



The Safe Disposal of Cytotoxic Contaminated Sharps and Waste

The introduction of the "UN Regulations for the Transportation of Dangerous Goods" on 1st January 1997 lead Sharpak Healthcare to carry out a study to review the issues concerning the safe disposal of sharps contaminated with Cytotoxic Drugs and Cytotoxic Waste. This study involved collecting and reviewing data taken from the British National Formulary, The Cytotoxic Handbook and pharmaceutical manufacturers data sheets on over thirty drugs in regular use today. (See list overleaf.)

It became clear that the majority of the drug manufacturers do not appear to mark their packaging with the packaging group classification in line with the products toxicity which would help the user in deciding what method of disposal should be used. It is also fair to say that when these types of drugs are used in the clinical environment it is more than possible that one could end up with a cocktail of drugs so specific classification becomes more difficult.

Following our own in-house review a copy of our report was passed to the Health and Safety Executive to establish whether they agreed with our interpretation of the regulations.

To summarise we believe that there are two specific issues relating to the packaging used for the disposal and subsequent transport of waste cytotoxic drugs:-

- a) Sharps containers used for the disposal of cytotoxic contaminated sharps
- b) Packaging suitable for the safe disposal of waste cytotoxic drugs.

CONTAMINATED SHARPS

In most cases, sharps contaminated with cytotoxic drugs will have been used for the treatment of a patient and thus the waste should be considered potentially infectious. Classifying goods which exhibit more than one hazardous property e.g. toxic and infectious, require special consideration. It states, in Section A, Part 5 of the Approved Requirements and test methods for the classification and packaging of dangerous goods for carriage, that where goods exhibit an infectious

hazard, this hazard should take precedence over the toxicity hazard the goods exhibit. Therefore sharps contaminated with pathogens as well as waste cytotoxics, should be disposed of in a sharps container which has been tested and approved to the UN standard for clinical waste (UN3291).

It is also permissible to dispose of sharps which are only contaminated with cytotoxic drugs, using a sharps container tested and approved to the UN standard for clinical waste, (UN3291) Packaging Groups II and III, as long as the limited quantities, as specified in CDGCLP2 (The Carriage of Dangerous Goods (Classification, Packaging and Labelling) schedule 3), are not exceeded, e.g.

Toxic substance (solid)	Packaging Group II	500g
Toxic substance (liquid)	Packaging Group II	100ml
Toxic substance (solid)	Packaging Group III	3 Kg
Toxic substance (liquid)	Packaging Group III	1 Litre

*Please note:- Part of the drugs manufacturers evaluation should have included establishing the products level of toxicity, in line with the criteria set out in CDGCLP2 part 5, to ensure the drugs are packaged correctly and safe for transportation.

The method of classification involves using the LD50 data of the drug which dictates which packaging group the product falls into and thus the type of packaging specified e.g. Packaging Groups I, II or III.

(*Note: Details on explanation of LD50, and packaging group selection available on request.)

The original Drug Packaging, Instructions for Use or Safety Data Sheets should indicate what packaging group the basic drug falls into. However, if the drug is diluted, its level of toxicity may reduce, thus for example, moving from packaging group II to packaging group III (or even unclassified) which in turn effects the amount that can be disposed of in the container. Any drugs having a packaging group I classification cannot be disposed of in a sharps container as they are only approved to groups II and III.

We appreciate that this subject is complicated and confusing but to avoid large amounts of cytotoxic contaminated sharps and waste accumulating in one container, we would recommend that the size of sharps container used should be selected to prevent this situation happening, thus avoiding exceeding the specified limited quantities.

DISPOSAL OF WASTE CYTOTOXIC

If for whatever reason you wish to dispose of larger amounts of cytotoxic waste, it is necessary for the classification of the waste to be established. This classification can be established easily if the drugs packaging specifies the packaging group number which will relate to the products main hazard. Once the packaging group number is known, this will help to establish what type of packaging should be used to dispose of the waste. It may also be necessary for the waste to be labelled with one of the other classifications, for example, UN1851, which relates to: MEDICINE, LIQUID, TOXIC, N.O.S. OR UN 3249:- MEDICINE, SOLID, TOXIC, N.O.S.



The Cytotoxic Drugs reviewed in our survey were:-

GENERIC NAME	BRAND NAME	MANUFACTURER / SUPPLIER
Amsacrine	Amsidine	Park Davis Laboratories Ltd.
Bleomycin		Lundbeck Ltd.
Busulphan	Myleran	Glaxo Wellcome UK Ltd.
Carboplatin	Paraplatin	Bristol-Myers Squidd Pharm. Ltd.; David Bull Labs Ltd.
Cerubidin		Rhone-Poulenc Rorer UK Ltd.
Chorambucil	Leukeran	Glaxo Wellcome UK Ltd.
Cisplatin		David Bull Labs Ltd.; Erba Ltd.; Pharmacia Ltd.
Carmustine	Bicnu	Bristol-Myers Pharm. Ltd.
Cyclophosphamide	Endoxana	Asta Medica Ltd.; Pharmacia Ltd.
Cyarabine	Alexan	Pfizer Ltd.; Upjohn Ltd.; David Bull Labs Ltd.
Dacarbazine	DTIC-Dome	Bayer (UK) Ltd.
Dactinomycin	Actinomycin-d	Merck, Sharpe & Dohme Ltd.
Daunorubicin	Cerubidin	Rhone-Poulenc Rorer UK Ltd.
Docetaxel	Taxotere	Rhone-Poulenc Rorer UK Ltd.
Doxorubicin		Pharmacia and Upjohn Ltd.
Epirubicin	Pharmorubicin	Pharmacia and Upjohn Ltd.
Etoposide	Vepesid	Bristol-Myers Pharm Ltd.
Fludarabine	Fludara	Schering Health Care Ltd.
Fluorouracil	5-Fluorouracil	Faulding DBL Ltd.
Hydroxyuera	Hydrea	Bristol-Myers Squibb Pharm Ltd.
Idarubicin	Zavedos	Pharmacia Ltd.
Ifosfamide	Mitoxana	ASTA Medica Ltd.
Melphalan	Alkeran	Wellcome Medical Div.
Mercaptopurine	Puri-Nethol	Glaxo Wellcome UK Ltd.
Methotrexate		Lederle Labs Ltd.; David Bull Labs Ltd.; Pharmacia Upjohn Ltd.
Mitomycin		Kyowa Hakko UK Ltd.
Mitozantrone	Novantrone	Lederle Labs Ltd.
Paclitaxel	Taxol	Bristol-Myers Squibb Pharm Ltd.
Pentostatin	Nipent	Wyeth Lederle Labs Ltd.
Thioguanine		Wellcome Medical Div.
Thiotepa		Lederle Labs Ltd.
Vinblastine		Eli Lilly & Co Ltd.; Lederle Labs Ltd.; Faulding DBL Ltd.
Vincristine	Oncovin	Eli Lilly & Co Ltd.; Faulding DBL Ltd.; Lederle Labs Ltd.
Vindesine	Eldisine	Eli Lilly & Co Ltd.

For details regarding SHARPAK distributors and world wide availability, please contact: Amcor Flexibles/SPS Laboratoires
 Winterbourne Road Stoke Gifford BRISTOL BS34 6PT
 Tel +44 (0)117 983 6003
 Fax +44 (0)117 983 6001
 E mail david.scarrow@amcor-flexibles.com
 www.sharapakforsharps.co.uk