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PVP-iodine 30/06 Application Guide: Differentiating dosage forms



Lampertheim, May 2019

BASF PVP-Iodine 30/06

The market leader in shelf life and stability

PHYSICO-CHEMICAL PROPERTIES

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

PRODUCT DETAILS

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



Disclaimer

The following formulations are exemplary.

The formulations have not been tested for their stability or shelf life or have been characterized by any analytical means.



Foams

- ✓ Suitable for large surface applications
- ✓ Easy to apply
- ✓ Fast spreading
- ✓ Non-leaking
- ✓ Clean application - prevents body, cloths and furniture from contamination

Model formulation

Phase	Ingredient	Role	Quantity w/w%
I	PVP-iodine 30/06	API	5 or 10
I	Kolliphor® P188	Emulsifier	3
I	Deionized water	Solvent	up to 100

Formulating procedure

1. Dissolve all phase I ingredients under shear.

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



5% PVP-I

10% PVP-I

Creams

- ✓ Improved sensory feeling compared to PVP-iodine ointments
- ✓ Better spreading compared to PVP-iodine ointments

Model formulation

Phase	Ingredient	Role	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 on overhead mixer and add oil phase. Spin at 500 rpm for 3 minutes.
3. Move mixed solution to homogenizer and spin at 5000 rpm for 5 minutes.
4. Move back solution to overhead mixer at 200 rpm.
5. Stop when temperature is 35 °C (use infrared thermometer recommend.)



Ointments

- ✓ Hydrophilic mineral oil free ointment

Model formulation

Phase	Ingredient	Role	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. Spin at 50 rpm until it thickens.



Sticks

- ✓ Provides occlusive barrier
- ✓ Simple, water-free formulation
- ✓ Suitable mainly for small skin surface areas
- ✓ Very precise and local application (“spot on”)
- ✓ Dry and clean application

Model formulation

Ingredient	Role	Quantity w/w%
Kolliwax® CSA 50	Consistency builder	50
Kollicream® OD	Solvent/Emollient	49
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 poloxamer gels

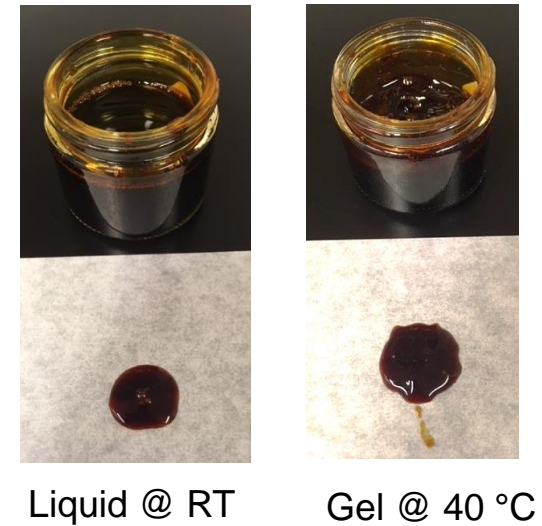
- ✓ Sprayable gel using thermo-reversible gellification upon contact with skin
- ✓ Local and precise application
- ✓ No leaking or easy wash-off

Model formulation

Phase	Ingredient	Role	w/w%
I	PVP Iodine 30/06	API	10
I	Deionized water	Solvent	70
II	Kolliphor® P407**	Gelling Agent	10
II	Kolliphor® P188	Gelling Agent	10

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

Formulating procedure
see slide 9



Hydrophilic poloxamer gels

Model formulation

Phase	Ingredient	Role	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 ≥ 20 % Kolliphor® P 407.

Formulating procedure

see slide 9



Formulating procedures: Sprayable thermo-reversible poloxamer gels and hydrophilic poloxamer gels

Hot process

- I. Weigh out and heat phase I to 70 °C for 10 minutes or until PVP-iodine 30/06 is fully dissolved.
- II. 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 that PVP-iodine 30/06 is completely in solution.

Cold process

- I. Weigh out phase I and apply shear until PVP-iodine 30/06 is fully dissolved (approx. 30 minutes at room temperature).
- II. Add in phase II and refrigerate at 4 °C overnight.
- III. 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.



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