FICHA TÉCNICA Y DOCUMENTACIÓN

COPA MENSTRUAL TALLA S
REFERENCIA: 00470

COPA MENSTRUAL + ESTERILIZADOR TALLA S
REFERENCIA: 00471

FÁBRICA
XI'AN FURUIZE BIOTECHNOLOGY CO., LTD.

incaFARMA

NOMBRE DEL PRODUCTO:

COPA MENSTRUAL Y ESTERILIZADOR

Tamaño S

DISTRIBUIDOR:

INCA PRODUCT S.L.
B-05115159
Calle Reyes Católicos, 8 2ºB
05001 Ávila
info@incaproduct.com
Telf.: 920269774

FABRICANTE:

XI'AN FURUIZE BIOTECHNOLOGY CO., LTD
Room 11131, building 3, i Duhui nº 11, Tangyan South Road. Zhangba Street Office, Hight-tech Zone, Xi'an City Shaanxi Providence.
China

CERTIFICACIONES y DOCUMENTACIÓN ADJUNTA:

-Imágenes fábrica.

-Ficha técnica e imágenes del producto.

-Certificado de registro de QUALITY MANAGMENT SYSTEM: **ISO 13485:2016**
Certificado emitido por NQA.
Certificado nº: 47763

-Certificado de conformidad conforme NO es un Producto Sanitario.

-Declaración de conformidad CE.

-Certificación ECM, conforme el producto indicado cumple y sigue con la regulación de Productos sanitarios con Clase I (No estéril).

-Registro FDA.

-Certificados de la materia prima utilizada:
Silicona WACKER ELASTOSIL R 406/40 CN
Aplicación recomendada para uso en la industria médico/ farmacéutica

-Certificado Raw material biocompatibilidad R 406/40 CN

-Ficha de seguridad (MSDS) FTT: nºHLF200005593E

-Certificado de toxicidad y biocompatibilidad.

-Test report MA nº SSMT-R-2020-0300901B
Fecha: 26/10/2020
In vitro Cytotoxicity test
ISO 10993-5:2009

-Test report MA nº SSMT-R-2020-03009-02B
Fecha: 30/10/2020
Skin irritation test
ISO 10993.10-2010

Test report MA nº SSMT-R-2020-03009-03B
Fecha: 19/11/ 2020
Skin sensitization test
ISO 10993.10-2010

Test report FTT nºHLF21001504EA
Fecha: 11/01/ 2021
As specified by client, to screen on Jun 16, 2020 the 209 Substances of Very High Concern (SVHC) under the regulation (EC) No 1907/2006 of REACH for the submitted samples .

Test report FTT nºHLF210015046E
Fecha:06/ 2021

RoHS Directive (EU)2015/863 amending Annex II to Direxitive 2011/65/EU–
Lead(Pb), Cadmium(Cd), Mercury(Hg), Hexavalent Chromium(CrVI),
Polybrominated Biphenyls (PBBs), Polybrominated Biphenyl Ethers(PBDEs),
Dibutyl phthalate (DBP), Butyl benzyl phthalate(BBP),
Bis-(2-ethylhexyl)phthalate(DEHP), Di-iso-butyl ortho-phthalate(DIBP)

REFERENCIA	EAN	DUM DISPLAY	DESCRIPCION	BLISTERS/PACK	BLISTERS/ MASTER
00470	8445588004705	98445588004708	IF-COPA MENSTRUAL-TALLA S	24	96
00471	8445588004712	98445588004715	IF-COPA MENST ESTERILIZADOR-TALLA S	12	72

FICHA TÉCNICA

Nombre: **COPA MENSTRUAL REUTILIZABLE**

Descripción: Una copa menstrual es un tipo de recipiente de higiene femenina reutilizable que se inserta en la vagina con el objetivo de atrapar y recoger el líquido del período. Es una copa pequeña y flexible en forma de embudo hecha con silicona de grado médico hipoalergénica.

NO es un producto sanitario.

Talla: S
Medidas copa : Ancho de 37mm x alto de 59,70 mm
Capacidad de flujo sanguíneo: 18 ml
Color: Rosa
Material: Silicona de grado médico.

Recomendación de uso talla S: Recomendada para mujeres menores de 20 años, de constitución pequeña, flujo medio-bajo y que no hayan tenido hijos por parto vaginal.

Fecha de caducidad: No se puede establecer una fecha concreta de caducidad aunque se estima en 10 años y dependerá del buen uso y cuidado del producto. El fabricante recomienda remplazarla cada 5 años.

Nombre: **ESTERILIZADOR DE COPA MENSTRUAL**

Descripción: Recipiente plegable de silicona de grado médico que ayuda a esterilizar la copa menstrual. También se utiliza como contenedor de copas para su transporte.

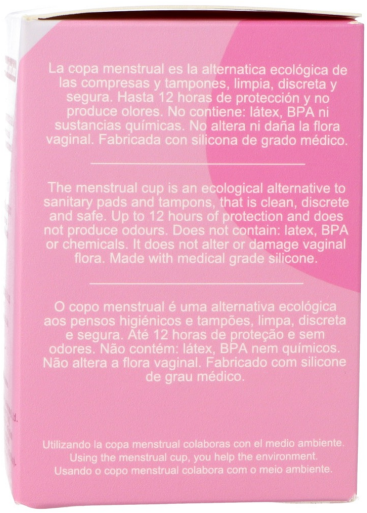
NO es un producto sanitario.

Talla única.
Medidas plegado: 8 cm de diámetro. Altura de 2 cm.
Medidas abierto: 8 cm de diámetro. Altura de 7,5 cm.
Color: Rosa
Material: Silicona de grado médico.

Fecha de caducidad: No se puede establecer una fecha concreta de caducidad aunque se estima en 10 años y dependerá del buen uso y cuidado del producto. El fabricante recomienda remplazarla cada 5 años.

DISEÑO PACKAGING Y FOTOS REALES COPA T. S

FOTOS **TALLA S** COPA MENSTRUAL:



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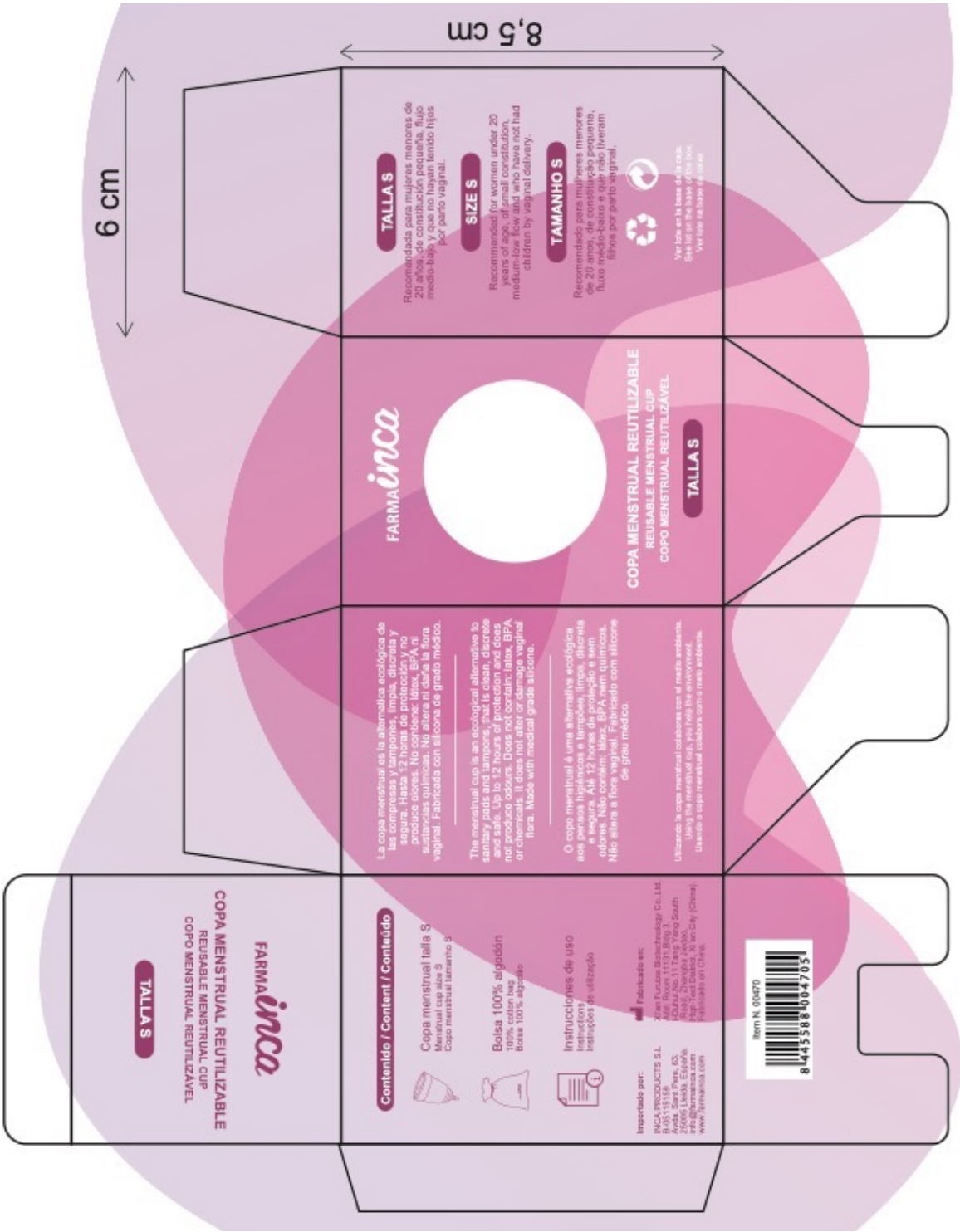
DISEÑO CAJA **TALLA S** COPA MENSTRUAL:



CAJA EXPOSITORA | 24 UDS

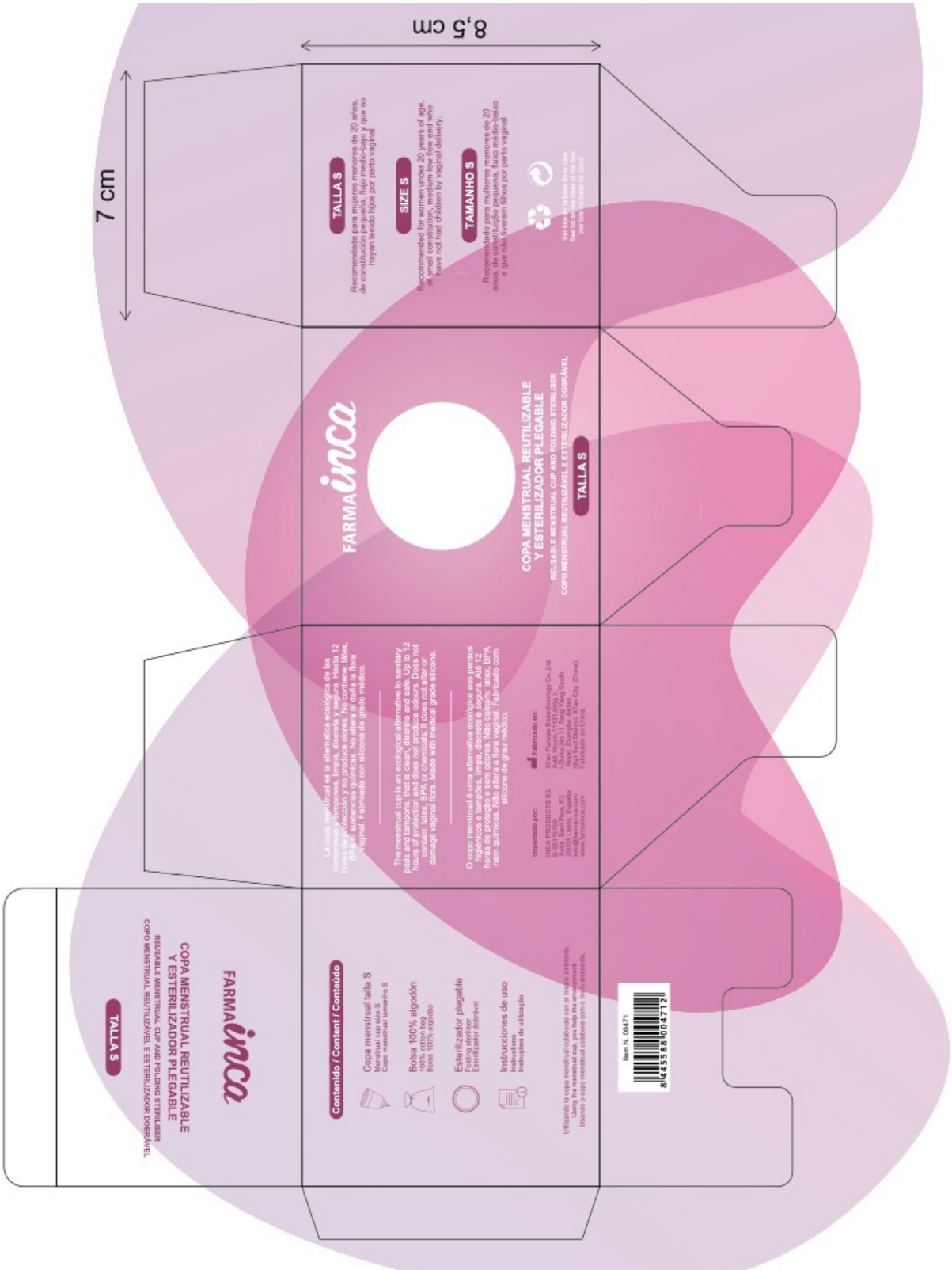
DISEÑO PACKAGING Y FOTOS REALES COPA + ESTERILIZADOR T. S

INCA PRODUCTS COPA MENSTRUAL TALLA S + ESTERILIZADOR REF.00471

FOTOS **TALLA S** COPA MENSTRUAL CON ESTRILIZADOR:

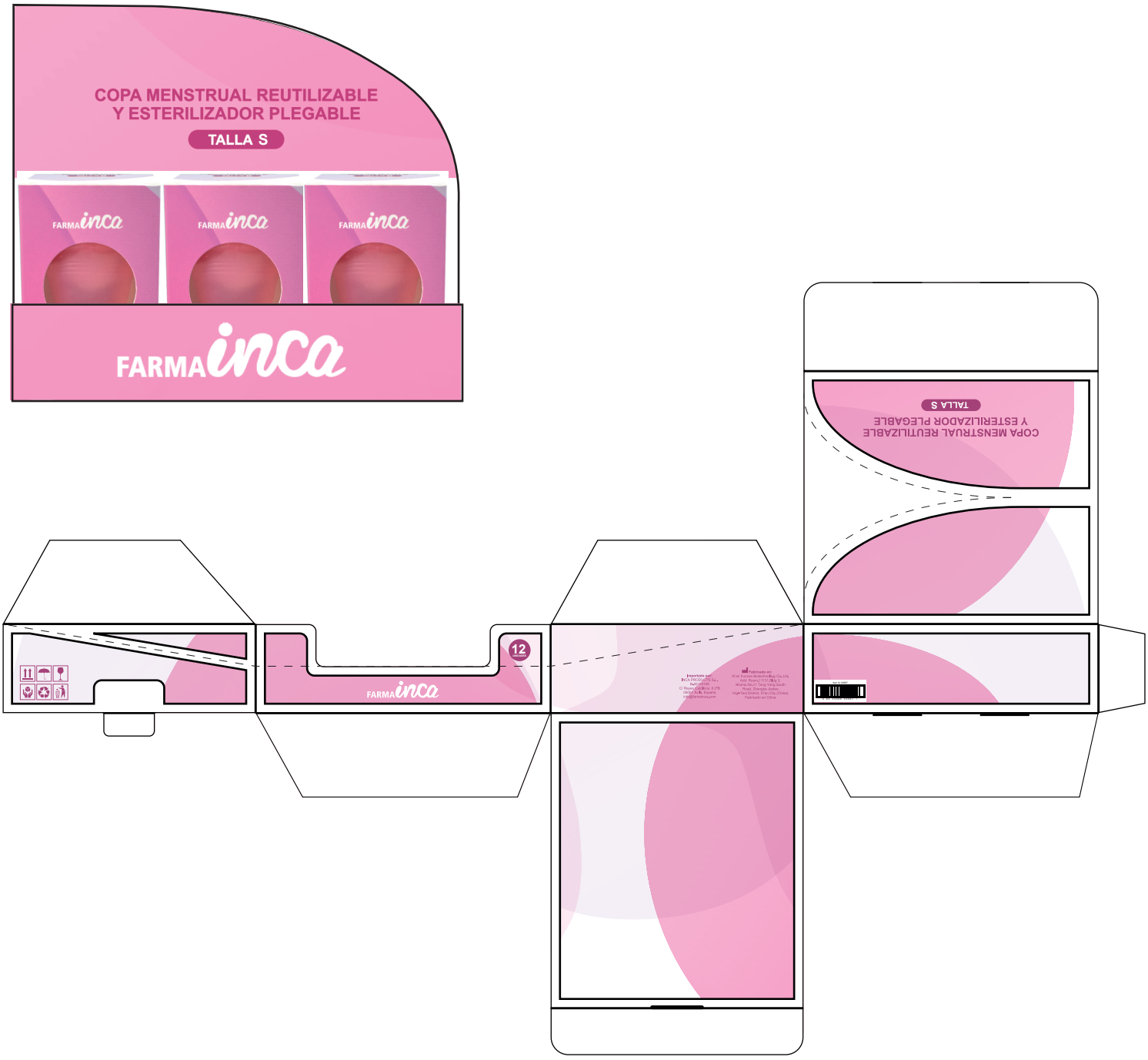
INCA PRODUCTS COPA MENSTRUAL TALLA S + ESTERILIZADOR REF.00471

DISEÑO CAJA **TALLA S** COPA MENSTRUAL CON ESTERILIZADOR:



incaFARMA

CAJA EXPOSITORA | 12 UDS



HOJA DE INSTRUCCIONES

Copa menstrual para la higiene íntima

Menstrual cup for intimate hygiene / Copo menstrual para a higiene íntima

ESPAÑOL

PRODUCTO

Acabas de adquirir una copa menstrual para la higiene íntima de las mujeres. Está elaborada con silicona de uso médico. No es un producto sanitario. La copa menstrual es la alternativa ecológica de las compresas y tampones, limpia, discreta y segura. Hasta 12 horas de protección. Recomendamos cambiar la copa menstrual cada dos años. No contiene látex, BPA ni filtratos. No altera ni daña la flora vaginal y no produce olores.

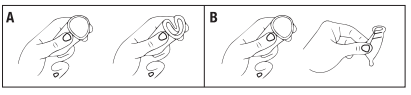
TALLAS

Talla S: Recomendada para mujeres menores de 20 años, de constitución pequeña, flujo medio-bajo y que no hayan tenido hijos por parto vaginal.
Talla M: Recomendada para mujeres menores de 25 años, flujo medio y que no hayan tenido hijos por parto vaginal.
Talla L: Recomendada para mujeres mayores de 25 años, con flujo abundante, suelo pélvico débil o que han tenido hijos por parto vaginal.

ANTES DEL PRIMER USO

La primera vez que utilices la copa menstrual debes esterilizarla. Llena un cazo con agua, cuando el agua esté hirviendo sumerge la copa durante 3-4 minutos.
Retira la copa y déjala enfriar boca abajo. Al final de cada ciclo menstrual se recomienda repetir este proceso para mantener la copa perfectamente limpia.

COLOCACIÓN



Lávate bien las manos y adopta la postura que te sientas más cómoda (sentada en el inodoro, de pie, de cuclillas...). Tienes dos opciones para plegar la copa: A. Presiona los lados de la copa hasta juntarlos y luego dobla la copa por la mitad hasta formar una 'U'. B. Coloca un dedo sobre el borde superior de la copa y presiona hacia adentro para formar un triángulo. Introduce la copa en dirección al coxis o base de la columna vertebral. La colocación ideal de la copa es más baja que la de los tampones. Una vez introducida en la vagina, suelta la copa, esta se abrirá y se adaptará.
Para saber si está bien colocada, gírala 360º cogiéndola por la base (encima del tirador). Si está bien puesta debe girar con facilidad.

