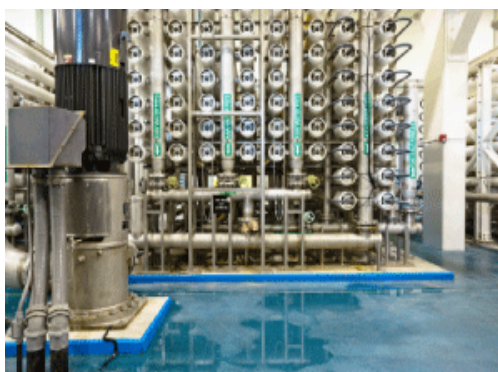


CLEANING VALIDATION



FOOD & BEVERAGE — WASTEWATER — LABORATORY — PHARMACEUTICAL & MEDICAL DEVICE

 **International Products**
CORPORATION

Company Overview

International Products Corporation, incorporated in 1923, manufactures specialty cleaners and lubricants.

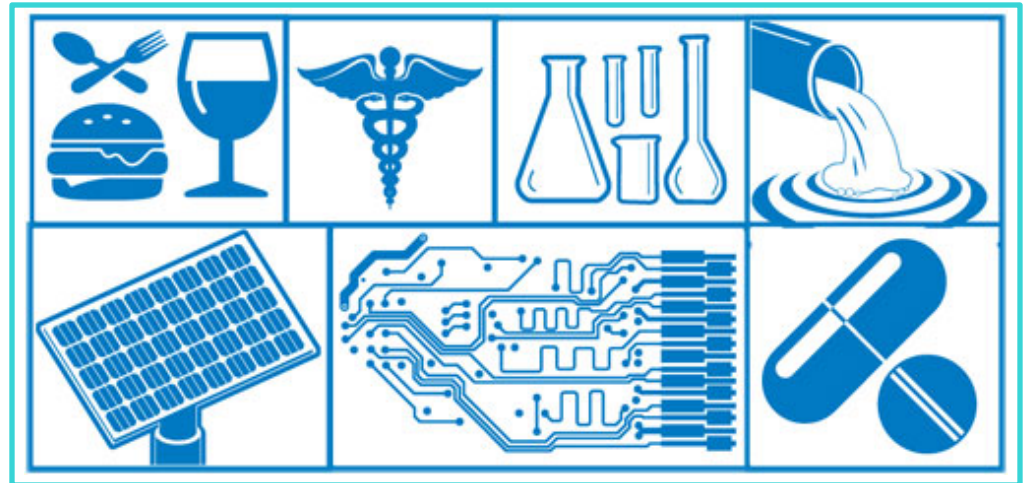
Headquartered in New Jersey with distribution in Asia and Europe. Products available worldwide through our network of global distributors.

An ISO 9001:2008 Certified Company



Cleaners and Validation

- Cleaners are designed to clean a diverse range of hard surfaces
 - Labware, metalworking parts, computer chips, processing equipment, filter membranes, pharmaceutical tanks, implantable devices, and on and on...
- Customers have different cleaning validation requirements



Validation – What Does it Mean?

CUSTOMERS' REQUIREMENTS

FDA vs non-FDA

Detection limits

WHAT'S BEING ANALYZED

Cleaner concentration

Lack of cleaner

Lack of soil

INSPECTION VARIABLES

Cleaner bath

Rinse water bath

Part inspection

Tank/equipment inspection

Swab analysis

TECHNIQUE VARIABLES

Quantitative vs. Qualitative

Basic, visual inspection to the use of analytical instruments



Cleaning Validation Techniques

1. Visual Inspection
2. Foam Test
3. Titration
4. Refractive Index
5. Conductivity
6. Methylene Blue
7. Methylene Blue w/ UV-visible Spectrophotometer
8. Black Light
9. TOC
10. GC/LC/IC



1. Visual Inspection

- Most basic technique
- Checks for soil
- Part inspection
- Water break rinse test
- Immediate results
- Low cost
- Qualitative results
- Gross contaminants
- Subjective
- Operator specific



