

**The Conseco Brand Sea Buckthorn Fruit Oil  
Towards  
Pre-market Notification for Dietary Supplement Substance in USA**

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Susan Walker, M.D.,  
Acting Director,  
Division of Dietary Supplements Programs,  
Office of Nutritional Products, Labeling and Dietary Supplements (HFS-820),  
Center for Food Safety and Applied Nutrition,  
Food and Drug Administration,  
5100 Paint Branch Parkway, College Park, MD 20740  
Telephone number: 301 436 - 2375

*O.P.B. / FDA*

Dear FDA Officer Dr. Susan Walker - Acting Director,

**Subject: Conseco Brand Sea Buckthorn Fruit Oil towards 75-Day Pre-market Notification  
for Dietary Supplement Substance in USA**

Thank you for your reading.

We are Conseco Sea buckthorn Co., Ltd.. Right now, we submit the documents about "Conseco Brand Sea Buckthorn Fruit Oil towards 75-Day Pre-market Notification for Dietary Supplement Substance in USA" to FDA CFSA. Please relevant Officers review the documents according to "Federal Food, Drug, and Cosmetic Act" of USA, and tell us all of your viewpoints, in order to let us finish the whole notification process of the product.

Thank you for your considering.

We are looking forward to hearing from you as soon as possible.

Sincerely yours,

*Han Xu*

Han Xu, M.D.  
Senior Researcher

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**Catalog**

My name and complete address: ..... 2

The name of the new dietary supplement:..... 2

    The Conseco Brand Sea Buckthorn Fruit Oil ..... 2

The description of the dietary supplement substance:..... 2

    Our products abide by following P. R. China Industry Standards:..... 2

    The level of the dietary ingredients in the product:..... 3

    The conditions of use of the product:..... 3

    The label contents of the product:..... 3

    The history of use like as herbal extraction in P. R. China:..... 4

    The other evidences of safety tests:..... 4

        Acute toxicity test for Sea buckthorn fruit oil..... 4

        Long-term toxic experiment..... 5

        Other adverse substances are limited by following P. R. China Industry Standards:.... 6

My signature by myself you can contact me if you have any questions. .... 6

Document Digest (P-1) ----- Attachments

Document Digest (T) ----- Attachments

Literature Digest (P-2) ----- Attachments

All of materials I will send an original and two copies (3 copies).

**My name and complete address:**

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**The name of the new dietary supplement:**

The Conseco Brand Sea Buckthorn Fruit Oil

**The description of the dietary supplement substance:**

This is the 100% natural herbal dietary supplement substance obtained from the botanical fruits of Sea buckthorn (*Hippophae rhamnoides* L.). Like as the material substance of dietary supplement, we recommend that the product can be used into the Soft Capsule of Sea Buckthorn Fruit Oil about dose 3g per day. [**Specification:** 0.45-0.5g/capsule][**Dosage:** 2-3 capsules/time, 2 times/day]

**Our products abide by following P. R. China Industry Standards:**

Sea buckthorn Fruit Oil

The Industry Standards of P. R. China

HB/QS 001—94

1994—06—08 Published

1994—10—17 Implemented

Published by National Sea buckthorn Coordination Office

[ **Detailed in Document Digest (P-1) ]**

Green Trade Standards of Importing & Exporting Medicinal Plants & Preparations

P. R. China Foreign Trade Industry Standards

WM2-2001

Ministry of Foreign Trade and Economic Cooperation, PRC

(Ministry of Commerce P. R. China)

2001—04—23 Published

2001—07—01 Implemented

[ **Detailed in Document Digest (T) ]**

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## Overview - The Conseco Brand Sea Buckthorn Fruit Oil

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The level of the dietary ingredients in the product:

**Dietary Ingredients:** Total Unsaturated Fatty,  $\geq 85\%$ .  
Sub-Oleic Acid, Flax Acid & Oleic Acid in Total Unsaturated Fatty,  $\geq 90\%$ .  
Sub-Oleic Acid & Flax Acid in Total Unsaturated Fatty,  $\geq 65\%$ .  
Total Carotenoid (mg/100g) ,  $\geq 150$   
 $\beta$  - carotene (mg/100g) ,  $\geq 5$   
Vitamin E (mg/100g) ,  $\geq 100$ .  
 $\alpha$  - tocopherol (mg/100g) ,  $\geq 60$ .

