GOBIERNO DE ESPAÑA
MINISTERIO DE TRABAJO, MIGRACIONES Y SEGURIDAD SOCIAL
insst
Instituto Nacional de Seguridad y Salud en el Trabajo

Handling hazardous drugs in the health care environment – tools and guidance by INSST

Healthy Workplaces Campaign 2018-19

Manage dangerous substances in the workplace

HWC Summit 2019 Bilbao

Nuria Jiménez
National Institute of Health and Safety in Spain
12 November 2019

European Agency for Safety and Health at Work

EU2019.FI

25 1994 - 2019

Healthy Workplaces

Background

The first group of drugs considered dangerous were **cytostatic drugs** (1979)
Workplace exposure to hazardous drugs has been well documented, and it first became a recognised safety risk in the United States

Studies:

- Secondary malignancies were reported in patients (1970s)
- Nurses had higher levels of mutagenic substances in urine
- Chromosomal aberrations in pharmacists and nurses who were handling cytostatic drugs
- Association between exposure to antineoplastic drugs and adverse reproductive effects
- Environmental contamination of areas in health care facilities where cytostatic drugs are prepared and administered (1990s)

Background

Different studies showed the need for :

- Change in the initial preparation form
- Establishment of guidelines for cytostatic drugs preparation
- Centralization in Pharmacy Services
- Other measures (e.g. Ventilation, use of closed-system drug transfer devices)

Objectives

- Raise awareness in the healthcare sector about exposure to dangerous medicines
- Establish a first list of hazardous drugs (HD's) to provide detailed help for the identification of hazards as a basis for adequate subsequent risk management
- Development of a practical web tool to facilitate the accessibility by the healthcare sector to information on HD's
- Build alliances with different agencies and with health facilities involved
- Encourage implementation of best practices following the instructions in the published technical documents

Background.
Studies HD's at the INSST

'80s

- Mutagenicity
- Chromosomal Aberrations
- Cytotoxic drugs

'90s

- Exposure assessment
- Cytotoxic drugs.

2000

- Surfaces contamination
- Biological monitoring
- Cytotoxic drugs

2016

- Guideline
- INFOMEP tool
- Hazardous drugs in general

What are hazardous drugs?

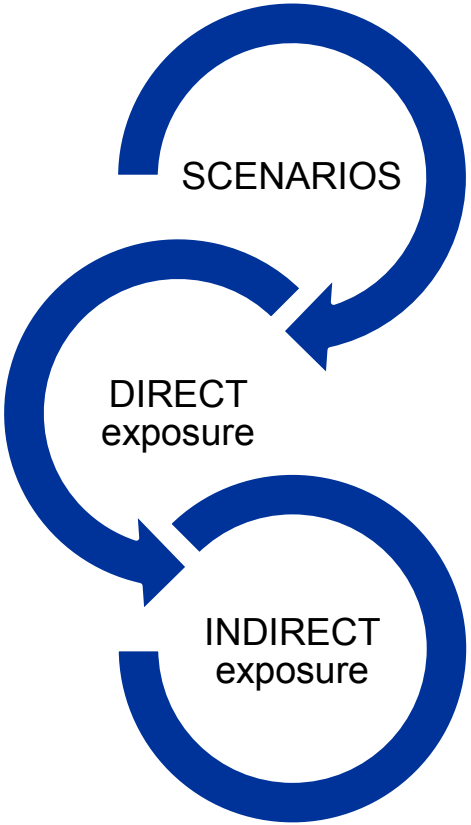
Medicines with adverse health effects: carcinogenicity, mutagenicity, reproduction and developmental toxicity, genotoxicity

Including **cytotoxic drugs** for anticancer treatments, and recently other treatments for non-cancerous diseases

