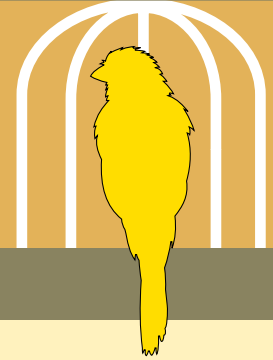


Cytotoxic Drugs

HEALTH AND SAFETY FACT SHEET

CUPE / Canadian Union
of Public Employees



What are cytotoxic drugs?

Cytotoxic drugs inhibit or prevent the function of cells. Cytotoxic drugs are primarily used to treat cancer, frequently as part of a chemotherapy regime. Recently, their uses have expanded to treat certain skin conditions (e.g., psoriasis), rheumatoid and juvenile rheumatoid arthritis, and steroid-resistant muscle conditions. The most common forms of cytotoxic drugs are known as antineoplastic. The terms 'antineoplastic' and 'cytotoxic' are often used interchangeably.

Cytotoxic drugs can prevent the rapid growth and division of cancer cells. They can also affect the growth of other quick dividing cells in the body, like hair follicles and the lining of the digestive system. As a result of the treatment, many normal cells are damaged along with the cancer cells.

There are no exposure limits set for cytotoxic drugs. CUPE's position is that even low-level exposure to cytotoxic drugs should be avoided. The only safe occupational exposure to cytotoxic drugs is no exposure.

What are the risks of occupational exposure to cytotoxic drugs?

The toxicity of cytotoxic drugs can make them dangerous to people who handle them. Health effects are well documented. Studies show frequently detectable levels of cytotoxic drugs in the air of hospital areas where the drugs are prepared without proper biological safety cabinets. Health care workers preparing the drugs without adequate precautions have tested positive for cytotoxic drugs in their urine.

Exposure to cytotoxic drugs has been reported to cause increased frequency of chromosome damage in exposed workers.¹ They can cause acute

skin, eye, and mucous membrane irritations, as well as nausea, headaches, and dizziness.

Cytotoxic drugs have also been associated with negative health effects for developing fetuses, including higher incidences of spontaneous abortions, congenital malformations, low birth weight, and infertility. As part of any cytotoxic exposure reduction plan, protective reassignment for a worker who is pregnant, breastfeeding or intends to conceive a child must be put in place.

Repeated long-term occupational exposure to small amounts of cytotoxic drugs has not been identified to cause of cancer. However, many cytotoxic drugs are known to be:

- **Genotoxic:** a substance that damages DNA. Such damage can lead to the growth of a malignant tumor.
- **Carcinogenetic:** a substance that may cause mutations leading to the development of tumors in otherwise healthy cells.
- **Mutagenic:** a substance that alters the DNA of a living being, increasing the likelihood of a mutation.

Who is at risk?

Anyone who works with patients receiving cytotoxic drugs is at risk of exposure, and must be protected while working with cytotoxic drugs. Exposure may occur when preparing, administering, or transporting drugs, handling patient waste, transporting and disposing of waste, or cleaning spills.

If at any time there is skin contact with any cytotoxic drug, the affected worker should thoroughly wash the affected area with soap and water.

The worker should not scrape or abrade the skin by using a scrub brush as this could increase exposure. If eye contact has occurred, flush the affected eye(s), while holding back the eyelid(s), with copious amounts of water for at least 15 minutes. After any type of exposure, it is always recommended to seek a medical evaluation by a physician.

Training and information

All staff who may handle cytotoxic drugs or waste by-products created by their use, including physicians, nurses, assistants, pharmacists, stores and receiving personnel, housekeeping and maintenance staff should receive training. Management and the health and safety committee should develop specific pre-employment worker training procedures for the proper handling, mixing, and disposal of cytotoxic drugs and waste by-products. These training procedures should:

- Be written, posted, and available to all employees
- Explain how training is developed, delivered, and evaluated
- Describe the roles of supervisors to ensure proper regulations are followed

A complete training program should cover the following topics:

- Hazards of cytotoxic drugs
- Methods of preparation
- Use and disposal procedures
- Patient care
- Proper use of protective equipment
- Spill procedures
- Maintenance of the facilities and equipment

The department responsible for cytotoxic drugs should maintain a record of information on toxicity, exposure treatment procedures, solubility, stability, and general descriptions of the appearance of all cytotoxic drugs that are used in the facility. This record should be easily accessible and available to staff who may come into contact with cytotoxic drugs.

