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## Inspections, Compliance, Enforcement, and Criminal Investigations

### A.T.I. Steam Activated Heat Sensitive Indicators

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**DEPT. OF HEALTH, EDUCATION, AND  
WELFARE PUBLIC HEALTH SERVICE  
FOOD AND DRUG ADMINISTRATION  
\*ORA/ORO/DEIO/IB\***

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#### ITG SUBJECT: A.T.I. STEAM ACTIVATED HEAT SENSITIVE INDICATORS

Part 128b.5(b) of the Low-Acid Canned Food GMPs requires that food processors mark all retort baskets, trucks, cars or crates containing unretorted food products or some of the containers on top of each basket with a heat sensitive indicator or by other effective means. Heat sensitive indicators are used to provide assurance that a retort load has not by-passed the retorting operation. Heat sensitive indicators are offered commercially in various forms including paints, lacquers, crayons, pellets, tapes, labels, and inks. Crayons, pellets, paints and lacquers change form or surface texture upon reaching a specific temperature. Some tapes and labels have an area that turns black upon reaching a certain temperature. This is accomplished by overlaying a thin sheet of black absorbent paper with a material of known melting point. When the melting temperature is reached, the cover sheet is absorbed into the paper so that the black indicating area can be seen. Other heat sensitive tapes are color coded and are available with stripes or other indicators that appear after the tape reaches a specific temperature. Except for the inks, all the indicators mentioned indicate only that a specific temperature has been reached at the location of the indicator and do not relate to time. In contrast chemical inks change from one color to another indicating that a particular time/temperature/steam condition has occurred.

The steam activated heat sensitive indicators most commonly observed in food processing plants are the Aseptic Thermo Indicator (A.T.I.) Company Cook-Chex [{{Registered Trademark}}](#) (Figure 1)<sup>4</sup> chemical indicator tags. The Cook-Chex [{{Registered Trademark}}](#) has been in use for over ten years but has recently received increased exposure with the advent of the Low-Acid Canned Food GMPs. The Cook-Chex [{{Registered Trademark}}](#) (Figure 1)<sup>5</sup> is a cardboard tag impregnated with a purple chemical indicator that changes to green when various conditions of time and temperature in a pure steam atmosphere are reached. The purple pigment is a chromium- chloride complex which is purple in its anhydrous form. When exposed to an atmosphere of pure steam this complex first picks up six molecules of water and with further exposure to temperature for a specified time a molecular shift takes place and the color changes to green \1\ . The Cook-Chex [{{Registered Trademark}}](#) will not react to dry heat.

Figure. 1<sup>6</sup>

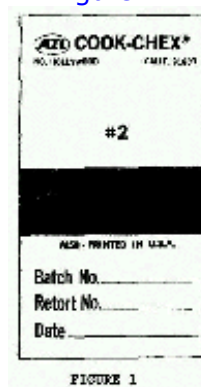


FIGURE 1 7

(image size 37KB)<sup>8</sup>

The Cook-Chex **Registered Trademark** was developed primarily for a 250 F sterilizing temperature, but will react at other time/temp combinations. There are presently fourteen standard Cook-Chex **Registered Trademark** time/temp formulations available. The various time/temperature Cook-Chex **Registered Trademark** formulations are identified by a number (1-14) printed on the upper half of the tag. The numbering is a recent improvement. The old Cook-Chex **Registered Trademark** tag formulation could only be identified by a small batch number on the face of the tag. In the past, if the tags were separated from the shipping paperwork, the company had to be contacted in order to correlate the batch number with the time/temp formulation. The various time delays are accomplished by addition of a temperature related retardant.