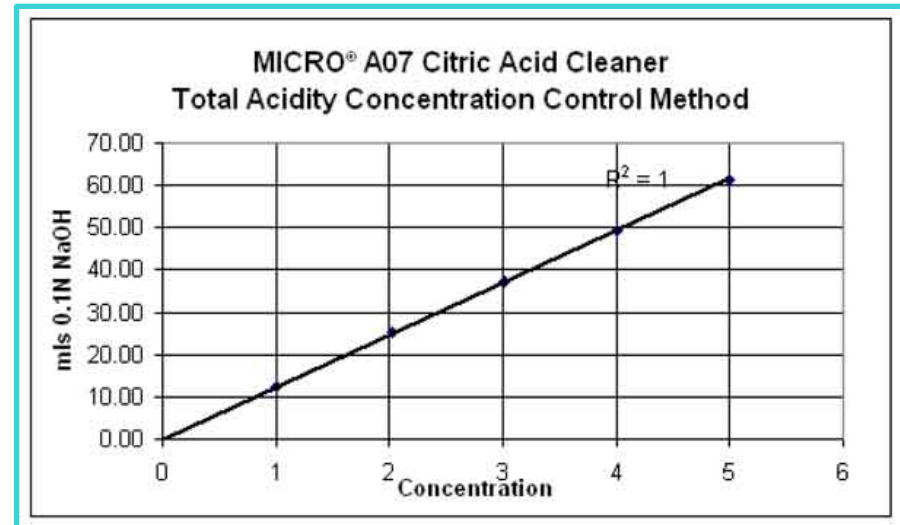
2. Foam

- Checks for cleaner carryover
- Rinse tanks
- Detection limit varies
 - $\sim 0.25\%$
- Quick results
- Minimal costs
- Soils, hard water may interfere
- Subjective
- Operator specific



3. Titrations

- Checks for cleaner
- Quantitative
- Detection limits to ~0.1%
- Quick, easy test
- Calibration curve is easy to develop
- Alkalinity or Acidity titration
- Low cost
- Ideally done in a lab
- Soils may interfere
- May need solvents



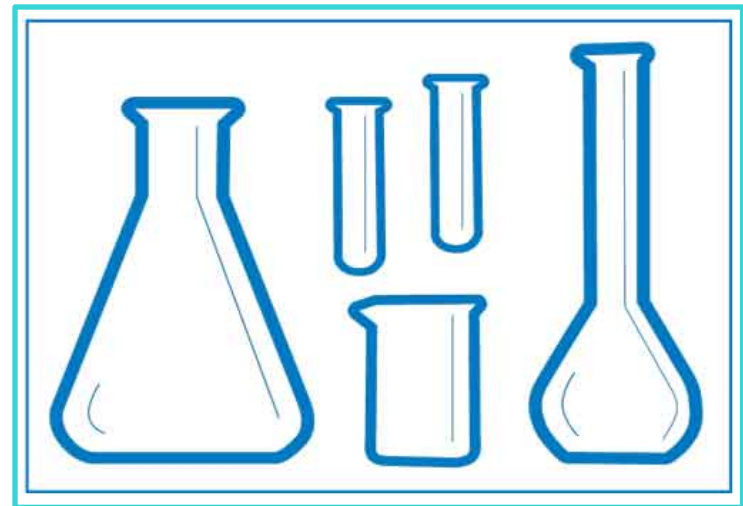
4. Refractive Index

- Checks for cleaner
- Quick results
- Minimal technique
- Can be done tank-side
- Quantitative
- Detection limit ~ 0.25%
- Calibration curve needed
- No disposal costs
- Minimal cost
- Foam, excess soils, cloudy solutions interfere with reading
- Need sufficient lighting



