



We create chemistry

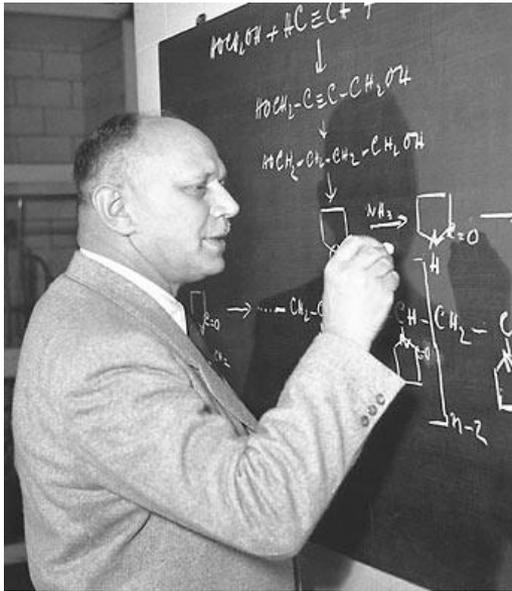
PeroXeal™

**The best packaging for
Povidone and Crospovidone**

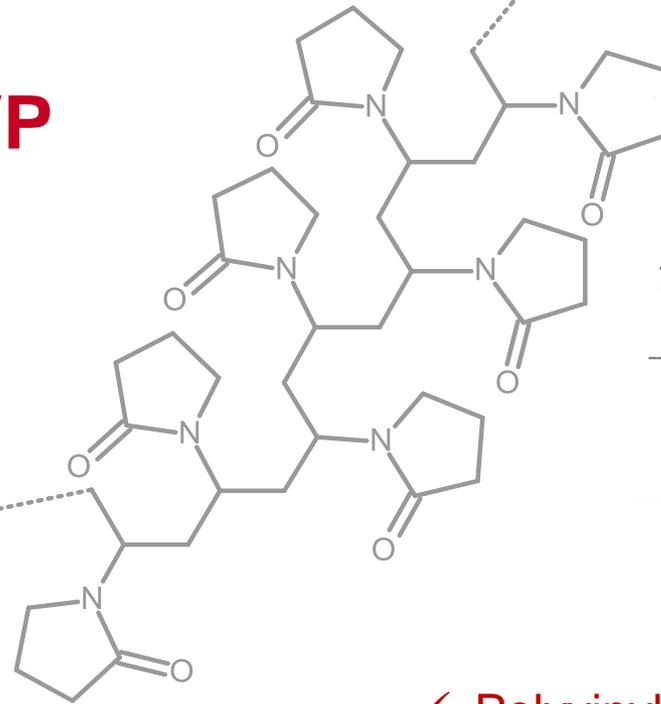
BASF Pharma Solutions | BASF SE



Kollidon® The Originator PVP



Prof. Dr. Walter Reppe, the inventor of povidone and the "Reppe-Chemistry".
BASF lab, Ludwigshafen Germany



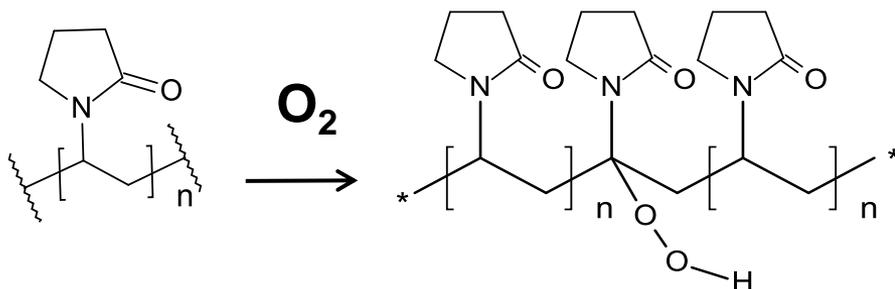
- ✓ Polyvinylpyrrolidone (PVP) was invented by BASF 80 years ago.
- ✓ Kollidon® is the originator PVP brand.
- ✓ Our commitment into Kollidon® is high ever since.



Background

Peroxide Formation in PVP

PVP always forms peroxides upon contact with atmospheric oxygen!



Peroxides can cause API damage or polymer cleavage.