Drug preparation and reconstitution

Cytotoxic drugs should only be prepared by personnel with the proper training in a centralized dedicated location. The hierarchy of hazard control should be put into effect to control the hazard as much as possible.

1. Engineering controls

The following engineering controls should be put in place where cytotoxic medications are being used:

1. A minimum of a Class II biological safety cabinet with HEPA filter exhaust systems that does not allow air to be circulated back into the room should be used while manipulating cytotoxic drugs.
2. The preparation area within the cabinet should be covered with a plastic backed, absorbent material to reduce dispersion and facilitate the clean-up of any spilled medication.
3. Medications should be isolated and locked out in such a manner that only those properly trained have access to the storage location.
4. CSA approved, puncture proof containers for the disposal of needles, syringes and vials must be provided. Labelled, sealable refuse bags for the puncture proof containers should also be available in the preparation area. Contaminated needles, syringes, and vials should be disposed of intact.
5. Negative pressure rooms that prevent any spilled medication from leaving the room are also recommended.

2. Personal Protective Equipment (PPE)

While handling any cytotoxic drugs, workers should use:

1. Protective gloves made of vinyl or nitrile rubber. Gloves should be changed frequently, or immediately if punctured, cut, or torn. It is also recommended that workers wear two pairs at a time for additional protection.

2. A moisture resistant, long sleeved gown with elastic cuffs.
3. Chemical splash goggles, and if necessary, full-face protection.
4. In cases where there is a possibility of the medication becoming airborne, a powered air purifying respirator is recommended.

To prevent the spread of medication, protective clothing should not be worn outside of the preparation area.

3. Additional controls

Special controls are required for the housekeeping and custodial staff regarding the potential hazards involved in handling laundry or other materials that may be contaminated with biological fluids contaminated with cytotoxic drugs.

Safe work procedures for handling these materials should be developed and taught to all affected staff. Proper signage informing all employees of the presence of cytotoxic drugs and their hazards must be developed and displayed in highly visible locations. Eating, drinking, smoking, applying makeup and the storage of food should be completely prohibited in the preparation area.

Safety while caring for patients

Personal care workers who could be exposed to biological fluid from a patient who has received cytotoxic drugs within the previous 48 hours, and workers handling potentially contaminated linen should wear protective gloves and disposable gowns that are discarded after use. It is up to management to ensure that all staff are informed as to when and where cytotoxic drugs are being used so appropriate measures can be taken.

Waste disposal

Plastic bags that are at least 2mm thick (if polypropylene) or 4mm thick (if polyethylene) should be used to collect potentially contaminated materials. Bags should be color-coded and labelled with a cytotoxic warning label. All sharps should be placed in puncture proof containers before bagging. All workplaces should have a policy for segregating waste materials

resulting from cytotoxic drug preparation and administration. These plans must meet or exceed the provincial regulations for hazardous waste disposal.

Housekeeping staff should wear protective gloves while handling waste containers. Cytotoxic waste must be handled differently than regular garbage and must be disposed according to provincial regulations. In cases where the waste is to be incinerated, it should be noted that completely sealed (airtight) containers that could build pressure and explode must be avoided. Temperatures of 1,000°C to 1,600°C should be used to render the cytotoxic drugs harmless.

Spills

1. Spill kit

A clearly labelled cytotoxic spill kit should be kept wherever cytotoxic medications are being prepared, stored, administered or received (shipping). The kit should contain:

- Fit tested NIOSH certified respirators for any one that would be working in these areas
- At least two sets of surgical gloves
- Disposable eye protection
- Shoe covers
- Scoop and scraper
- Sharps container
- Two large plastic disposal bags (minimum of 4mm thick)
- Warning signs
- Decontamination agent (i.e. a basic detergent of pH 8-9 and water)
- Puncture and leak resistant waste container
- Two sheets of absorbent material at least 30cm square

A spill needs to be cleaned by members of the staff that have received the appropriate training and have the appropriate protective equipment; others should vacate the area as soon as it is safe to do so until the spill is cleaned. All spills should be immediately marked with a warning sign to prevent exposure to others. Glass should never be

handled by hand; always use a scoop. The cleanup should be done by as few people as feasible, but there should be at least two people involved.

2. Small spill cleanup

Small spills (less than 5ml or 5mg) that occur outside of a biological safety cabinet should be cleaned immediately by personnel wearing gowns, doubled protective gloves and eye protection.

