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Phase™ VTA: Vapor PAA Sterilization

Field Trial with Krones aseptic filler

An innovative proprietary technology for sterilization in aseptic applications

Presented by Pavel Korzinek

March 2, 2018

FMC Global Peroxygens is now

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A highly focused company dedicated to the production and innovation of peroxygen chemistries and adjacent technologies.

Key Markets and Manufacturing Footprint

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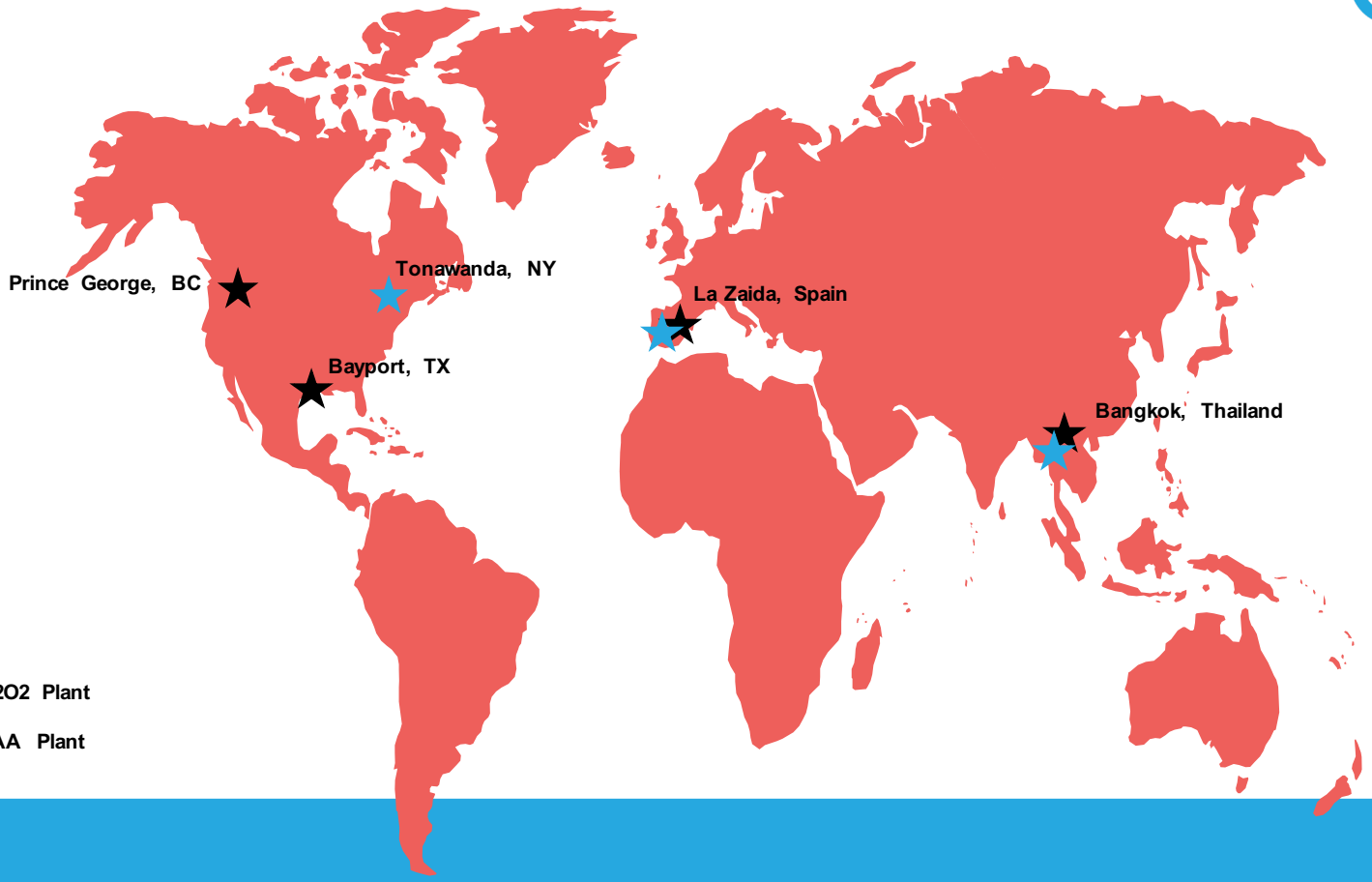
Food & Beverage

Environmental

Electronics

Energy



CHEMISTRY MICROBIOLOGY ENGINEERING REGULATORY

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What is Phase™ VTA?

