Technical Information

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PVP-Iodine grade

Povidone, iodinated Ph. Eur., Povidone-Iodine USP

Disinfectant

BASF
We create chemistry

Contents

Introduction

Iodine was formerly used in the form of iodine tincture or Lugol's solution for disinfecting minor wounds.

Despite its good efficacy there were obstacles to its broad use because these two formulations triggered a number of side effects such as strong irritation, allergies etc.

PVP-Iodine was first reported in the early 1950s.

This compound is a complex of polyvinyl pyrrolidone and iodine. Studies by H.U. Schenk et al [1] showed that the solid product probably has the following structure (Fig. 1):

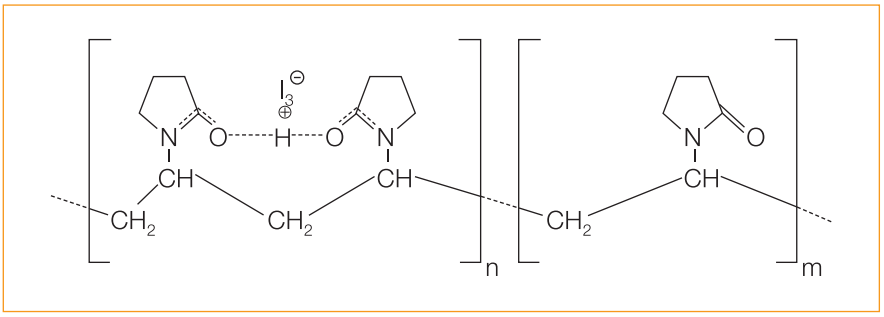


Fig. 1: Chemical structure of PVP-Iodine (n : m = 1 : 18)

In connection with the structure and the methods of determination it seems important to explain some terms.

Available iodine	=	iodine that can be titrated with sodium thiosulphate
Total iodine	=	iodide + titratable iodine
Free iodine	=	non-complexed iodine that can be determined in a dialysis test [3]
	=	iodine that can be extracted with heptane from an aqueous PVP-Iodine solution of defined concentration
	=	free iodine that can be determined in an electrochemical model [2]
Iodide	=	Iodide concentration required to form an iodine complex

An interesting and important factor in this context is the dependence of the concentration of free iodine on the concentration of PVP-Iodine or available iodine, as shown in Fig. 2. Looking at this curve, two facts about the commonly used concentrations of PVP-Iodine preparations (1 – 10% PVP-Iodine = 1 – 10 g available iodine/l) stand out:

1. The free iodine content is extremely low at 1 – 8 ppm
2. The 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.

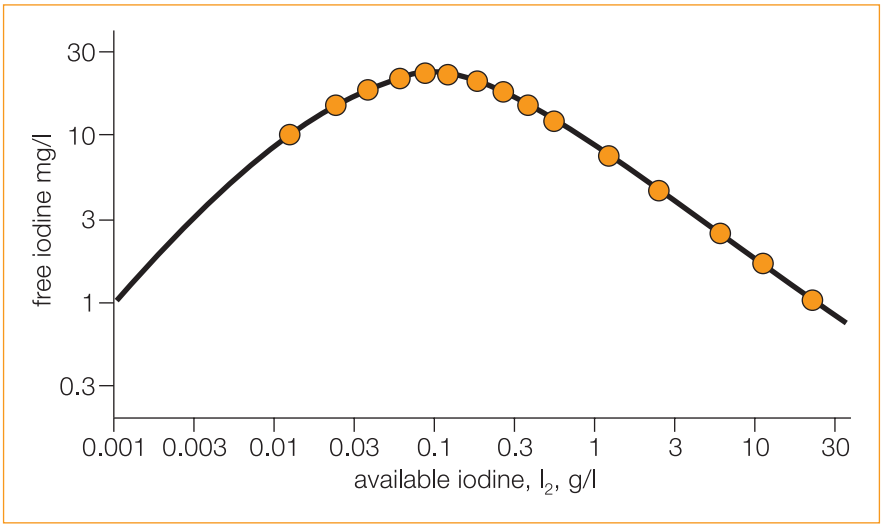


Fig. 2 Relationship between the free iodine concentration and the concentration of available iodine in aqueous solution.

