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SOCIEDAD ESPAÑOLA DE FARMACIA HOSPITALARIA
MÁLAGA 15-17 OCT 25

Sapere Aude
Reflexión ante nuevos retos

ACTUALIZACIÓN DE LA NORMATIVA SOBRE MANIPULACIÓN DE MEDICAMENTOS PELIGROSO

Análisis de la Lista NIOSH 2024

Dr José Mª Alonso Herreros
Hospital Los Arcos Mar Menor.
Jefe de Servicio
GRUPO DE FARMACOTECNIA

sefh Sociedad Española de Farmacia Hospitalaria

farmacotecnia
Grupo de trabajo Farmacotecnia de la sefh

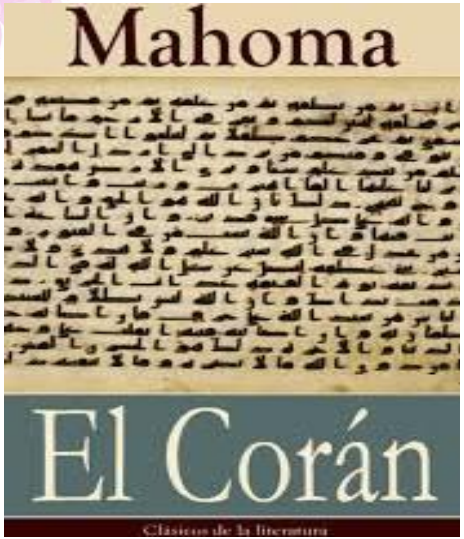


Tabla 1
Peligros para la salud contemplados en el reglamento CLP[10]

1. Toxicidad aguda.
2. Corrosión o irritación cutáneas.
3. Lesiones oculares graves o irritación ocular.
4. Sensibilización respiratoria o cutánea.
5. Mutagenicidad en células germinales.
6. Carcinogenicidad.
7. Toxicidad para la reproducción.
8. Toxicidad especifica en determinados órganos, exposición única.
9. Toxicidad especifica en determinados órganos, exposiciones repetidas.
10. Peligro por aspiración.

NIOSH List of Hazardous Drugs in Healthcare Settings, 2024

https://www.cdc.gov/niosh/docs/2023-129/2023-129.pdf?id=10.26616/NIOSHPUB2023129&id=10.26616/NIOSHPUB2025103