Phase™ VTA

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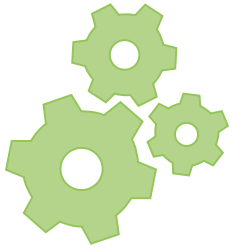
- Phase™ VTA patented sterilant[1]
  - Proprietary Peracetic acid based sterilizing agent
  - Registered in most key markets worldwide incl. EPA/FDA in the US
  - Reduced / eliminated residue

- Phase™ VTA patented technology[2]
  - Proprietary sterilization replacing vapor H2O2 (VHP) sterilization
  - Developed to minimize modifications of the existing VHP equipment

Phase™ VTA = **+** 

Sterilant **Technology**

[1]Patent #8,865,066, [2]Patent #8,696,986, #8,454,890

Chemical Decontamination

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Rinse "Wet" PAA	Vapor H2O2 (VHP)
+ Effective killing ratio at short contact times and low temperature	+ Reduced usage of sterilizing agent Reduced or eliminated rinse with sterile water
− High sterilant usage High rinse water usage	− Long contact and air-drying times High sterilization and drying temperatures / PET heat resistance limitations H_2O_2 residual limitations, H_2O_2 migration into PET matrix
→ **Wide Process Window / High TCO**	→ **Narrow Process Window / Low TCO**

Phase™ VTA vs 35% VHP

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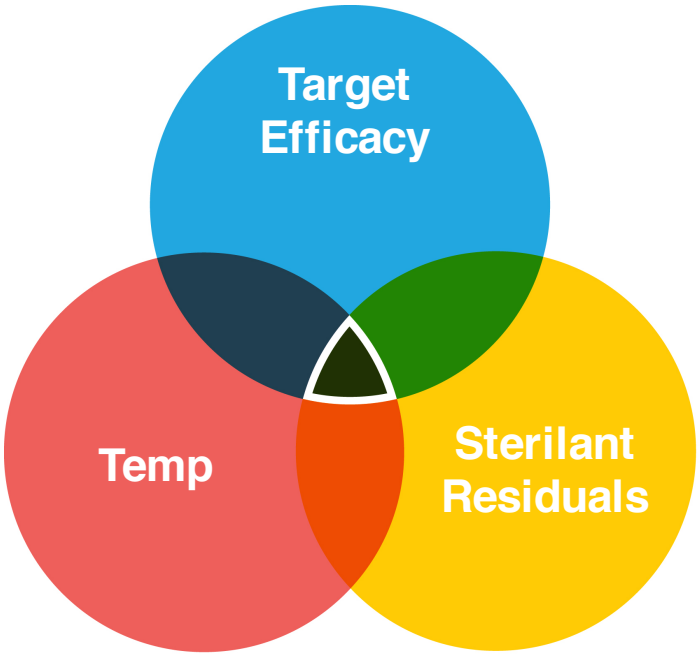
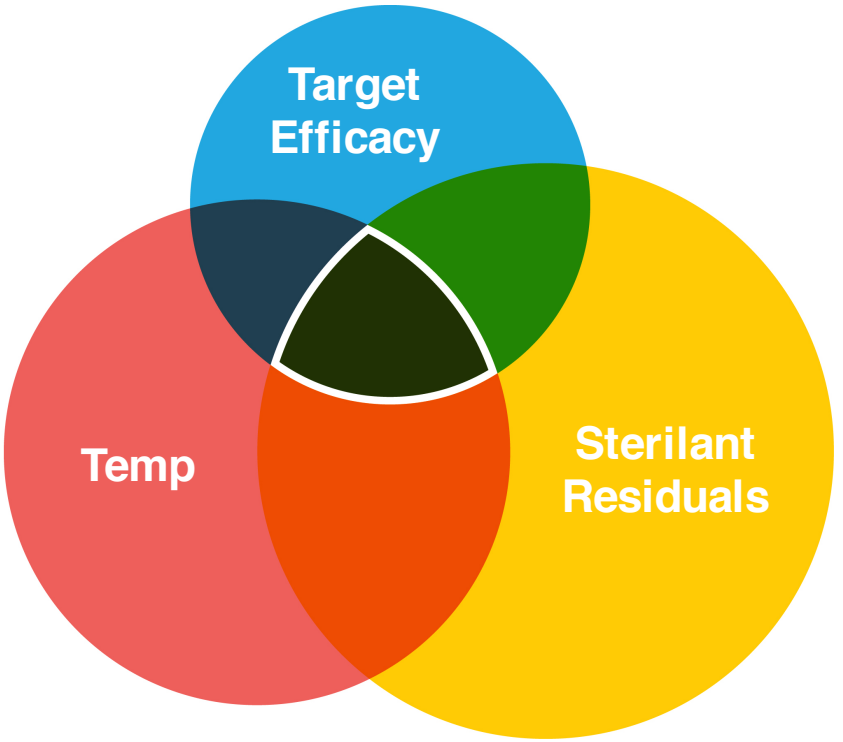
35% VHP