The conditions of use of the product:

Like as the botanical material substance of dietary supplement, we recommend that the product can be used into the Soft Capsule of Sea Buckthorn Fruit Oil about dose 3g per day [**Specification:** 0.45-0.5g/capsule] [**Dosage:** 2-3 capsules/time, 2 times/day].

The label contents of the product:

**Brand Name:** Conseco Brand.

**Product Name:** Sea Buckthorn Fruit Oil.

**Serving Size:** 100ml/bottle, 4.0 liter/barrel, or according to customer requirements.

**Dietary Ingredients:** Total Unsaturated Fatty,  $\geq 85\%$ .  
Sub-Oleic Acid, Flax Acid & Oleic Acid in Total Unsaturated Fatty,  $\geq 90\%$ .  
Sub-Oleic Acid & Flax Acid in Unsaturated Fatty,  $\geq 65\%$ .  
Total Carotenoid (mg/100g) ,  $\geq 150$ .  
 $\beta$  - carotene (mg/100g) ,  $\geq 5$   
Vitamin E (mg/100g) ,  $\geq 100$ .  
 $\alpha$  - tocopherol (mg/100g) ,  $\geq 60$

**Recommendation:** Like as the botanical material substance of dietary supplement, we recommend that the product can be used into the Soft Capsule of Sea Buckthorn Fruit Oil about dose 3g per day [**Specification:** 0.45-0.5g/capsule] [**Dosage:** 2-3 capsules/time, 2 times/day].

**Claim:** This is the 100% natural herbal dietary supplement. The statement has not been evaluated or approved by the FDA of USA. The product is not intended to diagnosis, treat, cure, or prevent any disease.

**Alert:** Keep out the children. Forbid in diarrhea.

**Store:** Store at a cool & dry location.

**Distributor:** Conseco Sea buckthorn Co., Ltd.  
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## Overview - The Conseco Brand Sea Buckthorn Fruit Oil

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### The history of use like as herbal extraction in P. R. China:

According to the P. R. China Industry Standards as following:

Sea buckthorn Fruit Oil

The Industry Standards of P. R. China

HB/QS 001—94

1994—06—08 Published

1994—10—17 Implemented

Published by National Sea buckthorn Coordination Office

The history of the product used as herbal extraction in P. R. China should be beginning in 1994-10-17 officially.

### The other evidences of safety tests:

The recommended human usage for Sea buckthorn Fruit Oil is 3g per day on our product label. This dosage does not present any safety concerns. According to 7-days acute toxic test and 90-days long-term test, the results cannot determine LD50 dosage in ICR mice and SD rats actually. But the results can indicate that, in 7-days acute toxicity test towards ICR mice, LD50>60ml/Kg.BW (equivalent to 55.2g/Kg.BW); in 7-days acute toxicity test towards SD rats, LD50>40ml/Kg.BW (equivalent to 36.8g/Kg.BW). (BW means body weight of animals.) The dosages used in the 90-days long-term toxicity studies, 2ml/Kg.BW, 5ml/Kg.BW, and 10ml/Kg.BW are equivalent to 12, 30, 60 times of human using dosage (in P. R. China). [10ml (9.2g) per day, average human body weight 60Kg] Towards our recommended human usage for Sea buckthorn Fruit Oil, 3g per day, the safety is enough.

### Acute toxicity test for Sea buckthorn fruit oil

Animal species: Little white mice, ICR species of body weight 18-22g; SD rats, SD species of body weight 170-200g, are supplied by Laboratory Animal Center, Xian Medical University in Shanxi Province. The 7-days acute toxicity tests have been done by Pharmacy School, Xian Medical University.

(a) The 80 ICR little white mice, body weight 18-22g are divided four groups, each group has 20 mice; control group mice are fed for water; the other three groups are fed Sea buckthorn fruit oil for 15ml/Kg.BW, 30ml/Kg.BW and 60ml/Kg.BW (divide 2 ingestions per day, interval 6 hours). After observe one week, the study doesn't find any mice death. At the first day, most mice presents with diarrhea and appetite decrease; the rest six days, every mouse is normal activity and appetite, and has no diarrhea. Therefore the 7-days study can not measure LD50 in mice under the conditions. Until 8th day, do autopsy, the results show that there are no significant difference

## Overview - The Conseco Brand Sea Buckthorn Fruit Oil

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comparison to control group; there are no macroscopic pathological changes in heart, liver, spleen, lung, kidney and intestine in the experimental groups mice.