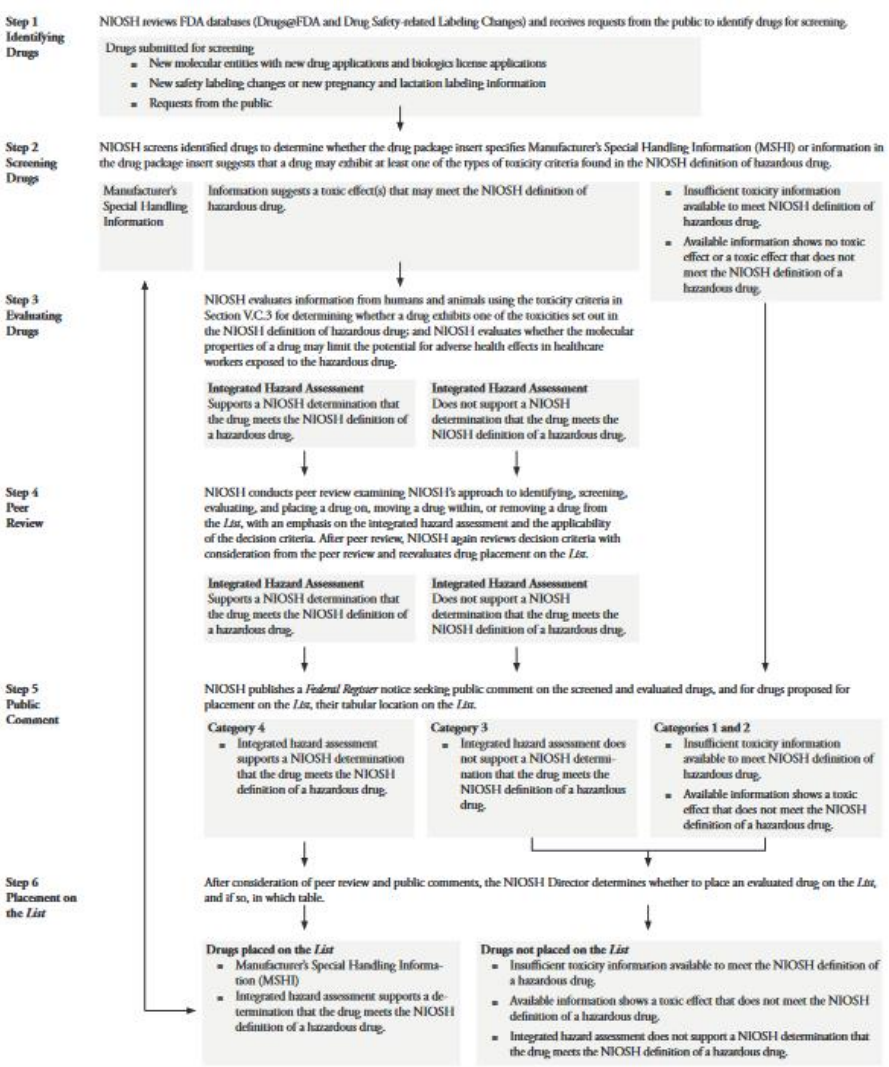
Managing Hazardous Drug Exposures:
Information for Healthcare Settings

Centers for Disease Control and Prevention
National Institute for Occupational Safety and Health

Procedures for Developing the NIOSH List of Hazardous Drugs in Healthcare Settings

Centers for Disease Control and Prevention
National Institute for Occupational Safety and Health

Figure 1. Identifying, Screening, Evaluating, and Reviewing Drugs for Placement on the List



Step 1
Identifying Drugs

NIOSH reviews FDA databases (Drugs@FDA and Drug Safety Labeling Changes) and receives requests from the public to identify drugs for screening.

Drugs submitted for screening
- New molecular entities with new drug applications and biologics license applications
- New safety labeling changes
- Requests from the public

Drug	AHFS Classification	Biologics License Application	Only Developmental and/or Reproductive Hazard†
warfarin	20:12.04.08 coumarin derivatives	No	Yes

Step 2
Screening Drugs

NIOSH screens identified drugs to determine whether the drug package insert specifies MSHI; or information in the drug package insert suggests that a drug may exhibit at least one of the types of toxicity criteria found in the NIOSH definition of hazardous drug.

Manufacturer's Special Handling Information

Information suggests a toxic effect(s) that may meet the NIOSH definition of hazardous drug.

- Insufficient toxicity information available to meet NIOSH definition of hazardous drug
- Available information shows a toxic effect that does not meet the NIOSH definition of a hazardous drug

FICHA TÉCNICA

MINISTERIO DE SANIDAD, POLÍTICA SOCIAL E IGUALDAD

agencia española de medicamentos y productos sanitarios

1. NOMBRE DEL MEDICAMENTO

PENTAMIDINA ACCORD 300 mg polvo y disolvente para solución inyectable
PENTAMIDINA ACCORD 300 mg polvo para solución para nebulizador

6.6. Instrucciones de uso /manipulación

Este producto debe ser reconstituido en una cabina de flujo laminar vertical.

Categories 1 and 2

- Insufficient toxicity information available to meet NIOSH definition of hazardous drug
- Available information shows a toxic effect that does not meet the NIOSH definition of a hazardous drug

s, the NIOSH Director will make a final determination on whether to place an ation of the drug on the List.

