UNITED NATIONS
ENVIRONMENT PROGRAMME (UNEP)

INTERNATIONAL REGISTER OF
POTENTIALLY TOXIC CHEMICALS
(IRPTC)

USSR STATE COMMITTEE FOR
SCIENCE AND TECHNOLOGY (GKNT)

USSR COMMISSION FOR UNEP
(UNEPCOM)

Second Meeting of Experts on Toxicological and Safety Data for Chemical Substances in International Trade

(Moscow, USSR, 5 - 9 December, 1983)

Summary Report

USSR-UNEP/IRPTC Project
"Control of Hazards Posed by Chemicals to Human Health and the Environment"

Centre of International Projects, GKNT
Moscow

Introduction

The continuing increase in chemicals, both in volume and in number, in international trade has resulted in the need for better information exchange between countries to adequately protect human health and the environment.

In response to this concern many actions have been taken at the national and international levels. The United Nations General Assembly emphasized the importance of control over chemicals and information exchange in its resolutions 34/173, 35/186, 36/166 and 37/137. The Governing Council of UNEP called the attention of Governments to the problem of international trade in potentially harmful chemicals and the need for information exchange on the toxicity and hazards of chemicals in its several decisions. Following consideration of this problem by the UNEP Governing Council and UN General Assembly and based on the recommendations made by an Ad Hoc Meeting of Senior Government Officials Expert in International Law held in Montevideo in 1981, the Governing Council by Decision 10/24 of 31 May 1982 authorized the Executive Director to convene in 1983/1984, after consultations with Governments and international organizations concerned, a meeting of government experts to consider guidelines or principles on the exchange of information related to trade in and use and handling of potentially harmful chemicals, in particular pesticides.

The Food and Agriculture Organization of the United Nations (FAO) is giving high priority to the international harmonization of pesticide registration requirements. It is collaborating with other concerned UN Agencies and organizations including WHO, UNEP and UNIDO in fulfilling this task. The main elements required for registration include chemical and physical properties, assessment of efficacy against target organisms, toxicology, particularly assessment of human health hazard, residues, prediction of environmental effects, registration procedures, labelling, packaging, storage and disposal. A model pesticide registration and control scheme [1] has been developed to enable countries to establish their own registration and control procedures. FAO, in cooperation with other organizations concerned, is also developing a Code of Conduct on the Distribution and Use of Pesticides identifying the potential hazards and appropriate action for their prevention and defining the responsibilities of the various parties involved.

Several other activities are being undertaken at the national, regional and international levels with the aim of harmonization and coordination of control and safe use of chemicals, notification procedures and information exchange related to export of chemicals.

Certain international organizations (e.g. CEC, CMEA and OECD) recognized the need for harmonization and developed lists of information required or recommended for chemicals traded between their member countries. However, there is still no universally accepted document which specifies the minimum information necessary for a hazard assessment of chemicals in commerce. This problem was addressed within the scope of the USSR-UNEP/IRPTC Project "Control of Hazards Posed by Chemicals to Human Health and the Environment" and a first draft document entitled "Toxicological and Safety Data for Chemical Substances in International Trade" was prepared.

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1) FAO Guidelines and Model Scheme for the Establishment of National Organizations for the Registration and Control of Pesticides, document AGP: PEST/RR/82/10, FAO, Rome (1982)

This document was discussed at an international meeting of experts held in Leningrad, USSR, June 22 - 27, 1981.[1] As a result of the discussions at the meeting a second draft of the document was developed which was then submitted to the Director, IRPTC, together with proposals for follow-up action. The IRPTC distributed the document for review to its National Correspondents, intergovernmental organizations and other international organizations and bodies, including industry associations. Comments received were evaluated and incorporated where appropriate in a third draft document which formed the basis for discussion at the present meeting.