EXTRACCIÓN

Vaciar la copa, como mínimo, una vez cada 12 horas, según la intensidad del flujo menstrual. Adopta la postura que te sientas más cómoda (sentada en el inodoro, de pie, de cuclillas...), busca el manguillo la base de la copa. Puedes ayudarte empujando con los músculos abdominales/pélvicos para retirarla más fácilmente. Tira suavemente hasta que salga lo suficiente para poderla sujetar firmemente por la base. Cuando la hayas retirado completamente, vacía el contenido en el inodoro.

MODO DE LIMPIEZA

Si no tienes esterilizador: Lava la copa con agua corriente (preferiblemente tibia) para que esté lista para un nuevo uso. También puedes utilizar jabón pH neutro y sin perfume. Si no dispones de agua potable, puedes utilizar papel higiénico y lavarla con agua corriente más tarde. Si tienes esterilizador: Introduce la copa en el esterilizador, llénalo de agua sin llegar al borde rígido. Tápalo y ponlo al microondas o al baño maría. Deja que hierva el agua durante 2-3 minutos. Retíralo y vacía el agua con cuidado de no quemarte.

CONSEJOS

Debes vaciar la copa al menos cada 12 horas.
Puedes utilizar la copa para dormir y para practicar cualquier deporte.
La copa menstrual es compatible con el DIU o diafragma. Pero te recomendamos lo consultes con tu ginecólogo antes del uso.
No es necesario retirar la copa para orinar o hacer de vientre.
Recomendamos cambiar la copa cada 5 años, aunque puedes usarla hasta 10 años.

SOLUCIÓN DE PROBLEMAS

Inserción: Al principio la inserción puede ser un poco incómoda por falta de práctica. Puedes mojar la copa con agua o utilizar lubricante con base agua para facilitar la colocación.
Extracción: Si tienes problemas para extraer la copa, mantén la calma. Lo importante es tener relajados los músculos, sobre todo los vaginales. Puedes cambiar de postura para facilitar la extracción. Empuja con los músculos abdominales/pélvicos varias veces para que, si la copa está demasiado alta en tu vagina, descienda por ella misma.
Pérdidas: Si tienes pérdidas una vez colocada la copa, probablemente no esté bien colocada. Comprueba (con un dedo) si la copa se ha desplegado correctamente o hazla girar sobre sí misma dentro de la vagina. Revisa la talla de la copa, quizás no es la adecuada y necesitar una talla superior. En caso de que sea la talla L, es posible hacer ciertos ejercicios para reforzar los músculos del suelo pélvico. Consulta con tu ginecólogo.
Molestias: Si sientes molestias puede ser que la copa no esté bien colocada. También puede ser que el tirador sea demasiado largo, puedes cortarlo. Lo importante es no deteriorar la parte inferior de la copa. El tirador no debe sobresalir de la vagina.

ADVERTENCIAS

Usar la copa solo durante la menstruación.
Debes extraer la copa antes de mantener relaciones sexuales, no es un método anticonceptivo ni protege de enfermedades de transmisión sexual.
Es un producto de uso íntimo, no debes compartirla.
No utilizar lubricantes de base oleosa para la inserción.
No guardar nunca la copa en una bolsa de plástico, ni en recipientes herméticos.
En caso de ardor, irritación, inflamación genital o vaginal, molestia al miccionar o cualquier otro síntoma que te parezca anormal, retirar la copa inmediatamente y consultar al médico.
Si tu copa está deteriorada, debes reemplazarla.
Mantener fuera del alcance de los niños.

ATENCIÓN: SINDROME DEL SHOCK TÓXICO (SST)

El Síndrome de Shock Tóxico es una enfermedad muy rara pero grave. Es causada por las toxinas producidas por una bacteria que habitualmente está presente en el organismo humano. El SST se suele relacionar con el uso de tampones. Los síntomas: si durante la menstruación de repente sientes un malestar, a pesar de haber estado sana, si tienes fiebre (39º C o más), vómitos, diarrea, siente dolor de garganta, si estás a punto de desmayarse, siente dolores musculares o si su piel presenta la misma reacción como en el caso de las quemaduras del sol, diríjase inmediatamente al médico. Si ya has sufrido el SST, consulte con el médico antes de volver a utilizar la copa. Las copas menstruales no se relacionan con esta enfermedad.

ENGLISH

PRODUCT

You have just purchased a menstrual cup for female intimate hygiene. It is made with medical grade silicone. It is not a medical device. The menstrual cup is an ecological alternative to sanitary pads and tampons that is clean, discrete and safe. Up to 12 hours of protection. We recommend to change the menstrual cup every two years. Does not contain: latex, BPA or chemicals . It does not alter or damage vaginal flora and does not produce odours.

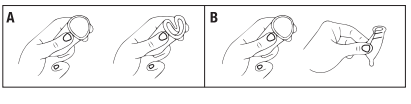
SIZES

Size S: Recommended for women under 20 years of age, of small constitution, medium-low flow and who have not had children by vaginal delivery.
Size M: Recommended for women under 25 years of age, medium flow and who have not had children by vaginal delivery.
Size L: Recommended for women over 25 years of age, with abundant flow, weak pelvic floor or who have had children by vaginal delivery.

BEFORE USING FOR THE FIRST TIME

You must sterilise the menstrual cup before using it for the first time. Fill a pan with water and when the water is boiling, submerge the menstrual cup for 3-4 minutes.
Take the cup out and leave it to cool down face down. After each menstrual cycle, we recommend to repeat this process to keep the menstrual cup perfectly clean.

INSERTION



Clean your hands thoroughly and get into a position that is the most comfortable for you (sitting on the toilet, standing, squatting). There are two options to fold the cup: A. Press the sides of the cup until they touch and then fold the cup in half to make a "U" shape. B. Put a finger on the top rim of the cup and press inwards to form a triangle. Introduce the cup towards the coccyx or base of the spine. The ideal place for the cup is lower than tampons. Once in the vagina, let go and the cup will open and adapt. In order to know if it has been inserted correctly, rotate it 360º by holding the base (over the stem). It should rotate easily if it is placed correctly.

HOW TO REMOVE

Empty the cup at least once every 12 hours, depending on the intensity of the menstrual flow.
Get into a position that is the most comfortable for you (sitting on the toilet, standing, squatting) and find the base of the cup.
You can help by pushing the abdominal/pelvic muscles to extract it easily.
Gently pull it until it comes out enough to firmly hold the base.
Once completely removed, empty the content in the toilet.

HOW TO CLEAN

If you do not have a steriliser: wash the cup with running water (preferably warm water) so it can be used again. You can also use a pH-neutral, perfume-free soap.
If you do not have running water, you can use toilet paper and wash it with running water later.
If you have a steriliser: place the menstrual cup in the steriliser, fill with water but not reaching the rigid rim.
Cover it and put it in the microwave or bain-marie. Leave it to boil for 2-3 minutes.
Remove it and empty the water carefully so as not to burn yourself.

RECOMMENDATIONS

You should empty the cup at least every 12 hours.
You can use the cup while sleeping or exercising.
The menstrual cup is compatible with an IUD or diaphragm. We recommend you consult your gynaecologist before using.
The cup does not need to be removed when using the toilet.
We recommend changing the cup every 5 years, although you can use it for up to 10 years.

PROBLEM SOLVING

Insertion: At first, insertion can be slightly uncomfortable due to the lack of practice.You can wet the cup with water or use a water-based lubricant to help placing it.
Removal: If you have any problems when removing the cup, keep calm. It is important to keep the muscles relaxed, especially the vaginal muscles. You can change position to help removal. Push with your abdominal/pelvic muscles several times to help lower the cup if it is too high in your vagina.
Leakages: If there are leakages once the cup is placed, it is most likely not placed correctly. Check (with a finger) if the cup is correctly unfolded or make it rotate inside the vagina. Check the size of the cup, it might not be a suitable size and a larger size may be needed. In the case of size L, it is possible to do certain exercises to strengthen the pelvic floor muscles. Consult your gynaecologist.
Discomfort: If you feel discomfort it may be that the cup is not placed correctly. The stem may also be too long, you can cut it. It is important to not deteriorate the inferior part of the cup. The stem should be fully inside the vagina.

WARNINGS

Only use the cup during menstruation.
You should remove the cup before sexual relations. It is not a contraceptive method and does not prevent sexually transmitted diseases.
It is an intimate hygiene product, do not share it.
Do not use oil-based lubricants to insert it.
Do not store the cup in a plastic bag or air-tight container.
In the event of burning, irritation, genital or vaginal inflammation, discomfort when urinating or another symptoms that are not normal, remove the cup immediately and consult a doctor.
If your cup is damaged, you must replace it.
Keep out of reach of children.

CAREFUL: TOXIC SHOCK SYNDROME (TSS)

Toxic shock syndrome is a very rare, but serious condition. It is caused by bacteria getting into the body and releasing toxins. TSS is usually related to tampon use.
Symptoms: if during menstruation you suddenly feel ill, despite being healthy, if you have a fever (39 ºC or more), vomiting, diarrhoea, sore throat, if you are about to faint, muscle pain, if your skin has the same reaction as sunburn, seek medical attention immediately. If you have suffered from TSS, consult your doctor before using the cup again. Menstrual cups are not related to this disease.

PORTUGUÊS

PRODUTO

Acaba de adquirir um copo menstrual para a higiene íntima feminina.
É fabricado com silicone medicinal. Não é um produto sanitário.
O copo menstrual é uma alternativa ecológica aos pensos higiénicos e tampões, limpa, discreta e segura.
Até 12 horas de proteção. Recomendamos a substituição de copo menstrual a cada dois anos.
Não contém látex, BPA nem químicos. Não altera nem danifica a flora vaginal e não liberta odores.

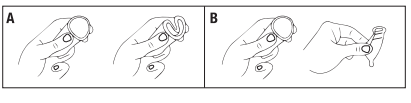
TAMANHOS

Tamanho S: Recomendado para mulheres menores de 20 anos, de constituição pequena, fluxo médio-baixo e que não tiveram filhos por parto vaginal.
Tamanho M: Recomendado para mulheres menores de 25 anos, fluxo médio e que não tiveram filhos por parto vaginal.
Tamanho L: Recomendado para mulheres acima de 25 anos, com fluxo abundante, assoalho pélvico fraco ou que tiveram filhos de parto vaginal.

