

**VERIFICATION OF AN AEROSOL LEAK DETECTOR
FOR THE ALTERNATIVE TO THE WATERBATH METHOD
FOR
RAUPACK LIMITED**

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BY

BURGOYNE CONSULTANTS LIMITED

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1. INTRODUCTION

Raupack Ltd. wish to market an aerosol microleak detector, the Aerocan 100, and reject system in the UK which will form a key element of the UN approved alternative test method for aerosol testing to ensure aerosols leaving an aerosol filling operation are safe for transport and safe to the consumer.

Raupack have approached Burgoyne Consultants Ltd. (BCL) to verify that their machine complies with the UN requirements as set out in The European Agreement concerning the International Carriage of Goods by Road, ADR 2007.

The machine which Raupack wish to market is manufactured in Germany by Bautz Engineering and is of a type which has been in use at Biersdorf, an aerosol filler, for over 25 years, providing leak detection post water bath on lines where line speeds preclude visual identification of leaking aerosols.

Bautz Engineering have been manufacturing machinery for the pharmaceutical, cosmetic and aerosol industries since 1947.

2. BACKGROUND

Aerosol dispensers (aerosols) have been in commercial production for around fifty years. Aerosols use pressure from liquefied, or permanent gas (propellant) to provide the driving force to dispense the product from the aerosol can. The internal pressure from the propellant means that aerosol cans store a significant amount of energy which, if suddenly released (i.e. a bursting can), would have the potential to give rise to high velocity missiles (can fragments). In addition the liquefied gas propellants commonly used are highly flammable (e.g. propane / butane mixtures, or dimethyl ether (DME) and if these are released either due to a leak from a can, or due to a can bursting, they may pose fire and explosion hazards. In manufacture of aerosol products it is therefore necessary to confirm that the containers are acceptably leak tight and pressure stable, so that when they are stored, transported and sold to the public there is minimal risk of them causing injuries or property damage through bursting or leaking (i.e. resulting in a fire / explosion). In regulatory terms this means complying with EU and international transport regulations for dangerous goods and the Aerosol Dispensers Directive (75/324/EEC).

Investigations in the 1940s found that, during transport and distribution in hot climates, pallet loads of aerosols may experience temperatures of up to 55°C. This led to the development of the hot water bath test to ensure that no filled aerosols would burst after leaving the factory. Using this test method every filled aerosol is immersed in a hot water bath to allow the contents to equilibrate at the bath temperature, subsequently the hot water bath test has also been used to detect leaking aerosols by monitoring for bubbles of gas escaping whilst the aerosols are immersed. Studies have shown that this test can detect leak rates of 1×10^{-2} mbar.l.s⁻¹. Leaks below this rate are deemed not to present a fire risk in transport, distribution or consumer use.

In the 1990s, the European Aerosol Federation (FEA) investigated possible 'alternative methods' to the hot water bath and concluded that for an 'alternative method' to be acceptable it must be shown to be as effective as the hot water bath test at eliminating faulty and leaking aerosols. In 2002, to demonstrate this principle FEA developed the 'FEA alternative method', based on the principle that quality assurance and on-line testing may be used to ensure that all sub-standard aerosols are eliminated before they leave the filling line.

Following validation FEA presented the work to the UN Sub-Committee of Experts on the Transport of Dangerous Goods which accepted that the 'FEA alternative method' provides an equivalent level of safety to the hot water bath test.

The UN Committee agreed to insert a framework for acceptable 'alternative methods' into the UN 2005 Model Regulations for the Transport of Dangerous Goods. The option to use an 'alternative method' to ensure that filled aerosols are safe to be transported as 'dangerous goods in limited quantities' has been implemented in the EU in the 2007 modal transport regulations (e.g. The European Agreement Concerning the International Carriage of Dangerous Goods by Road ADR 2007) and so in national law in all Member States by 1 July 2007.

In the UK, the Department of Transport (DfT), which is the UK competent authority for ADR 2007, has indicated that any filler who can demonstrate that it has in place an 'alternative method' complying with the requirements of ADR 2007 may apply to use it.

To take advantage of this derogation, the filler will need to verify that their 'alternative method' provides an equivalent level of safety to the hot water bath test. Currently the only 'alternative method' that has been demonstrated to comply with the requirements set out in ADR 2007 is the one developed by FEA which has three key elements:

- A Quality System that ensures all aerosols that leak or are deformed are rejected and not offered for sale.
- Pressure testing of all empty aerosols to ensure that they do not deform when filled and leak at a rate less than $3.3 \times 10^{-2} \text{ mbar.l.s}^{-1}$.
- Leak testing of all filled aerosols so that they do not leak at a rate greater than $2.0 \times 10^{-3} \text{ mbar.l.s}^{-1}$.

