» Alcohol Products

Innovation with commodity products is not an easy process. However, Micronclean has developed a range of GMP transfer based alcohols to meet current demands

These alcohol products not only benefit from all the known properties of Isopropyl alcohol or Denatured Alcohol 70%/30% WFI but also from:

- Risk management
- Ergonomics
- Logistics

Parameter	Specification Isopropyl Alcohol (IPA)	Specification Denatured Alcohol (IMS)
Alcohol concentration	70% v/v	70% v/v
Diluent water	Water for injection 30%v/v	Water for injection 30%v/v
Gamma irradiation	≥25kGy	≥25kGy
Sterility test	USP sterility compliant	USP sterility compliant
Colour	Colourless	Colourless
Odour	Characteristic of IPA	Slight spiritous
Clarity	Clear	Clear
Filtration level	0.2 micron	0.2 micron
Specific gravity @ 20˚C	0.872 to 0.883	0.850 to 0.880

Micronclean Provides

- A device in which each trigger's hold up volume is less than 0.3%, significantly better than any other product on the market by some margin
- Trigger Sprays double bagged and gamma sterilised using a validated process
- Certificates of conformity, irradiation and sterility with every batch
- Passes CEN test 1276:1997 for bactericidal efficacy

Compliance 100© IPA 70%/30% WFI Trigger Spray, sterile, double bagged

	500ml	950ml
Order code	ZSAL64499	ZSAL64950
No. of bottles per box	24	15

Compliance 100© IMS 70%/30% WFI Trigger Spray, sterile, double bagged

	500ml	950ml
Order code	ZSAL65499	ZSAL65950
No. of bottles per box	24	15

Where Microclean is Different

Risk Management

Some manufacturers promote the use of either propellant aerosol or 'bag-in-bottle' devices in order to protect the alcohol solution from aspiration of viable and non-viable particles into the solution, thus managing the risk of spraying these particles within the cleanroom.

Much research has elucidated that this assumption is unfounded[1 & 2]. The trigger is only being operated within a clean GMP environment, thus the particle and bioburden is already managed and well below acceptance criteria for GMP cleanrooms. The research is clear that there is no risk to product sterility or particle burden if a trigger spray product is not a 'bag-in-bottle' design.

The cost of engineering and producing 'bags in bottles' or aerosol manufacture is very high, just at a time when costs are being scrutinised, moreover when these costs are not necessary.

However, Microclean has added redundant low cost safety to their spray device. The unique trigger head only allows air to enter the bottle through an integral Gore filter, thus ensuring the integrity of the IPA/WFI solution is maintained throughout usage.

The tamper-proof neck connection ensures both a hermetic seal is formed without torque (a problem sometimes encountered with threaded neck designs) and that the trigger head is non-removable, ensuring that bottles cannot be re-used or refilled.

Ergonomics

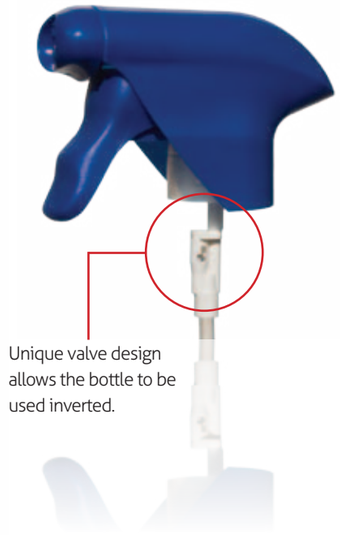
Based on guidance produced by the Health and Safety Executive and The Canadian Centre for Occupational Health & Safety, it is clear that improvement can be made to bottle/trigger designs to both avoid repetitive strain injuries and to improve the ease of using the devices.

Consequently Microclean have developed an ergonomic trigger spray, and offer this in two sizes:

- 500ml nominal capacity
- 950ml nominal capacity

The 950ml unit feels slightly smaller than many on the market due to its shape. It is far more ergonomically pleasant to use and thus more efficient.

Additionally the product can be used in an inverted position minimising strain on the hand or wrist during use.



Unique valve design allows the bottle to be used inverted.

[1] Soltis, Hollands and Spivey, ITW Texwipe April 2006 "Is Your IPA Bottle Doing More Harm Than Good?"
[2] "Broth Fill Testing of the Microclean Compliance 100® Trigger Spray System" - G. Cochran, Microclean RD&T©