ANTES DA PRIMEIRA UTILIZAÇÃO

Antes da primeira utilização deve esterilizar o copo menstrual.
Encha uma panela com água, quando a água estiver a ferver mergulhe o copo durante 3-4 minutos. Retire o copo e deixe arrefecer virado para baixo.
No final de cada ciclo menstrual deve repetir este procedimento para manter o copo perfeitamente limpo.

COLOCAÇÃO



Lave bem as mãos e coloque-se numa posição confortável (sentada na sanita, de pé, de cócoras …). Tem duas opções para dobrar o copo: A. Pressione as laterais do copo uma contra a outra e dobre-o ao meio até formar um "U". B. Coloque um dedo na borda superior do copo e pressione para dentro para formar um triângulo. Introduza o copo em direção ao cóccix ou à base da coluna vertebral. A colocação ideal do copo é mais abaixo na vagina do que os tampões.Uma vez introduzido na vagina, solte o copo, este irá abrir-se e adaptar-se.Para saber se está corretamente posicionado, gire o copo 360º segurando-o pela base (acima da pega). Se estiver bem colocado deve girar com facilidade.

REMOÇÃO

Esvazie o copo no mínimo a cada 12 horas, segundo a intensidade do fluxo menstrual. Adopte a posição mais confortável (sentada na sanita, de pé, de cócoras…), procure a pega na base do copo. Pode ajudar empurrar com os músculos abdominais/pélvicos para retirá-lo mais fácilmente.
Tire suavemente até que saia o suficiente para poder segurá-lo firmemente pela base.
Depois de removê-lo completamente, esvazie o conteúno na sanita.

MODO DE LIMPEZA

Se não tiver esterilizador: Lave o copo com água corrente (preferencialmente morna) para que fique pronto para uma nova utilização. Também pode utilizar sabão com pH neutro e sem perfume.
Se não dispõe de água potável, pode utilizar papel higiénico e lavar mais tarde com água corrente.
Se tiver esterilizador: Coloque o copo no esterilizador, encha-o com água sem atingir a borda rígida.
Tape-o e coloque-o no microondas ou em banho maría. Deixe a água ferver 2-3 minutos.
Retire-o e esvazie a água com cuidado para não se queimar.

CONSELHOS

Deve esvaziar o copo no mínimo a cada 12 horas.
Pode utilizar o copo para dormir e para praticar qualquer desporto.
O copo menstrual é compatível com o DIU ou diafragma. No entanto é recomendado consultar o médico ginecologista antes da sua utilização.
Não é necessário tirar o copo para urinar ou evacuar.
Recomendamos trocar o copo a cada 5 anos, embora você possa usá-lo por até 10 anos.

RESOLUÇÃO DE PROBLEMAS

Inserção: No início a inserção pode ser um pouco incómoda por falta de prática. Pode molhar o copo com água ou utilizar um lubrificante à base de água para facilitar a colocação.
Remoção: Se tiver problemas em retirar o copo, mantenha a calma. O importante é ter os músculos relaxados, sobretudo os vaginais. Pode mudar de posição para facilitar a remoção.
Empurre com os músculos abdominais/ pélvicos várias vezes para que, se o copo estiver numa posição demasiado alta na vagina, desça.
Perdas: Se tem perdas uma vez colocado o copo, provavelmente não está bem colocado. Confirme (com um dedo) se o copo abriu corretamente ou gire-o sobre si mesmo dentro da vagina. Verifique o tamanho do copo, talvez não seja o adequado e precise de uma tamanho maior. Caso seja o tamanho L, é possível fazer certos exercícios para reforçar os músculos do assoalho pélvico. Consulte o seu ginecologista.
Incómodo: Se sente desconforto pode ser que o copo não esteja bem colocado. Também pode ser que a pega seja demasiado longa, pode cortá-la. O importante é não danificar a parte inferior do copo. A pega não deve sair da vagina.

ADVERTÊNCIAS

Usar o copo apenas durante a menstruação.
Deve retirar o copo antes de ter relações sexuais, não é um método contracetivo nem protege de doenças sexualmente transmissíveis.
É um produto de uso íntimo, não deve partilhá-lo.
Não utilizar lubrificante de base oleosa para a sua colocação.
Nunca guarde o copo numa bolsa de plástico, nem em recipientes herméticos.
Em caso de ardor, irritação, inflamação genital ou vaginal, incómodo ao urinar ou qualquer outro sintoma que pareça anormal, retire o copo de imediato e consulte um médico.
Se o copo estiver danificado, deve substituí-lo.
Manter fora do alcance das crianças.

ATENÇÃO: SÍNDROME DO CHOQUE TÓXICO (SCT)

O Síndrome de Choque Tóxico é uma doença muito rara mas grave. É causada pelas toxinas produzidas por uma bacteria que habitualmente está presente no organismo humano.
O SCT está frequentemente relacionado ao uso de tampões. Síntomas: se durante a menstruação de repente sentir um mal estar, apesar de estar saudável, se tem febre (39 ºC ou mais), vómitos, diarreia, sentir dor de garganta, se está a ponto de desmaiar, sente dores musculares ou a sua pele apresenta a mesma reação como em caso de queimadura solar, procure de imediato assintência médica. Se já sofreu de SCT, consulte o seu médico antes de voltar a usar o copo. Os copos menstruais não estão relacionados com esta doença.

Fabricado en: Xi'an Furuize Biotechnology Co.,Ltd.
Add: Room.11131,Bldg 3, i-Duhui,No.11 Tang Yang South Road, Zhangba Jiedao, Higt-Tect District, Xi'an City (China)
Fabricado en China.

Importado por: INCA PRODUCTS S.L. B-05115159
Avda. Sant Pere, 63 25005 Lleida, España

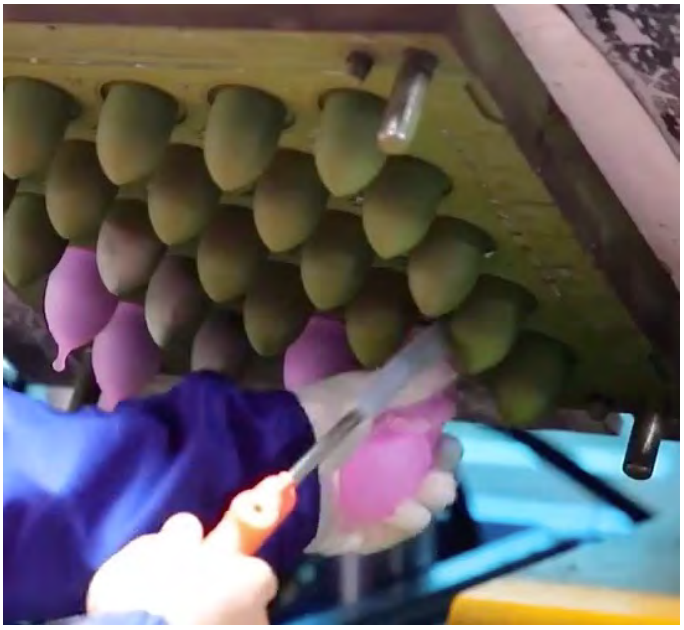
info@farmainca.com
www.farmainca.com

Ver lote en la base de la caja.

DOCUMENTACIÓN

inca FARMA

FÁBRICA:



Certificate of Registration

nqa.

This is to certify that the Quality Management System of

Xi'an Furuize Biotechnology Co., Ltd.

Unified Social Credit Code： 91610113587430746L
Operation Address : Room 11131, Building 3, i Duhui, No.11, Tangyan South Road, Zhangba Street Office, High-tech Zone, Xi'an City, Shaanxi Province, China
Registered Address : Room 11131, Building 3, i Duhui, No.11, Tangyan South Road, Zhangba Street Office, High-tech Zone, Xi'an City, Shaanxi Province, China

applicable to

Sales of menstrual cup (export to United States, Canada, Mexico, Australia, South America, Japan, Vietnam)

has been assessed and registered by NQA against the provisions of

ISO 13485: 2016

This registration is subject to the company maintaining a quality management system, to the above standard, which will be monitored by NQA.
Certified Clients shall accept regular surveillance assessments, the validity of certificates shall be maintained for the positive result of audit.
The information of this certificate can be checked on CNCA's website (www.cnca.gov.cn)
SNQA's website : www.snqa.com.cn

Managing Director

Certificate Number **47763**

Date: 19 June 2020
Valid Until: 19 June 2023
EAC Code: 29

UKAS MANAGEMENT SYSTEMS 015

IAF MEMBER OF MULTILATERAL RECOGNITION ARRANGEMENT

Xi'an Furuize Biotechnology Co.,Ltd
Tel:+86-13389223500 Email:zrsw@xazrsw.com

Letter of Declaration

We,**Xi'an Furuize Biotechnology Co.,Ltd.** Company Headquartered in Room 11131,Building 3, i Duhui, No.11,Tangyan south Road, Zhangba Street Office,High-tech Zone,Xi'an, Shaanxi, China. which is the manufacturer of menstrual cups, here declare that menstrual cup is not belongs to Medical Device in China

Company : Xi'an Furuize Biotechnology Co., Ltd.

Signature

Name :Frank Wang

Title : General manager

Date :6th May.2021

Add.: RM No.11131, Bldg No.3, i-Duhui , No.11 Tangyan south Road,Zhangba Street Office ,High-tech Zone ,Xi'an, Shaanxi, China.

Xi'an Furuize Biotechnology Co.,Ltd
Tel:+86-13389223500 Email:zrsw@xazrsw.com

CE Declaration of Conformity

Declaration Number: DC202203006

The Manufacturer:

Xi'an Furuize Biotechnology Co.,Ltd

RM No.11131, Bldg No.3, i-Duhui,
No.11 Tangyan south Road,Zhangba Street Office,
High-tech Zone ,Xi'an, Shaanxi, China.

Declare that the product: **Menstrual cup**

is conformal to the following standards:

Technical Documentation compatible with the European Medical Devices Regulation 2017/745 Annex I. Technical documentation identified with the no.MCTCFO918-MDR. This document has been issued on the basis of the regulation on ECM.

This declaration of conformity is issued under the exclusive responsibility of the manufacturer

Issued on: 2022-3-10, Xi'an, China

Frank Wang
General manager of Xi'an Furuize Biotechnology Co., Ltd.