Drugs not placed on the *List*

- Insufficient toxicity information in the drug package insert to meet the NIOSH Definition of hazardous drug
- Available information shows a toxic effect that does not meet the NIOSH definition of a hazardous drug
- Integrated hazard assessment does not support a NIOSH determination that the drug meets the NIOSH definition of a hazardous drug

2024 Hazardous Drugs List Changes

The 2024 *List* adds 25 drugs, 12 of which have special handling[10] information from the manufacturers, and removes 7 drugs[11] from the list. Drugs reviewed for this update were new drug approvals or received new safety-related warnings from FDA during the period from

Notice

July 17, 2025

Drugs approved by the U.S. Food and Drug Administration's Center for Drug Evaluation and Research that have manufacturer's special handling information (MSHI) meet the NIOSH definition of a hazardous drug, see the NIOSH Procedures for developing the NIOSH list of hazardous drugs in healthcare settings . The manufacturers of datopotamab deruxtecan (Datroway®), treosulfan (Grafapex™), and telisotuzumab vedotin (Emrelis™) include MSHI in the package insert. Therefore, NIOSH considers these drugs to be included in Table 1 of the NIOSH list of

Changes to the Placement of Drugs From the 2016 *List*

Drug	Notation
Bacillus Calmette Guerin (BCG)	NIOSH removed BCG from the *List* because it is an infectious agent and not classified as a drug by FDA. For handling recommendations, see drug package insert.
ergonovine	Ergonovine was never approved for use in humans by the FDA in the United States.
liraglutide	NIOSH reviewed data from studies provided by the manufacturer and determined it is unlikely that liraglutide poses a carcinogenic, reproductive, or developmental hazard to workers in a healthcare setting and is no longer considered a hazardous drug by NIOSH.
paliperidone	NIOSH reviewed data from studies provided by the manufacturer and determined it is unlikely that paliperidone poses a carcinogenic, reproductive, or developmental hazard to workers in a healthcare setting and is no longer considered a hazardous drug by NIOSH.
pertuzumab	NIOSH reviewed data from studies provided by the manufacturer and determined it is unlikely that pertuzumab poses a carcinogenic, reproductive, or developmental hazard to workers in a healthcare setting and is no longer considered a hazardous drug by NIOSH.
risperidone	NIOSH reviewed data from studies provided by the manufacturer and determined it is unlikely that risperidone poses a carcinogenic, reproductive, or developmental hazard to workers in a healthcare setting and is no longer considered a hazardous drug by NIOSH.
telavancin	NIOSH removed telavancin from the *List* based on data from reproductive studies provided by the manufacturer concerning its lack of reproductive toxicity.

Drug	Notation
Bacillus Calmette Guerin (BCG)	NIOSH removed BCG from the *List* because it is an infectious agent and not classified as a drug by FDA. For handling recommendations, see drug package insert.

BCG LIVE

(FOR INTRAVESICAL USE)

TICE® BCG

WARNING

TICE® BCG contains live, attenuated mycobacteria. Because of the potential risk for transmission, it should be prepared, handled, and disposed of as a biohazard material (see PRECAUTIONS and DOSAGE AND ADMINISTRATION).

PRECAUTIONS

General

TICE® BCG contains live mycobacteria and should be prepared and handled using aseptic technique (see **Preparation of Agent** subsection of DOSAGE AND ADMINISTRATION). BCG infections have been reported in health care workers preparing BCG for administration. Needle stick injuries should be avoided during the handling and mixing of TICE® BCG. Nosocomial infections have been reported in patients receiving parenteral drugs which were prepared in areas in which BCG was prepared.[4]

Preparation of Agent

The preparation of the TICE® BCG suspension should be done using aseptic technique. To avoid cross-contamination, parenteral drugs should not be prepared in areas where BCG has been prepared. A separate area for the preparation of the TICE® BCG suspension is recommended. All equipment, supplies and receptacles in contact with TICE® BCG should be handled and disposed of as biohazardous. The pharmacist or individual responsible for mixing the agent should wear gloves and take precautions to avoid contact of BCG with broken skin. If preparation cannot be performed in a biocontainment hood, then a mask and gown should be worn to avoid inhalation of BCG organisms and inadvertent exposure to broken skin.