Specifications

	PVP-Iodine 30/06
Identity	corresponds
Available iodine (potentiometric)	9.0 – 12.0%
Iodide	≤ 6.0%
pH (10% in water)	1.5 – 5.0
Nitrogen	9.5 – 11.5%
Heavy metals	≤ 10.0 ppm
Losses on drying	≤ 8.0%
Ash	≤ 0.1%

The methods can be found in the current monographs “Povidone, iodinated” (Ph. Eur.) or “Povidone-Iodine” (USP).

Regulatory status

Product meets current Povidone, iodinated Ph. Eur., USP, JP and IP monographs.

Production

For the production of PVP-Iodine 30/06 a Povidone K 30 is used that meets the requirements of the corresponding pharmacopoeia in accordance with the above Ph. Eur. monograph. The figure “30” in the PVP-Iodine 30/06 nomenclature indicates the K value and thus the molecular weight of the povidone used.

Properties

Description

PVP-Iodine 30/06 is a brown, free-flowing powder.

Solubility

Water
Ethanol
Propanol
Acetone
Chloroform
Methylene chloride
Heptane
Hexane

Viscosity

	Water	Ethanol
5%	2	2
10%	7	5
20%	230	20

These guide values are based on measurements at 25 °C and are given in mPa·s.

Particle size distribution

	PVP-Iodine 30/06
Smaller than 20 µm	–
Smaller than 50 µm	<25%
Greater than 250 µm	< 5%

These data are guide values. The values were determined on a dispersion of PVP-Iodine in heptane with a Malvern Mastersizer. In the case of PVP-Iodine 30/06 they can also be measured with an air jet sieve.

Stability

PVP-Iodine 30/06 remains stable for 36 months in unopened containers.

The following rapid test, corresponding to storage for about 15 months at room temperature, is suitable for easy and fast assessment of the stability of PVP-Iodine in aqueous preparations. It can be used for assessing the stability of PVP-Iodine from different sources and for preparing new formulations.

A PVP-Iodine solution containing 1% available iodine is produced. This solution is stored in a sealed glass flask for 14 days at 52 °C or 15 hours at 80 °C. The available iodine content is determined and the iodine loss calculated before and after storage.

An indication of stability is incorporated in the product name PVP-Iodine 30/06. The figure “06” indicates that the iodine loss in the above stress test does not exceed 6%.

One of the above stress tests was employed to predict the stability of practically all aqueous formulations that have been developed in the BASF laboratory. These tests are also highly suitable for predicting the compatibility of PVP-Iodine with different excipients and packaging materials.

Fig. 3 shows by way of example the result of testing the compatibility of aqueous PVP-Iodine solutions with glass and two high- and low-density polyethylene grades (Lupolen®) using one of these stress tests.

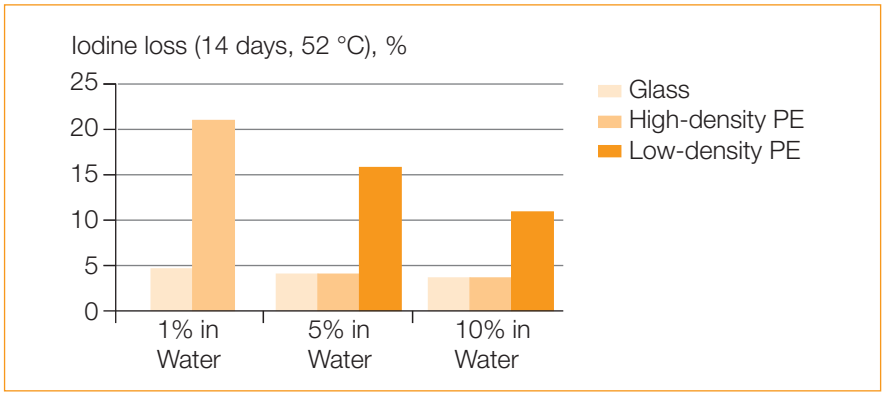


Fig. 3: Influence of the concentration of aqueous solutions and packaging material on the stability of PVP-Iodine solutions

Incompatibilities

PVP-Iodine is not stable in combination with reducing agents and many surfactants. Even some other excipients or their impurities like rests 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 (see Fig. 4).

