

**To:UniqueProducts, Co. Ltd..  
Test Report  
August 31,2009  
Received No: B0907051-001**

**Bloom Co., Ltd.**

**Test Report**

**No:B0907051-001  
Aug 31, 2009**

**To: Unique Products, Co., Ltd.**

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**Bloom Co., Ltd**  
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The result of the examination inspection of requested supplied product is as follows:

<b>Supplied product name</b>	<b>Cyber Clean</b>
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**The result of the examination inspection**

<b>Test items</b>	<b>Test result</b>	<b>Remarks</b>
<b>Single time oral administering toxicity examination (limiting test)</b>	<b>Attached paper report</b>	

**Remarks**

**Please receive our approval when you publish this report or this.**

**JBS-09-ROAC-035**

# **Final Report**

**Single time oral administering toxicity examination in rat  
on  
Cyber Clean  
(Limiting Test)**

**Test number : JBS-09-ROAC-035**

**2009/8/24**

**Japan Bioscience Center Ltd.**

**JBS-09-ROAC-035**

**Signing name**

**Title: Single time oral administering toxicity examination in rat of "Cyber Clean" (limit examination)**

**Test Number : JBS-09-ROAC-035**

**Test facility and its location :**

**Japan Bioscience Center Ltd.**

**Gifu Laboratory**

**〒503-0628 Gifu Prefecture Umizu city Kaizu-cho Fukue 52**

**(TEL 0584-54-5631、 FAX 0584-54-5104)**

**Start of the examination day: July 29, 2009**

**Examination end date: August 24, 2009 (final report writing day)**

**Study director: Kunitsukasa Katsuyoshi**

**(report writer person)**

**Date: August 24, 2009**

## Summary

As a part of the safety estimate of Cyber Clean, Cyber Clean in 2000 mg/kg dosage, the single time oral was administered to Slc: Sprague-Dawley rat's male or female, and the toxicity was examined. The dosage of the examination was set 2000 mg/kg assumed to be an upper bound dosage of the single dose according to the toxicity examination method guideline of the medicine.

Neither a death nor a general abnormal state were admitted even in the bodies of both male or female of 2000 mg/kg administering group of Cyber Clean. In weight, male or female showed both good transitions through the term of the surveillance, and abnormality was not admitted by male or female of all examples in the autopsy finding.

Therefore, when Cyber Clean of 2000 mg/kg dosage was administered to Slc:SD rats of male or female by the single time oral dosage, the death case was not admitted by 2000 mg/kg dosage. Based on this, the fatal dose of the outline of Cyber Clean was guessed more than 2000 mg/kg dosage.

## Purpose of examination

As a part of the safety estimate of Cyber Clean, Cyber Clean was examined in the toxicity when the single time oral was administered to the rat. The examination was executed by the GLP non-application.

## Testing material and method

### 1. Effect material and medium

Cyber Clean that received the offer from Bloom Ltd. (Shape: slime) was used for the effect material. The effect material was preserved under the room temperature condition until using it. The injection solvent (Otsuka Drug Industry Ltd. and Japanese pharmacopeia) was used for the medium.

### 2. Adjusting method of effect material

10<sub>w</sub> / v % Administering liquid

- ① The effect material of 6g was weighed in the schale by an electronic balance.
- ② It was moved to the mortar, and was mixed with the pestle adding the injection solvent to be suspended.
- ③ It was put in the graduated cylinder to be matched to 60mL.
- ④ After the graduated cylinder was closely stopped by parafilm and falled/ mixed, it was moved to a brown airtight glass container.

### 3. Used animals and breeding condition

#### 3.1 Used animals

SD system rats (Slc:SD SPF) of five weeks which were produced by Japan SLC were bought, and were quarantined and adapted for 6 days . The animals that had grown well by a general state and the weight result for quarantine and the adaptation period were used for the examination. The age in week when beginning to be administered was six weeks, and the range of weight was male:166-174g, and female 113-125g.

#### 3.2 Breeding condition

The animals were accommodated in the barrier breeding room adjusted to temperature 20-26°C, relative humidity 40-70%, and times of ventilation frequency 10-15/hour, and during 12 hours in time of lighting(7:00-19:00). (Quarantine and adaptation period: II title area I Title room. After division of the crowd: II title area III Title room). It accommodated 2-3 rats/cage in stainless steel making suspender cage (33.5cmD×22cmW×20cmH). The water supply paper (The tray mat: Shinwa Ltd.) was sterilized and used for the excrement saucer. The exchange of cages exchanged the excrement saucers once every two weeks at the frequency twice a week.

Fodder was radiation sterilization fodder (FR-2 by Funabashi Farm Ltd. (Chiba Prefecture). It was freely taken. However, the fast began from day and night before it was administered, and was renewed during 2-3 hour after it had been administered.

The drinking water was freely taken by the waterworks water (Gifu Prefecture Umizu city Kaizu-cho) by the automatic water supply device.

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#### 4. Crowd composition, mode of administration, and dosage

##### 4.1 Crowd composition

The effect material administering group were like the next table: Crowd's total. The number of animals assumed to be a crowd composition made male/female each five/group.

