



# Test Report

No. S2017102718

Date: 2018-1-15

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## SECTION 1: Identification of the substance/mixture and of the company/undertaking

- **1.1 Product identifier**
- **Trade name:** SAI AO-102 Medical Silicon Oil
- **Registration number:** Data not available
- **1.2 Relevant identified uses of the substance or mixture and uses advised against on**
- **Application of the substance/ mixture:** Material for industrial manufacture.
- **1.3 Details of the supplier of the safety data sheet**
- **Manufacturer/Supplier:**  
Wei Hai Hua Kang Biomaterials Technology Co., Ltd  
NO.9 Bo Quan Da Huangwan Dong Xi Hu Area Wu Han City,P.R.CHINA  
Tel: 0631-5968786
- **Only Representative/other EU contact point:** Information not available
- **Further information obtainable from:** Wei Hai Hua Kang Biomaterials Technology Co., Ltd.

## SECTION 2: Physical and chemical properties

- **2.1 Physical state:** Colorless transparent liquid
- **2.2 Density:**  $\approx 0.962 / \text{CM}(20)^3$  (20°C)
- **2.3 Refractive Index:**  $\approx 1.4028$
- **2.4 Viscosity mm<sup>2</sup>/s:** 100
- **2.5 Heavy metals, %:** <0.0005

## SECTION 3: Hemolysis,% GB/T 16886.4-2003

$$HR = \frac{A-B}{C-B} \times 100\%$$

3.1 HR--- Hemolysis rate % ; A--- Absorbance of test sample;

B--- Absorbance of negative; C--- Absorbance of positive

3.2 Test Sample: Rabbits

3.3 Test results

	1	2	3	Average Absorbance
Absorbance of test sample	0.0299	0.0198	0.0238	0.0245
Absorbance of negative	0.0263	0.0180	0.0141	0.0195
Absorbance of positive	0.8300	0.8104	0.8361	0.8255
Hemolysis rate %	0.6%			



Greatesing Service (Shanghai) Co., Ltd.  
上海量通检测技术有限公司

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## SECTION 4: Toxicological Information GB/T 16886.11-2011

3.1 Test Sample: Rats (weight: 17g-23g)

3.2 SC testing group: Test Rats ; SC normal group: normal rats IV: Intravenously 50ml/kgs

3.2 Test results:

Chart 1:

Group	Testing way	pcs	0H	24H	48H	72H	Dead Rats
Test Rats	IV	5	20.0+/- 1.3	21.6+/- 1.4	23.4+/- 1.4	25.5+/- 1.6	0
normal rats	IV	5	20.0+/- 1.2	21.6+/- 1.3	23.4+/- 1.3	25.5+/- 1.4	0

Chart 2:

	SC testing group	SC normal group
Immediately	AN	AN
4H	AN	AN
24H	AN	AN
48H	AN	AN
72H	AN	AN

An: Normally

U: Abnormal

## SECTION 5: Intradermal reaction test GB/T 16886.10-2005

5.1 Test Sample: Rabbits (<2kg)

5.2 Test results:

Rabbit Lot#	Weight (KG)	Medium respectively	Results											
			Testing group						Control group					
			24H		48H		72H		24H		48H		72H	
			ER	ED	ER	ED	ER	ED	ER	ED	ER	ED	ER	ED
1#	2.5	CSO	0	0	0	0	0	0	0	0	0	0	0	0
			0	0	0	0	0	0	0	0	0	0	0	0
			0	0	0	0	0	0	0	0	0	0	0	0
			0	0	0	0	0	0	0	0	0	0	0	0
			0	0	0	0	0	0	0	0	0	0	0	0
2#	2.7	CSO	0	0	0	0	0	0	0	0	0	0	0	0
			0	0	0	0	0	0	0	0	0	0	0	0
			0	0	0	0	0	0	0	0	0	0	0	0
			0	0	0	0	0	0	0	0	0	0	0	0
			0	0	0	0	0	0	0	0	0	0	0	0

ER: Erythema ED: Edema



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## SECTION 6: Photo of test sample



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