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We create chemistry

## **PVP-Iodine 30/06** Healthcare Antiseptic

# Delivering what matters



We produce excipients and active ingredients of high quality and performance. Our team of experienced industry specialists supports you in developing effective formulations – giving you a vital advantage in a highly demanding market.



PVP-Iodine is an antiseptic that offers a broad spectrum of coverage, demonstrating antiviral, antibacterial, and antifungal activity.<sup>1</sup> Found on the World Health Organization's Model List of Essential Medicines, PVP-Iodine's potent efficacy is balanced with its established safety profile in a wide range of ages spanning from pediatric to geriatric patients.<sup>1,2</sup> In-vitro studies of PVP-Iodine-based topical formulations including skin cleansers, topical scrubs, and gargle/mouthwashes have indicated that PVP-Iodine products reduce viral load of certain coronaviruses such as MERS-CoV, SARS-CoV-1, and SARS-CoV-2.\*<sup>1,3,4,5</sup>

## References

1. Eggers M. Infectious Disease Management and Control with Povidone Iodine [published correction appears in *Infect Dis Ther.* 2019 Aug 22;]. *Infect Dis Ther.* 2019;8(4):581–593.
2. World Health Organization. World Health Organization Model List of Essential Medicines. 21st List. 2019. <https://apps.who.int/iris/bitstream/handle/10665/325771/WHO-MVP-EMP-IAU-2019.06-eng.pdf?ua=1>.
3. Eggers M, Koburger-Janssen T, Eickmann M, Zorn J. In Vitro Bactericidal and Virucidal Efficacy of Povidone-Iodine Gargle/Mouthwash Against Respiratory and Oral Tract Pathogens. *Infect Dis Ther.* 2018;7(2):249–259.
4. Eggers M, Eickmann M, Zorn J. Rapid and Effective Virucidal Activity of Povidone-Iodine Products Against Middle East Respiratory Syndrome Coronavirus (MERS-CoV) and Modified Vaccinia Virus Ankara (MVA). *Infect Dis Ther.* 2015;4(4):491–501.
5. Chin A, Chu J, Perera M, Hui K, Yen H-L, Chan M, Peiris M, Poon L. Stability of SARS-CoV-2 in Different Environmental Conditions. *Lancet Microbe.* 2020;1(1). doi: 10.1016/S2666-5247(20)30003-3.

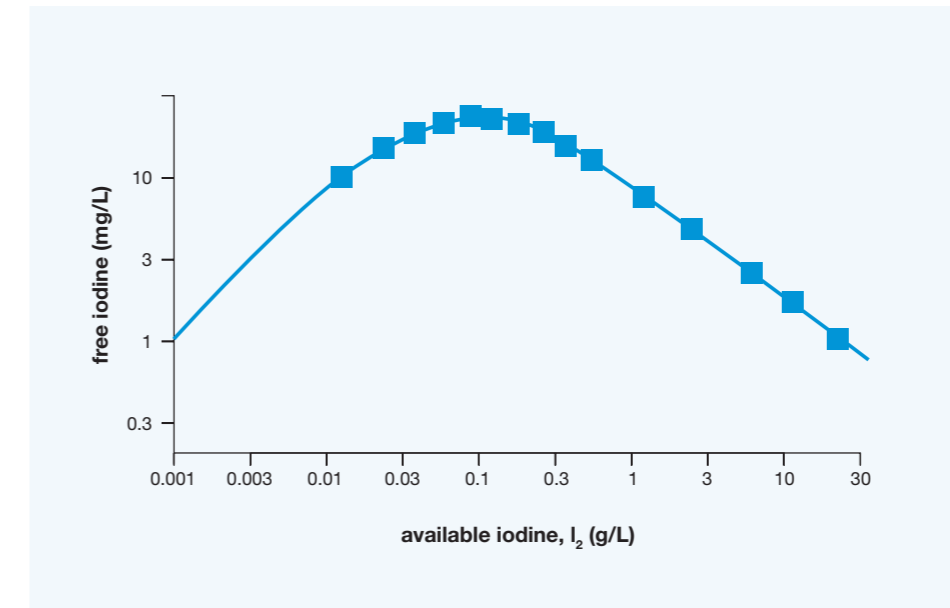
\*BASF has not tested the activity of PVP-Iodine against MERS-CoV, SARS-CoV-1, SARS-CoV-2, bacteria, or fungi; therefore, such activity has not been established through BASF testing at this time.

