



## Project Summary

# Alternative Formulations to Reduce CFC Use in U.S. Exempted and Excluded Aerosol Products

Thomas P. Nelson and Sharon L. Wevill

***Chlorofluorocarbons (CFCs) were banned from use as aerosol propellants in the U.S. in 1978. However, the ban allowed for certain exemptions if it could be demonstrated that no acceptable alternative propellants were available and that the products were essential. Essentiality was based on three criteria: 1) the economic significance of the product; 2) the environmental and health impacts of the product and its substitutes; and 3) the effects on the quality of life resulting from no longer having the product or a reasonable substitute available. If a CFC served some purpose other than as the propellant, that product was excluded from the regulation. This report examines the products exempted and excluded from the 1978 ban, the present consumption of CFCs still utilized for these products in the U.S., and alternative formulations which may be used to reduce or eliminate the CFC content of these products. The study shows that about 40% of the CFC usage in these products can be immediately replaced by available substitutes. Seven categories of products were identified for which immediate replacement of all of the CFC content is not technically feasible. Complete CFC replacement in these products must await the commercialization of newer substitutes currently being developed by industry. However, some reformulation is possible in the interim for***

***some of these seven categories, allowing for reduction of CFC usage. The product category requiring the longest time to reformulate appears to be metered-dose inhalant drug products which will require the newer chemicals and which must also be subjected to regulatory approval by the U.S. Food and Drug Administration.***

***This Project Summary was developed by EPA's Air and Energy Engineering Research Laboratory, Research Triangle Park, NC,, to announce key findings of the research project that is fully documented in a separate report of the same title (see Project Report ordering information at back).***

### Introduction

The use of chlorofluorocarbons (CFCs) in categories of aerosol propellant use considered "nonessential" was banned in the U.S. by regulations promulgated in 1978. An aerosol was defined as a package consisting of a self-pressurized, non-returnable container constructed of metal, glass, or plastic that contains a fluid product and that is fitted with a valve for expelling the product as a spray, liquid, gas, foam, powder, or paste. The banned CFC propellants were the fully halogenated types: CFC-11, CFC-12, CFC-113, CFC-114, and CFC-115.

New EPA regulations were promulgated in 1988 to implement the Montreal Protocol of 1987. Under the 1988 regulations, the entire supply of

fully halogenated chlorofluorocarbons will be reduced.

In view of the recent renewed interest in reducing worldwide production and consumption of CFCs and other chemicals implicated in the depletion of the Earth's stratospheric ozone layer, the U.S. Environmental Protection Agency (EPA) undertook a study of currently exempted and excluded CFC aerosol applications and their alternatives. The report of that study is summarized in this document.

The EPA report lists CFC aerosol applications exempted and excluded by the 1978 regulations and provides the rationale for those cases. Technically feasible methods for reducing CFCs in these aerosol products are suggested.

Formulation options for a number of products that currently use regulated CFCs are presented, as are the factors considered in developing the alternative formulations. Formulation options are presented in the context of flammability (one of the most important considerations), manufacturing difficulty, cost, and end-use acceptability.

Conclusions are presented for seven categories of aerosol uses in which CFCs are most difficult to eliminate, and partial or interim reformulations of some categories to decrease CFC use are noted. Possible CFC reductions, based on several scenarios, are shown.

Elements of the proposed CFC reduction plan are compared with the scheduled reductions called for by the 1987 Montreal Protocol, and additional studies on aerosol formulation are recommended.

## Exempted/Excluded CFC Aerosol Applications

Table 1 lists CFC aerosol applications exempted from EPA's 1978 regulation. The 14 applications shown in Table 1 were exempted because they required a CFC propellant for reasons of safety, health, or national security. Some CFC aerosol applications were excluded from the 1978 regulation because they contain propellant only; that is, the propellant is the sole ingredient and may be considered the product itself. If the CFC serves any purpose other than as the propelling agent, the CFC is deemed an active ingredient and the product is also excluded from regulation. Table 2 lists such excluded CFC aerosol applications.