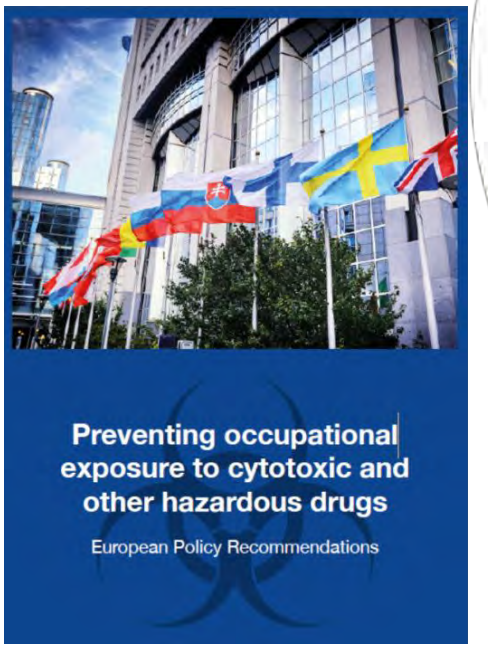
Cytotoxic drugs (cytostatic or antineoplastic drugs) describe a group of medicines used in a variety of healthcare settings, prominently in the treatment of cancer and other (non-cancerous) diseases

Who may be exposed at work?

- Pharmacy workers
- Nurses
- Physicians and physicians´ assistants
- Healthcare auxiliary nurses
- Veterinary workers
- Cleaning workers
- Laundry workers
- Hazardous waste disposal workers
- Transport workers



In this European Parliament Report, there are ***11 Policy RECOMMENDATIONS*** for the EU and Member States Policy by the exposure of healthcare workers to chemical risks during preparation and administration of cytotoxic an another hazardous drugs

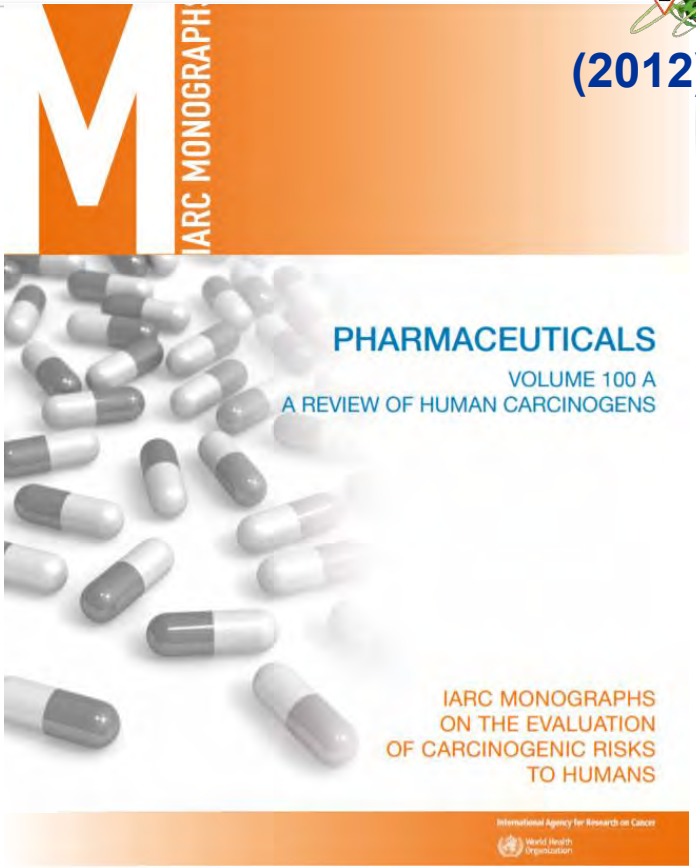


Hazardous drugs. IARC

(2012)

Carcinogenic risk of cytotoxic drugs to humans

Nº	**IARC** (International Agency for Research on Cancer) (140 were studied)
0	*4 = **Probably not carcinogenic** to humans*
15	3 = Is **Not classifiable** as to its carcinogenicity to humans
17	2B = **Possibly** carcinogenic to humans
13	2A = **Probably** carcinogenic to humans
13	1 = **Carcinogenic** to humans