Figure. 2<sup>9</sup>



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(image size 21KB)<sup>11</sup>

The A.T.I. Steam-Clox (Figure 2)<sup>12</sup> is a steam activated autoclave sterilization indicator using the same chemical composition as the Cook-Chex **Registered Trademark**. The Steam-Clox consists of four purple sections which turn green to indicate that the indicator has been exposed to a time/temp interval in pure steam for progressive periods of time. The Steam-Clox number one section is equivalent to the #2 Cook-Chex **Registered Trademark**, the number two section is equivalent to the #3 Cook-Chex **Registered Trademark**, the number three is equivalent to the #4 Cook-Chex **Registered Trademark** and the number four is equivalent to the #8 Cook-Chex **Registered Trademark**. The Steam-Clox was designed to indicate conditions of understerilization and oversterilization.

Figure. 3<sup>13</sup>



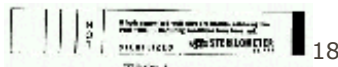
14

(image size 22KB)<sup>15</sup>

The A.T.I. High Temp (Figure 3)<sup>16</sup> sterilization indicator was developed for the high temperature type

sterilizers (270 - 275 F). This tag contains a single spot of chemical indicator with formulation and reaction similar to the Cook-Chex [{{Registered Trademark}}](#) and Steam-Clox.

Figure. 4<sup>17</sup>



(image size 26KB)<sup>19</sup>

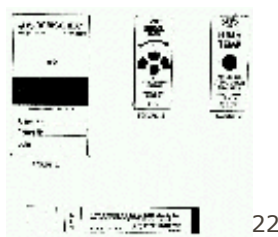
The A.T.I. Sterilometer (Figure 4)<sup>20</sup> is a steam activated indicator with narrow and wide bars that change color from white to black when conditions of time/temp have been met in a steam atmosphere. The wide bar is overprinted with the word "NOT" so that initially the Sterilometer reads "Not Sterilized". When steam penetrates the narrow bar it turns black providing a comparison color. The wide bar turns black, obscuring the word "NOT", when the correct conditions of time/temp/steam have been met. An excessively wet steam environment will cause the Sterilometer to change a grey color instead of black. \2\

The A.T.I. chemical indicator time/temp reactions are based on ideal conditions (exposure in a pure steam atmosphere). Conditions other than this and variations in application and formulation of the chemical agent can cause the indicators to show an incomplete reaction or to react too quickly. For example, a processed Cook-Chex [{{Registered Trademark}}](#) that shows blotches or specks of purple over the indicator area may indicate that the process temperature was too low, the time too short, an air-steam mixture, the wrong Cook-Chex [{{Registered Trademark}}](#), or a defective Cook-Chex [{{Registered Trademark}}](#). Under wet steam conditions the Cook-Chex [{{Registered Trademark}}](#) and Steam-Clox turn a blue-grey color. If the Cook-Chex [{{Registered Trademark}}](#) or Steam-Clox is exposed to dripping or sprayed water a leaching of the indicator chemicals results in an erratic reaction retarding the color change when exposed to specified time/temp/steam conditions. Cook-Chex [{{Registered Trademark}}](#) and Steam-Clox indicators are manufactured in lots of 60,000 to 100,000 and minor variations within a lot in the applied thickness of the indicator chemical ink can cause variation in the amount of time it takes for complete indicator color change. Storage in high humidity and temperature will also effect the reaction time of chemical indicators. Chemical ink indicators should never be used as an indication that commercial sterility of a load of canned food has been achieved; or, in the case of drugs and medical devices, that sterility has been achieved. Although an accurate chemical indicator will show, under ideal conditions, whether a specific time/temp condition was achieved where the indicator was located, their use is limited to providing assurance that a load of canned food (or batch of drugs or devices) has not by-passed the retorting (or autoclaving) operation.

\1\Protection Plus In Canning - Aseptic Thermo Indicator Co. pamphlet.

\2\Principles and practice of Autoclave Sterilization - Aseptic-Thermo Indicator Co., pamphlet, revised 1971.

#### FIGURES 1-4 ASEPTIC THERMO INDICATOR COMPANY STEAM ACTIVATED HEAT SENSITIVE INDICATORS<sup>21</sup>



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(image size 128KB)<sup>24</sup>

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