELECTRONIC DATA TRANSFER OF PRODUCTS IN ITALY

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### Abstract

Article 10 of the Legislative decree n. 285 of 16 July 1988, which implements in Italy the dir. 88/379/EEC, concerning classification, packaging and labelling of dangerous preparations, requires the creation of a database of dangerous preparations.

The Decree 19 April 2000 of the Ministry of Health, published in the Official Journal of Italian Republic of 23 November 2000 (Gazzetta Ufficiale della Repubblica Italiana del 23 Novembre 2000), appoints the ISS, Laboratory of Applied Toxicology, as the institution responsible for the computerized database, which will contain relevant information on dangerous preparations placed on the Italian market.

The information is requested for all dangerous preparations covered by the Legislative decree n. 285 (directive 88/379/EEC), and shall be given using an appropriate programme (ISS Formula) which can be downloaded from the ISS internet site or which can be obtained as CD-ROM from the ISS or from several Italian Industrial Associations.

The database constitutes a reference tool in the framework of prevention and protection of consumers and workers accidentally or professionally exposed to chemical preparations. The easy and quick access to the chemical composition of dangerous preparation placed on the Italian market will allow a more rapid intervention in case of accidental poisoning and will make preventive actions more effective.

As a derogation from the general rule to fill in the electronic form, it will be permitted to the companies having internal computerized archives to transfer the requested data to the Data Bank on Dangerous Preparations by transforming their internal data into a compatible format, i.e. without using the programme "ISS Formula".

To this purpose, the trace of the record of the ISS Formula programme (Export File), is also made available within the ISS web site ([www.iss.it](http://www.iss.it)) or directly within the dangerous preparation web site ([www.preparatipericolosi.iss.it](http://www.preparatipericolosi.iss.it)).

Any problems concerning the retrieval and the use of the "ISS Formula" will have to be addressed only to the ISS. Conversely, as regards the transfer of data included in internal companies databases using a format compatible with the database on dangerous preparations, the ISS is not in the position to give technical assistance to the companies, as it is a procedure in derogation from the general rule. In this case the companies will manage directly this procedure, if necessary with the cooperation of professional informatics advisors for whom ISS does not assume any responsibility.

As already said above, the sending of the data requested by the D.M. 19.4.2000 is mandatory for the companies who put on the Italian market dangerous preparations falling in the scope of Legislative Decree (D.Lgs.) 285/98 implementing in Italy the directive 88/379/EEC. Nevertheless, due to the relevance of the project in terms of human protection, all companies are invited to forward the same information, using the same way, also for:

- Preparations not falling into the scope of D.Lgs. 285/98, independent of their classifiability as dangerous (e.g. cosmetics, plant protection products etc.);
- Preparations falling, as intended uses, in the scope of D.Lgs. 285/98, but not classified as dangerous. A particular interest is addressed to those preparations containing dangerous substances below the cut-off classification limits.

For that reason the program ISS Formula requests also to flag whether or not the preparation is classified as dangerous; in any case it is not requested to report, for the dangerous preparations, the adopted labeling.

The preparations falling into the scope of directive 78/631, implemented in Italy by D.P.R. 223/88, are not covered by the D.M. 19.4.2000 because they are not in the scope of D.Lgs. 285/98. We remind anyway that as from 1<sup>st</sup> August 2004 D.P.R. 223/88 will be repealed by a new national Act implementing the new dangerous preparations directive (1999/45/EEC). As from this date, therefore, also these categories of preparations will be subject to the obligation of declaration as prescribed by D.M. 19.4.2000.

D.M. 19.4.2000 prescribes that a declaration has to be forwarded also for preparations that, at the date of entering in force of the Decree itself (8.12.2000) were no longer on the market, but it is not indicated how long before the preparation should have been removed from the market for not being obliged to declaration. The spirit of the Decree is to collect information for those preparations which may still be in use, as source of possible poisoning, even though they are no longer marketed. It is logic in fact to suppose that, especially for the preparations sold to the general public, the products remain often on the shelf of the retailer for quite a long time. It is therefore assumed that if a preparation has not been put on the market for 5 years the declaration may be omitted.

If the responsible for the placing of a preparation in the Italian market is not aware of the exact chemical composition of the preparation itself, he will make any effort to get the needed information from the producer, either EU or non-EU. In any case, if the manufacturer of a preparation subject to the provisions of D.M. 19.4.2000 is located in the EU we expect a declaration be forwarded by himself, since he puts a preparation on the Italian market. In such a case the national distributor can make reference to the manufacturer's declaration. In case the preparation is manufactured outside EU the problem is more complex: the EU importer has in fact the burden to forward the declaration, but likely he could have the same problems with the manufacturer, i.e. a not sufficient knowledge of the chemical composition of the preparation. It is possible, in such cases, through an agreement between the parts, to accept that the electronic form could be forwarded directly by the non-EU manufacturer, of course using the same way and reporting in the "Company Details" the generalities of the importer.

The program ISS Formula prescribes to indicate a Company Code as identifier. The VAT Number of the Fiscal Code of the company are suitable for the purpose.

For the products intended for domestic use, like detergents, maintenance products, disinfectants and similar, it would be wise, in order to take note of the needs of the Poison Centers, that companies make any effort to provide some information usually considered as optional, particularly in those cases where such information may be determinant for characterizing the risk potency of the product. We refer in particular to the following parameters:

- Odor;
- Color;
- pH of the product as such;
- pH of the product at use (diluted);
- Description of the packaging. In such description also the capacity (in vol. or weight) and the weight of eventual disposable doses should possibly be reported.

The program is structured in such a way to allow the maximum automatism during compilation, in order to avoid as far as possible errors of manual entering. Wherever

possible, therefore, the program provides lists where it is possible to retrieve the information in the requested format (e.g. list of substances classified in Annex I, intended uses, physical state, chemical family for non dangerous components).

The Annex I (list of chemicals officially classified by EU according to dir. 67/548/EEC) contains nevertheless a number of general entries; we remind that in such cases it is anyway mandatory to report the exact chemical name of the substance.

For the non dangerous components D.M. 19.4.2000 allows the use of generic names, i.e. the chemical family the substance belongs to, even though it is always possible, on a voluntary basis, to report the exact chemical name. In case the choice is for the generic name, it is mandatory to use one of the entries expressly listed in the program. For the non dangerous components the 5% limit is intended for single chemical substance.

The requested data may be forwarded directly to the ISS by FTP procedure, by e-mail as attached file, or by sending by ordinary mail a diskette properly compiled according to the prescriptions reported in the program. In any case the sending must be accompanied by a cover note, where the generalities of the company and the contact person are to be fully reported. A receipt message will be automatically generated by the system and forwarded to the contact person; we underline that such message means simply that the electronic form is arrived. Subsequently the ISS commits to verify that all data received are in line with the requested standard format. Should any problem of incompatibility arise, a specific problem letter will be generated. If the company doesn't give any answer to that, the original sending will be considered as invalid.

Another kind of control, more about the quality of the information provided, will be performed in a second time, which may also generate another kind of problem letters.

It is suggested that companies, who have already forwarded their electronic forms, verify the correspondence of the data contained in such forms with the indications and precisions provided with these Explanatory Remarks, eventually updating their forms.

In case the forms were filled using a previous release of the program with reference to that presently on line and downloadable from the web page of the ISS, we also suggest to update the program with the last available release (data already inserted will not be lost), to be used for the updating of the electronic forms.