(b) In the second part of 7-days acute toxic experiment in SD rats, SD species of body weight 170-200g, half male, and half female, the 40 rats are divided four groups, each group has 10 rats. 10 control group rats are fed water; the other three groups rats are fed Sea buckthorn fruit oil for 10ml/Kg.BW, 20ml/Kg.BW, and 40ml/Kg.BW (divide 2 ingestions per day, interval 6 hours). After observe one week, they don't find any rats death. At the first day, some rats' appetite decrease and daily activity decrease; the rest six days, every rat is normal activity. Therefore the study cannot measure LD50 in rats under the conditions.

### Long-term toxic experiment

(c) In the third part of 90-days long-term toxic experiment in SD rats, SD species of body weight 100-150g, half male, half female, total 80 SD rats. The study continues to feed each mice for 90 days, 80 SD rats are divided into three groups for experiment and another group for control; each group contains 20 rats. Control group rats received water, experimental group rats received 2ml/Kg.BW, 5ml/Kg.BW, 10ml/Kg.BW Sea buckthorn Fruit Oil (1 ingestion per day, equal to 12, 30, and 60 times of human using dosage in P. R. China). After observing for 90 days, there is no death. About hair growth and behavior change in the three experiment groups, there is no significant difference comparison by control group. About body weight, balance BW each time per 10 days, there is no significant difference comparison by control group ( $p>0.05$ ). Also they do the blood test including HB, RBC, WBC indexes, all the blood test are in the normal range. There is no significant difference comparison by control group rats ( $P>0.05$ ). As well as they do the blood index test, including SGPT, SGOT, BUN, creatinine and blood sugar, all test results are in the normal range, there is no significant difference comparison to control group rats ( $P>0.05$ ). There are no macroscopic pathological changes in the heart, liver, spleen, lung, kidney, adrenal gland, testis, womb & oval gland, and thymus gland, all organ weight are in the normal range, there is no significant difference comparison to control group mice ( $P>0.05$ ). The dosages in the three experiment groups used in the 90-days toxicity studies, 2ml/Kg.BW, 5ml/Kg, 10ml/Kg are equivalent to 12, 30, 60 times of using dosage (10ml per day or 9.2g per day, average body weight 60Kg) in human (in P. R. China). Therefore the study cannot get LD50 in SD rats under the conditions.

**[ Detailed in Literature Digest (P-1) ]**

## Overview - The Conseco Brand Sea Buckthorn Fruit Oil

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Other adverse substances are limited by following P. R. China Industry Standards:

Sea buckthorn Fruit Oil

The Industry Standards of P. R. China

HB/QS 001—94

1994—06—08 Published

1994—10—17 Implemented

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**[ Detailed in Document Digest (P-1) ]**

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Document Digest (P-1) ----- Attachments

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## --- Document Digest (P-1) ---

Sea buckthorn Fruit Oil

The Industry Standards of P. R. China

HB/QS 001—94

1994—06—08 Published

1994—10—17 Implemented

Published by National Sea buckthorn Coordination Office

Table 1 Appearance Indexes

Item	Index
	Sea buckthorn Fruit Oil
Description	Brown red transparency uniformity oil state liquid, viscous under low temperature.
Odor & Taste	Contain Sea buckthorn Fruit Oil inherent flavour and taste, no offodour.

Table 2 Indexes of Physics And Chemistry

Item	Index
	Sea buckthorn Fruit Oil
Density (20°C)	0.9100—0.9400
Refractive Index (20°C)	1.4500—1.4800
Acid value (mg KOH/g), ≤	40
Iodin value (g/100g)	18—70
Saponification value (mg KOH/g)	130—200
Nonsaponification (%) ≥	1
Total Carotenoid (mg/100g), ≥	150
β - carotene (mg/100g), ≥	5
Vitamin E (mg/100g), ≥	100
α - tocopherol (mg/100g), ≥	60
Character Value (C60, %), ≥	25
Moisture (%), <	0.3

