



COLOUR INDICATOR CHOSEN

Solubility:

1mg/ml in water

Toxicity :

DL₁₀₀ ≥ 500 mg/kg by oral absorption in rats

Background:

This patented colour indicator was selected as it showed to be a broad indicator of microbiological growth. **The compound is reduced by microbial metabolism.**

The exact route of the reduction reaction of the compound due to microbial metabolism was never clearly identified, however publications tend to show that the reduction could be linked to the oxidation of NADH in the mitochondrial metabolism.

Since the color indicator is a Redox chemical component, in anaerobic atmosphere, the absence of oxygen in the environment induces its reduction and the spontaneous color change from pink to yellow.

Change in pH plays a very limited role in the discoloration of the colour indicator: from pH 9,1 down to 5,4 the indicator still keeps its pink colour emitting at 600nm, just with a decrease of the intensity of the colour.

Cleaning:

As an example, the following cleaning procedure has been demonstrated to clean residuals of the colour indicator in an aseptic process:

- **First washing step**
 - o with Purified Water and Detergent (KOH)
 - o 1 200L at 1% KOH at 75°C
- **Second rinsing step**
 - o with Purified Water
 - o 1 500L at 75°C
- **Third rinsing step**
 - o with Water For Injection
 - o 600L at 75°C

