

T&T Sensitive Label FAQ

What is a "healthcare product"?

Healthcare products are all drug products or substances that include - but are not limited to - raw material, active pharmaceutical ingredients (API), excipients, medical devices, biological products, plasma, clinical trial materials or any product identified by the healthcare shipper, at the time of shipment, as temperature sensitive.

Should the label ruling applies only to healthcare products or applicable to any type shipment requiring temperature control, regardless of the industry?

The mandatory Time and Temperature Sensitive label is foreseen specifically to the healthcare industry and must be affixed to all shipments booked as temperature controlled cargo.

Which services require the label and which services do not require the label?

Shipments requiring temperature-controlled service, which have also been booked as such must be labeled with the Time and Temperature label. The requirements apply to air cargo/freight shipments related to an Air Waybill number booked as time and temperature sensitive shipments. The requirements of Perishable Cargo Regulations (PCR) Chapter 17 do not apply to airmail, parcel or passenger/courier bags.

To what does the temperature range on the label relate?

The temperature range indicated on the Time & Temperature Sensitive label always reflects the temperature external (or ambient temperature) to the package allowed during transportation and distribution and not the actual product (internal) temperature.

Does the label guarantee that my shipment will be transported in the requested temperature range at all times?

The correct usage and affixing of the label only, does not guarantee that the shipment will be transported at the required temperature range at all times. This will depend on the booked service, on the established SOP and on the airlines/transporter's infrastructure and capabilities.



Do the IATA T&T Sensitive Label requirements also apply to domestic shipments?

The IATA Time and Temperature Sensitive Label requirements apply to domestic and international shipment, as the temperature-controlled service booked would be the same whether the shipment is sent domestically or internationally.

How should be handled shipments using dry ice (carbon dioxide solid) as a refrigerant?

Dry ice is classified as "dangerous goods" when used as a refrigerant and it is therefore necessary to refer to the IATA Dangerous Good Regulations for details of additional labeling and marking requirements (Perishable Cargo Regulations PCR Chapter 17 section 17.10.6.1).

A dry ice shipment could be considered as time and temperature sensitive healthcare shipment depending on the commodity transported and service booked. If it is a healthcare shipment using dry ice as a refrigerant and was booked with temperature-controlled service then it would have to be labeled with the Time and Temperature Sensitive label. The requirement of a 24 hours emergency contact number would apply.

What are the risks of adverse exposure?

Exposures to temperatures outside of that range can and will occur during normal air cargo operations and sufficient protection must be provided by the shipper to mitigate those risks.

Who is responsible for placing the label on the shipment? Can the shipper also delegate this to a subcontractor?

It is the responsibility of the shipper (or designated shipper's agent by service agreement) to ensure the label is applied properly for time and temperature sensitive healthcare cargo shipments booked as such.

Where can I get the label?

The label can be purchased using the following link on the IATA website: <u>Handling Label</u>.

What do I have to put on the bottom half of the label?

The lower half of the label must never be left blank and indicate the external transportation temperature range of the shipment. The temperature range must only be shown in Celsius.



No other temperature information must be indicated on the label except, when agreed between the parties it may be used to communicate the Standard Operating Procedures (SOP) number.

Can the transportation temperature range be inserted manually (hand written) on the lower half of the label?

The transportation temperature range indicated on the label can be hand written as long as the temperature is visible, legible and sufficiently durable to withstand normal transport conditions.

In all cases, the temperature range must only be shown in Celsius and the text should be in English.

What do I put on the bottom half of the label if I use passive packaging with an expiration date where the transportation temperature must be changed after a certain date or in case of a delay?

The transportation temperature range must be indicated on the lower half of the label and exceptions related to the transportation would be mentioned in a specific standard operating procedure (SOP).

If the lower half of the label must indicate the transportation temperature range, how should be handled the indications "keep frozen" or "do not freeze"?

The commonly accepted transportation temperature ranges, or indications are subject to airlines' acceptance. The reason why a transportation temperature range should be mentioned on the label is to have clear instructions as to how the shipment should be handled.