The Aerocan 100 leak detector which Raupack wish to market will have to conform with the latter key element above in order to be instrumental in demonstrating compliance with the approved 'alternative method'.

Furthermore, as the UK is the intended market it would be beneficial if the machine also conformed to the British Aerosol Manufacturer's Association (BAMA) standards. Whilst not a legal requirement, the BAMA standards lay down a guide to best practise which is accepted as such by the HSE.

3. **RISK ASSESSMENT**

3.1 **Flammable Atmosphere**

Due to the quality assurance requirements for aerosol cans to have passed a pressure test prior to filling under the Alternative method and the quality controls on filing and crimping etc., the likelihood of a major can failure is effectively managed, especially when compared to the water bath which is a live pressure test with hazardous materials.

Any remaining leaking cans will be leaking at a very low rate if at all.

The Raupack machine enclosure is designed to be ventilated so as to prevent a flammable atmosphere building up and the machine is interlocked such that it can only run with the ventilation. Furthermore the machine is fitted with Lower Explosive Limit (LEL) probes, configured to safely shut-down the machine before the LEL is reached.

The number of aerosol cans entering the machine is controlled to a minimum, and their residence time in the machine is extremely short, especially in comparison to the water bath.

As such the ventilation can therefore be considered as high degree with regard to the possible release source and its availability can be considered as good.

3.2 **Flame Ionisation Detector**

The Raupack machine utilises a flame ionisation detector (FID) to measure and evaluate leaks. Such detectors are well known to be sensitive and yet robust against poisoning, and have been used in the chemical industry for many years.

Hydrogen is burnt in very small combustion chamber into which a sample is introduced. The sample is completely destroyed and any ions produced are detected.

Combustion devices fall outside of the scope of DSEAR. Flammable atmosphere inside the FID are controlled by burner management to avoid accumulation of unburnt or incomplete combusted gases:

- The system is pre-purged to avoid flammable atmospheres during start-up.
- The fuel enters the combustion chamber in such a condition that it will ignite readily and burn efficiently (e.g. correct gas pressure).
- The fuel does not enter the combustion chamber unless a source of ignition is present that will ignite the fuel without delay.
- The fuel supply is shut off automatically if the flame is extinguished and manual attention must be required before the fuel supply can be re-established.
- Adequate ventilation is available, so that once the fuel is ignited it is burned completely, and so that the products of combustion are removed from the combustion chamber.

With the highly reliable burner management, failure is considered a catastrophic event not warranting area classification.

Flash-back is suitably protected against by flame arrestors, thereby avoiding the FID acting as an ignition source within the general machine enclosure.

3.3 Hazard

The residual hazard is limited to an unlikely but possible fire from a slow leaking can within the machine.

Operators cannot access the interior of the machine enclosure without causing the machine to shutdown.

3.4 Reject Bin

Although not a direct component of the leak detector the associated reject bin needs consideration.

The reject bin will periodically contain aerosol cans which are leaking at greater than 2×10^{-3} mbar l/s although it will not contain bursting aerosols as the reject bin from a water bath might.

The interior of the reject bin should therefore be ZONE 1 and be surrounded by a ZONE 2 extending 1m vertically and 1m horizontally and down to solid floor level.

The Raupack machine includes a reject signal for a mechanism to be sited at least 1m from the microleak detector enclosure to ensure that the detector lies outside of the zoned area of the reject bin.

3.5 Basis of Safety

The basis of safety for the Raupack detector is therefore avoidance of flammable atmosphere and control of ignition sources.

Following the BSEN 60079 : 10 standard for hazardous area classification, the interior of the Raupack enclosure can be considered non-hazardous with regards to zoning.

This does not affect the zone exterior to the machine, i.e. the zone of the area in which the machine is to be sited. This exterior zone will have to be assessed on a site by site basis by each operator.

3.6 BAMA Standard

The BAMA standard provides a framework to demonstrate that all of the hazards that could arise from aerosol operations have been considered and that action to ensure that the risk of these hazards being realised have been reduced to an acceptable level.

In module 3.3 of the BAMA standard, BAMA state:

“When filling aerosols with flammable gases and liquids, an explosive atmosphere could be generated if accidental release occurs during any part of the aerosol filling process. This represents a major hazard and so is a key part of the DSEAR Risk Assessment of the operation. As a result of the risk assessment, each part of the aerosol filling line should be zone classified.