„...The FDA is concerned that drug manufacturers using excipients containing high levels of peroxides will observe a loss in drug potency and the formation of excessive impurities during the product shelf life...“

FDA U.S. Drug and Food Administration
<http://www.fda.gov/Drugs/DrugSafety/ucm230492.htm>



BASF Kollidon® PVPs are available in PeroXeal™: The best packaging for high quality PVP

PeroXeal™ minimizes peroxide formation by excluding oxygen in the packaging



BASF PeroXeal™

Heat-seal

Liner closed by air-tight heat-seal

Inert filling*

Filling under inert conditions followed by vacuumization

Oxygen impermeable liner

based on EVOH**

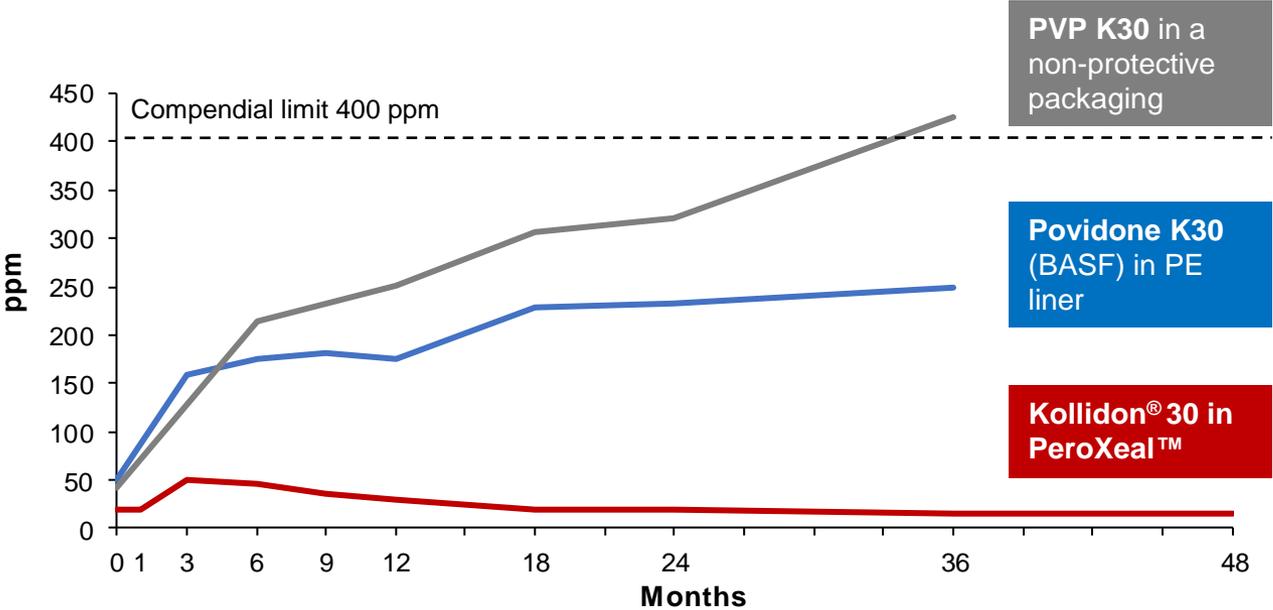
* only for material with origin Germany

** EVOH: Ethylene-vinylalcohol-copolymer



The PeroXeal™ Effect: Stability Data Kollidon® 30

PeroXeal™ effectively prevents peroxide formation in Kollidon® 30



The PeroXeal™ Effect: Commercial packaging Kollidon® 25

Kollidon® 25 (lot #75479709T0)

- ▶ Manufacturing date: Nov 2016
- ▶ Release Date: Nov 2016
 - CoA value: 70 ppm

- ▶ Testing March 2019
 - Box #247: 34 ppm
 - Box #254: 40 ppm
 - Box #257: 31 ppm



PRD 30034967
Article 57254799
25 kg cardboard box with EVOH liner
(PeroXeal™)

The material was in BASF original PeroXeal™ packaging for 28 months.
Three boxes were analyzed for peroxides and all gave < 50 ppm!
This clearly proves the effectiveness of PeroXeal™



PeroXeal™

Product Overview

PeroXeal™ packaging is implemented for:

- Kollidon® 25
- Kollidon® 30(*) & 30 LP
- Kollidon® 90 F
- Kollidon® CL
- Kollidon® CL-F
- Kollidon® CL-SF
- Kollidon® 12 PF
- Kollidon® 17 PF

PeroXeal™ fully replaced former BASF povidone and crospovidone packaging!



(*) PeroXeal™ only for Kollidon® 30 with origin Germany. The US material has the same packaging but no inert filling.



PeroXeal™ is also implemented for samples

For all commercial materials in PeroXeal™, samples are in PeroXeal™, too.

Sample packaging: EVOH liner in PE bucket



Summary

PeroXeal™

- minimizes oxygen in povidone and crospovidone packaging
- effectively prevents from peroxide formation over long time
- “passive” peroxide protection by oxygen exclusion
- peroxide values even decrease in the packaging with time ⇒ longer shelf-life



 **BASF**

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