I. Opening of the Meeting

The meeting was opened by Dr. B.F. Kudashev, Deputy Director of the Centre of International Projects, GKNT. In his opening address on behalf of the Centre he welcomed the participants and wished them success in their deliberations. Dr. A.I. Zaychenko, Deputy Head of Sanitary and Epidemiological Department, the USSR Ministry of Health welcomed the participants in the meeting on behalf of the USSR Ministry of Health. Prof. N.F. Izmerov, Corresponding Member of the USSR Academy of Medical Sciences, welcoming the participants emphasized the urgency of the problem being discussed and the importance of the results of the meeting. Dr. J.W. Huismans, Director of IRPTC/UNEP, in his welcome to the participants emphasized the significance of toxicological and safety data for assessing possible hazards of various chemicals for importing countries, especially for developing countries as well as the importance of results and recommendations of the present meeting.

The meeting was attended by 37 experts and observers including representatives of UNEP/IRPTC, IPCS and the Secretariat of the USSR-UNEP/IRPTC Project (See Annex 1).

II. Appointment of Officers

The meeting unanimously elected Prof. N.F. Izmerov (USSR) Chairman with Prof. W.F. Almeida (Brasil) as Vice-Chairman. Dr. P.R. Toft (Canada) and Dr. I.P. Ulanova (USSR) were elected Rapporteurs.

III. Adoption of Draft Agenda

The provisional Agenda was adopted by the meeting without amendments (See Annex 2).

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1) Report of the Expert Meeting on Basic Principles of Definition of Toxicological and Safety Data for Chemical Substances in International Trade, Leningrad, USSR, 22 to 27 June 1981, GKNT, Moscow and IRPTC, Geneva (1981).

IV. Introductory Statements

The following introductory statements were made to the participants of the meeting: Dr. J.W. Huismans, Director, IRPTC briefly described the basic activities of International Register of Potentially Toxic Chemicals and emphasized the main tasks and goals of the meeting; Professor N.F. Izmerov, Director, Research Institute of Industrial Hygiene and Occupational Diseases, Scientific Manager of the USSR-UNEP/IRPTC Project informed the participants of the meeting about the achievements and perspectives of the activities of the Project "Control of Hazards Posed by Chemicals to Human Health and the Environment" and the Soviet Toxicological Centre of the USSR Ministry of Health acting as the USSR National Correspondent for IRPTC; Dr. A.I. Kucherenko, Scientific Affairs Officer, IRPTC emphasized the important role of some international organizations (e.g. FAO, IMO, CEC, OECD) in information exchange on chemicals and the development of toxicological and safety data requirements related to the use of chemicals; Dr. I. Rovny, Expert, Department of Public Health, CMEA made a statement on the relevant activities of the Council for Mutual Economic Assistance; Dr. M.I. Gounar, Scientist, IPCS, briefly informed the participants on the recent developments of the International Programme on Chemical Safety and preparation of criteria documents on chemicals; Professor I.V. Sanotsky, Head of Toxicological Department, Research Institute of Industrial Hygiene and Occupational Diseases and Dr. L.S. Salnikova, Senior Scientist, Research Institute for Rubber and Latex Substances presented an evaluation review of comments received on the document "Toxicological and Safety Data for Chemical Substances in International Trade" as well as a revised draft data set with its underlying principles.

V. Discussion

In considering the toxicological and safety data for chemical substances in international trade and their underlying basic principles the meeting generally endorsed the view that a certain set of data on chemicals would be needed to allow for an adequate assessment of their hazards to man and the environment. The participants in the meeting unanimously supported the idea of the establishment of such a set and the importance of exchange of adequate information on chemicals traded internationally, especially for the developing countries. It was suggested and agreed that the title of the document should be "Basic Set of Data for Chemicals in International Trade Required for an Assessment of Hazard to Man and the Environment and Conditions of Safe Use".

Several participants stressed the fact that it is not possible to provide assurance that any chemical will be absolutely safe. The use of a chemical always has some element of potential hazard to human health and the environment, however small. It was nevertheless felt that on the basis of present scientific knowledge generally sufficient certainty can be obtained about the magnitude of the hazard involved in the use of a chemical to allow for adequate control measures by competent national authorities. Governments may differ however considerably in their opinion as to which level of risk would be acceptable as a result of differences in intended use and expectations about the benefits of such use. It was pointed out that the basic data set should not be considered as being a maximum list of necessary information. It should rather be considered as a minimum list, and additional data may be required depending upon the properties and use of the chemical.