Add.: RM No.11131, Bldg No.3, i-Duhui , No.11 Tangyan south Road,Zhangba Street Office ,High-tech Zone,Xi'an, Shaanxi, China.

Review Report –审查报告–검토 보고서– Rapport d'Evaluation

Form QAT_10-M06, version 00, effective since March 25th, 2020

Documentation Review

No. 0P210924.SQCQT65

Holder: Xi'an Furuize Biotechnology Co., Ltd.
Room 11131, Building 3, I Duhui, No.11, Tangyan South Road, Zhangba Street Office, High-Tech Zone, Xi'an City, Shaanxi, China.

Review goal: Verification of the presence of Technical Documentation compatible with the Medical Devices Regulation 2017/745 Annex I

Product: Menstrual Cup (Menstrual Disc)

Model(s): XL, L, M, S, XS

Classification: Class I (Not Sterile according to the Manufacturer's declaration – therefore not requiring NB intervention.)

Review output: This document has been issued on a voluntary basis and upon request of the manufacturer. It is our opinion that the Technical Documentation shared with us by the manufacturer is compatible with the European Standard for Medical Devices.
Technical documentation identified with the no. MCTCF0918-MDR.
The manufacturer is responsible for the CE Marking process, and not exempted to carry out all necessary compliance activities. This document has been issued on the basis of the regulation on ECM Voluntary Mark for the certification of products. RG01_ECM rev.3 available at: www.entecerma.it

Date of issue 24 September 2021
Approver
ECM Service Director
Luca Bedonni

Expiry date 23 september 2026
Technical Expert
Amanda Payne

Ente Certificazione Macchine

Gold Plus Supplier Assessment Certificate

Verified

Certificate Number: 20184769_T

Presented to

Xi'an Furuize Biotechnology Co., Ltd.

西安泽瑞生物科技有限公司

For details,please refer to http://menstrualcup-yonicare.en.alibaba.com

Onsite assessment was conducted for Xi'an Furuize Biotechnology Co., Ltd. by SGS

Assessed by Tony Su on 27 May, 2020. Valid from 28 May, 2020, Valid until: 27 May, 2021

Signature:

Title: Director of SGS eCommerce,Government&Institution Services,SGS CHK

Alibaba.com

SGS

ELASTOSIL® R 406/40 CN

Preliminary Data Sheet

HCR SILICONE RUBBER

Characteristics

ELASTOSIL® R 406/40 CN is fume grade high consistence silicone rubber for general purpose application.

ELASTOSIL® R 406/40 CN could be cured by both peroxide and Platinum catalyst system. Cured articles are noted for the good flexibility and good transparence and elasticity properties. The compounds are easily pigmented with pigment pastes and have a good processing characteristic.

The various grades can be blended in any proportion to achieve intermediate hardness.

Application

Postcured parts can be used for applications in the pharmaceutical and food industries and comply with the recommendations “XV. Silicone” of the BfR and FDA § 177.2600 under observance of any given limitations on extractable and volatile substances.

Processing

ELASTOSIL® R 406/40 CN is designed for both press curing and extrusion application.

For detailed information, please refer to our brochure "Processing ELASTOSIL® R Solid Silicone Rubber".

Storage

The “Best use before end” date of each batch is shown on the product label.

Storage beyond the date specified on the label does not necessarily mean that the product is no longer usable. In this case however, the properties required for the intended use must be checked for quality assurance reasons.

Safety information

Comprehensive instructions are given in the corresponding Material Safety Data Sheets. They are available on request from WACKER subsidiaries or may be printed via WACKER web site http://www.wacker.com.

ELASTOSIL® R 406/40 CN

Typical general characteristics	Inspection Method	Unit	Typical Value
Appearance			Transparent
Specific gravity	DIN EN ISO 1183-1 A	[g/cm³]	1.12
Curing Agent E			
Hardness Shore A	DIN 53505 - A	Shore A	45
Tensile strength	DIN 53504 S1	N/mm²	9
Elongation at break	DIN 53504 S1	%	450
Tear strength	ASTM D 624 B	N/mm	25
Curing Agent C6			
Hardness Shore A	DIN 53505 - A	Shore A	45
Tensile strength	DIN 53504 S1	N/mm²	10
Elongation at break	DIN 53504 S1	%	600
Tear strength	ASTM D 624 B	N/mm	28
Platinum Catalyst	**R406/70CN : (AUX 4K-X) :(AUX 4K-I) : (AUX Batch PT1) = 100 : 5 : 2.5 : 1.5**		
Hardness Shore A	DIN 53505 - A	Shore A	45
Tensile strength	DIN 53504 S1	N/mm²	9
Elongation at break	DIN 53504 S1	%	600
Tear strength	ASTM D 624 B	N/mm	30

Cure conditions

Curing agent		%	Cure	Post-cure
E	50% paste of bis-(2,4-dichlorobenzoyl)- peroxide in silicone fluid	1.5	10 min / 135 °C	4 h / 200 °C
C1	Dicumyl peroxide (98%)	0.7	15 min / 165 °C	4 h / 200 °C
C6	45% paste of 2,5-bis-(t-butylperoxy)-2,5-dimethyl-hexane in silicone rubber	1.2	15 min / 165 °C	4 h / 200 °C
PT catalyst	ELASTOSIL® AUX 4K-X, AUX 4K-I, AUX Batch PT1		5 min / 165 °C	4 h / 200 °C

Curing Agent C6 yields similar values to those obtained with C1.
These figures are only intended as a guide and should not be used in preparing specifications.

The management system has been certified according to DIN EN ISO 9001 and DIN EN ISO 14001

WACKER

ELASTOSIL® is a trademark of Wacker Chemie AG.

For technical, quality, or product safety questions, please contact:

Wacker Chemicals (China) Company Ltd.

Bldg.3 Hongmei Road 1535, Shanghai, China 200233
info.silicones@wacker.com

www.wacker.com

SGS-CSTC Standards Technical Services (Shanghai) Co., Ltd.
Life Science Services Laboratory

T:021-61152161, 61152160 F:021-64951517
中国.上海.徐汇区宜山路 889 号 3 号楼 7 楼
7/F, the 3rd Building, Yishan Road , Xuhui District, Shanghai, China 200233

Test Report

Date: 22nd Jan. 2018

Client name: WACKER CHEMICALS (CHINA) CO., LTD

Client address: Bldg. 3, 1535 Hongmei Road Caohejing Hi-Tech Park Shanghai 200233, China

Assignment ID: 14A1705104

Sample No.: 14S17019580

Report on the submitted sample identified by the client as below:

Product Name	EL R 406/70 CN
Quantity Received	1 bag
Sample Receiving Condition	Room temperature
Sample Receiving Date	02nd Nov.2017
Testing Period	23rd Nov.2017 –05th Dec.2017

Test Requested, Test Method and Test Results:

Please refer to the following page(s), **Attachment 1**.

The test was carried out by SGS subcontractor certified ISO 17025 by CNAS. The results contained in this Report are in the scope of ISO 17025 certification.

Signed for and on behalf of SGS

.....Sia Tong.....

Sia Tong
Life Science Quality Assurance
Authorized Signature

Attachment 1: Test for skin sensitization (Murine local lymph node assay, LLNA)

SUMMARY

Murine Local Lymph Node Assay（LLNA）of the test article, EL R 406/70 CN, was conducted to evaluate the skin sensitizing potential. This study was based on the International Organization for Standardization ISO 10993-10:2010: Biological evaluation of medical devices part 10: Tests for irritation and skin sensitization; ISO10993-12: 2012: Biological evaluation of medical devices Part 12: Sample preparation and reference materials.

The extract of the test article was contacted on ears of mice for three consecutive days. At 48h after the last treatment, inject inter-peritoneally BrdU into mice. And then measured the extent of lymphocyte proliferation in the lymph node cells by ELISA. Finally the Stimulation Index（SI）were determined.

Under the conditions of this study, SI of the DMSO test group was 0.8 and SI of the SC test group was 1.2. It could be concluded that the extract of the test article had no evidence of causing sensitization in the mice.

MATERIALS

The test article was provided by the sponsor was identified and handled as follows:

Test Article:	EL R 406/70 CN
Sterilization Status:	Non-sterile
Storage Conditions:	Room temperature
Extraction Vehicle:	①SC; ②DMSO
Test Article Preparation:	According the requirement of the sponsor，the test article was sterilized by ethylene oxide two weeks before testing. Based on the ISO 10993-12:2012, the ratio of 1.25 cm^2:1 ml (Surface area of the test article to volume of extraction vehicle), 12.5 cm^2 of the test article were covered with 10 ml of extraction vehicle under aseptic conditions for preparing the SC and DMSO test extract at 37 °C for 72 h. The extracts were used after extraction.
Reagent Control:	Extraction vehicles without the test article was similarly prepared.

Positive Control:	2,4-Dinitrochlorobenzene (DNCB) was prepared at a 0.25% concentration in DMSO.
Condition of extract	The extract of the test article and controls were all clear and without any special treatments.

METHODS

Test System

Species:	Healthy mice of the BALB/c strain
Grade:	SPF
Source:	SHANGHAI JIESIJIE LAB ANIMAL CO., LTD
Sex:	Female
Body Weight Range:	17.5 g to 19.2 g
Age:	9 weeks
Number of animals:	Twenty-five

Animal Management:

Husbandry:	Conditions conformed to "Laboratory animal-Requirements of environment and housing facilities"; "ISO 10993-2:2006: Biological evaluation of medical devices Part 2: Animal welfare requirements".
Food:	Diet was provided from Shanghai Pu Lu Teng Biological Technology Co., Ltd.
Water:	Pure Water
Housing:	Healthy animals were acclimatized to the laboratory conditions for 7 days before the treatment, and then they were individually housed in stainless steel suspended cages identified by a card indicating the Identification No. of the test article and first treatment date.
Environmental:	The room temperature and humidity were monitored daily. The temperature range for the room was from 20 ℃ to 26 ℃. The room humidity range was from 50 % to 70 %.
Personnel:	Associates involved were appropriately qualified and trained.
Selection:	Only healthy, unused animals were selected.

Experimental Procedure:

1. Treatment groups:

   Prior to dosing, the mice were identified and weighted. Twenty-five mice were divided into five groups. Five mice were used per group, with the test extracts group (SC and DMSO), the reagent control groups (SC and DMSO), and the positive control group. Each group was applied to the dorsal side of each ear of designated mice at a dose of 25μl per day for three consecutive days.