Supplementary analytical methods

K value

The average molecular weight of the povidone contained in PVP-Iodine 30/06 can be indicated by the K value. It is determined in accordance with the Ph. Eur. monograph “Povidones”, but to measure the relative viscosity the solution must be decolourised before being adjusted to a concentration of 1% povidone by adding a 25% solution of sodium thiosulphate.

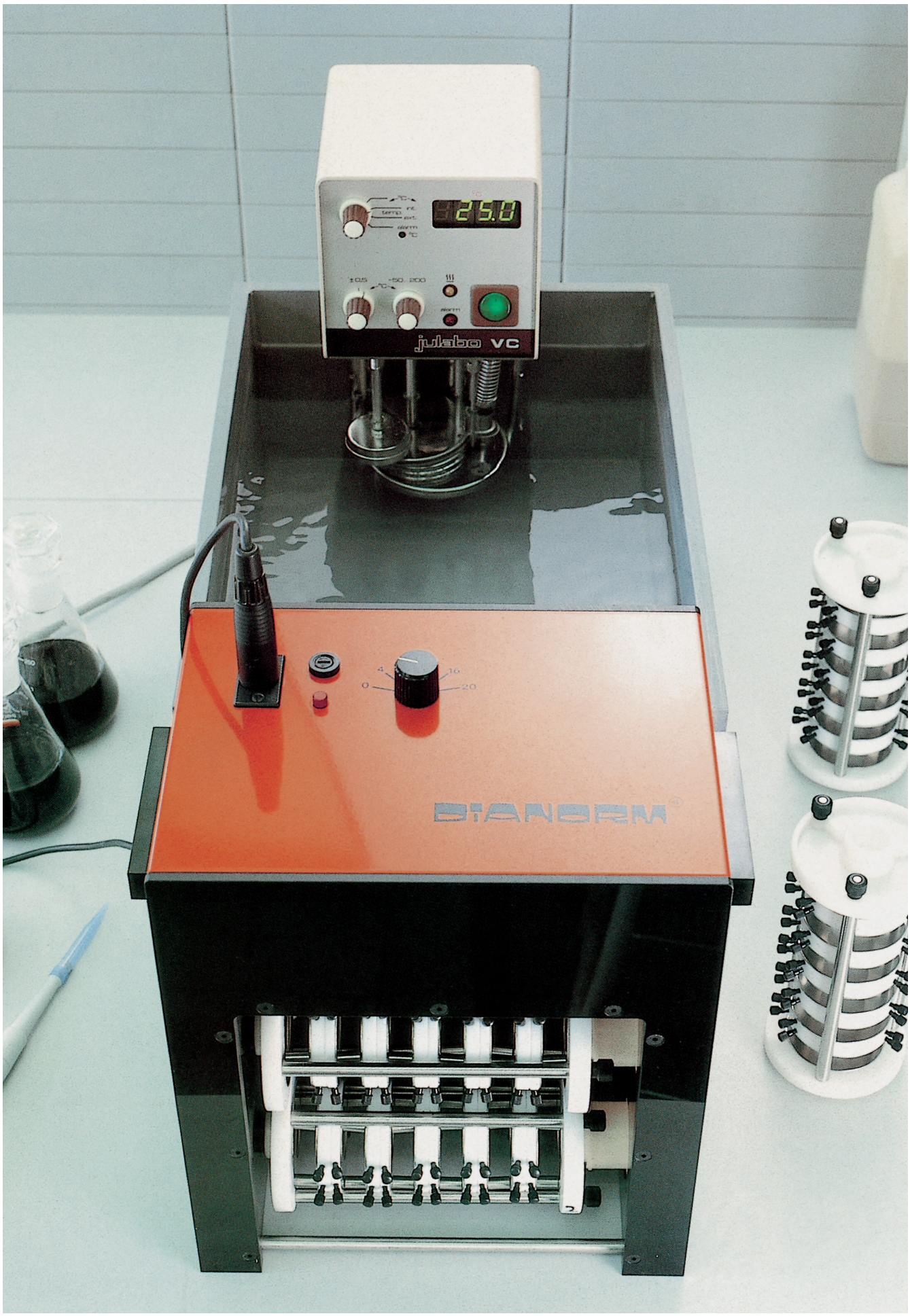
Free iodine (dialysis)