The meeting discussed at length the applicability of the data set with regard to chemicals on the world market. It was decided to recommend that, apart from individual chemical substances, the set would also apply to chemicals in preparations, formulations and mixtures as well as those present as significant impurities. It was recognized that the terms preparations, formulations and mixtures have no generally agreed meaning and would need further definition.

For new chemicals the manufacturer will be the primary source of toxicological information. For chemicals which have been on the market for some time, information will be available from the manufacturer, scientific literature and international organizations.

Participants indicated that many countries and especially developing countries, will require assistance in assessing the information provided in the basic data set. Training programmes should be particularly useful in this regard and international organizations have an important role to play in this area.

Participants also recognized that attention should be paid to minimizing the number of laboratory animals used in toxicological testing.

The meeting then discussed in detail the working documents and developed a list of data requirements for industrial chemicals, entitled: "Basic Set of Data for Chemicals in International Trade Required for an Assessment of Hazard to Man and the Environment and Conditions of Safe Use", which is attached as Annex 3.

VI. Conclusions and Recommendations

1. The Basic Set of Data for Chemicals in International Trade Required for an Assessment of Hazard to Man and the Environment and Conditions of Safe Use responds to the needs identified in several UNEP Governing Council decisions and U.N. General Assembly resolutions (e.g. Resolution 37/137 on protection against products harmful to health and the environment) aimed at improved information exchange procedures on chemicals in international trade.

2. It is recommended that consideration be given to using this document as working paper for the UNEP Ad Hoc Working Group of Experts for the Exchange of Information on Trade and Management of Potentially Harmful Chemicals, in Particular Pesticides to be convened in the Netherlands in March 1984.

3. It is recommended that the Director of IRPTC explore the possible need for the preparation of guidelines on how basic data sets should be prepared and how the data can be assessed.

4. It is recommended that international organizations (in particular the International Programme on Chemical Safety) develop training programmes in order to assist national authorities in assessing data contained in basic data sets.

Annex 1

LIST OF PARTICIPANTS

ALMEIDA, W.F.	Professor, State University of Campinas, Department of Preventive and Social Medicine, Campinas, Sao Paulo, Brazil
BATES, M.N.	Principal Toxicologist, Department of Health, Wellington, New Zealand
BOON-LONG, J.	Chief of Toxic and Hazardous Substances Section, Environmental Quality Standards Division, Office of the National Environment Board (ONEB), Bangkok, Thailand
CAROLI, S.	Government Officer, Istituto Superiore di Sanità, Lab. Tossicologia, Rome, Italy
DESCHAMPS, P.	Chef de Mission, Secrétariat d'Etat à l'environnement, Neuilly-sur-Seine, France
IZMEROV, N.F.	Director, Research Institute of Industrial Hygiene and Occupational Diseases, USSR Academy of Medical Sciences, and Scientific Adviser of the USSR-UNEP/IRPTC Project, Moscow, USSR
KAZAKOV, I.V.	Head of Department, Commodity Market Research Institute, USSR Ministry of Foreign Trade, Moscow, USSR
KRISOR, K.	Administrator, Commission of the European Communities (CEC) Brussels, Belgium
KUNDIEV, Yu. I.	Director, Research Institute of Industrial Hygiene and Occupational Diseases, Kiev, USSR
LATYSHEV, V.I.	Head of Department, V/O "Soyuzchimexport", Moscow, USSR
LEVTCHENKO, M.N.	Head of Department, Occupational Safety, Industrial and Natural Protection, Ministry of Chemical Industry, Moscow, USSR
MAHESWARAN, A.	Director, Environmental Control, Department of Environment, Ministry of Science, Technology and Environment, Kuala Lumpur, Malaysia
DE REEDER, P.L.	Coordinator for International Environmental Affairs, Akzo NV, Arnhem, Netherlands
SANOTSKY, I.V.	Head of Toxicology Department, Research Institute of Industrial Hygiene and Occupational Diseases, USSR Academy of Medical Sciences, Moscow, USSR

