SpecKare™ PO-PIROCTONE OLAMINE

(The Versatile Anti-Microbial/-Dandruff/-Acne/-Odor Ingredient)

(Tentative Version)
Spec Chem
Sep.20 2019

GROUP
斯开科
Good Quality Comes
From Qualified Materials

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1 Piroctone Olamine Introduction

Piroctone Olamine (PO) has been already subject to Scientific Committee of Cosmetology (SCC) for evaluation at **1980** and the result of the respective evaluation and the opinion of the SCC is laid down at **1987**.

More than **30-year user experience** proved its safety and efficacy (up to 3%) and had been approved for use in cosmetic products at a maximal concentration of 1 % (rinse-off products) or 0.5 % (other products).

Nowadays people pay more and more attention to the safety of the daily use personal care(PC) products, **SpecKare™ PO caters for this new trend**, it provide formulators **more flexibility** to make more safety and efficacy PC products due to **Spec Chem's** production capacity.

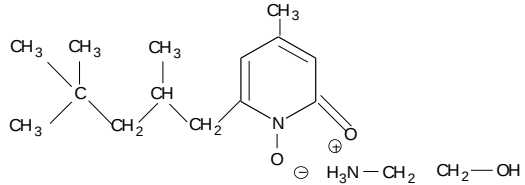
Inventory Status of chemicals, regulated on:

- IECSC--Inventory of Existing Chemical Substances in China
- EINECS—European Inventory of Existing Commercial Chemical Substances
- DSL- Canada Domestic Substances List
- PICCS—Philippine Inventory of Chemicals and Chemical Substances
- NZIoC—New Zealand Inventory of Chemicals
- AICS- Australian Inventory of Chemical Substances
- ECL—Korean Existing Chemicals List
- TCSI—Taiwan Chemical Substance Inventory
- IECIC—Inventory of Existing Cosmetic Ingredients in China

Inventory Status of cosmetics, regulated on:

- CTFA-International Cosmetic Ingredient Dictionary and Handbook
- IECIC-Inventory of Existing Cosmetic Ingredients in China
- Cosing-European Commission database for information on cosmetic substances and ingredients

3 SpecKare™ PO Information

Trade Name：	SpecKare™ PO
Product No：	SC-4707
INCI Name：	Piroctone Olamine
CAS NO：	68890-66-4
EINECS NO：	272-574-2
Chemical Name：	1-Hydroxy-4-methyl-6-(2,4,4-trimethylpentyl)pyridin-2(1H)-one, compound with 2-aminoethanol (1:1)
Structure:	

Package: 1kg/battle & 5kg/battle & 25kg/carbon. Storage: Cool and dry place. Shelf life: 2 year.

Item	Standard
Appearance	White crystalized powder
Odor	Characteristic
Assay, %	≥98
pH （1% water solution）	8.5-10.0
Meliting point, ℃	130-135
Loss on drying, %	≤0.2
Ashed (SO_4), %	≤0.2

3 SpecKare™ PO Information

The Features of SpecKare™ PO:

- ✓ Formaldehyde-free, Paraben-free, Broad-spectrum Anti-Microbial
- ✓ Effectively eliminate unpleasent odor, both for Human & Pet
- ✓ Excellently anti-dandruff active that soothes inflamed scalps and reduces flaking
- ✓ Increase the mean hair shaft thickness, suitable for volume-up formula
- ✓ Decreasing the sebum output at the skin surface, suitable for anti-acne application
- ✓ Additional thickening properties
- ✓ Clinically approved effective, Safe to use, Non-irritating

4.1 Safety

*Following Results from SCCNPF 《OPINION OF THE SCIENTIFIC COMMITTEE **Regarding PO** ON COSMETIC PRODUCTS AND NON-FOOD PRODUCTS INTENDED FOR CONSUMERS》 Feb.27th 2002*

Irritation (skin)

OECD 404: Three New Zealand White rabbits were treated topically with concentrations of 2.0 % (left flank) or 3.0 % (right flank). Exposure time was 4 hours. The test compound was kept in contact with the skin by semi-occlusive dressing. Cutaneous reactions were observed and scored 1 hour, 24, 48 and 72 hours after removal of the dressing.