U.S. Department of Health and Human Services
Public Health Service
Centers for Disease Control and Prevention
National Institutes of Health

Revised June 2020

cdc.gov/labs/pdf/SF__19_308133-A_BMBL6_00-BOOK-WEB-final-3.pdf

BSL: biosafety level

recommended for non-aerosol-producing manipulations of clinical specimens. Manipulation of small quantities of the attenuated vaccine strain *M. bovis* Bacillus Calmette-Guérin (BCG) can be performed at BSL-2 in laboratories that do not culture *M. tuberculosis* and do not have BSL-3 facilities. However, considerable care is suggested to verify the identity of the strain and to ensure that cultures are not contaminated with virulent *M. tuberculosis* or other *M. bovis* strains.

BSL-2 practices, containment equipment, and facilities are recommended for activities using clinical materials and diagnostic quantities of infectious cultures. It is recommended that special emphasis be placed on personal protective equipment, handwashing, manipulation of faucet handles, and decontamination of work surfaces to decrease the risk of LAI. For work involving production quantities or high concentrations of cultures, and for activities with a high potential for aerosol production, it is recommended that a BSC be used and

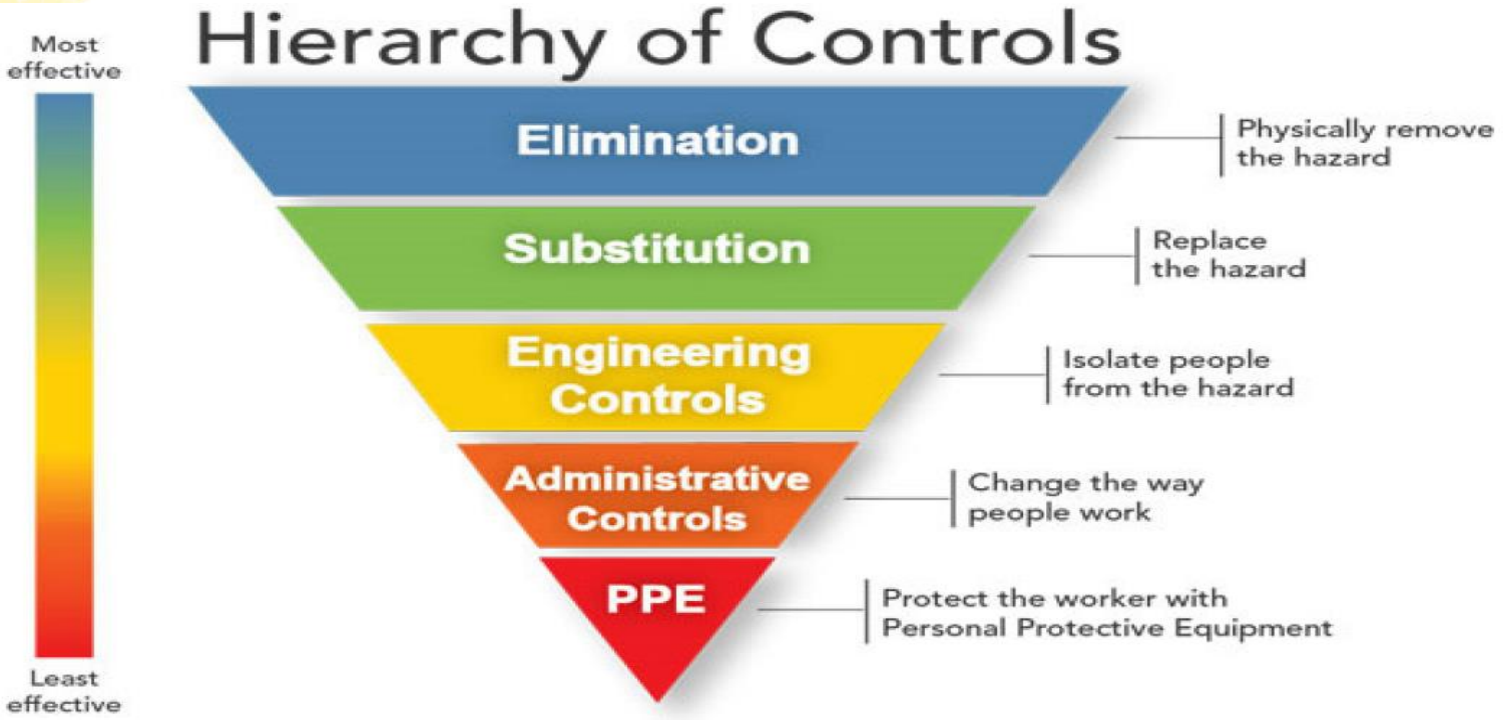


Figure 2. Hierarchy of Controls, NIOSH [2015], https://www.cdc.gov/niosh/topics/hierarchy/

Fecha	31/03/2021
Hora	10:59
Remitente	[redacted]
Asunto	Problemas administración BCG MEDAC
Mensaje	Buenos días, Desde el Servicio de Urología nos han notificado problemas a la hora de administrar BCG [redacted] debidos al dispositivo de administración (el que viene con el vial). Comentan que el líquido no cae por gravedad y que hay que hacer presión con las manos para que fluya. El sistema no es luer-lock por lo que al hacer presión puede haber riesgo de "fugas". Por último, al no poder arrastrar la medicación que queda en el sistema tras la administración, enfermería comenta que al retirar la sonda gotea algo de medicación. Hemos hablado con el laboratorio y nos han dicho que no han tenido ninguna notificación en relación a este problema.

LISTA SEFH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AISLADOR DE PROTECCION 1.2 M
UV