SALNIKOVA, L.S. (Ms)	Senior Scientist, Research Institute for Rubber and Latex Substances, Moscow, USSR
SIDOROV, K.K.	Senior Researcher, Research Institute of Industrial Hygiene and Occupational Diseases, USSR Academy of Medical Sciences, Moscow, USSR
STACKERUD, G.M. (Ms)	National Environment Protection Board, Solna, Sweden
TOFT, P.	Acting Director, Health Protection Branch, Bureau of Chemical Hazards, Environmental Health Directorate, Department of Health and Welfare, Ottawa, Canada
ULANOVA, I.P. (Ms)	Head of Laboratory, Research Institute of Industrial Hygiene and Occupational Diseases, USSR Academy of Medical Sciences, Moscow, USSR
UNGVARY, G.	Head of Toxicology Section, National Institute of Occupational Health, Budapest, Hungary
VASHAKIDZE, V.I. (Ms)	Director, Research Institute of Industrial Hygiene and Occupational Diseases, Tbilisi, USSR
ZAYICHENKO, A.I.	Deputy Head, Main Sanitary-Epidemiologic Department, USSR Ministry of Health, Moscow, USSR
ZAYKOV, Kh.	Head of Laboratory, Department of Environmental Hygiene, Institute of Hygiene and Occupational Health, Sofia, Bulgaria

Observers

RODRIGUEZ, C.	Hygiene Department, Ministry for Public Health, Havana, Cuba
ROGAS, D. (Ms)	Head of the Laboratory of Toxicology, Institute of Professional Diseases, Havana, Cuba
CUE, M.	Pharmacy Department, Ministry for Public Health, Havana, Cuba

Representatives of International Organizations

GOUNAR, M.I.	Scientist, International Programme on Chemical Safety (IPCS), WHO, Geneva, Switzerland
ROVNY, I.	Expert, Department of Public Health, Council for Mutual Economic Assistance (CMEA) Moscow, USSR

SHULTSOVA, M. (Ms)	Head of Hygiene Department, Ministry for Public Health of the Slovak Socialist Republic, Representative of CMEA, Bratislava, CSSR

IRPTC Secretariat

HUISMANS, J.W.	Director, International Register of Potentially Toxic Chemicals (IRPTC/UNEP), Geneva, Switzerland
KUCHERENKO, A.I.	Scientific Affairs Officer, International Register of Potentially Toxic Chemicals (IRPTC/UNEP), Geneva, Switzerland

Secretariat of the Project on "Control of Hazards Posed by Chemicals to Human Health and the Environment"

VORONIN, V.P.	Deputy Director, Centre of International Projects, USSR State Committee for Science and Technology, Director USSR-UNEP/IRPTC Project, Moscow, USSR
GERTCHIKOV, L.N.	Deputy Director, USSR-UNEP/IRPTC Project, Centre of International Projects, USSR State Committee for Science and Technology, Moscow, USSR
BABENKO, Z.I. (Ms)	Project Officer, Moscow, USSR
KLIMOVA, M. Yu. (Ms)	Project Officer, Moscow, USSR
KONYSHEVA, L.N. (Ms)	Project Officer, Moscow, USSR
SEMILETKINA, N.N. (Ms)	Project Officer, Moscow, USSR

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Annex 2

A G E N D A

1. Opening of the Meeting

2. Appointment of Officers

3. Adoption of the Agenda

4. Organization of work

5. Presentation of the review of comments on "Toxicological and Safety Data for Chemical Substances in International Trade".

6. Presentation of the document "Toxicological and Safety Data for Chemical Substances in International Trade" redrafted in accordance with the comments and proposals received.

7. Discussion of changes and additions to the "Toxicological and Safety Data for Chemical Substances in International Trade".

8. Discussion and approval of the final draft of the "Toxicological and Safety Data for Chemical Substances in International Trade".

9. Discussion of proposals for recommendations and conclusions of the Meeting.

10. Adoption of a summary report with recommendations

11. Other business

12. Closure of the Meeting

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BASIC SET OF DATA FOR CHEMICALS IN INTERNATIONAL TRADE REQUIRED FOR AN ASSESSMENT OF HAZARD TO MAN AND THE ENVIRONMENT AND CONDITIONS FOR SAFE USE

1. Introduction

1.1. At present, more than 50,000 chemicals are traded internationally and an estimated 1,000 new chemicals are introduced into commerce each year. There is a lack of basic information on the toxicity of many of these chemicals, some of which may cause currently unrecognized effects on human beings and the environment.