## Rationale for Exempting, Excluding, or Not Regulating

The rationale applied in 1978 and 1979 by EPA and the Food and Drug Administration (FDA) when considering proposed exemptions included:

- The need for a nonflammable product;
- The 5 years often taken by the Drug Division of the FDA to approve an Amended New Drug Application (applies to bronchodilators and other inhalants);
- Required solvency and purity profiles;
- Doctrine of equivalency--that highly similar products cannot reasonably be treated differently
- Limited availability of substitute propellants or products;
- Stratospheric ozone impact (e.g., production tonnage per year) and
- Life-saving potential of the proposed exempted product (e.g., medical, military, flammable gas alarm systems).

The rationale for exempting specific essential uses of CFC aerosols is examined. The 14 specific applications listed in Table 1 are discussed, as are specific excluded applications (such as skin chillers used for medical purposes) and nonregulated applications.

Approximately 28 product types and groups have been or are being produced in aerosol formulas that contain CFCs. Background data on each product or product group are provided, including how the CFC component functions. Industry's interest in preserving the CFC ingredient(s) is explained. The primary reasons for requesting exempted status were the unavailability of substitutes, the long delays while obtaining approval from the FDA, solvency and purity profiles (especially for CFC-113 uses), life-saving potential of the product, and regulations in hospitals, aircraft organizations, etc. against the use of flammable propellants in aerosols.

During the 1977 to 1978 transition period, no nonflammable liquid propellant alternatives to CFCs were toxicologically approved and commercially available for use. Today the situation has changed, with the clearance of HCFC-22 and certain blends of HCFC-22/142b, and the forthcoming availability of HFC-134a, HCFC-123, HCFC-141b, and HCFC-124.

As may be anticipated, some exempted, or excluded, products are no

longer in use or have been replaced with ones that contain alternative propellants. However, inhalant and solvent type products are steadily growing in sales volume.

## Factors Considered When Developing Alternative Formulations

Two or more formulation options are presented for a number of products that currently use regulated CFCs. Some have a relatively greater potential than others for stratospheric ozone depletion.

The following factors were considered when developing the alternative formulations:

- Production of sprays with desired particle size distribution;
- Control of flammability;
- Precautionary use of questionable solvents, such as methylene chloride;
- Minimum changes in anticipated use patterns;
- Maintenance of dispenser and organoleptic stabilities;
- Cost of alternative formulations;
- Availability of the alternative, including Toxic Substance Control Act (TSCA) considerations;
- Pressure limitations;
- Product utility or efficacy for intended uses;
- Toxicological factors; and
- Spray rate and use-up rate optimization.

## Aerosol Reformulation Options (1989-1993)

When substituting alternative aerosol formulas for CFC-based aerosol products, one of the most important considerations is flammability. Depending on circumstances, one or more of three main formulation routes (shown in Figure 1) will be taken.

For companies producing CFC aerosols, the transition to non-CFC formulations will increase in difficulty and cost (and often decrease in acceptability) as the replacement formulas go from Type 1A to 3B (shown in Figure 1).

## Costs of Converting Filling Lines

Many of the current fillers and marketers of non-pharmaceutical CFC-type aerosol products are not equipped to handle flammable propellants. To handle Type 3 products, most would either have to 1) commit capital, time, and training resources to convert, while