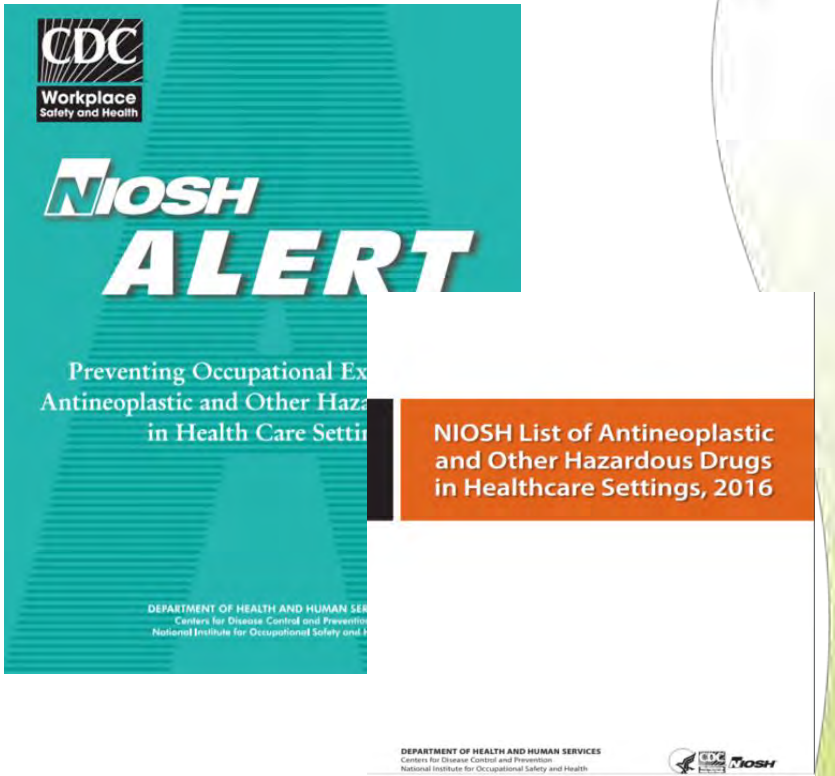


NIOSH. List of hazardous drugs

The NIOSH definition of hazardous drugs is based on a definition developed in 1990 by the ASHP

Recommendations for assessing the hazards, handling drugs, and using and maintaining equipment

The latest list of hazardous drugs was published in 2016.



NIOSH: National Institute for Occupational Safety and Health, USA
ASHP: American Society of Hospital Pharmacists

Hazardous drugs included in NIOSH list

Drugs considered hazardous include one or more of the following effects in humans or animals:

- Carcinogenicity
- Teratogenicity or other developmental toxicity.
- Reproductive toxicity
- Organ chronic toxicity at low doses
- Genotoxicity
- Structure and toxicity profiles of new drugs that mimic existing drugs determined as hazardous.

Hazardous drugs in NIOSH list

- **Group 1**: Antineoplastic drugs
- **Group 2**: Non-antineoplastic drugs that meet one or more of the NIOSH criteria for a Hazardous drugs
- **Group 3:** Drugs with reproductive risk, including those relevant to men and women trying to conceive and women who are pregnant or breast feeding

Knowing the dangers of hazardous drugs is essential for risk management of these medications within healthcare professionals and other workers.

¿HOW TO IDENTIFY HAZARD?

Hazardous drugs information

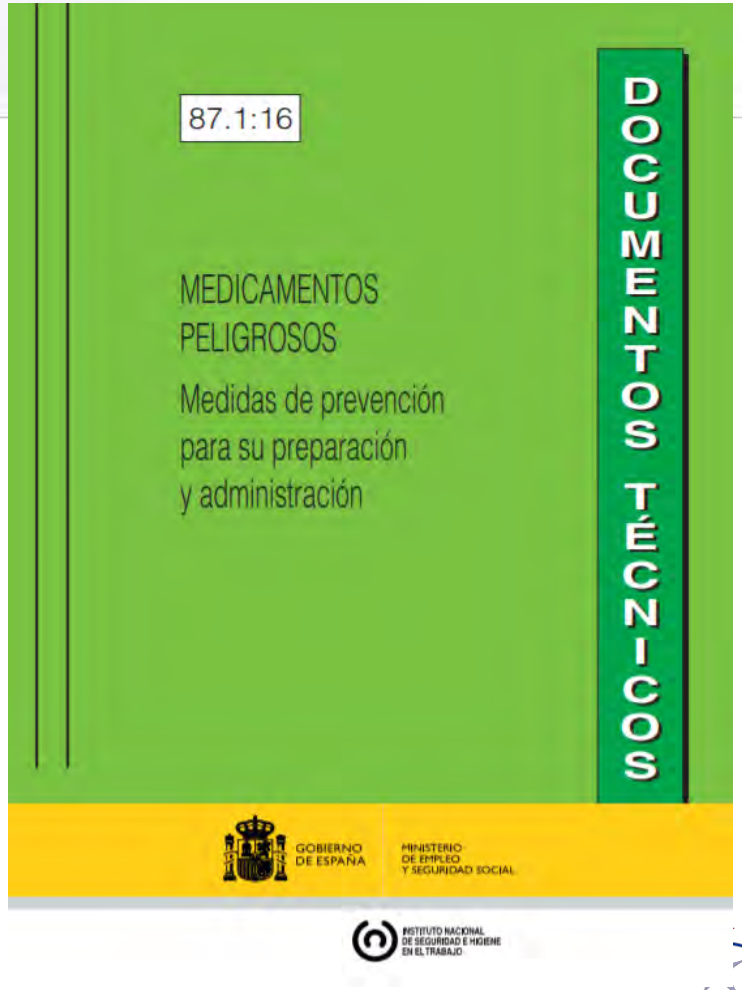
CLP regulation does not apply
Lack of safety data sheets for medicinal products.
No labels with hazard pictograms, and hazard statements.