## Antimicrobial Efficacy of PVP-Iodine

The antimicrobial efficacy of PVP-Iodine is dependent on two major factors:

- Available iodine = iodine that can be titrated with sodium thiosulphate
- Free iodine = non-complexed, free iodine that can be determined in a dialysis test or an electrochemical model<sup>6,7</sup>

Free iodine content is inversely proportional to the concentration of PVP-Iodine or available iodine. Tests on micro-organisms have shown that the rate of microbicidal action is proportional to the free iodine content.



Relationship between the free iodine concentration and the concentration of available iodine in aqueous solution.

## References

6. Der Gehalt an freiem Iod in wäßrigen Lösungen von PVP-Iod. Gottardi W.; *Hyg. + Med.* 8, 203-209 (1983).
7. Physical-chemical Fundamentals of the Microbicidal Action of PVP-Iodine. Horn D., Ditter W.; Proceedings of the International Symp. on Povidone (1983).



## PVP-Iodine Efficacy Against Bacteria and Fungi<sup>8</sup>

Organism	Strains	PVP-I (mg/kg iodine)	Time of Contact (seconds)
Staphylococcus aureus	2	1000	15
	1	67	60
	1	1000	30
	1	1000	30
	85	1000	30
	6	100	180
	13	2500	60
Proteus mirabilis	4	1000	120
	7	2500	90
	2	2500	60
Proteus vulgaris	1	1000	60
	5	2500	90
Escherichia coli	3	1000	120
	1	1000	60
	1	1000	60
	0	1000	30
	5	2500	60
	2	1000	30
	2	200	120
Enterobacter aerogenes	1	2500	60
Enterobacter spp.	3	1000	60

Organism	Strains	PVP-I (mg/kg iodine)	Time of Contact (seconds)
Streptococcus faecalis	1	4	10
	2	2500	300
	2	200	60
Streptococcus pyogenes	1	1000	60
	1	2500	60
Streptococcus hemolyticus	2	1000	15
Salmonella typhimurium	2	1000	30
Salmonella typhosa	2	1000	15
Salmonella Type C-1	1	2500	60
Salmonella spp.	2	2500	60
Serratia marcescens	2	2500	60
	1	200	120

Organism	Strains	PVP-I (mg/kg iodine)	Time of Contact (seconds)
Serratia spp.	1	1000	60
	4	2500	60
Shigella sonnei	2	1000	30
Pseudomonas aeruginosa	2	1000	15
	1	1000	900
	13	25	900
	2	2500	300
	2	500	60
Klebsiella pneumoniae	1	500	60
Diplococcus pneumoniae	1	1000	60
	2	2500	60
Mycobacterium tuberculosis	1	2500	60
Bacillus subtilis	1	1000	30
Clostridium tetani	1	1000	30

Organism	Strains	PVP-I (mg/kg iodine)	Time of Contact (seconds)
Clostridium septicum	1	1000	30
Bacillus subtilis spores	2	10000	7200
Trichophyton rubrum	1	1000	60
Candida albicans	1	4	10
	1	1000	120
	1	1000	60
	1	1000	30
	1	500	60
Trichomonas vaginalis	4	400	30
	1	1000	30
Aspergillus flavus	1	1000	30
Aspergillus niger	1	1000	30

### References

8. Microbiological Efficacy of PVP-Iodine. A Critical Review (A. F. Petersen).





## PVP-Iodine 30/06

### Physico-chemical properties

Chemistry	Polyvinylpyrrolidone iodine
CAS number	25655-41-8
Physical form	Brown free-flowing powder Micronization causes color to change from pale brown to orange



