

CLEANROOM THERMAL PAPER

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INTRODUCTION



Climet frequently receives questions about cleanroom thermal paper. The following is offered as general information, and each Quality Manager should make the appropriate determination for using either thermal paper, cleanroom thermal paper, or none at all.

Poly synthetic thermal biaxial oriented polypropylene paper, or simply, **cleanroom thermal paper**, is made of a polypropylene, or a plastic film with a thermal sensitive coating that turns black when heated. This type of paper is designed not to generate particles when cut. It is *not* sterile, since heat (autoclaving), irradiation, and chemicals will activate the thermal coating or quickly degrade the thermal properties. Cleanroom thermal paper is manufactured in a controlled environment, and after being cut into

appropriate widths, is cleaned with compressed air to remove particulates.

Cleanroom thermal paper differs from standard **thermal paper**, in that the latter can contribute to the particle burden of the cleanroom, particularly when cut or torn.

Cleanroom thermal paper also differs from **cleanroom paper**, in that the latter is manufactured from polyethylene, has no thermal coating, and can subsequently be autoclaved, irradiated, and cleaned by chemicals.

Limited Shelf Life

Storing thermal products requires you to make a few special concessions. For example, they need to be kept in dark areas as it will also degrade quickly when exposed to UV light. Thermal paper should also be stored in a place that has a relative humidity of 45 to 60 percent, and the temperature should be kept between 68- 77° Fahrenheit.

In most cases, if you can maintain these temperature, humidity, and light requirements, you can expect a satisfactory performance from your thermal paper roll for approximately **three years** after it has been manufactured.

Limited Image Life

After you have printed on the thermal paper, it is expected that the image is going to remain legible for a period of at least seven years. This is with the assumption that the document is stored properly and that the above temperature, humidity, and light specifications are maintained.

Fade Resistance

The majority of thermal products utilize co-reactant and dye technology to create the image or text. The combination is sensitive to UV light and may suffer from some image decline if it is continually exposed to office light or sunlight. The stability of the image created is going to depend on the original image developed, the intensity of UV light present, and the individual product design. If the paper is exposed to UV light for a prolonged period of time, sheet discoloration may also occur.

Contact Storage

It is highly recommended that the thermal paper not be exposed to the following materials for best results:

- Any type of organic solvent (ethers, esters, ketones, alcohol)
- Cleaning fluids
- Plasticizers
- Petroleum solvents
- Carbon papers
- Wet-type diazo copy paper
- Cast coated papers
- Water
- Certain oils
- Ammonia
- Carbonless paper solvents
- Other thermal systems

An exception to these general guidelines would be any type of thermal paper that has been specially coated.

The majority of thermal papers, regardless of who manufactured them, are susceptible to damage from the items listed here. The bottom line is that if you don't store your thermal paper properly, or if you don't keep it in the right conditions, issues may arise.

Even then, thermal paper has a limited life.

Data Integrity Concerns

In regulated cleanrooms, there is an additional concern regarding Data Integrity. Using printed sample data records, and manually transcribing this data into a database introduces human error into your process.

The sample data should be automatically exported to a secure directory on the network and backed-up with a RAID-5. Here, the sample data is stored, generally for the manufactured life of the product. Climet also has software solutions to ensure sample data is a true and original copy. In particular, Climet

offers a very affordable DataPro 2.5e software solution that's also capable of trending data, generating reports, etc. Lonzo Moda™, and Climet's USB Translator utility will also comply with 21 CFR Part 11, provides the ability to determine if sample data is invalid or has been manipulated.

Based on **best practices** for the regulated industry, (1) no paper records are used and manual error-prone processes are eliminated; (2) Full 21 CFR Part 11 compliance; and (3) device integration and direct download of sample data.

More information about particle counter [data integrity](#) is provided here.

Risk Assessment & Conclusion

Use of thermal paper or cleanroom thermal paper should be justified by the end user's risk assessment, and it's use should also be considered on a case-by-case basis.

Regarding use in laboratories engaged in the manufacture of medicinal products, consideration should be made on the basis of whether the drug product is topical, enteral, or parenteral. Cleanroom classification should also be considered, and whether or not the clean area is considered aseptic, or not. Use of thermal paper or cleanroom thermal paper introduces certain risks into the process, which must be carefully assessed. For these reasons, Climet highly recommends no paper in critical processes and sample data be uploaded at the end of every shift for sequential monitoring applications.

Climet Part Numbers

	Description	Part Number
Climet Portable Particle Counters	Standard Thermal Paper	76002800
Climet Portable Particle Counters	Cleanroom Thermal Paper	76002801

Sold by the role, and each role is sealed.



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