Result: No cutaneous reactions were observed in the study. The test substance was rated to be non-irritant to the skin of rabbits at concentrations up 3.0 %.

Irritation (mucous membranes)

OECD 405: The eyes of three New Zealand White rabbits were treated with 0.1 ml concentrations of 2.0 % (left eye) or 3.0 % (right eye). The eyes were not rinsed after application of the test substance. Ocular reactions were observed and scored 1 hour, 24, 48 and 72 hours after administration.

Result: With the exception of a single case of a slight and transient corneal opacity (3.0 %, day 2), ocular reactions were limited to the conjunctiva (redness, chemosis and discharge). At 2.0 % very slight to moderate conjunctival reactions were observed in all animals and persisted up to day nine of the study. At 3.0 %, very slight to moderate conjunctival reactions (redness; chemosis, discharge) and a single case of mild, transient corneal opacity (day 2 only) was observed in all animals and persisted up to day three. On the basis of the irritation scores, the test substance was rated to be a slight irritant in rabbits.

Human Data

In a double-blind study in humans (report in French language) the tolerance of two cream formulations, i.e. 47JP12 and 47JP2, containing 1.0 % and 0.5 % octopirox (piroctone olamine, PO), respectively. With the exception of the different content of PO, the formulation ingredients were identical. The creams were applied once a day, morning or evening, to the face of 65 volunteers, 5 times a week, for a total of four weeks.

Result: No difference was noted in the tolerance of these formulations. Both creams showed a good acceptance and tolerance. These data support the tolerance of 1.0 % PO in face creams.

Efficacy Test of SpecKare™ PO

4.1 Safety

Evaluation of skin reaction:

Erythema and Eschar Formation	Score
No erythema	0
Vary light erythema (barely perceptible)	1
Well-defined erythema	2
Moderate to severe erythema	3
Severe erythema (beet-redness) to slight eschar formation (injuries in depth)4	4

Edema Formation	Score
No edema	0
Very slight edema (barely perceptible)	1
Slight edema (edges of area well defined by definite raising)	2
Moderate edema(raised approxzimately 1mm)	3
Severe edema(raised more than 1mm and extending beyond the area of expose	4

Testing NO.	Gender	Body Weight (KG)	Skin Irritation Score					
			1h		24h		48h	
			Test	Control	Test	Control	Test	Control
1	♂	2.5	0	0	0	0	0	0
2	♀	2.6	0	0	0	0	0	0
3	♀	2.5	0	0	0	0	0	0
4	♂	2.7	0	0	0	0	0	0
Mean irritation index			0	0	0	0	0	0

PO has no acute irritation to skin

Efficacy Test of SpecKare™ PO

4.1 Safety

Toxicity Comparative Study of PO VS ZPT VS Climbazole

	SpecKare™ PO	ZPT	Climbazole
Acute toxicity Oral (Mouse, LTD50, mg/kg weight)	8100	170	400
Subacute toxicity NOEL	100mg/kgb.w./d (Test Method:Oral)	15 ppm/diet (Test Method:Feed)	15mg/kgb.w./d (Test Method:Oral)
Animal embryos induced toxicity NOEL	Mouse: Oral -, Skin Coating -, Limit Amout 2000** Rabbit: Oral 63**, Skin Coating -, Limit Amout -	Mouse: Oral 7.5, Skin Coating 15**, Limit Amout - Rabbit: Oral 1.0, Skin Coating 100**, Limit Amout -	Mouse: Oral 30, Skin Coating -, Limit Amout - –

Summary:

Overall speaking, PO has **the lowest toxicity & highest safety**, therefore is **the best choice** among these three common multifunction ingredients! So PO can be used **in leave-on products** (such as facial cream, deodorant, hair oil, conditioner, fixature, and hair dye), remaining working on the scalp and skin.

4.2 Antiodor （still ongoing）

4.3 Anti-dandruff

Mechanism of Anti-dandruff

The scalp depends itself against micro-organisms and fungus infections.