## PVP-Iodine 30/06

### Product details

PRD number	30034963
Packaging size and article number	70 kg PE drum (55087443); 500 kg IBC (51955355)
Sample and article number	0.5 kg plastic bottle (50539452)
Manufacturing site	Geismar (USA)
Regulatory status	<ul style="list-style-type: none"> <li>Meets the requirements of the current monographs of Ph. Eur. "Povidone, iodinated" and USP "Povidone-Iodine"</li> <li>All tests of the monograph of JP "Povidone-Iodine" are performed in Japan for compliance with the current version of this monograph.</li> <li>CEP, US DMF and J-DMF are available</li> </ul>

**i** For further regulatory information please contact your sales representative.

## PVP-Iodine 30/06

### Recommendations for formulating with PVP-Iodine

Incompatibilities	PVP-Iodine is not stable in combination with reducing agents and many surfactants. Even some other excipients or their impurities like residual quantities of solvents (e.g. acetone) can impair the stability of PVP-Iodine preparations. Furthermore, a pH above 5 has a marked adverse effect on the stability of a formulation.
pH	The pH of the PVP-Iodine preparation can be of great importance for its stability. A pH of about 4.5 for aqueous solutions is a good compromise between good skin compatibility and acceptable stability.
Concentration of PVP-Iodine	The PVP-Iodine concentration in a preparation also has an influence on its stability. Commonly used concentrations are therefore never below 1% PVP-Iodine. At lower values stability is too poor; best values are achieved at concentrations of 8% to 10%.

**i** Note:  
 All shown formulations are exemplary. The formulations presented in this booklet have not been tested for their stability, shelf life, antiseptic activity, nor characterized by any analytical means. No clinical trials were conducted. Formulating procedures are recommendations based on established laboratory conditions and may require alterations dependent on the final application.

## Foam

- ✓ Easy to apply
- ✓ Fast spreading
- ✓ Non-leaking
- ✓ Clean application – prevents body, clothes, and furniture from contamination

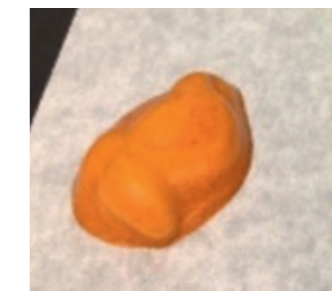
### Model Formulation

Phase	Ingredient	Functionality	Quantity (w/w%)
I	PVP-Iodine 30/06	API	5 or 10
I	Kolliphor® P 188	Emulsifier	3
I	Deionized water	Solvent	QS to 100

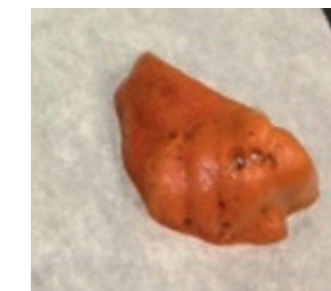
### Formulating Procedure

1. Dissolve all phase I ingredients under shear.

Use of foam pump bottles are required for best foaming performance.



Foam with 5% PVP-Iodine



Foam with 10% PVP-Iodine



## Cream

- ✓ Enhanced sensory feeling with moisture retention properties
- ✓ Easily spread for targeted application

### Model Formulation

Phase	Ingredient	Functionality	Quantity (w/w%)
I	PVP-Iodine 30/06	API	5
I	Deionized water	Solvent	80
I	Kollisolv® PG	Solvent	3
II	Kolliphor® CS 20	Emulsifier	2
II	Kolliwax® CSA 50	Viscogen	10

### Formulating Procedure

1. Heat phase I and II in separate containers at 80°C for 10 minutes (metal containers recommended) or until dissolved.
2. Place phase I beaker under overhead propeller mixer and mix at 500 rpm. Add phase II and continue mixing for 5 minutes.
3. Move mixed solution to homogenizer and homogenize at 5000 rpm for 5 minutes.
4. Return mixture to overhead mixer and mix at 200 rpm.
5. Stop when temperature is 35°C (use of infrared thermometer recommend).



Cream with 5% PVP-Iodine



## Ointment

- ✓ Hydrophilic and free of mineral oil
- ✓ Higher viscosity for improved richness and care feeling

### Model Formulation

Phase	Ingredient	Functionality	Quantity (w/w%)
I	PVP-Iodine 30/06	API	10
I	Kollisolv® PG	Solvent	30
II	Kollisolv® PEG 400	Solvent	30
II	Kollisolv® PEG 3350*	Viscogen	30

\*Kollisolv® PEG 3350 is commercially available only in the USA and Canada.