1.2. The continuing increase in international trade in chemicals has resulted in the need for better coordination of information exchange between countries. Certain international organizations (e.g. CEC, CMEA and OECD) have recognized this need and developed lists of information required or recommended for chemicals traded between their member countries (1, 2, 3). However, there is still no universally accepted document which specifies the basic data set necessary for a hazard assessment of chemicals in international trade.

1.3. The development of this document is a step towards international coordination and harmonization of information exchange on chemicals in commerce.

2. Purpose and Scope

2.1. The purpose of this document is to assist the competent authorities to assess the hazards of chemicals both to human health and the environment. It does not refer to chemical substances according to their use but it is intended to provide guidance on the data requirements for the large number of (industrial) chemicals which are often not subject to regulation in many countries. Certain substances are used in pharmaceuticals, food and feed additives, and agrochemicals. Such chemicals are often subject to national regulations and registration requirements. Other international organizations (e.g. FAO and WHO) have published documents detailing information requirements for hazard assessment of these categories of chemicals and are working toward international harmonization of registration requirements (4, 5) A Code of Conduct on Distribution and Use of Pesticides is presently being developed by FAO in consultation with other international organizations.

2.2. The basic set of data in this document can also be used as guidance for national authorities as the minimum information necessary for developing their own legal instruments for control of chemicals. In general it is believed to be sufficient for an evaluation of the health and environmental effects of chemicals in commerce. The data requirements listed are also consistent with the data profile structure for chemicals included in the IRPTC (6).

2.3. The basic set of data is applicable to the full range of chemicals on the world market, including chemical elements and their compounds as they occur in the natural state or as produced by industry, and any additives required for the purpose of placing them on the market, as well as chemicals in preparations, formulations, mixtures, or present as significant impurities.

2.4. It should be stressed that this basic set of data is not in itself an assessment of the hazard posed by the chemical. The hazard should be assessed by experts in the importing country according to the intended use and particular circumstances of that country. In most cases the list of data will be sufficient, but for some chemicals additional information may be required.

2.5. There is a point of view that the use of a chemical always has an element of risk to health and the environment, however small. No amount of testing can ever demonstrate that a hazard does not exist and that the chemical is absolutely safe. The competent authorities of the importing country should therefore evaluate the extent of possible risk and provide adequate measures to minimize the risk compatible with best available technology and simultaneously permit the full exploitation of the benefits expected from the use of the chemical.

3. Provision of Basic Information for the Data Set

3.1. There should be available for each newly manufactured and traded chemical substance information on its identity, intended use, physico-chemical properties, possible pathways into the environment, analytical methods, acute and sub-acute toxicity information, short-term mutagenicity test data, ecotoxicity data and conditions of safe handling. If less information is provided than is described in the data set the reasons should be given. It should also be recognized however that it will not be necessary to provide a complete data set in all cases - for example where the results of certain tests indicate a low toxicity or where the substance is used in closed systems.

As regards other substances complete data sets should be provided when the information is available. Such information may be obtained from a number of different sources, e.g. the results of previous tests, information required by international rules on the transport of dangerous substances, information taken from reference works and the scientific literature or information derived from practical experience.

It is obvious that a comprehensive set of data cannot be immediately developed for all chemicals. It is therefore necessary to develop more test data on priority chemicals based on such factors as chemical structure, environmental distribution, degree of exposure, amount of chemical in commerce, available toxicological data, and use.

Special attention should be paid, where appropriate, to the possibility of synergistic and additive effects caused by constituents present in preparations, formulations and mixtures.

3.2. When additional relevant information becomes available on a chemical already in commerce, the manufacturer or exporter should provide this new information. When a chemical has been in use for a period of time, an unforeseen hazard may be suspected. In such cases additional information to allow for an assessment of this hazard, should be developed and provided.