2. Experimental schedule:

   On Day 5, injected 5 mg BrdU inter-peritoneally. On Day 6, recorded the weight of each mice and any clinical observation. Approximately 24 hours（24h）after BrdU injection. Euthanized the mice. Excised the draining auricular lymph nodes from each mouse ear. Then preparation of cell suspensions.

3. Observation and record:

   Each day recorded the behaviour and body weight of the mice at Day 1 and Day 6. Both ears of each mouse were observed for erythema and scored.

4. Determination of cellular proliferation

   Briefly, 100μl of the LNC suspension was added to the wells of a flat-bottom microplate in triplicate. After fixation and denaturation of the LNC, anti- BrdU antibody was added to each well. Subsequently the anti- BrdU antibody was removed. Absorbance at 370 nm with a reference wavelength of 492nm was then measured. Measure the level of BrdU incorporation of lymphocyte proliferation in the lymph node cells by ELISA.

5. Calculation of results

   Results for each group were expressed as the SI. The SI was derived by dividing the mean BrdU labelling index for test group by the mean BrdU labelling index for the solvent group.
   A SI of 3 or more(≥3) shall be considered positive for designating a test article as a sensitizer.

Results

Clinical Observation:

All animals appeared clinically normal throughout the study. All the erythema grades of the SC and DMSO extract of the test articles were 0.

Stimulation Index（SI）:

The result of SI was given below:

Group	SI
SC reagent control	1
DMSO reagent control	1
SC extract of test article	1.2
DMSO extract of test article	0.8
The positive control	3.1

CONCLUSION

Under the conditions of this study, the extract of the test article had no evidence of causing sensitization in the mice.

PHOTOGRAPH OF THE TEST ARTICLE

Remark: Results and conclusions apply only to the test article tested provided by Client. Therefore, this Report contains the results obtained in the test of the provided samples only and do not express any opinion upon the lot from which the samples were drawn or any similar samples.

***End of Report ***

Test Report

Applicant : Xi'an Furuize Biotechnology Co., Ltd.

Address : Room 11131 , Building 3,i Duhui, No.11 ,Tangyan South Road ,Zhangba Street Office , High-tech Zone ,Xi'an City, Shaanxi, China.

The following sample(s) and sample information was/were submitted and identified by/on behalf of the client

Sample Name	:	Menstrual cup
Sample Model	:	014
Sample Lot	:	1225
Sample Received Date	:	Jan 5, 2021
Test Completed Date	:	Jan 11, 2021
Test Requested	:	As specified by client, to screen on Jun 16, 2020 the 209 Substances of Very High Concern (SVHC) under the regulation (EC) No 1907/2006 of REACH for the submitted samples .
Test Method	:	In-House method – Analyzed by ICP-OES, PLM, UV-VIS, LC-MS, GC-MS and colorimetric method.
Test Results	:	Refer to the next page(s).

Test Conclusion :		
According to the specified scope and evaluation screening, the test results of SVHC are ≤ 0.1% (w/w) in the submitted sample.	PASS	

Reviewed by: Lab Senior Engineer

Authorized Signature: Technology Manager

FLION TESTING TECHNOLOGIES
Add :Gangzi Industrial Park,Furong Industrial Area, Xinqiao Village, Shajing Town, Bao'an District, Shenzhen City
Tel : 86-0755-2724 8885 Fax : 86-0755-2746 0090 Http://www.cnftt.com

REACH SVHCs Test Results:

No.	Test Item	CAS No.	EC No.	RL(%)	Result (%)
1	4,4'-Diaminodiphenylmethane	101-77-9	202-974-4	0.05	N.D.
2	5-tert-butyl-2,4,6-trinitro-m-xylene (musk xylene)	81-15-2	201-329-4	0.05	N.D.
3	Alkanes,C10-13,chloro(Short Chain Chlorinated Paraffins)	85535-84-8	287-476-5	0.05	N.D.
4	Anthracene	120-12-7	204-371-1	0.05	N.D.
5	Benzyl butyl phthalate (BBP)	85-68-7	201-622-7	0.05	N.D.
6	Bis (2-ethyl(hexyl)phthalate) (DEHP)	117-81-7	204-211-0	0.05	N.D.
7	Bis(tributyltin)oxide (TBTO)*	56-35-9	200-268-0	0.05	N.D.
8	Cobalt dichloride*	7646-79-9	231-589-4	0.05	N.D.
9	Diarsenic pentaoxide*	1303-28-2	215-116-9	0.05	N.D.
10	Diarsenic trioxide*	1327-53-3	215-481-4	0.05	N.D.
11	Dibutyl phthalate (DBP)	84-74-2	201-557-4	0.05	N.D.
12	Hexabromocyclododecane (HBCDD) and all major diastereoisomers identified: α-HBCDD β-HBCDD γ-HBCDD	25637-99-4 3194-55-6 (134237-51-7 134237-50-6 134237-52-8)	247-148-4 221-695-9	0.05	N.D.
13	Lead hydrogen arsenate*	7784-40-9	232-064-2	0.05	N.D.
14	Sodium dichromate*	10588-01-9 7789-12-0	234-190-3	0.05	N.D.
15	Triethyl arsenate*	15606-95-8	427-700-2	0.05	N.D.
16	2,4-Dinitrotoluene	121-14-2	204-450-0	0.05	N.D.
17	Acrylamide	79-06-1	201-173-7	0.05	N.D.

Test Report

No.	Test Item	CAS No.	EC No.	RL(%)	Result (%)
18	Anthracene oil *	90640-80-5	292-602-7	0.05	N.D.
19	Anthracene oil, anthracene paste*	90640-81-6	292-603-2	0.05	N.D.
20	Anthracene oil, anthracene paste, anthrancene fraction *	91995-15-2	295-275-9	0.05	N.D.
21	Anthracene oil, anthracene paste, distn. lights *	91995-17-4	295-278-5	0.05	N.D.
22	Anthracene oil, anthracene-low *	90640-82-7	292-604-8	0.05	N.D.
23	Diisobutyl phthalate(DIBP)	84-69-5	201-553-2	0.05	N.D.
24	Lead chromate*	7758-97-6	231-846-0	0.05	N.D.
25	Lead chromate molybdate sulphate red (C.I.Pigment Red 104)*	12656-85-8	235-759-9	0.05	N.D.
26	Lead sulfochromate yellow (C.I.Pigment Yellew 34)*	1344-37-2	215-693-7	0.05	N.D.
27	Pitch, coal tar, high-temp. *	65996-93-2	266-028-2	0.05	N.D.
28	Tris(2-chloroethyl)phosphate (TCEP)	115-96-8	204-118-5	0.05	N.D.
29	Ammonium dichromate*	7789-09-5	232-143-1	0.05	N.D.
30	Boric acid*	10043-35-3 11113-50-1	233-139-2 234-343-4	0.05	N.D.
31	Disodium tetraborate, anhydrous*	1303-96-4 1330-43-4 12179-04-3	215-540-4	0.05	N.D.
32	Potassium chromate*	7789-00-6	232-140-5	0.05	N.D.
33	Potassium dichromate*	7778-50-9	231-906-6	0.05	N.D.
34	Sodium chromate*	7775-11-3	231-889-5	0.05	N.D.
35	Tetraboron disodium heptaoxide, hydrate*	12267-73-1	235-541-3	0.05	N.D.
36	Trichloroethylene	79-01-6	201-167-4	0.05	N.D.

Test Report

No.	Test Item	CAS No.	EC No.	RL(%)	Result (%)
37	2-Ethoxyethanol	110-80-5	203-804-1	0.05	N.D.
38	2-Methoxyethanol	109-86-4	203-713-7	0.05	N.D.
39	Acids generated from chromium trioxide and their oligomers:Chromic acid, Dichromic acid, Oligomers of chromic acid and dichromic acid. *	7738-94-5 13530-68-2	231-801-5 236-881-5	0.05	N.D.
40	Chromium trioxide*	1333-82-0	215-607-8	0.05	N.D.
41	Cobalt(II) carbonate*	513-79-1	208-169-4	0.05	N.D.
42	Cobalt(II) diacetate*	71-48-7	200-755-8	0.05	N.D.
43	Cobalt(II) dinitrate*	10141-05-6	233-402-1	0.05	N.D.
44	Cobalt(II) sulphate*	10124-43-3	233-334-2	0.05	N.D.
45	1,2,3-trichloropropane	96-18-4	202-486-1	0.05	N.D.
46	1,2-Benzenedicarboxylic acid, di-(C6-8)-branched alkyl esters, C7-rich	71888-89-6	276-158-1	0.05	N.D.
47	1,2-Benzenedicarboxylic acid, di-(C7-11)-branched and linear alkyl eaters (DHNUP)	68515-42-4	271-084-6	0.05	N.D.
48	1-Methyl-2-pyrrolidone	872-50-4	212-828-1	0.05	N.D.
49	2-Ethoxyethyl acetate	111-15-9	203-839-2	0.05	N.D.
50	Hydrazine	7803-57-8 302-01-2	206-114-9	0.05	N.D.
51	Strontium chromate*	7789-06-2	232-142-6	0.05	N.D.
52	1,2-Dichloroethane	107-06-2	203-458-1	0.05	N.D.
53	(2,2'-dichloro-4,4'-methylenedianiline (MOCA)	101-14-4	202-918-9	0.05	N.D.