Medicinal products Directive.
Information in the medicinal products datasheet and the package leaflet.

Lack of hazardous drugs information for workers that are handling them

Only sometimes information on preventive measures in the datasheet is available

GUIDELINE.
Hazardous Drugs.
Prevention measures for preparation and administration.
INSST (2016)



INSST GUIDELINE

- 173 medicines for humans from the NIOSH list marketed in Spain in juny 2016.
- The name of medicinal product marketed and galenical form were included for each medicine.
- Recommendations: NIOSH, USP 800, ISOPP, Guide of best practices for the preparation of medicines of the Ministry of Health, SEFH Monograph, AMMTAS Guide, were evaluated.
- Working groups of the Spanish Society of Hospital Pharmacists (SEFH) participating: Oncology Pharmacy Group, Pharmacotechnics Group and Health Products Group of different hospitals in Spain.

USP : United States Pharmacopeia
ISOPP: International Society of Oncology Pharmacy Practitioners
AMMTAS: Association of Occupational Health in the Healthcare from Madrid

TOOL: INFOMEP database

Active substances classified by NIOSH as dangerous (2016)… and the **medicines** that contain them.

It includes general **preventive recommendations**. This tool is not a workplace risk assessment.

It’s an initial hazard identification

Información para trabajadores sanitarios sobre medicamentos peligrosos

Medicamento | Principio activo | Motivo

Presentación | Grupo Terapéutico | Buscar | Limpiar

Resultados de la búsqueda

Criterios de la búsqueda:

Todavía no se ha realizado ninguna búsqueda

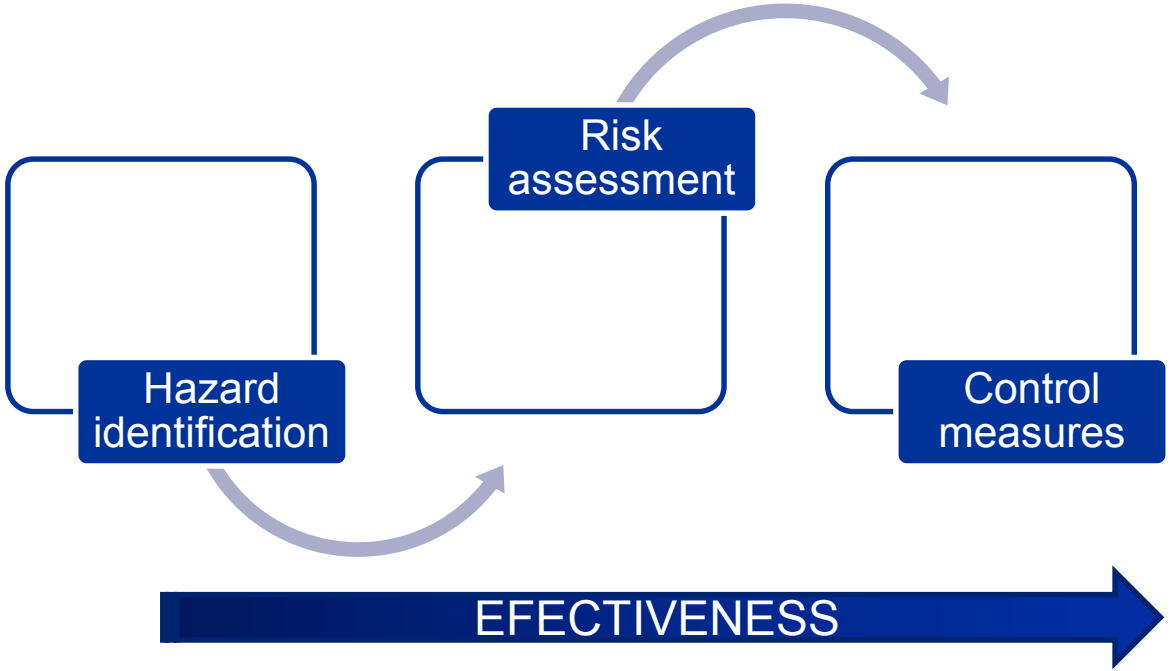
Descargar: CSV EXCEL

Especialidad	Principio Activo	Presentación	Categoría de riesgo	Acciones
Todavía no se ha realizado ninguna búsqueda				

TOOL INFOMEP

- The list of all pharmaceutical specialties marketed in Spain, included in the “medicinal products database”, is included. The database has provided knowledge to professionals who are not experts about pharmacology
- Includes preventive recommendations based on the galenical form for each medicine
- Includes other data of interest, such as drug classification, from the IARC document
- Web tool allows periodic update
- In collaboration with SEFH

RISK ASSESSMENT PROCESS



HIERACHY OF CONTROL

Starting from level 1, if a level is impossible or insufficient, then the next one is applied.

1

Level 1 – Elimination, substitution, replacement
Replace the product by a less or non toxic one.

Level 1 is not an option for cytotoxic drugs as replacement would have a dramatic and undesirable therapeutic effects for the patients.

2

Level 2 – Isolation of the hazard/source containment
Use of closed systems to prevent the occurrence of any form of contamination.

3

Level 3 – Engineering controls/ventilation
Use of local and general ventilation measures.

3b

Level 3b – Administrative controls/organisation measures
Organise the work in such a way that the duration of exposure and the number of employees exposed is reduced.

4

Level 4 – Use of personal protection measures
Use personal tools such as gloves, masks, gowns, goggles or face shields and other equipment to create a temporary barrier between the contamination and the operator.

Source: Report: Preventing Occupational exposure to cytotoxic and other hazardous drugs

RESULTS

- The technical document has helped to put on the table the hazardous properties of some drugs that were not taken into account previously.
- The web tool has helped to inform and raise awareness.
- Dissemination actions have been carried out and best practice guidelines have been developed in some regions of Spain.
- The workers representative and unions are collaborating in the dissemination of the guide and the database.
- Health facilities are reassessing the risk to adapt control measures.

Thank You!

Nuria Jiménez
National Institute for Health and Safety of Spain
nuria.jimenez@insst.mitramiss.es

Specific Technical Documents. INSST

NTP 163: Occupational Exposure to cytotoxic drugs (1984)

NTP 740: Occupational Exposure in the healthcare sector (2006).

NTP 1134: Occupational exposure to hazardous drugs: safe systems for its preparation. (2018).

NTP 1135: Hazardous drugs: administration and available equipment. (2018).

Reports from the INSST

Manipulation of cytostatic agents in hospitals. Techniques for exposure assessment *Solans Lampurlanés, X. Mapfre Medicina, 9 (2). 1998.*

Biological monitoring of occupational exposure to cytostatics in health workers. Urinary mutagenicity assay. *Solans Lampurlanés, X; Ballester Gimeno, R; Pérez Nicolás, J. Mapfre Medicina, 15 (2). 2004.*

Exposure to cytostatics in health facilities. Determination of cyclophosphamide on work surfaces and on the outside of vials. *Xavier Guardino Solá, Mª Gracia Rosell Farrás, Susana Torrado (2005)*