Updates in this document include reducing the number of tables to two and reorganizing how drugs are placed in a table. The *List* no longer uses "antineoplastic" as a table descriptor in the title of Table 1 and does not have a separate table (previously Table 3) for drugs that may be only a developmental and/or reproductive hazard. This document also notes those drugs with approval under a biologics

NIOSH List of Antineoplastic and Other Hazardous Drugs in Healthcare Settings, 2016

- Group 1: Antineoplastic drugs (AHFS Classification 10:00) [ASHP/AHFS DI 2016]. Note that many of these drugs may also pose a reproductive risk for susceptible populations (Table 1).
- Group 2: Non-antineoplastic drugs that meet one or more of the NIOSH criteria for a hazardous drug. Note that some of these drugs may also pose a reproductive risk for susceptible populations (Table 2).
- Group 3: Drugs that primarily pose a reproductive risk to men and women who are actively trying to conceive and women who are pregnant or breast feeding, because some of these drugs may be present in breast milk (Table 3).

TABLA 1: Requisitos de HD en

- Información del fabricante (Manufacturer Special Handling Information-MSHI)
- Programa Nacional de Toxicología (NTP)
- IARC (International Agency for Research on Cancer
- FDA CDER – Biologics Licence Aplication

TABLA 2: Requisitos de HD pero NO de esas tres fuentes. Advertencia especifica para la toxicidad reproductiva

87 cambios

Drugs Moved to a Different Table

Drug	Notation
abiraterone	Moved from Table 1 to Table 2
acitretin	Moved from Table 3 to Table 2
afatinib	Moved from Table 1 to Table 2
alitretinoin	Moved from Table 3 to Table 2
ambrisentan	Moved from Table 3 to Table 2
anastrozole	Moved from Table 1 to Table 2
axitinib	Moved from Table 1 to Table 2
azathioprine	Moved from Table 2 to Table 1
bexarotene	Moved from Table 1 to Table 2
bicalutamide	Moved from Table 1 to Table 2

Table 1 (Continued). Drugs that have MSHI in the package insert and/or meet the NIOSH definition of a hazardous drug and one or more of the following criteria: are classified by the NTP as "known to be a human carcinogen," or are classified by IARC as (Group 1 "carcinogenic to humans") or (Group 2A "probably carcinogenic to humans.")

