



# Multilateral Fund

for the Implementation of the Montreal Protocol

## OBJECTIVE

To establish the suitability of KC-6 technology as a viable replacement for HCFC-141b as a solvent in the manufacturing of medical devices



## DEMONSTRATION OF ISOPARAFFIN AND SILOXANE (KC-6) TECHNOLOGY FOR CLEANING IN THE MANUFACTURE OF MEDICAL DEVICES

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|------------------------------|---|
| Project title                | Demonstration project for conversion from HCFC-141b-based technology to isoparaffin and siloxane (KC-6) technology for cleaning in the manufacture of medical devices at Zhejiang Kindly Medical Devices Co. Ltd. |
| Country                      | China   |
| Agency                       | UNDP/Japan  |
| Sector                       | Solvent   |
| Subsector/application        | Medical devices   |
| Enterprise/ systems house    | Zhejiang Kindly Medical Devices Co. Ltd. (KDL)  |
| Baseline technology          | HCFC-141b   |
| Alternative technology       | Isoparaffin and siloxane (KC-6)   |
| GWP (alternative technology) | Negligible  |
| Potential safety issues      | Flammable   |
| ODS phase-out (mt)           | 27.82   |
| ODS phase-out (ODP tonnes)   | 3.06  |

## DESCRIPTION

Puncture instruments, such as medical needles, need to be coated with a layer of silicone oil on the blade and the tube (silicification). The purpose of silicification is to reduce frictional resistance and the patients' pain when the needle pierces the skin. This process is completed at the silicification working station of assembly machines.

The project consisted in the conversion of one production line for disposable medical devices, particularly medical needles, to use KC-6 instead of HCFC-141b in the process of silicification. The project activities included:

- Production line equipment redesign and installation, including adjustment to the silicification tooling cleaning lines and process changes to the needle assembly line
- Workshop modifications, including installation of safety equipment and adjustments to the production process to address the flammability of KC-6
- Confirmation of biocompatibility and drug compatibility

- Demonstration and training.

## RESULTS

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The demonstration revealed that KC-6 had exhibited good solvent properties for silicone oil and that the compound with silicone oil provided good coating quality on the surface of medical devices. Biocompatibility and drug compatibility were also tested and the results met the national standard.

The results of performance tests conducted on needles manufactured using KC-6 as solvent showed that the cleaning quality and product durability met the product requirements.

As KC-6 has a higher boiling point and chemical stability than HCFC 141b, emission reduction was easier to manage, resulting in less consumption.

The flammability of KC-6 was addressed through the use of fireproof material, workshop ventilation, and the installation of fire alarm and sprinkler facilities.

Training was provided to workers for the safe operation of the converted line. KDL also shared with other enterprises its experience in managing silicification fluid and in optimized equipment operation to obtain qualified products.

## COST ANALYSIS

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The overall incremental capital cost of US \$360,005 for conversion was similar to the approved amount of US \$352,051 with some variations in individual cost items. On average, the total conversion cost was 2% higher than approved. The incremental operating cost of US \$205,616 has been disbursed to the enterprise and US \$11,984 was co-financed by the enterprise. The price of KC-6 is US \$6.8 per kg.

## CONCLUSION

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The suitability of KC-6 technology as a viable replacement for HCFC-141b as a solvent in the manufacture of needles has been established.

The demonstration project has also contributed to the sector phase-out programme, as based on the result of this demonstration six enterprises have selected KC-6 as an alternative technology and signed contracts to phase out HCFC-141b consumption in manufacturing medical devices.

There are no patents related to the application of KC-6 held by KDL. KC-6 is developed by Beijing Aerospace Technology Innovation Co. Ltd. and is available on the market.

## FINAL REPORT AND SECRETARIAT'S COMMENTS

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Additional details on this project are available in the link below:

<http://www.multilateralfund.org/73/English/1/7317a1.pdf>  
(paragraphs 32 to 40 and Annex III in page 75)