**Table 1. Exempted Aerosol Propellant Applications-1978**

1. Release agents for molds used to produce plastic and elastomeric materials.
2. Lubricants for rotary-type press-punches for the production of pharmaceutical tablets.
3. Lubricants, cleaner-solvents, de-dusters or coatings for industrial/institutional applications to electronic or electrical equipment.
4. Mercaptan stench warning devices for mines.
5. Other warning devices, such as intruder alarms; boat horns, bicycle horns.
6. Flying insect pesticides for use in commercial food handling areas, except when applied by total release or metered valve aerosol devices.
7. Propellants for flying insect pesticides for the fumigation of aircraft.
8. Flying insect spray for tobacco barns.
9. Metered dose inhalant drugs, as follows:
  - steroid drugs for humans, (oral and nasal),
  - Ergotamine tartrate drugs, and
  - Adrenergic bronchodilator drugs (oral).
10. Contraceptive vaginal foams for human use.
11. Aerosols for the maintenance and operation of aircraft.
12. Aerosols necessary for the military preparedness of the U.S.
13. Diamond grit sprays.
14. CFC-115 (CClF<sub>2</sub>-CF<sub>3</sub>) for the aeration of puffed food product.

**Table 2. Nonregulated CFC Aerosol Applications (Propellant as Active Ingredient)**

1. CFC-12 used as a polyurethane blowing agent (insulation foams).
2. CFC-12 and CFC-114 mixtures used in tire inflators.
3. Certain specialty foams, whips, and puffs.
4. Medical solvents such as silicone-based bandage adhesive (CFC-113) and bandage adhesive remover (CFC-113, with 5% CO<sub>2</sub>).
5. CFC-12 and CFC-114 refrigeration and air-conditioning system refill units.
6. Drain openers.
7. Microscope slide cleaners.
8. Computer cleaners and dusters (equivalent to No. 3 in Table 1).
9. Boat horns.
10. Halon fire extinguishers (4 and 15 oz. containers)
11. Intruder alarm sonic devices for homes and cars.
12. Skin chillers (medical).

still accepting a statistical risk of fire or 2) use a contract filler equipped to handle flammable propellants.

The conversion cost for a medium-speed Type 3 aerosol line would average \$900,000. Smaller operators would probably use contract fillers rather than convert. Some of the larger operators would be expected to convert only one line, while the remaining larger operators would probably convert only to Type 1 and Type 2 products or use a contract filler.

Table 3 shows estimates of the total industry costs of in-house filler conversions from CFCs to the Type 1, 2, and 3 products defined in Figure 1.

## Conclusions

Seven categories of aerosol uses involving CFCs have been judged most difficult to eliminate:

1. Certain mold releases.
2. Lubricants for electrical and electronic applications;
3. Lubricants for pharmaceutical pill and tablet presses;
4. Solvent cleaners and dusters for electronic and electrical equipment;
5. Metered-dose inhalant drugs;
6. Contraceptives for human use; and
7. Solvents for medical use.

Partial or interim reformulations for some of the products in these categories are

noted, as are possible reductions, based on several scenarios, for CFC consumption in the U. S.

The perceived need for CFCs in these seven product categories is based on the lack of available alternatives that can completely replace the CFCs at the present time; however, approximately 40 percent of the CFCs now used in exempted, or excluded U.S. aerosol products can be replaced immediately. Further, alternative non-CFC formulations for some of the seven remaining CFC-dependent categories are judged technically feasible, pending the commercial availability of four "future" HCFCs and HFCs. Longer-range CFC

---

*T. Nelson and S. Wevill are with Radian Corp., Austin, TX 78720*

*N. Dean Smith is the EPA Project Officer (see below).*

*The complete report, entitled "Alternative Formulations to Reduce CFC Use in U.S. Exempted and Excluded Aerosol Products," (Order No. PB90 149972/IAS; Cost: \$23.00, subject to change) will be available only from:*

*National Technical Information Service*

*5285 Port Royal Road*

*Springfield, VA 22161*

*Telephone: 703-487-4650*

*The EPA Project Officer can be contacted at:*

*Air and Energy Engineering Research Laboratory*

*U.S. Environmental Protection Agency*

*Research Triangle Park, NC 27711*

United States  
Environmental Protection  
Agency

Center for Environmental Research  
Information  
Cincinnati OH 45268

---

Official Business  
Penalty for Private Use \$300

EPA/600/S2-89/061

• •

• •