Phase™ VTA



Phase VTA provides for larger process window:

- Same target killing rate (6 log reduction)
- Effective at lower temperature: Increased bottle options
- Less chemical input: less H_2O_2 residuals

Phase™ VTA vs 35% H_2O_2 (VHP)

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	Phase VTA	35% H_2O_2 (VHP)
Efficacy	6 log red (*B. atrophaeus*)	6 log red (*B. atrophaeus*)
Flow rate, g/min per track	0.6 – 1.2	3 – 9
Contact time, s	2 – 4	2 – 6
Sterilant Vapor temp, °C	90	100 – 270
Activate/Dwell steps	No	Up to 3
Drying steps	Up to 3	Up to 6
Drying temp, °C	Ambient – 60	100 – 120
H_2O_2 residuals after treatment, ppm	< 0.1	< 0.5

Advantages of Phase VTA

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- Robust decontamination
  - Lower contact temperature, no hot-air activation vs. H2O2
  - Variety of lightweight packaging materials (PET, HDPE, closures)
- Reduction of chemical input in the process
  - No need for water or hot-air rinse, meets 24 hr H2O2 residual limits
- Reduction in energy consumption
- Reduced machine footprint

More process flexibility at reduced TCO

Phase VTA Commercialization

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Commercialization Timeline:

1. Extensive simulations in PeroxyChem labs
2. OEMs specific pilot tests to replicate lab simulations
3. OEMs specific customer site trials
4. Validation trials, FDA filing if applicable
5. Commercial production

PeroxyChem Support

- PeroxyChem's support includes:
  - Optimization of chemistry and application parameters
  - Microbiology and chemistry support
- Automatic Phase VTA concentrate dilution and dosing system
  - Reduced handling and storage
  - Increased safety
  - Sustainability

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KRONES Aseptic Filler Field Trials

Krones Field Trials

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1.July '17

- **Feasibility test:**
- Aseptic filler as-is – no equipment modifications
- PET bottles, interior only at 6 Log_{10} *B. atrophaeus*
- Zero positives -- achieved target efficacy
- No concerns with residues (< 0.5ppm)

1.November '17

- **Comprehensive sterilization test (H2O2 baseline vs Phase VTA):**
- Bottle interior / exterior sterilization
- Cap sterilization
- Machine sterilization

KRONES: Comprehensive Sterilization Test

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BOTTLES

Key parameters (other parameters were kept the same):

	Sterilant flow kg/hr	Air flow kg/hr	H_2O_2 / PAA residues	Operational observations
H_2O_2	5.7	295	Target < 0.5 ppm	No noticeable differences
Phase VTA	**2.5[1]**	**119**	**0.3 / 0.02 ppm**	

[1] as Phase VTA concentrate

Efficacy results: B. *atrophaeus*

Sterilant	Position	Target Level, Log_{10}	Pre-warm[2]	Reduction, Log_{10}
H_2O_2 baseline	interior	6	on	6.4
Phase VTA	**interior**	**6**	**on**	**6.4**
Phase VTA	**interior**	**6**	**off**	**6.4**
H_2O_2 baseline	exterior	6	on	6.5
Phase VTA	**exterior**	**6**	**on**	**6.5**
Phase VTA	**exterior**	**6**	**off**	**6.5**

[2]: Bottle pre-warm is typical for H_2O_2 for better efficacy.
Tested "on" for Phase VTA to simulate warm bottles out of a blow-molder.

KRONES: Comprehensive Sterilization Test

CAPS

Key parameters (treatment time was kept the same):

	Sterilant flow kg/hr	Air flow kg/hr	Cap chamber temp °C	Operational observations
H_2O_2	2.0	118	60	No noticeable differences
Phase VTA	**0.5[1]**	**57.5**	**50**	

[1] as VTA concentrate

Efficacy results: *B. atrophaeus,* 2 levels of inoculation

Sterilant	Target Level, Log_{10}	Reductions, Log_{10}
H_2O_2 baseline	6	6.3
Phase VTA	**6**	**6.3**
Phase VTA	**5**	**5.3**

KRONES: Comprehensive Sterilization Test

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MACHINE

Key parameters:

	Sterilant flow kg/hr	Air flow kg/hr	Treatment time seconds	CIP included	Operational observations
H_2O_2	25	1500	850	Yes	No noticeable differences
Phase VTA	**4.8[1]**	**1500**	**850 & 360**	**Yes & No**	

[1] as Phase VTA concentrate

Efficacy results: *B. atrophaeus*; 30 positions

Sterilant	Treatment time seconds	CIP included Yes/No	Reduction Log_{10}
H_2O_2 baseline	850	Yes	6.0
Phase VTA #1	**850**	**Yes**	**6.0**
Phase VTA #2	**850**	**No**	**5.7**
Phase VTA #3	**360**	**No**	**3.8**