Piroctone olamine has a specific action against Pityrosporum Ovale, the agent responsible for the production of dandruff.

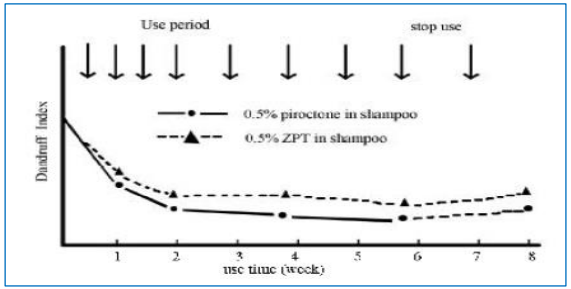
The anti-dandruff product containing piroctone olamine destroys the fungus infection that is responsible for the dandruff and works against the formation of new dandruff, makes the scalp stays clean, itch free and prevents the formation of new dandruff, you become free of all the inconvenience relating to dandruff.

Efficacy Test of SpecKare™ PO

4.3 Anti-dandruff

Antidandruff Effect Comparative Study of **PO VS ZPT**

Antidandruff Effect Comparative Study of 0.5 (w/w%) PO VS 0.5 (w/w%) ZPT in Shampoo



Summary: using shampoo containing 0.5% ZPT 0.5% PO separately 8 times for 6 weeks, the results show that PO can reduce dandruff more effectively than ZPT, the former reduces by 81.7% while the later reduce by 68.6%.

Antidandruff Effect Comparative Study of PO VS ZPT after using for 2 weeks

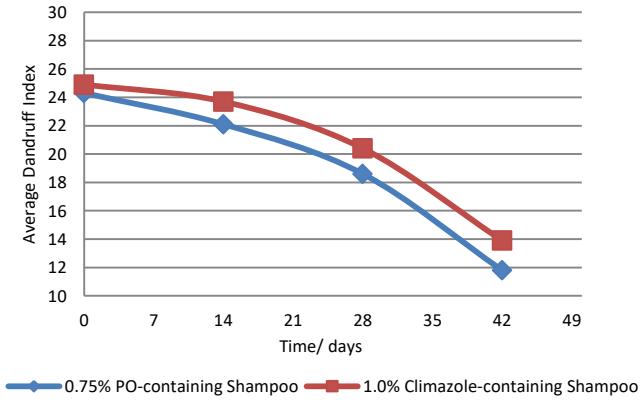
ITEM	P.O	Z.P.T	Percentage of cases in total subjects	
	%	%	Z.P.T＞P.O.	P.O.＞Z.P.T
Hair care essence	0.3	0.3	9	29
	0.5	1.0	8	33
Shampoo	0.75	1.0	7	47
	1.0	1.0	8	49

Summary: shampoo containing 0.5%, 0.75% and 1% piroctone are markedlysuperior to shampoo containing 1% Z.P.T in antidandruff effect. *Note: ">" in table means that the antidandruff effect performs better*

Efficacy Test of SpecKare™ PO

4.3 Anti-dandruff

Antidandruff Effect Comparative Study of **PO VS Climbazole**



Type	Time（d）											
	Note: B- shampoo contains 1% Climbazole; C- shampoo contains 0.75% PO.											
	-1			14			28			42		
	B	C		B	C	△	B	C	△	B	C	△
Average Dandruff	24.9	24.3	N=32	23.7	22.1		20.4	18.6		13.9	11.8	
Dandruff Reduction				1.2	2.2	1	4.5	5.7	1.2	11	12.5	1.5
Dandruff Reduction Percentage (%)				4.8	9.1		18.1	23.5		44.2	51.4	

Summary: The results show that PO has superior short-term & long-term antidandruff effect than Climbazole, even the use level of PO (0.75%) is less than Climbazole (1.0%) in same shampoo.