Determination is carried out e. g. in a Dianorm® dialysis machine as shown on page 8.

The dialysis cells are filled by means of automatic pipettes with 2.00 ml PVP-Iodine solution on one side and water on the other side. The membrane between the two sides consists of HDPE (e. g. Lupolen 1804 H) with a thickness of 50 – 70 µm. The dialysis time at a speed of 20 rpm is about 5 hours for normal aqueous PVP-Iodine solutions.

0.25 ml of a 10% potassium iodide solution are placed in the measuring cells. 1.00 ml is taken from the water side of the dialysis cells and added quickly to the potassium iodide solution. After brief shaking the absorption is measured at 351 nm against a mixture of 0.25 ml potassium iodide solution and 1.00 ml water. The free iodine content is calculated by the following equation:

$$\text{Free iodine (ppm)} = \frac{\text{Absorption} \times 316.25}{\text{Cell diameter} \times 25}$$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Application

General points

PVP-Iodine is noted for its wide range of uses. Its major applications are in the field of **prophylaxis**:

– skin and mucous membrane antisepsis
– surgical and hygienic hand disinfection

and in the field of **treatment**:

– treatment of burns, decubitus and varicose ulcers
– use in the treatment of dermatomycosis, pyoderma and acne
– use in the treatment of vaginitis

The advantage of PVP-Iodine is that it can be incorporated in a wide range of formulations.

pH

The pH of the PVP-Iodine preparation can be of great importance for its stability. As Fig. 4 shows, a pH of about 4.5 for aqueous solutions is a good compromise between good skin compatibility and acceptable stability.

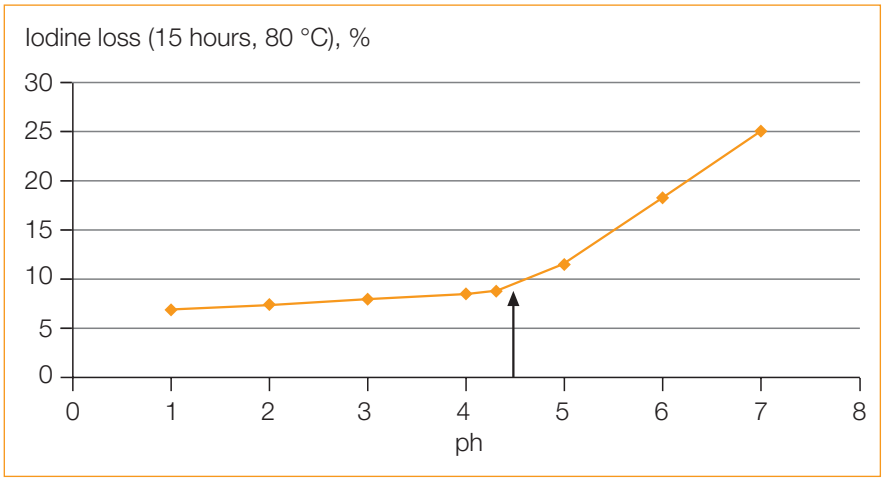

Fig. 4: Influence of the pH on the stability of PVP-Iodine 30/06 solutions

Concentration of PVP-Iodine

The concentration of PVP-Iodine in the preparation also has an influence on its stability. Fig. 5 shows why the commonly used concentrations are therefore never below 1% PVP-Iodine. At lower values stability is too poor.