Table 3 Hygiene Indexes

Item	Index
Peroxy Value (ex factory, %), ≤	0.40
As (ppm), ≤	0.1
Hg (ppm), ≤	0.05
Residue Solvent (ppm)	0

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## --- Document Digest (T) ---

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#### 4. Limited Quantity Indexes

4. 1. Heavy Metal and Arsenate

4. 1. 1. Total Heavy Metal  $\leq 20.0$  mg/kg

4. 1. 2. Pb  $\leq 5.0$  mg/kg

4. 1. 3. Cd  $\leq 0.3$  mg/kg

4. 1. 4. Hg  $\leq 0.2$  mg/kg

4. 1. 5. Cu  $\leq 20.0$  mg/kg

4. 1. 6. As  $\leq 2.0$  mg/kg

4. 2. Aflatoxin Content

4. 2. 1. BI(Aflatoxin)  $\leq 5$   $\mu$  g/kg

4. 3. Pesticide Residual Quantity

4. 3. 1. BHC  $\leq 0.1$  mg/kg

4. 3. 2. DDT  $\leq 0.1$  mg/kg

4. 3. 3. PCNB  $\leq 0.1$  mg/kg

4. 3. 4. Aldrin  $\leq 0.02$  mg/kg

4. 4. Microbiology Indexes: Escherichia coli -- 0/g or 0/ml

Staphylococcus aureus -- 0/g or 0/ml

Pseudomonas aeruginosa -- 0/g or 0/ml

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## Attachments

### --- Literature Digest (P-1) ---

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An experimental study of toxicity of Hippophae rhamnoides L. fruit oil

Che Xi-Ping, Wang Shi-Xiang, Kang Jun, Tang Cheng-Han

Pharmacy School, Xian Medical University, Shanxi, Xian 710061

Hippophae 2001.09; 14(3): 30-34

**Material Sample:** Sea buckthorn (Hippophae rhamnoides L.) Fruit Oil. Density is 0.92g/ml.

**Animals:** ICR mice, SD rats. Supplied by Laboratory Animal Center, Xian Medical University

#### **Methods and Results:**

According to acute toxic test and long-term test, the article cannot determine LD50 dosage in ICR mice and SD rats actually. But the article results can indicate that, in 7-days acute toxicity test towards ICR mice, LD50>60ml/Kg.BW (equivalent to 55.2g/Kg.BW), and in 7-days acute toxicity test towards SD rats, LD50>40ml/Kg.BW (equivalent to 36.8g/Kg.BW). (BW means body weight of animals.) The dosages in the three experimental groups used in the 90-days long-term toxicity studies, 2ml/Kg.BW, 5ml/Kg.BW, and 10ml/Kg.BW are equivalent to 12, 30, 60 times of human using dosage (in P. R. China). [The human using dosage should be 10ml (9.2g) per day and the average human body weight should be 60Kg (in P. R. China).] The results of the experimental groups in the long-term toxicity studies show that there is no significant difference comparison to control group. There are no macroscopic pathological changes in major organs.

- Acute toxicity test:

Towards ICR mice:

The 80 ICR little white mice, body weight (BW) 18-22g, half male, half female, are divided four groups random according to body weight and sex, and each group has 20 mice. After fasting 14 hours, group 1, group 2 and group 3 mice are fed for 15ml/Kg.BW, 30ml/Kg.BW and 60ml/Kg.BW of Sea buckthorn fruit oil, but control group, group 4 mice are fed for water. [With ig (injection gastric) each time, 2 times each day, interval 6 hours] Divide cages and foster crowds with same conditions, solid feedstuff and normal drink. Observe 7 days at room temperature (20°C -25°C), and record animal changes and death. After the 7 days, they don't find any mice death. At the day 1, most mice presents with activity and appetite decrease, and the high dose group mice appear oiliness dejecta; day 2 - day 3, appetite, defecation, and activity recover gradually; there is no significant difference comparison with control group. Therefore the article results cannot measure LD50 in mice actually. (Just only indicate LD50>60ml/Kg.BW in mice.) Until day 8, end experiment, do autopsy, the results show that there is no significant difference comparison to control group; there are no macroscopic pathological changes in heart, liver, spleen, lung, kidney and intestine in the experimental group mice.