Small amounts of liquid should be wiped with absorbent pads, while solids should be wiped with a wet absorbent gauze. Spill areas should be cleaned at least three times with the detergent (described above). Broken glass should be placed in a small container and placed in the disposal bags. All contaminated materials should also be placed in the garbage bags.

Unbroken glassware or reusable items that have been contaminated should be placed in a plastic bag and washed, following the procedures for cleaning reusable items that have been developed for the workplace.

3. Large spill cleanup

For spills that are larger than 5ml or 5mg, the cleaner's initial concern (after personal protection) should be limiting the spread of cytotoxic drugs through the work environment. Cover the spill with an absorbent sheet or spill control pads. If the drug is in powder form, a wet or damp cloth should be used. For large spills, protective clothing should be worn with the addition of the respirator to protect against any airborne powder or aerosols. The use of chemical inactivates is not recommended as they may create a hazardous by-product. As with small spills, all contaminated areas should be cleaned a minimum of three times, and all contaminated products and equipment should be disposed of or cleaned in an appropriate manner.

4. Spills in a biological safety cabinet

After the procedures described above are followed, the interior of the hood may also require cleaning. If the HEPA filter has been contaminated, the unit must be labelled "Contaminated, DO NOT USE". The filter must then be changed

and disposed of as soon as possible by trained personnel who are wearing the appropriate protective clothing. Protective goggles (if not disposed of) should be thoroughly cleaned with an alcohol wipe after cleanup.

Storing and transport

Areas where cytotoxic drugs are stored should be separated from regular storage, and clearly marked. Engineering controls (locks, limited access key card systems) should be in place to prevent unauthorized personnel from entering the storage area. An inventory of the cytotoxic drugs that is frequently reviewed should be kept in the room, along with instructions for cleaning spills. Where possible, other drugs should not be stored with cytotoxic drugs. Clear warning labels should be used to identify the cytotoxic drugs and point out their hazards. Shelves should also be fitted with a lip or back slope that prevents the drugs from falling to the floor.

When a damaged container is found, it should only be handled by trained personnel with personal protective equipment described previously. Broken containers and contaminated packing material should all be placed in the appropriate puncture proof container and disposed of as cytotoxic biological waste.

Cytotoxic drugs should be securely capped and sealed and should be packed in impervious packing material. Labels of all boxes, containers and vials should indicate that the substance is a cytotoxic drug.

Legislation regarding cytotoxic drugs in Canada

Most jurisdictions do not specifically cover cytotoxic drugs in legislation or regulations. However, in all Canadian jurisdictions it is the general duty of the employer to keep the workplace safe and to eliminate foreseeable hazards.

Two provinces that do specifically cover cytotoxins are B.C. and Saskatchewan. B.C. legislation states that the employer must "develop and implement an exposure control plan" (sections 6.42-6.58 of the Occupational Health and Safety Regulation). The legislation also specifies

that employees should be aware of information regarding the (a) acute and chronic toxicity, including any potential reproductive hazard, (b) acute exposure treatment, (c) safe handling of, and (d) the proper labeling of cytotoxic drugs and their storage areas. Safe work procedures must also be developed for receiving, preparation, administration, storage, disposal and waste handling.

In Saskatchewan, legislation states that the employer shall “take all practicable steps to minimize the exposure of workers to cytotoxic drugs or to materials or equipment contaminated with cytotoxic drugs” (section 471 of the Occupational Health and Safety Regulations). The legislation also covers (a) installation and maintenance of the biological safety cabinets, (b) development of a program to protect the workers from exposure, (c) emergency procedures in case of exposure, (d) disposal of cytotoxic drugs, and (e) equipment used to administer the drugs.

CUPE’s position

There is no safe exposure level for any carcinogen, including cytotoxic drugs. All steps must be taken to ensure the safest and healthiest workplaces possible, and that workers are made aware of the locations where cytotoxic drugs may be present so that they can take the appropriate precautions. Some cytotoxic drugs are mutagens that may damage the DNA in sperm of male workers and the ova of female workers. As previously stated, workers who are pregnant or considering reproduction should demand protective re-assignment with no loss of pay or benefits.

The information contained in this fact sheet relates to the minimal requirements for cytotoxic drug administration and use, and should be considered only as a basic starting point in the development of healthy work practices.

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