4.4 Antipruritic

Comparison of anti- itch effect between piroctone and Z.P.T in hair essence and shampoo

Type	P.O.	Z.P.T	Percentage of cases in total subjects	
	%	%	Z.P.T＞P.O.	P.O.＞Z.P.T
Hair condition	0.15	0.3	10	30
	0.3	0.3	20	31
	0.5	1.0	10	25
Shampoo	0.75	1.0	16	33
	1.0	160	15	34

Note: “>” in table means that the antipruritic effect performs better

Efficacy Test of SpecKare™ PO

4.5 Antiseborrhoeic

Antiseborrhoeic effect of PO—A: 50% Aqueous Isopropanol, B Shampoo with 0.2% PO， twice/day for 4 weeks

Testing Subjects Gender	Total epidermal lipids（μg/cm²） A Before treament	A After treaement	B Before treament	B After treaement	Decrease in sebum A	B	△	P
1 ♂	50	34	43	34	↓↓↓	↓↓↓		
2 ♂	46	40	43	33	↓↓	↓↓↓		
3 ♀	46	46	43	47	→	↑		
4 ♀	30	30	30	32	→	↑		
5 ♀	43	47	43	40	↑	↓		
6 ♂	43	30	37	32	↓↓↓	↓↓		
7 ♂	31	29	32	28	↓	↓		
8 ♀	39	34	42	36	↓↓	↓↓		
9 ♀	39	32	40	37	↓↓	↓		
10 ♂	40	46	38	42	↑↑	↑		
Average： 40.7		36.8	39.1	36.1	-3.9 ≤-9.6%	-3.0 ≤-7.7%	-0.9	Ns

Efficacy Test of SpecKare™ PO

4.6 Antimicrobial **(SPEC CHEM's Microbial Challenge Testing Laboratory)**

The MIC of piroctone olamine to 11 microorganisms

Microorganisms			MIC (mg/L)
Bacteria	Aerobic	Staphybcoccus aureus	6.25
		Staphylococcus epidermidis	6.25
		Escherichia Coli	12.5
	Anaerobic	Propionibacterim acnes	6.25
Fungi	Cutameous fungi	Trichophyton rubrum	6.25
		T. mentagrophytes	12.5
		Microsporum canis	12.5
		Epidermophyton floccosum	6.25
	Candida	Candida albicans	25
		Candida tropicalis	25
	Malassezia furfur		12.5

SpecKare™ PO :

- ✓ The MIC of PO against 11 microorganisms stabilizes between 6.25 and 25mg/L. *(Theoretical minimum dosage 0.0025%)*
- ✓ Wide-spectrum of antibacteria and antifungi properties

4.7 Thickening (still ongoing)

Synergistically increasing Formula's Viscosity—additional value of PO

PO has an obvious action of increasing viscosity of shampoo (Shampoo Base: 8% AES, 4%AME-Mg, 3%AAB, and water) when the PO dosage in formula reaches 0.3-0.4% , the viscosity of shampoo is about 3000m.pas.

This not only simplifies the production process but also raise the product stability , reduce product cost.

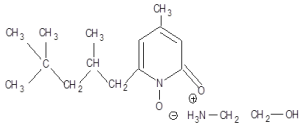
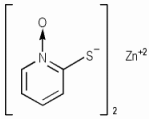
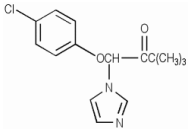
Application Guide of SpecKare™ PO

Application: PO is a broad spectrumof microbiocide/microbiostat,may be used in formulatingantidandruff shampoo, hair keep and hair care, soap, etc..

Recommend Use Level

Antidandruff rinse-off:	0.1-1.0%
Antidandruff leave-on :	0.05-0.5%
Anti-acne rinse-off:	0.1-1.0%
Anti-acne leave-on:	0.05-0.5%
Pet care rinse-off:	0.1-1.0%
Pet care leave-on:	0.05-0.5%
Deodorant Spray:	0.2-0.5%
Other Industries:	Depends