3.3. The testing of chemical substances should be carried out in accordance with the principles, criteria and methods recognized and recommended by international organizations such as CEC (7), CMEA (8), IPCS (9), OECD (10), and ISO (11). The data provided should include essential details such as species and number of animals tested, dose regime, and pathological effects observed. Where possible S.I. units should be used in reporting data.

3.4. The competent authority in the importing country should protect the proprietary rights of the manufacturer by safeguarding confidential information.

4. Provision of Additional Information

4.1. Competent authorities may obtain additional information on chemicals from data banks specializing in toxicological information, and especially from UN agencies such as IRPTC, which is the leading international organization for the collection, storage and dissemination of such data on chemicals. The International Programme on Chemical Safety has published criteria documents on certain priority chemicals and is preparing additional hazard assessments on other chemicals, and the International Agency for Research on Cancer publishes monographs on the carcinogenic risk of chemicals to man.

5. Language

5.1. The choice of language used in providing data will be a matter of agreement between the exporter or manufacturer and the importing country.

References

1. Council Directive (79/831/EEC) of 18 September 1979 amending for the sixth time Directive 67/548/EEC on the approximation of the laws, regulations and administrative provisions relating to the classification, packaging and labelling of dangerous substances.

2. Toxicological Passport for Chemical Compounds Subject to Introduction into the Economy and Domestic Life of CMEA Countries (in "Proceedings of the XIth Session of the CMEA Permanent Commission on Co-operation in the Field of Health, in Russian).

3. OECD Minimum Pre-Marketing Set of Data. Document ENV/CHEM/HLM/80.4, OECD, Paris (1980).

4. Report of the Second Government Consultation in International Harmonization of Pesticide Registration Requirements, held in Rome, Italy, 11 - 15 October 1982, FAO, Rome (1982).

5. Certification Scheme on the Quality of Pharmaceutical Products Moving in International Commerce, World Health Assembly Resolution 28.65, WHO, Geneva (1975).

6. International Register of Potentially Toxic Chemicals - Part A, IRPTC, Geneva (1982).

7. Draft Commission Directive adapting to technical progress for the sixth time Council Directive 67/548/EEC on the approximation of the laws, regulations and administrative provisions relating to the classification, packaging and labelling of dangerous substances.

8. Problems of Industrial Toxicology. Permanent Commission on Co-operation in the Field of Health, Council for Mutual Economic Assistance, CMEA, Moscow (1982).

9. Principles and Methods for Evaluating the Toxicity of Chemicals. Part I. Environmental Health Criteria 6, WHO, Geneva (1978).

10. OECD Guidelines for Testing of Chemicals, OECD, Paris (1981).

11. International Standards, ISO, Geneva

BASIC SET OF DATA

1. CHEMICAL IDENTIFICATION DATA

1.1. Individual Substances

- chemical name (IUPAC) and other names
- CAS number
- empirical formula
- structural formula
- molecular weight
- physical form or state
- organoleptic properties (e.g. colour, odour, odour threshold)
- spectral characterization (e.g. UV, IR, mass-spectra, NMR)
- known impurities and additives including percentage concentrations.

1.2. Chemicals in Preparations, Formulations and Mixtures

Where appropriate the same information for each constituent as is listed in Part 1.1., but including percentages, should be provided.

2. U S E

2.1. Proposed Use

Information should be provided on the intended use for which the chemical is being imported, including details of whether the proposed use will involve open or closed systems.

Other uses for the chemical known to the manufacturer or importer.

2.2. Methods of Application

Information on the methods of application of the chemical is required, with particular emphasis on those which may result in human exposure, e.g. in aerosols or as respirable powders (less than 5 microns).

2.3. Estimated Quantity to be Imported per Year

3. PHYSICO-CHEMICAL PROPERTIES

The following parameters are the minimum desirable. If additional relevant information is available it should be included.

3.1. Melting point
3.2. Boiling point
3.3. Relative density
3.4. Vapour pressure
3.5. Solubility in:
- water
- specified organic solvents
- fat

3.6. Partition coefficient (n-Octanol/water)
3.7. pH
3.8. Flash point
3.9. Explosive properties

4. POSSIBLE ROUTES OF ENTRY INTO THE ENVIRONMENT

For the proposed uses of the chemical, the manufacturer or exporter should indicate the probable routes of entry of the substance into the environment with particular reference in each case to the relative importance of air, water and soil as receiving compartments.