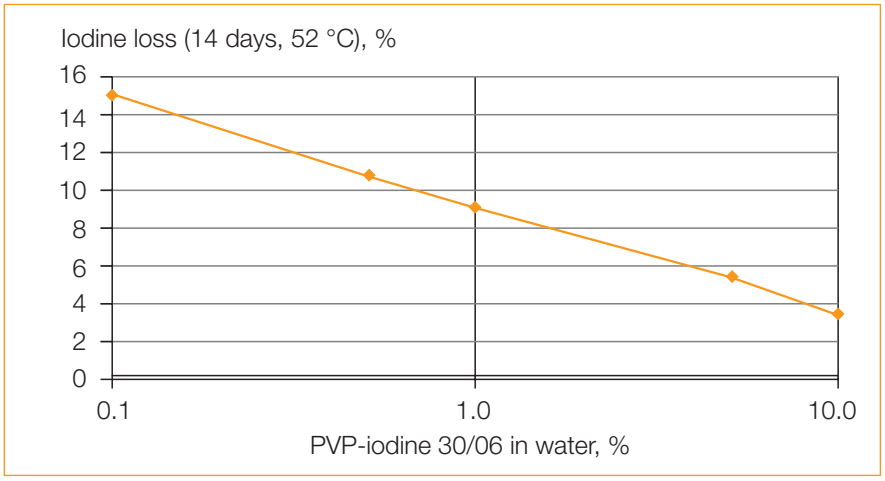

Fig. 5: Influence of the concentration on the stability of PVP-Iodine 30/06 solutions

Formulations

Details of the following formulations (e. g. the stability) and also further examples of preparations can be taken from the file or the CD-ROM “Generic Drug Formulations”. The sources of supply of the excipients listed are given on page 19.

Solutions

Formulation 1

PVP-Iodine 30/06	10 g
Citric acid-phosphate buffer solution pH 5.0	to 100 ml

pH of the solution: 4.5

Formulation 2

PVP-Iodine 30/06	10.00 g
Kolliphor® P 407	0.25 g
Kollisolv® PEG 300	0.50 g
Citric acid-phosphate buffer solution pH 5.0	to 100 ml

pH of the solution: 4.3

Production:
First of all the buffer solution is produced and the other liquid components added. The PVP-Iodine powder is added steadily to the clear solution while stirring until a clear brown solution is obtained.

Formulation 3 (“seamless” solution)

PVP-Iodine 30/06	10.00 g
Natrosol® 250 HR	1.00 g
Kolliphor® P 407	0.20 g
Sodium hydroxide solution 1 M	3.15 g
Water	ad 100.00 g

pH of the solution: 2.95

Production:
Kolliphor® P 407 is added to the water and Natrosol® 250 HR is incorporated. As soon as the Natrosol® 250 HR has dissolved, the PVP-Iodine is added while stirring. The sodium hydroxide solution is then added to the finished solution.

Liquid soaps

Formulation 4

PVP-Iodine 30/06	7.5 g
Neutronyx® S 60	25.0 g
Super Amide® L-9	4.0 g
Water	63.5 g

Production:
Super Amide® L-9 is dissolved in a little water at 60 °C. The remaining water is then added. PVP-Iodine is dissolved while stirring. Neutronyx® S 60 is then added to the clear solution.

There are a limited number of substitutes available for Neutronyx® S 60 and Super Amide® L-9.

Substitutes for Neutronyx® S 60:	Kolliphor® SLS Lutensit AES
Substitutes for Super Amide® L-9:	Comperlan® LD

A suitable product for perfuming the liquid soap is the FDO product Floral Bouquet No. PC 516 715 (FDO, USA).

Shampoo

Formulation 5

PVP-Iodine 30/06	7.5 g
Super Amide® L-9	4.0 g
Natrosol® HR 250	0.7 g
Neutronyx® S 60	25.0 g
Water	62.8 g

Production:
Super Amide® L-9 and Natrosol®* 250 HR are dissolved in water at 50 – 60 °C. PVP-Iodine is then dissolved in this and cooled, after which Neutronyx® S 60 is added. The viscosity can be adjusted with Natrosol® 250 HR.