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KRONES Field Trial -- CONCLUSIONS

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- The trial has proven that Phase VTA works on Krones aseptic filler
  - No need for equipment modifications to convert VHP to Phase VTA
  - No noticeable differences in filler operation
  - Achieved target efficacy requirements on Bottles, Caps, and Machine
  - Low H_2O_2/PAA residues

- Potentials for TCO reductions
  - Potential to reduce treatment time → increase speed
  - Reduce energy usage: lower air flow and operating temperature
  - Room for machine footprint reduction and design optimization

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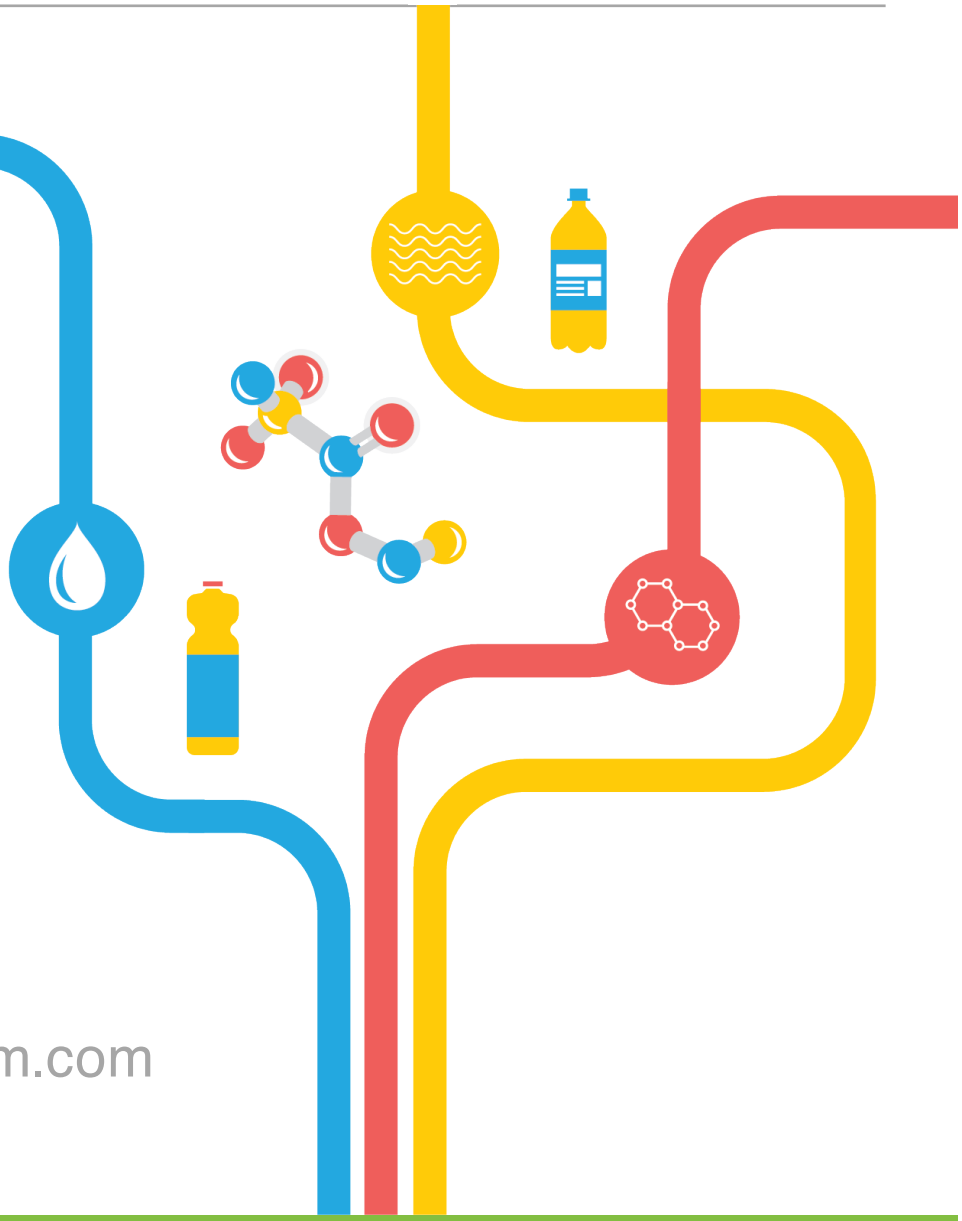
We deliver more than manufacturing solutions.



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chemistry microbiology engineering dosing system regulatory issues