No.	Test Item	CAS No.	EC No.	RL(%)	Result (%)
54	2-Methoxyaniline; o-Anisidine	90-04-0	201-963-1	0.05	N.D.
55	4-(1,1,3,3-tetramethylbutyl)phenol	140-66-9	205-426-2	0.05	N.D.
56	Aluminosilicate Refractory Ceramic Fibres *	650-017-00-8 (Index No.)	--	0.05	N.D.
57	Arsenic acid*	7778-39-4	231-901-9	0.05	N.D.
58	Bis(2-methoxyethyl)ether	111-96-6	203-924-4	0.05	N.D.
59	Bis(2-methoxyethyl) phthalate	117-82-8	204-212-6	0.05	N.D.
60	Calcium arsenate*	7778-44-1	231-904-5	0.05	N.D.
61	Dichromium tris(chromate)*	24613-89-6	246-356-2	0.05	N.D.
62	Formaldehyde, oligomeric reaction products with aniline	25214-70-4	500-036-1	0.05	N.D.
63	Lead diazide, Lead azide*	13424-46-9	236-542-1	0.05	N.D.
64	Lead dipicrate*	6477-64-1	229-335-2	0.05	N.D.
65	Lead styphnate*	15245-44-0	239-290-0	0.05	N.D.
66	N,N-dimethylacetamide (DMAC)	127-19-5	204-826-4	0.05	N.D.
67	Pentazinc chromate octahydroxide*	49663-84-5	256-418-0	0.05	N.D.
68	Phenolphthalein	77-09-8	201-004-7	0.05	N.D.
69	Potassium hydroxyoctaoxodizincatedi-chromate*	11103-86-9	234-329-8	0.05	N.D.
70	Trilead diarsenate*	3687-31-8	222-979-5	0.05	N.D.
71	Zirconia Aluminosilicate Refractory Ceramic Fibres *	650-017-00-8 (Index No.)	--	0.05	N.D.

No.	Test Item	CAS No.	EC No.	RL(%)	Result (%)
72	[4-[[4-anilino-1-naphthyl][4-dimethylamino)phenyl]methylene]cyclohexa-2,5-dien-1-ylidene]dimethylammo nium chloride (C.I.Basic Blue26)	2580-56-5	219-943-6	0.05	N.D.
73	4-[4,4'-bis(dimethylamino)benzhydrylidene]cyclohexa-2,5-dien-1-ylidene]dimethylammonium chloride (C.I. Basic Violet 3)	548-62-9	208-953-6	0.05	N.D.
74	1,2-bis(2-methoxyethoxy)ethane(TEGDMEP;triglyme)	112-49-2	203-977-3	0.05	N.D.
75	1,2-dimethoxyethane; ethylene glycol dimethyl ether(EGDME)	110-71-4	203-794-9	0.05	N.D.
76	4,4'-bis(dimethylamino)benzophenone (Michler's ketone)	90-94-8	202-027-5	0.05	N.D.
77	4,4'-bis(dimethylamino)-4''-(methylamino)trityl alcohol	561-41-1	209-218-2	0.05	N.D.
78	Diboron trioxide*	1303-86-2	215-125-8	0.05	N.D.
79	Formamide	75-12-7	200-842-0	0.05	N.D.
80	Lead(II) bis(methanesulfonate)*	17570-76-2	401-750-5	0.05	N.D.
81	N,N,N',N'-tetramethyl-4,4'-methylenedianiline (Michler's base)	101-61-1	202-959-2	0.05	N.D.
82	1,3,5-Tris(oxiran-2-ylmethyl)-1,3,5-triazinane-2,4,6-trione (TGIC)	2451-62-9	219-514-3	0.05	N.D.
83	α,α-Bis[4-(dimethylamino)phenyl]-4 (phenylamino)naphthalene-1-methanol (C.I. Solvent Blue 4)	6786-83-0	229-851-8	0.05	N.D.
84	1,3,5-tris[(2S and 2R)-2,3-epoxypropyl]-1,3,5-triazine-2,4,6-(1H,3H,5H)-trione (β-TGIC)	59653-74-6	423-400-0	0.05	N.D.
85	[Phthalato(2-)]dioxotrilead *	69011-06-9	273-688-5	0.05	N.D.
86	1,2-Benzenedicarboxylic acid, dipentylester, branched and linear	84777-06-0	284-032-2	0.05	N.D.
87	1,2-Diethoxyethane	629-14-1	211-076-1	0.05	N.D.

No.	Test Item	CAS No.	EC No.	RL(%)	Result (%)
88	1-bromopropane (n-propyl bromide)	106-94-5	203-445-0	0.05	N.D.
89	3-ethyl-2-methyl-2-(3-methylbutyl)-1,3-oxazolidine	143860-04-2	421-150-7	0.05	N.D.
90	4-(1,1,3,3-tetramethylbutyl)phenol, ethoxylated	--	--	0.05	N.D.
91	4,4'-methylenedi-o-toluidine	838-88-0	212-658-8	0.05	N.D.
92	4,4'-oxydianiline and its salts	101-80-4	202-977-0	0.05	N.D.
93	4-Aminoazobenzene	60-09-3	200-453-6	0.05	N.D.
94	4-methyl-m-phenylenediamine (toluene-diamine)	95-80-7	202-453-1	0.05	N.D.
95	4-Nonylphenol, branched and linear	--	--	0.05	N.D.
96	6-methoxy-m-toluidine (p-cresidine)	120-71-8	204-419-1	0.05	N.D.
97	Acetic acid, lead salt, basic*	51404-69-4	257-175-3	0.05	N.D.
98	Biphenyl-4-ylamine	92-67-1	202-177-1	0.05	N.D.
99	Bis(pentabromophenyl) ether (decabromodiphenyl ether; DecaBDE)	1163-19-5	214-604-9	0.05	N.D.
100	Cyclohexane-1,2-dicarboxylic anhydride cis-cyclohexane-1,2-dicarboxylic anhydride trans-cyclohexane-1,2-dicarboxylic anhydride	85-42-7 13149-00-3 14166-21-3	201-604-9 236-086-3 238-009-9	0.05	N.D.
101	Diazene-1,2-dicarboxamide (C,C'-azodi(formamide))	123-77-3	204-650-8	0.05	N.D.
102	Dibutyltin dichloride (DBTC)	683-18-1	211-670-0	0.05	N.D.
103	Diethyl sulphate	64-67-5	200-589-6	0.05	N.D.
104	Diisopentylphthalate	605-50-5	210-088-4	0.05	N.D.
105	Dimethyl sulphate	77-78-1	201-058-1	0.05	N.D.
106	Dinoseb (6-sec-butyl-2,4-dinitrophenol)	88-85-7	201-861-7	0.05	N.D.

No.	Test Item	CAS No.	EC No.	RL(%)	Result (%)
107	Dioxobis(stearato)trilead*	12578-12-0	235-702-8	0.05	N.D.
108	Fatty acids, C16-18, lead salts*	91031-62-8	292-966-7	0.05	N.D.
109	Furan	110-00-9	203-727-3	0.05	N.D.
110	Henicosafluoroundecanoic acid	2058-94-8	218-165-4	0.05	N.D.
111	Heptacosafluorotetradecanoic acid	376-06-7	206-803-4	0.05	N.D.
112	Hexahydromethylphathalic anhydride, Hexahydro-4-methylphathalic anhydride, Hexahydro-1-methylphathalic anhydride, Hexahydro-3-methylphathalic anhydride	25550-51-0 19438-60-9 48122-14-1 57110-29-9	247-094-1 243-072-0 256-356-4 260-566-1	0.05	N.D.
113	Lead bis(tetrafluoroborate)*	13814-96-5	237-486-0	0.05	N.D.
114	Lead cynamidate*	20837-86-9	244-073-9	0.05	N.D.
115	Lead dinitrate*	10099-74-8	233-245-9	0.05	N.D.
116	Lead monoxide (lead oxide)*	1317-36-8	215-267-0	0.05	N.D.
117	Lead oxide sulfate*	12036-76-9	234-853-7	0.05	N.D.
118	Orange lead (lead tetroxide) *	1314-41-6	215-235-6	0.05	N.D.
119	Lead titanium trioxide*	12060-00-3	235-038-9	0.05	N.D.
120	Lead Titanium Zirconium Oxide*	12626-81-2	235-727-4	0.05	N.D.
121	Methoxyacetic acid	625-45-6	210-894-6	0.05	N.D.
122	Methyloxirane (Propylene oxide)	75-56-9	200-879-2	0.05	N.D.
123	N,N-dimethylformamide	68-12-2	200-679-5	0.05	N.D.

No.	Test Item	CAS No.	EC No.	RL(%)	Result (%)
124	N-methylacetamide	79-16-3	201-182-6	0.05	N.D.
125	N-pentyl-isopentylphtalate	776297-69-9	--	0.05	N.D.
126	o-aminoazotoluene	97-56-3	202-591-2	0.05	N.D.
127	o-Toluidine	95-53-4	202-429-0	0.05	N.D.
128	Pentacosafluorotridecanoic acid	72629-94-8	276-745-2	0.05	N.D.
129	Pentalead tetraoxide sulphate*	12065-90-6	235-067-7	0.05	N.D.
130	Pyrochlore, antimony lead yellow*	8012-00-8	232-382-1	0.05	N.D.
131	Silicic acid (H2Si2O5), barium salt (1:1), lead-doped*	68784-75-8	272-271-5	0.05	N.D.
132	Silicic acid, lead salt*	11120-22-2	234-363-3	0.05	N.D.
133	Sulfurous acid, lead salt, dibasic*	62229-08-7	263-467-1	0.05	N.D.
134	Tetraethyllead*	78-00-2	201-075-4	0.05	N.D.
135	Tetralead trioxide sulphate*	12202-17-4	235-380-9	0.05	N.D.
136	Tricosafluorododecanoic acid	307-55-1	206-203-2	0.05	N.D.
137	Trilead bis(carbonate)dihydroxide *	1319-46-6	215-290-6	0.05	N.D.
138	Trilead dioxide phosphonate*	12141-20-7	235-252-2	0.05	N.D.
139	4-Nonylphenol, branched and linear, ethoxylated	--	--	0.05	N.D.
140	Ammonium pentadecafluorooctanoate (APFO)	3825-26-1	223-320-4	0.05	N.D.
141	Cadmium oxide*	1306-19-0	215-146-2	0.05	N.D.