### Formulating Procedure

1. Heat phase I and II in separate containers at 80°C for 10 minutes (metal containers recommended) or until dissolved.
2. Place phase II beaker on overhead mixer and add phase I. Mix at 50 rpm until it thickens.



Ointment with 10% PVP-Iodine



## Stick

- ✓ Provides occlusive barrier
- ✓ Simple, water-free formulation
- ✓ Ideal for precise application on small surface areas
- ✓ Dry and clean application

### Model Formulation

Phase	Ingredient	Functionality	Quantity (w/w%)
I	Kolliwax® CSA 50	Viscogen	50
I	Kollicream® OD	Solvent/Emollient	49
I	PVP-Iodine 30/06	API	1

### Formulating Procedure

1. Melt all ingredients together at 75–80°C until it is a clear solution.
2. Stir until homogenous with propeller mixer (no heat) at approx. 300 rpm for 5–7 minutes.
3. Pour contents into solid stick dispensers
4. Allow to cool/solidify overnight.

Process steps might need to be adjusted to adapt to different waxes, melting points, cooling rates, etc.



## Sprayable Thermo-Reversible Gel

- ✓ Sprayable gel using thermo-reversible gellification upon contact with skin
- ✓ Local and precise application
- ✓ Non-leaking and easy removal

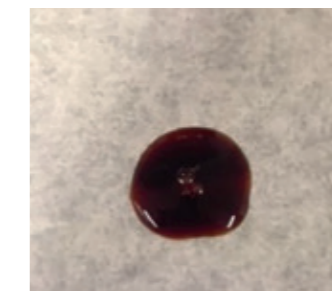
### Model Formulation

Phase	Ingredient	Functionality	Quantity (w/w%)
I	PVP-Iodine 30/06	API	10
I	Deionized water	Solvent	70
II	Kolliphor® P 407*	Gelling Agent	10
II	Kolliphor® P 188	Gelling Agent	10

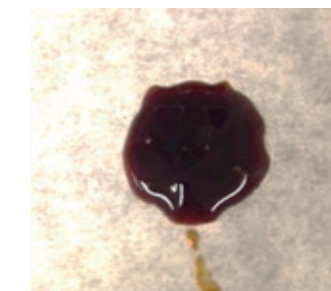
\* The use of Kolliphor® P 407 (10 to 20%) only results in thermogels.

### Formulating Procedure

The different formulating procedures are described on page 11.



Liquid at room temperature



Gel at 40°C



## Hydrophilic Poloxamer Gel

- ✓ Thermo-reversible gelling agent builds viscosity upon contact with skin
- ✓ Cool, refreshing feeling
- ✓ Easily spread
- ✓ Targeted application to small or large surface areas

### Model Formulation

Phase	Ingredients	Functionality	Quantity (w/w%)
I	PVP-Iodine 30/06	API	10
I	Deionized water	Solvent	70
II	Kolliphor® P 407*	Gelling Agent	20

\* The gel is formed at room temperature when using  $\geq 20\%$  Kolliphor® P 407.

### Formulating Procedure

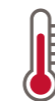
The different formulating procedures are described on page 11.



Gel with 10 % PVP-Iodine



## Formulating Procedures Sprayable Thermo-Reversible Gel and Hydrophilic Poloxamer Gel



### Hot Process

1. Weigh out and heat phase I to 70°C for 10 minutes or until PVP-Iodine 30/06 is fully dissolved.
2. Slowly add in phase II (over 2 minutes) and mix on overhead mixer at 100 rpm for 1 hour at room temperature.

#### Note:

This process ensures PVP-Iodine 30/06 is completely in solution.



### Cold Process

1. Weigh out phase I and apply shear until PVP-Iodine 30/06 is fully dissolved (approx. 30 minutes at room temperature).
2. Add in phase II and refrigerate at 4°C overnight.
3. Slowly mix and bring up to room temperature.

#### Note:

While PVP-Iodine 30/06 is completely dissolved at the beginning of this process, it can settle and form aggregates in the final gel.



# Our service offer

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