5. ENVIRONMENTAL FATE

Most chemicals eventually enter the natural environment. The following data are useful in the assessment of their occurrence in particular environmental compartments (air, water, soil, biota), transformation into other substances which may be more toxic, and possible occurrence in food and water supplies:

- persistence
- migration between environmental compartments
- transformation in other substances (abiotic and biological degradation)
- absorption/adsorption/desorption on soils and sediments
- bioaccumulation

When actual monitoring data on the concentration of the chemical in the environment (e.g. in food, flora and fauna) are available, they should be provided.

6. ANALYTICAL METHODS

It is important that workers in the importing country who will handle the chemical receive at least the same degree of protection as that afforded to workers in the country of manufacture. Information on analytical methods suitable for regulatory purposes in the workplace should therefore be provided.

For certain chemicals (e.g. persistent substances) sensitive methods may be required to monitor their presence in the environment (air, water, soil and biota). Where these are available, details of such methods should be provided. In those instances where methods are available for analyzing the chemical or its metabolites in human tissues and body fluids, those should also be provided.

In every case, a full description of the methods used or the appropriate bibliographic references should be given.

7. ACUTE TOXICITY IN LABORATORY ANIMALS

7.1. - acute oral toxicity
- acute dermal toxicity
- acute inhalation toxicity

Data should be provided on the toxicity of the chemical following administration of a single dose. (LD_{50} or LC_{50}). Substances other than gases should be administered via at least two routes, one of which should be the oral route. The other route will depend upon the intended use and the physical properties of the substances.

Gases and volatile liquids should be administered by inhalation.

Information on the specific organs affected and when available information on the lowest dose which causes a toxic effect should be included.

7.2. - skin irritation

7.3. - eye irritation

8. SUBACUTE TOXICITY IN LABORATORY ANIMALS

Information should be provided on studies on animals which have been dosed repeatedly for up to 28 days.

This will include:

- effects observed on the animal and organs, including results from clinical and laboratory investigations
- highest dose for which no toxic effect is observed in each species
- data on accumulative properties, when available.

9. SKIN SENSITIZATION IN LABORATORY ANIMALS

10. MUTAGENICITY

Data from short-term tests on mutagenicity should be provided. Results from long-term mutagenicity studies, when available, should also be provided.

11. CHRONIC TOXICITY DATA IN LABORATORY ANIMALS

Chronic toxicity data may be needed for substances, for example, whose use pattern results in substantial or long-term human exposure or for substances which are bioaccumulative. The result of other tests may suggest the need for additional toxicity information, e.g. carcinogenicity and teratogenicity studies. Further studies may assist in determining the potential effects on for example the nervous system and the cardiovascular system and other organs or systems. Chronic toxicity data will, however, not be needed for all chemicals.

12. HUMAN TOXICITY DATA

Information obtained from instances of poisoning or accidental overexposure when available should be provided. This should be taken to include information on sensitization properties.

It should be noted that epidemiological studies are a valuable source of information on the effects of chemicals on human populations. The results of such studies should be provided when available.

13. ECOTOXICITY DATA

13.1. Toxicity to aquatic organisms including fish and Daphnia

13.2. Other information relating to effects on organisms in the environment should be provided when available

14. STANDARDS AND REGULATIONS

The manufacturer or exporter should provide details on standards or regulations related to the chemical which apply in the country of origin; e.g. occupational standards, drinking water standards, food standards etc.

When available information on standards and regulations in other countries should also be included.

15. PRODUCT SAFETY DATA SHEET

The manufacturer or exporter should provide a product safety data sheet to the importing country which will contain information on recommended procedures for:

- transportation
- handling
- storage
- decontamination
- disposal
- methods to clean up spillages
- personal protection measures
- first aid
- consequences of foreseeable misuse
- labelling

16. ORGANIZATION/COMPANY/FIRM

16.1. Name(s) and address(es) of organization(s) or firm(s) responsible for the testing.

16.2. Manufacturer of the chemical

16.3. Agent responsible for completing the Data Set.

16.4. Date of issue.

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