The indications "keep frozen" and "do not freeze" still exist and can be included in bilaterally agreed SOP and/or SLA between the supply chain partners.

Can I leave the bottom half of the label blank?

It is not allowed to leave the lower half of the label blank. In the event that the shipper fails to complete the lower half of the label or, in case of discrepancy, the transportation temperature indicated on the Air Waybill prevails.

Can the label be affixed to shipments that are time and temperature sensitive but have not been booked as such with the air carrier?

The initial booking triggers the specific handling and as such the label only supports the booking, thus if a product has a label but the appropriate service was not booked, airline will treat is as general cargo.



The label give carriers the opportunity to crosscheck the transportation temperature indicated on the Air Waybill (or on the SOP or SLA if no temperature is mentioned on the Air Waybill) and use the 24-hour emergency contact number to confirm / correct the service booked.

Shippers should contact their carrier to confirm how labels will be handled.

What information do I need to put on the Master Air Waybill to match the use of the label?

There must be one temperature range that is identical on Air Waybill, Booking and on the Label. The label only supports the booking, thus the transportation temperature range specified on the label must match the transportation temperature range stated on the Air Waybill, Service Level Agreement (SLA) or Standard Operating Procedures (SOP). In case of any discrepancy, the transportation temperature range indicated on the Air Waybill prevails.

When using the label should an individual SOP with the Carrier be established or is the Carrier's standard SOP enough?

The Standard SOP would apply. However often now, carriers offer a branded service with defined procedures based on Good Distribution Practices (GDP) and developed to meet the needs of that type of temperature sensitive product. Any variation in this process is bilaterally agreed between the supply chain partners and defined in either an SOP or SLA.

Where do I put the label on my shipment? On each piece? On how many sides?

The label, when used, must be affixed to at least one side panel of the outermost visible means of containment. Labels on packages within a palletized shipment must be clearly visible or else be reproduced on the outer package. Shipments that require to be split or broken down should have labels applied to every outer package.

For situations where more than one label would be useful, for example in palletized shipments, it is permissible to use the label on as many sides as desired in order to enhance visibility of the label – and the temperature instructions printed on it. Note that there is a risk that a palletized shipment may be subject to a TSA or other regulatory inspection, which may require the removal of the stretch wrap and subsequent destruction of the label. If the label is applied to the stretch wrap it may be unusable. If transparent stretch wrap is used the label may be applied to the carton but visible through the stretch wrap.

As a last resort, pouches are also permitted as an option so that labels could be removed and reinserted to a pouch under this scenario. When an operator discovers that labels have become lost, detached or illegible, he should replace it them in



accordance with the information provided on the Air Waybill, Service Level Agreement (SLA) or Standard Operating Procedures (SOP) or as bilaterally agreed.

Should the loose boxes within an active container be labeled as well?

The shipment inside the active temperature controlled container may be labeled with the required transportation temperature range, in order to provide information in case removed from the active temperature controlled container.

Do I also have to place the label on the active containers and if yes, where?

Time and temperature sensitive healthcare cargo shipments transported with Active Temperature Controlled Containers must be labeled with the standard IATA "Time and Temperature Sensitive" label. Carriers or container manufacturers may incorporate the Time and Temperature Sensitive label into the IATA ULD label or tag already in use. The lower half on the label must be used to indicate the external transportation temperature range.

What happens if conflicting labels are affixed on the shipment?

Labels required by other international or national transportation regulations are permitted in addition to labels required by these Regulations, if they cannot be confused with or conflict with any labels prescribed by these Regulations, because of their color, design or shape.

Where can I include additional instructions for my passive shipments?

The IATA Time and Temperature Label is only to be used to indicate the transport temperature (or SOP number) for shipment booked as temperature controlled. Any other instructions should be placed outside of the label. These instructions should not conflict with the instructions on the IATA label and need to be agreed to by all parties involved.