Comparative Study of PO VS ZPT VS Climbazole

	SpecKare™ PO	ZPT	Climbazole
INCI Name	Piroctone Olamine	Pyrithione Zinc	Climbazole
Chemical/IUPAC Name	1-Hydroxy-4-methyl-6-(2,4,4-trimethylpentyl)pyridin-2(1H)-one, compound with 2-aminoethanol (1:1)	Pyridine-2-thiol-1-oxide, zinc complex (2:1)	(R,S)-1-(4-chlorophenoxy)-1-imidazol-1-yl-3,3-dimethylbutan-2-one
Structure			
EU Functions	PRESERVATIVE	ANTIDANDRUFF ANTISEBORRHOEIC HAIR CONDITIONING PRESERVATIVE	ANTIDANDRUFF ANTIMICROBIAL PRESERVATIVE
EU Regulations	(a) Preservatives a) Rinse-off products 1.0% b) Other products 0.5% (b) SCCS Non-Preservatives Up to 3.0%	(a) Not be used oral hygiene products (b) As a preservative: a) Rinse-off products (excluding oral hygiene products) 0.5% b) Rinse off hair products 1.0% (c) SCCS Rinse-off anti-dandruff hair care Up to 2% (d) Leave-on hair products 0.1%	(a) Hair lotions 0.2% (b) Face creams 0.2% (c) Foot care products 0.2% (d) Rinse-off shampoo 0.5% (e) Rinse-off anti-dandruff shampoo 2.0%

Compatibility:

PO is compatible with common cosmetic ingredients, also compatible with cationic surfactants and cationic active components despite the anionic character of the active ingredient molecule. The aldehyde and keto groups in some specific frag may cause color problems.

Stability:

a). pH: Stable (in solution) at pH 3-9

b). Heat: Excellent temperature tolerance, stable even heat above 80℃ for a while

Formulation (Shampoo) with PO (@pH=5.5-7.0)PO passed 1-year stability test (@ above 40℃)

c). Light: Decompose under direct ultraviolet radiation. keep in dark place

d). Metals: PO Solution degrades in the presence of cupric and ferric ions.

Solubility:

Freely soluble in ethanol-containing (1-10%) & surfactant-containing solution

Slightly soluble in water (0.05%) and in Oil (0.05%-0.1%) , and solubility in water various with solution pH, better solubility can be observed in neutral and weakly alkaline than acidic pH

Formulation Example 1: Antidandruff and soft shampoo Lot#: 08060101B

Ingredients	%
Aqua	To 100
EDTA-2Na	0.10
AESA（70%）	8
$K_{12}A$(70%)	8
TC-8025	5
TC-14-S	0.15
Cetearyl alcohol	0.5
Pearling agent	1.0
CMEA	1
TC-23	0.5
TC-SHD	3
CAB-35	2
TC-1352	2
Kathon	0.05
P.O.	0.5
Citric acid	pH(6.0-6.2)
Essence	Q.S

Operation Process:

1. Disperse TC-14-S in water;
2. Add TC-8025 and EDTA-2Na;
3. Heat AESA, K12A to 75-80 ℃, and add them to above system
4. Pearling agent, CMEA, cetostearyl alcohol heated to 80 ℃ while stirring for 15-20 minutes, and add all of them to above system;
5, Cool to 50 ℃, add TC-1352 silicone emulsion, TC-SHD, CAB-35;
6, Pre-disperse PO in deionized water , add to the system;
7, Add citric acid while stirring to adjusted pH;

Formulation Example 2: Hair Conditioner

Ingredients		(%)
A-1: Oil phase	octadecyl alcohol	6
	Docosyltrimethylammonium chloride	1
A-2	TC-1214（100cst）	1.5
	TC-1233	1.5
B: Water phase	Glycine	3
	HEC	0.5
	TC-POLYQUAT 200L	0.3
	Aqua	To 100
C	P.O.	0.3
	Preservative	Q.S
	Essence	Q.S

Operation process:

1. Heat A-1: Oil phase to 75 ℃

2.Heat B: Water phase to 70-75 ℃

3. Add A-1 into B while stirring

4. Cool to 55-60 ℃, add phase A-2 and homogenize for three minutes.

5. Continue to cool to 40-45 ℃, add phase C-PO, preservative and essence while stirring 10-15 minutes .

Thank you for your attention!

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