## Attachments

### --- Literature Digest (P-1) ---

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Towards rats:

In the second part of acute toxic experiment in SD rats, SD species of body weight 170-200g, half male, half female, 40 rats is divided four groups random according to body weight and sex, each group has 10 rats. The 10 control group mice (group 4) are fed water; another three groups rats (group 1, group 2 and group 3) are fed Sea buckthorn fruit oil for 10ml/Kg.BW, 20ml/Kg.BW, and 40ml/Kg.BW. [With ig (injection gastric) each time, 2 times each day, interval 6 hours] Divide cages and foster crowds with same conditions, solid feedstuff and normal drink. Observe 7 days at room temperature (20°C-25°C), and record animal changes and death. At the day 1, most rats presents with activity and appetite decrease, and the high dose group rats appear oiliness dejecta; day 2 - day 3, appetite, defecation, and activity recover gradually; there is no significant difference comparison with control group. After observe the experiment, the article results don't find any rats death in all of groups. Therefore the article results cannot measure LD50 in SD rats actually. (But just only the results indicate LD50>40ml/Kg.BW.)

- Long-term toxic experiment in SD rats

In the long-term toxic experiment in SD rats, SD species of weight 100-150g, half male, half female, total 80 SD rats. After feed one week in laboratory conditions and be divided four groups random according to body weight and sex, the 80 SD rats are divided into three groups (group 2, group 3, group 4) for experiment and another group for control (group 1); each group contains 20 rats. The control group rats (group 1) received water 10ml/Kg.BW, and the experimental group rats (group 2, group 3, group 4) received Sea buckthorn fruit oil 2ml/Kg.BW, 5ml/Kg.BW, and 10ml/Kg.BW [equal to 12, 30, and 60 times of human using dosage (in P. R. China)], [one time per day, with ig (injection gastric) each time] and continue to feed each rat for 3 months. Divide cages and foster crowds with same conditions, solid feedstuff and normal drink. The rats are measured body weight per 10 days, and observed activity, appetite, dejecta, and hair color. After observing for 3 months, there is no significant difference comparison by control group ( $p>0.05$ ) in body weight (BW) (Table 1), and there is no death. About hair color and behavior change in the three groups, there is no significant difference comparison by control group, except some high dose group rats have soft dejecta, light yellow hair, and a little appetite decrease. Also they do the blood tests (Table 2), including HB, RBC, and WBC indexes, all the blood tests are in the normal range. There is no significant difference comparison by control group SD rats ( $P>0.05$ ). As well as they do other blood biochemistry index tests (Table 3), including SGPT, SGOT, BUN, creatinine and blood sugar, all test results are in the normal range, and there is no significant difference comparison to control group SD rats ( $P>0.05$ ). There are no macroscopic pathological changes in the heart, liver, spleen, kidney, adrenal gland, testis, womb & oval gland, and thymus gland, all organ weights (Table 4) are in the normal ranges, there is no significant difference comparison to control group SD rats ( $P>0.05$ ).

## Attachments

### --- Literature Digest (P-1) ---

[Attend in following tables in the long-term toxic experiment in SD rats: **group 1**, control group, received water 10ml/Kg.BW per day; **group 2**, low dose group, received Sea buckthorn fruit oil 2ml/Kg.BW per day; **group 3**, middle dose group, received Sea buckthorn fruit oil 5ml/Kg.BW per day; **group 4**, high dose group, received Sea buckthorn fruit oil 10ml/Kg.BW per day.]

Table 1 - Sea buckthorn Fruit Oil towards SD rat body weight (BW)

Group	Animal amount	Body weight (BW) (g • Average ± SD)			
		Before received injection gastric	After received injection gastric (days)		
			30	60	90
Group 1	20	140.0 ± 20.2	220.9 ± 32.4	263.6 ± 46.2	280.1 ± 48.3
Group 2	20	138.8 ± 19.6	218.3 ± 46.4	262.9 ± 44.8	285.6 ± 46.3
Group 3	20	139.9 ± 7.1	216.6 ± 29.3	264.2 ± 49.1	276.4 ± 48.1
Group 4	20	141.6 ± 33.9	210.9 ± 36.6	253.7 ± 46.4	265.6 ± 44.4