The effect material	Dosage (mg/kg)	Concentration % (w/v)	Administering liquid amount (mL/kg)	Male		Female	
				Number of animals	Animal number	Number of animals	Animal number
Cyber Clean	2000	10	20	5	1-5	5	501-505

##### 4.2 Administration route

Per oral administration (single times)

##### 4.3 Mode of administration

To administering, 5mL disposable injection cylinder (Minimum scale 0.2mL and Terumo syringe R; Terumo Corp.), and an oral sonde (1.5mm×L85mm; Fuchigami Machine Ltd.) were used. The administering liquid measure is assumed to be 20mL/kg. It was calculated according to the solid based on the weight on the administering day according to a minimum scale of the injection cylinder.

## **5. Observation and inspection items**

### **5.1 Observation of general state and life and death**

The administering day is reckoned on the 0th. A general state and life and death of all samples were observed for 14 days.

On the administering day, it was observed once before it administer, and after it administers, it was a continuance observation doing until two hours. After it had administered it, it was observed once every hour by 3-5 hour. After the administering next day, it was observed twice a day (the observation end date of the period once) on the first

### **5.2 Measurement of body weight**

Weight of all samples was measured by an electronic balance (PM3000 and METTLER TOLEDO Ltd.) on 1, 3, 6, 10, and 14(sectio cadaveris day) after it had administered it on the administering day (the 0th).

### **5.3 Sectio cadaveris**

Sectio cadaveris after venisection under ether anesthetizing was made euthanatized at observation end date of period of all samples. The presence of naked eye abnormality of each organ and the organization was observed by sectio cadaveris.



## **Examination result**

1. **General state (individual table 1)**  
Neither a death nor a general abnormal state were admitted even in the individual of both male or female.
2. **Weight (individual table 2)**  
Both male and female showed good transitions through the term of the surveillance.
3. **Autopsy finding (individual table 3)**  
Abnormality was not admitted in all examples of male and female.

## **Summary and consideration**

As a part of the safety estimate of Cyber Clean, 2000 mg/kg dosage of Cyber Clean was administered to Slc: Sprague-Dawley rat of male and female by the single time oral, and the toxicity was examined. The dosage of the examination set 2000 mg/kg assumed to be an upper bound dosage of the single dose according to the toxicity examination method guideline of the medicine.

Neither a death nor a general abnormal state were admitted even in the individual of both male and female of 2000 mg/kg administering group of Cyber Clean.

In weight, both male and female showed good transitions through the term of the surveillance, and abnormality was not admitted by male or female of all examples in the autopsy finding.

Therefore, when Cyber Clean in 2000 mg/kg dosage was administered to Slc:Sprague-Dawley rat of male or female by the single time oral, the death case was not admitted by 2000 mg/kg dosage. Consequently, the fatal dose of the outline of Cyber Clean was guessed more than 2000 mg/kg dosage.



**Individual table 1    general state**

Effect material	Sex	Dosage (mg/kg)	Animal number	Before it administers	After it administers											
					Hours					Days						
					~2	3	4	5	1	2	3	4	5	6	7	8~14
Cyber Clean	Male	2000	1	—	—	—	—	—	—	—	—	—	—	—	—	—
			2	—	—	—	—	—	—	—	—	—	—	—	—	—
			3	—	—	—	—	—	—	—	—	—	—	—	—	—
			4	—	—	—	—	—	—	—	—	—	—	—	—	—
			5	—	—	—	—	—	—	—	—	—	—	—	—	—
	Female	2000	501	—	—	—	—	—	—	—	—	—	—	—	—	—
			502	—	—	—	—	—	—	—	—	—	—	—	—	—
			503	—	—	—	—	—	—	—	—	—	—	—	—	—
			504	—	—	—	—	—	—	—	—	—	—	—	—	—
			505	—	—	—	—	—	—	—	—	—	—	—	—	—

— : Abnormality is not found.

**Individual table 2 Weight**

Effect material	Sex	Dosage (mg/kg)	Animal number	Weight(g)					
				Days					
				0	1	3	6	10	14
Cyber Clean	Male	2000	1	172	198	213	236	270	301
			2	174	197	215	235	267	291
			3	172	194	210	232	258	285
			4	169	191	210	236	269	302
			5	166	188	203	225	253	277
			Mean	171	194	210	233	263	291
	S.D.	3	4	5	5	8	11		
	Female	2000	501	125	141	156	172	193	213
			502	124	140	147	162	177	191
			503	120	136	150	161	176	191
			504	115	132	142	159	182	203
505			113	132	141	150	166	182	
Mean	119	136	147	161	179	196			
S.D.	5	4	6	8	10	12			

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**Individual table 3 Autopsy opinion**

Effect material	Sex	Dosage (mg/kg)	Animal number	Section cadaveris day	Organ/Tissue	Naked eye observation
Cyber Clean	Male	2000	1	14	All Organ/Tissue	No abnormality
			2	14	All Organ/Tissue	No abnormality
			3	14	All Organ/Tissue	No abnormality
			4	14	All Organ/Tissue	No abnormality
			5	14	All Organ/Tissue	No abnormality
	Female	2000	501	14	All Organ/Tissue	No abnormality
			502	14	All Organ/Tissue	No abnormality
			503	14	All Organ/Tissue	No abnormality
			504	14	All Organ/Tissue	No abnormality
			505	14	All Organ/Tissue	No abnormality

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