An area is non-hazardous when explosive vapour / air mixtures are not expected to occur; hence zoning is not necessary where only non-flammable product and propellants are filled. The risks for small-scale installations should be considered to be exactly the same as for larger operations. For operations using flammable products and / or propellants, the following area classifications should be considered.

- **Zone 1** – *within the primary enclosure of aerosol gassing machines, the product filling machine (depending on the product using e.g. alcohol), the propellant and product service connections, the water bath and any bins containing aerosols rejected from the production line.*
- **Zone 2** – *all machine enclosures on the aerosol filling line not classed as Zone 1 and all transportation routes of the aerosol up to the water bath or leak tester. Possible faulty or abnormal conditions include puncturing of containers by starwheels, so downstream equipment such as the actuator placing and capping machines should be considered for classification as Zone 2.”*

BAMA also state that:

“the objective of Module 3.3 is to ensure the safety of an aerosols filling operation. The approach taken is to prescribe the level of safety and to offer a set of Good Practice requirements as a means of achieving that level of safety. However, it may be possible to achieve the prescribed level of a particular activity using an alternative approach to the one set out in the requirements. Such cases will be in compliance with The BAMA Standard if the approach is fully documented and supported by a risk assessment that shows the level of safety achieved is at least that achieved by complying with the Good Practice requirements.”

Therefore as explosive vapour / air mixtures are not expected to occur inside the enclosure due to the controls on the Raupack detector, the BAMA standard allow the area inside the enclosure to be designated non-hazardous.

BCL conclude that whilst the Raupack machine complies with the requirements of the BAMA standard, its installation is not any guarantee that the entire operation is then wholly in compliance.

4. TEST WORK

4.1 Visit to Bautz Engineering 31st January 2008

The purpose of this visit was to examine the design of the machine. Items discussed included:-

- choice of detector
- calibration issues
- data logging and security
- safety features
- internal and external Quality Assurance

The issues raised have been incorporated into the following documents:

- * Leak Tester, Hardware Design Specification Document No. 07-273-002
- * Leak Tester, Functional Specification Document No. 07-273-001
- * Leak Tester, Appendix Document No. 07-273-003
- * Leak Tester, Installation Qualification Document No. 07-273-004

During the visit evidence of the Quality Assurance System was presented from a previous project ref. T28000. There was complete traceability and all corrective actions and tests were completed in line with GMP for the pharmaceutical industry.

Also during the visit a video was presented of the machine in question at Biersdorf running at 200 cans per minute.

4.2 Visit to Bautz Engineering 25th July 2008

The purpose of this visit was to witness the Factory Acceptance Test as defined in document number 07-273-004, performed on a built machine in the factory prior to dispatch to a filler.

Leaking aerosols were simulated by fitting a control device to the valve on an aerosol can. This device was set to allow one 1mm diameter bubble to be released every second which equates to a leakage rate of 5.24×10^{-4} mbar.l/sec. These test cans were checked before and after each test run. Whilst there is liquid propellant inside the aerosol, the aerosol internal pressure will be constant and therefore the leakage rate can be expected to be constant.

The leaking cans were reliably detected and rejected when placed at random positions within each run, and for every can size tested.

A random sample of machine components were checked and found to have been supplied by reputable manufacturers and subject to a QA system.

A number of minor non-conformances were noted and auctioned to Raupack / Bautz.

4.3 Visit to UK Site 12th September 2008

The purpose of this visit was to witness the machine at a fillers site in the UK to verify all the non-conformances had been completed and to verify that the machine is capable of fulfilling the requirement of ADR 2007.

During the visit all the non-conformances previously noted were confirmed as having been completed satisfactorily. All safety devices were checked and confirmed to be operational and fail-safe.

As before, leaking cans were reliably detected and rejected.

The original manufacturer's user manual was inspected and found to be satisfactory giving details of installation, usage, maintenance and calibration required in the users' language.

5. CONCLUSION

- 5.1** The machine as supplied by Raupack designated Aerocan 100 (the machine) is capable of fulfilling the requirements of ADR 2007 of a leak tester for filled aerosols as part of the approved alternative to the Water Bath method.
- 5.2** The machine has sufficient controls in place so as to present minimal risk of explosion.
- 5.3** The machine can be considered to avoid flammable atmospheres in normal operation by design thereby presenting no additional zoning requirement to its environs, and having an internal zone classified as non-hazardous.
- 5.4** The machine can be considered as complying with the BAMA standard.
- 5.5** The machine by itself does not ensure complete compliance with the ADR 2007 alternative to the Water Bath method.
- 5.6** BCL conclude that the Raupack machine itself complies with the requirements of the BAMA standard however compliance of the entire operation is dependant on further measures and therefore not guaranteed by its installation alone.

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