Note: group received Sea buckthorn fruit oil comparison by control group P>0.05

Table 2 - Sea buckthorn Fruit Oil towards SD rat blood indexes

Group	Animal amount	Hb (g/L)	RBC (10 <sup>12</sup> /L)	WBC (10 <sup>9</sup> /L)	WBC Classify	
					Neutrophilic Granulocytes	Lymphocytes
Group 1	20	139.5 ± 9.7	7.7 ± 0.3	10.1 ± 1.9	0.30 ± 0.04	0.69 ± 0.09
Group 2	20	133.2 ± 14.1	7.5 ± 0.7	10.0 ± 2.2	0.29 ± 0.07	0.70 ± 0.06
Group 3	20	129.9 ± 11.6	7.4 ± 0.4	11.9 ± 2.3	0.28 ± 0.07	0.71 ± 0.09
Group 4	20	136.0 ± 14.6	7.6 ± 0.5	10.3 ± 2.4	0.31 ± 0.08	0.69 ± 0.07

Note: group received Sea buckthorn fruit oil comparison by control group P>0.05

Table 3 - Sea buckthorn Fruit Oil towards SD rat blood biochemistry indexes

Blood biochemistry indexes	Group (n=20)			
	Group 1	Group 2	Group 3	Group 4
SGPT (μ/L)	30.9 ± 7.3	28.7 ± 11.7	32.4 ± 9.6	31.9 ± 15.8
SGOT (μ/L)	79.2 ± 9.7	76.4 ± 10.6	76.2 ± 11.4	82.3 ± 10.3
BUN (mmol/L)	5.95 ± 1.19	6.02 ± 2.05	5.34 ± 1.04	5.46 ± 1.22
Creatinine (μ mol/L)	105.2 ± 20.3	104.3 ± 16.8	114.0 ± 15.1	112.3 ± 22.0
Blood sugar (mmol/L)	5.63 ± 1.17	5.59 ± 1.18	5.89 ± 1.29	5.82 ± 1.46

Note: group received Sea buckthorn fruit oil comparison by control group P>0.05

## Attachments

### --- Literature Digest (P-1) ---

[Attend in following tables in the long-term toxic experiment in SD rats: **group 1**, control group, received water 10ml/Kg.BW per day; **group 2**, low dose group, received Sea buckthorn fruit oil 2ml/Kg.BW per day; **group 3**, middle dose group, received Sea buckthorn fruit oil 5ml/Kg.BW per day; **group 4**, high dose group, received Sea buckthorn fruit oil 10ml/Kg.BW per day.]

Table 4 - Sea buckthorn Fruit Oil towards SD rat major organs' wet weight

Organ	major organ wet weight/body weight (g/100g, mean $\pm$ s, n=20 )			
	Group 1	Group 2	Group 3	Group 4
Heart	0.36 $\pm$ 0.03	0.34 $\pm$ 0.08	0.36 $\pm$ 0.07	0.35 $\pm$ 0.08
Liver	3.52 $\pm$ 0.69	3.81 $\pm$ 0.26	3.79 $\pm$ 0.35	3.77 $\pm$ 0.67
Spleen	0.32 $\pm$ 0.06	0.34 $\pm$ 0.05	0.31 $\pm$ 0.09	0.35 $\pm$ 0.05
Lung	0.64 $\pm$ 0.09	0.70 $\pm$ 0.16	0.71 $\pm$ 0.11	0.64 $\pm$ 0.07
Kidney	0.68 $\pm$ 0.09	0.73 $\pm$ 0.07	0.75 $\pm$ 0.17	0.74 $\pm$ 0.09
Thymus Gland	0.12 $\pm$ 0.04	0.10 $\pm$ 0.08	0.13 $\pm$ 0.05	0.10 $\pm$ 0.04
Testis (n=10)	1.08 $\pm$ 0.19	1.04 $\pm$ 0.15	1.12 $\pm$ 0.47	1.10 $\pm$ 0.22
Womb & Oval Gland (n=10)	0.28 $\pm$ 0.06	0.31 $\pm$ 0.05	0.30 $\pm$ 0.08	0.29 $\pm$ 0.06
Adrenal Gland (mg/100g)	16.93 $\pm$ 6.29	17.22 $\pm$ 6.09	18.47 $\pm$ 4.65	18.59 $\pm$ 6.15

Note: group received Sea buckthorn fruit oil comparison by control group  $P > 0.05$