Drug	AHFS Classification	MSHI	Biologics License Application	IARC and NTP Classification
trabectedin	10:00 antineoplastic agents	Yes	No	
trifluridine	10:00 antineoplastic agents	Yes	No	
uracil mustard	NA	Yes	No	IARC Group 2B*
valganciclovir	8:18.32 nucleosides and nucleotides	Yes	No	
belantamab mafodotin	10:00 antineoplastic agents	Yes	Yes	

Table 2 (Continued). Drugs that meet the NIOSH definition of a hazardous drug and do not have MSHI, are not classified by NTP as "known to be a human carcinogen," and are not classified by IARC as Group 1, "carcinogenic to humans," or Group 2A, "probably carcinogenic to humans." (**Some may also have adverse developmental and/or reproductive effects.**)

Drug	AHFS Classification	Biologics License Application	Only Developmental and/or Reproductive Hazard[†]
nilotinib	10:00 antineoplastic agents	No	Yes
olaparib	10:00 antineoplastic agents	No	No
ospemifene	68:16.12 estrogen agonist-antagonists	No	No
oxcarbazepine	28:12.92 anticonvulsants, miscellaneous	No	No
oxytocin	76:00 oxytocics	No	Yes[††]

[illegible]

[††]Only an occupational developmental hazard in the third trimester of pregnancy.

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CDC NIOSH Centers for Disease Control and Prevention National Institute for Occupational Safety and Health

Table of Control Approaches for Safer Handling of Hazardous Drugs, by Activity and Formulation

		Control Approaches						
		Engineering Controls			Personal Protective Equipment			
Activity	Formulation	Ventilated engineering control (BSC or CACI)*	Closed system drug transfer device	Other	Double chemotherapy gloves (ASTM rated)	Protective gown (impervious, single use)	Eye, face, hair, sleeve, and shoe protection	Respiratory protection†
Compounding‡	Oral liquid drug	Yes§	NA*	NA*	Yes¶	Yes	Hair and shoe covers; Add eye and face protection, if not done in a ventilated engineering control	Yes, if not using a ventilated engineering control
	Topical drug	Yes§ (Note: some drugs such as carmustine, thiotepa, and mechlorethamine are volatile)	NA*	NA*	Yes¶	Yes	Hair and shoe covers. Add eye and face protection, if not done in a ventilated engineering control	Yes, if not done using a ventilated engineering control
	Injections withdrawn from a vial	Yes§	Yes, when dosage form allows	NA*	Yes¶	Yes	Hair and shoe covers; Add eye and face protection, if not done in a ventilated engineering control	Yes, if not using a ventilated engineering control
	Mixing injections from a vial	Yes§	Yes, when dosage form allows	NA*	Yes¶	Yes	Hair and shoe covers; Add eye and face protection, if not done in a ventilated engineering control	Yes, if not using a ventilated engineering control

(Continued)

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6.5 Surface Contamination

Measurement of surface contamination is currently the best indication of the environmental contamination level in areas where hazardous drugs are prepared, administered to patients, or otherwise handled (such as receiving areas, transit routes throughout the facility, and waste storage areas) [Hon et al. 2011]. Environmental wipe sampling for hazardous drug residue should be performed routinely (e.g., initially as a benchmark and at least every 6 months or more often as needed, to verify containment)

A MODO DE CONCLUSIÓN (personales)

1 – Necesidad de actualizar INFOMEP

2 – No debería tener consecuencias en las recomendaciones manejo BCG (INSHT y documento de consenso con la AEU)

3 – Por operatividad y seguridad de los manipuladores, se debería mantener listas de medicamentos con riesgo reproductivo

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sefh Sociedad Española de Farmacia Hospitalaria

farmacotecnia
Grupo de trabajo Farmacotecnia de la sefh

Gracias

Josem.alonso@carm.es

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