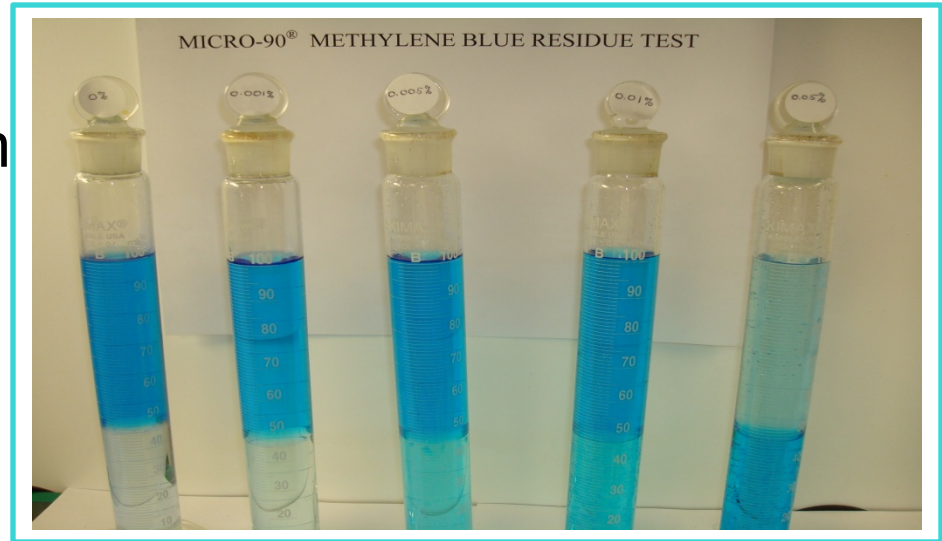
5. Conductivity

- Checks cleaner concentration
 - Immediate results
 - Requires minimal technique
 - Calibration curve
 - Quantitative
 - Detection limits $\sim 0.05\%$
 - Low to moderate initial cost
 - Automated , or hand-held meters
 - Popular with both FDA- and non-FDA regulated companies
 - Sometimes used in conjunction with analytical techniques
- Ideal with deionized water
 - Tap water may be a problem
 - Temperature dependent
 - Not suited for pH-neutral cleaners



6. Methylene Blue

- Checks for cleaner
- Rinse tanks
- Semi-Quantitative
- Detection limit: 10–50 ppm
- Minimal cost
- Quick results
- Subjective
- Ingredient specific
- Need solvent – chloroform or nPB
- Need sufficient lighting



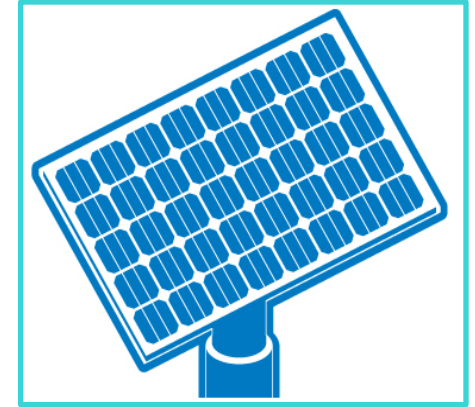
7. Methylene Blue with UV-visible Spectrophotometer

- Detection limit greatly enhanced
 - < 10 ppm detection
- FDA regulated companies
- Not subjective
- Least expensive choice for ppm detection
- Need lab equipment
 - UV-visible; centrifuge
- Calibration curve
- Results in 30 minutes to an hour
- Solvents



8. Black Light

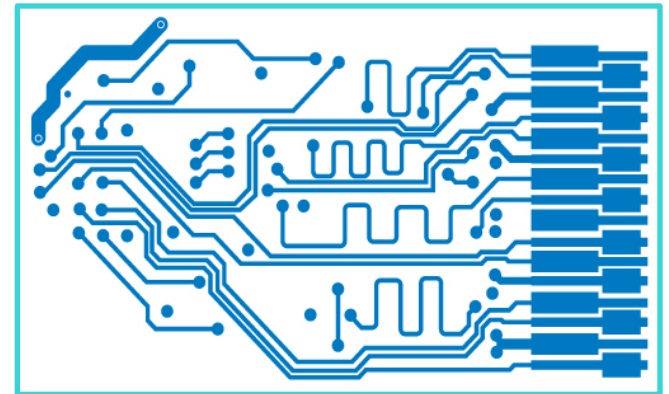
- Checks for soil or cleaner residue
- Common wavelengths
 - 254 nm
 - 366 nm
- Part – soil, cleaner check
- Tank, equipment - coverage check
- Qualitative
- Low to moderate initial costs
- Dark area required
- Cleaner residue or soil may not be fluorescent



- Detection significantly enhanced with fluorescent pigment
 - Works at low concentrations
- Possible hazards with black light
 - Skin, eyes exposure

9. Total Organic Carbon (TOC)

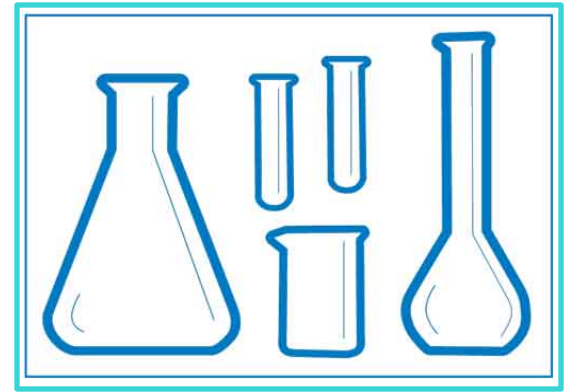
- Checks for organic carbon
- Rinse water or wash water from part
- Quantitative
- ppm detection
- Fast results
- FDA-regulated customers
- Not ingredient specific
 - Result could be cleaner, soil, contaminant
- High initial cost
- Need lab
- Water-based only
 - Solvents interfere