Bar soap

Formulation 6

PVP-Iodine 30/06	50.0 g
Water	75.0 g
Perfume oil	10.0 g
e.g. Syndet base 5078	940.0 g

Production:
PVP-Iodine is dissolved in water and mixed together with the perfume oil in the soap noodles. The mixture is passed four times through the roller mills for complete homogenisation and then pressed three times through a fine perforated screen. The soap pieces are then extruded through a large perforated screen in combination with a plodder attachment, preheated to 50 °C.

The machine required is manufactured by Weber + Seeländer, Helmstedt (FRG) and others.

Ointment, transparent

Formulation 7

PVP-Iodine 30/06	10.0 g
Kollisolv® PEG 400	60.0 g
Sodium hydroxide 1 M	4.6 g
Kollisolv® PEG 4000	25.0 g
Water	5.0 g

pH-value: 4

Production:
PVP-Iodine is dissolved in the mixture of Kollisolv® PEG 4000, water and sodium hydroxide solution and heated to 60 – 65 °C, when the Kollisolv® PEG 4000 is added while stirring vigorously. The mixture is then allowed to cool while stirring.

Gel

Formulation 8

PVP-Iodine 30/06	10.0 g
Sodium chloride	1.0 g
Kolliphor® P 407	20.0 g
Sodium hydroxide 1 M	7.9 g
Water	70.0 g

Production:
PVP-Iodine and NaCl are dissolved in water and Kolliphor® P 407 is added at approx. 6 °C. The sodium hydroxide solution is then added.

pH-value 4.6

Gargle solution

Formulation 9

I.	PVP-Iodine 30/06	7.5 g
	Saccharin sodium	0.5 g
	Water	15.0 g
II.	Menthol	0.2 g
	Aniseed oil/eucalyptus oil 1 + 1	0.1 g
	Kollisolv® PEG 400	15.0 g
	Ethanol 96%	50.0 g

Production:
PVP-Iodine and saccharin are dissolved in H_2O and then mixed with II. The solution contains 7.5 g PVP-Iodine in 100 ml. It can be diluted before use.

PRD-No.

PVP-Iodine 30/06: 30034963

Packaging

PVP-Iodine 30/06: 70 kg PE lidded drum with PE inner bag
500 kg PE big bag

Homogenization of the product is recommended prior to sampling or partial removal of the PVP-Iodine powder from an individual drum.

Stability

PVP-Iodine 30/06:
At room temperature the retest period for this product is 36 months when stored in unopened original containers.

Safety data sheet

Safety data sheets are available on request and are sent with every consignment.

Physiological effects

1 Acute toxicity

LD_{50} rats oral: 5990 mg/kg
LD_{50} mice i. p.: 360 mg/kg

2. Compatibility with the skin and mucous membranes

Both 1% and 10% solutions were checked for compatibility with the skin and mucous membranes, and no negative results were observed.

3 Mutagenicity

Tests on Chinese hamsters, the micronucleus test, and the dominant lethal test.
No indications of mutagenicity were obtained.

Microbiological efficiency
Extracts from [4]

Organisms	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
	9	1000	30
	5	2500	60
	2	1000	30
	2	200	120
Enterobacter aerogenes	1	2500	60
Enterobacter spp.	3	1000	60
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
Serratia spp.	1	1000	60
	4	2500	60
Shigella sonni	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
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

Microbiological efficacy of preparations

Assessment of the in-vitro efficacy differs widely from country to country depending on the test model, and the requirements can also vary greatly.

A literature survey follows, giving a small selection of publications on the individual fields of application.

Literature review

Analysis of chemical structure

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Microbiological efficacy/skin and hand disinfection

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[17] Irrigation of subcutaneous tissue with Providone-Iodine solution for prevention of surgical wound infections. Sindelar W. F., Mason J. R.; Surg., Gynecol. Obstet. **148,** 227–231 (1979).

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