10. GC/LC/IC

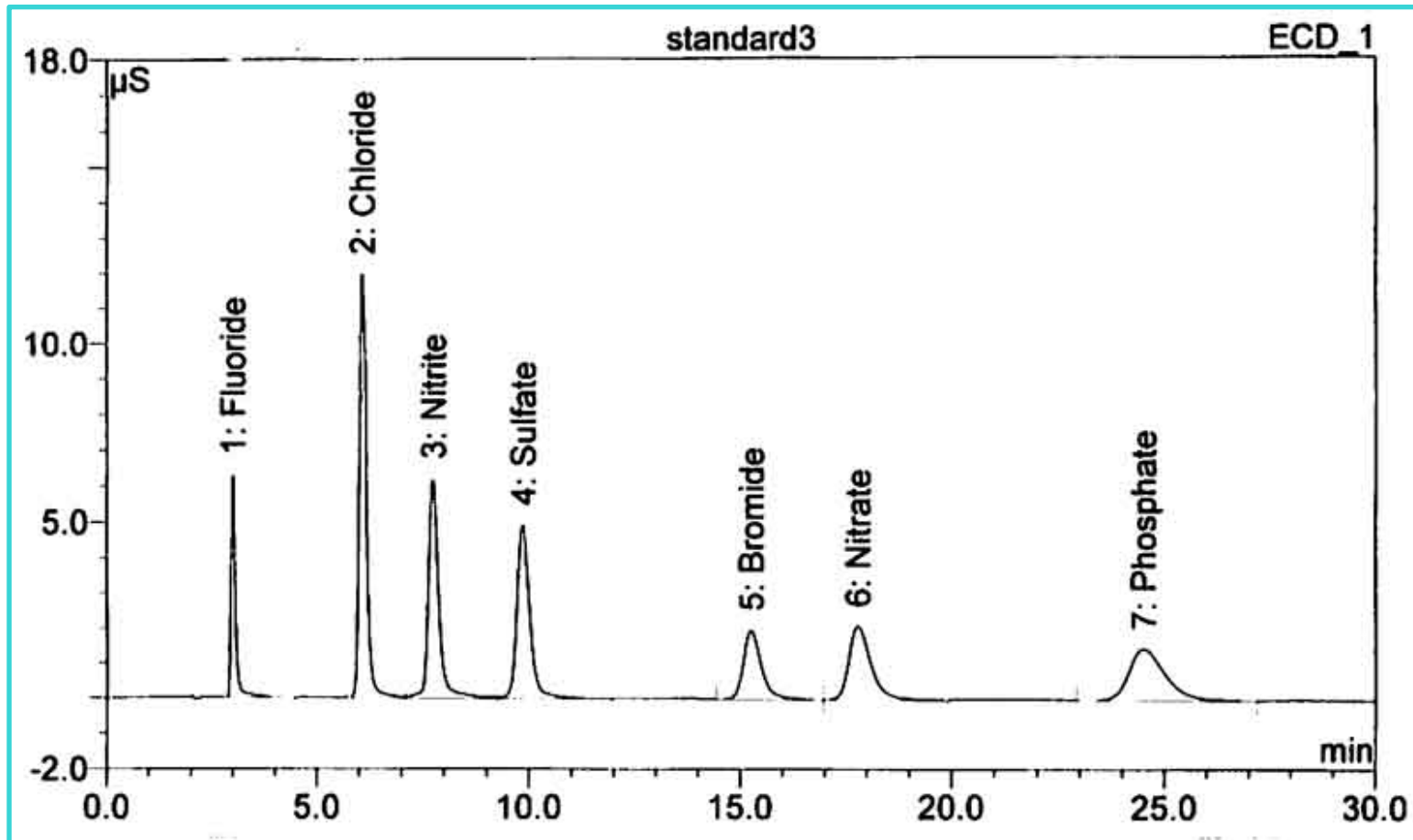
Gas/Liquid/Ion Chromatography

- Checks for cleaner
- Rinse water or swab
- Most versatile techniques
- Quantitative
- ppm or better detection
- Ingredient specific
- Results in several to many minutes
- FDA-regulated companies
- Automated – set-up and let run



- High costs – initial and upkeep
- Solvents, reagents, high purity water
- Need technician
- Method development
- Sample preparation

Typical IC Analysis



International Products
CORPORATION

Contact Us

For a
Cleaning Validation Technique chart
and Validation Methods

Contact us:

by phone: 609-386-8770

by e-mail: mkt@ipcol.com

online: www.ipcol.com

Thank You!