No.	Test Item	CAS No.	EC No.	RL(%)	Result (%)
142	Cadmium	7440-43-9	231-152-8	0.05	N.D.
143	Dipentyl phthalate(DPP)	131-18-0	205-017-9	0.05	N.D.
144	Pentadecafluorooctanoic acid (PFOA)	335-67-1	206-397-9	0.05	N.D.
145	Cadmium sulphide*	1306-23-6	215-147-8	0.05	N.D.
146	Dihexyl phthalate	84-75-3	201-559-5	0.05	N.D.
147	Disodium 3,3'-[[1,1'-biphenyl]-4,4'-diylbis(azo)]bis(4-aminonaphthalene-1-sulphonate) (C.I. Direct Red 28)	573-58-0	209-358-4	0.05	N.D.
148	Disodium 4-amino-3-[[4'-[(2,4-diaminophenyl)azo] [1,1'-biphenyl]-4-yl]azo] -5-hydroxy-6-(phenylazo)naphthalene-2, 7-disulphonate (C.I. Direct Black 38)	1937-37-7	217-710-3	0.05	N.D.
149	Imidazolidine-2-thione (2-imidazoline-2-thiol)	96-45-7	202-506-9	0.05	N.D.
150	Lead di(acetate)*	301-04-2	206-104-4	0.05	N.D.
151	Trixylyl phosphate	25155-23-1	246-677-8	0.05	N.D.
152	1,2-Benzenedicarboxylic acid, dihexylester, branched and linear	68515-50-4	271-093-5	0.05	N.D.
153	Cadmium chloride*	10108-64-2	233-296-7	0.05	N.D.
154	Sodium perborate;perboric acid, sodium salt*	--	239-172-9 234-390-0	0.05	N.D.
155	Sodium peroxometaborate*	7632-4-4	231-556-4	0.05	N.D.
156	2-(2H-benzotriazol-2-yl)-4,6-ditertpentyl phenol (UV-328) .	25973-55-1	247-284-8	0.05	N.D.
157	2-benzotriazol-2-yl-4,6-di-tert-butylphen ol (UV-320)	3846-71-7	223-346-6	0.05	N.D.
158	2-ethylhexyl 10-ethyl-4,4-dioctyl-7-oxo-8-oxa-3,5-dith ia-4-stannatetradecanoate (DOTE).	15571-58-1	239-622-4	0.05	N.D.

No.	Test Item	CAS No.	EC No.	RL(%)	Result (%)
159	Cadmium fluoride*	7790-79-6	232-222-0	0.05	N.D.
160	Cadmium sulphate*	10124-36-4 31119-53-6	233-331-6	0.05	N.D.
161	Reaction mass of 2-ethylhexyl10-ethyl-4,4-dioctyl-7-oxo-8-oxa-3,5-dithia-4-stannatetradecanoate& 2-ethylhexyl 10-ethyl-4-[[2-[(2-ethylhexyl)oxy]-2-oxoethyl]thio]-4-octyl-7-oxo-8-oxa-3,5-dithia-4-stannatetradecanoate (reaction mass of DOTE & MOTE).	--	--	0.05	N.D.
162	Phthalate (C6 - C10) alkyl ester	--	--	0.05	N.D.
163	Karanal	117933-89-8	--	0.05	N.D.
164	Nitrobenzene	98-95-3	202-716-0	0.05	N.D.
165	2,4-di-tert-butyl-6-(5-chlorobenzotriazol-2-yl)phenol (UV-327)	3864-99-1	223-383-8	0.05	N.D.
166	2-(2H-benzotriazol-2-yl)-4-(tert-butyl)-6-(sec-butyl)phenol (UV-350)	36437-37-3	253-037-1	0.05	N.D.
167	1,3-propanesultone	1120-71-4	214-317-9	0.05	N.D.
168	Perfluorononan-1-oic-acid and its sodium and ammonium salts	375-95-1 21049-39-8 4149-60-4	206-801-3	0.05	N.D.
169	Benzo[def]chrysene	200-028-5	50-32-8	0.05	N.D.
170	4,4'-Isopropylidenediphenol(bisphenol A) .	1980/5/7	201-245-8	0.05	N.D.
171	4-Heptylphenol, branched and linear .	/	/	0.05	N.D.
172	Nonadecafluorodecanoic acid (PFDA) and its sodium and ammonium salts.	3108-42-7 335-76-2 3830-45-3	/ 206-400-3 221-470-5	0.05	N.D.
173	p-(1,1-dimethylpropyl)phenol .	80-46-6	201-280-9	0.05	N.D.
174	Perfluorohexane-1-sulphonic acid and its salts (PFHxS)	355-46-4	206-587-1	0.05	N.D.

No.	Test Item	CAS No.	EC No.	RL(%)	Result (%)
175	Chrysene	218-01-9	205-923-4	0.05	N.D.
176	Benz[a]anthracene	56-55-3	200-280-6	0.05	N.D.
177	Cadmium nitrate*	10325-94-7	233-710-6	0.05	N.D.
178	Cadmium hydroxide*	21041-95-2	244-168-5	0.05	N.D.
179	Cadmium carbonate*	513-78-0	208-168-9	0.05	N.D.
180	Dechlorane plus (including any of its individual anti- and syn-isomers or any combination thereof)	13560-89-9 135821-74-8 135821-03-3	/	0.05	N.D.
181	Reaction products of 1,3,4-thiadiazolidine-2,5-dithione,formaldehyde and 4-heptylphenol, branched and linear (RP-HP) [with ≥0.1% w/w 4-heptylphenol, branched and linear]	/	/	0.05	N.D.
182	Dicyclohexyl phthalate (DCHP)	84-61-7	201-545-9	0.05	N.D.
183	Benzene -1,2,4- tricarboxylic acid 1,2- acid anhydride (triphthalic anhydride)	552-30-7	209-008-0	0.05	N.D.
184	Benzo(ghi)perylene	191-24-2	205-883-8	0.05	N.D.
185	Decamethylcyclopentasiloxane(D5)	541-02-6	208-764-9	0.05	N.D.
186	Disodium octaborate *,	12008-41-2	234-541-0	0.05	N.D.
187	Dodecamethylcyclohexasiloxane(D6)	540-97-6	208-762-8	0.05	N.D.
188	Ethanediamine	107-15-3	203-468-6	0.05	N.D.
189	Lead*	7439-92-1	231-100-4	0.05	N.D.
190	Octamethylcyclotetrasiloxane(D4)	556-67-2	209-136-7	0.05	N.D.
191	Tridiphenylhydrogenation	61788-32-7	262-967-7	0.05	N.D.
192	2,2-bis(4'-hydroxyphenyl)-4-methylpentane	6807-17-6	401-720-1	0.05	N.D.
193	Benzo[k]fluoranthene	207-08-9	205-916-6	0.05	N.D.
194	Fluoranthene	206-44-0	205-912-4	0.05	N.D.

Test Report

No.	Test Item	CAS No.	EC No.	RL(%)	Result (%)
195	Phenanthrene	85-01-8	201-581-5	0.05	N.D.
196	Pyrene	129-00-0	204-927-3	0.05	N.D.
197	1,7,7-trimethyl-3-(phenylmethylene)bicyclo[2.2.1]heptan-2-one	15087-24-8	239-139-9	0.05	N.D.
198	4-tert-Butylphenol	98-54-4	202-679-0	0.05	N.D.
199	2,3,3,3, -tetrafluoro-2 - (sevofluoropropoxy) propionic acid and its salts and acyl halides (including monomers and combinations) (hfpo-da)	--	--	0.05	N.D.
200	2-methoxy ethyl acetate	110-49-6	203-772-9	0.05	N.D.
201	Tris(4-nonyliphenyl,branched and linear) phosphite (TNPP)with⩾0.1% w/w bf 4-nonylphenol, branched and linear(4-NP)	--	--	0.05	N.D.
202	2-benzyl-2-dimethylamino-4'-morpholinobutyrophenone	119313-12-1	404-360-3	0.05	N.D.
203	2-methyl -1-(4-methylthiophenyl)-2-morpholinopropan-1-one	71868-10-5	404-360-3	0.05	N.D.
204	Diisohexyl phthalate	71850-09-04	276-090-2	0.05	N.D.
205	Perfluorobutane sulfonic acid (PFBS) and its salts	--	--	0.05	N.D.
206	1-vinylimidazole	1072-63-5	214-012-0	0.05	N.D
207	2-methylimidazole	693-98-1	211-765-7	0.05	N.D
208	Butyl 4-hydroxybenzoate	94-26-8	202-318-7	0.05	N.D
209	Dibutylbis (pentane-2,4 - dionato - O,O")tin*	22673-19-4	245-152-0	0.05	N.D

Note:
(1) 1 mg/kg = 1 ppm = 0.0001%; 0.1wt% = 1000 ppm
(2) N.D. = Not Detected(<RL)
(3) *The test result is based on the calculation of selected element(s) and to the worst-case scenario
(4) Calculated concentration of boric compounds are based on the water extractive boron by ICP-OES
The above result(s) was/were only given as the informality value and only for reference

FLION TESTING TECHNOLOGIES
Add :Gangzi Industrial Park,Furong Industrial Area, Xinqiao Village, Shajing Town, Bao'an District, Shenzhen City
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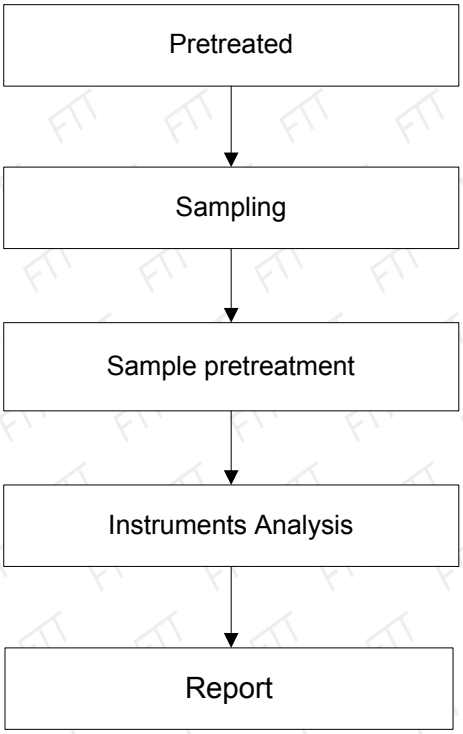
REACH SVHCs Testing Flow Chart:



Test Part Description: Silicone

Sample Photo

Note: The results shown in this report refer only to the sample(s) tested.

* * * * * End of Report * * * * *

Test Report

Applicant : Xi'an Furuize Biotechnology Co., Ltd.

Address : No. 11, Tangyan South Road, High-Tech Zone, Xi'an, Shaanxi, China

The following sample(s) and sample information was/were submitted and identified by/on behalf of the client

Sample Name : Menstrual Cup

Sample Model : sport cup

Sample Lot : /

Sample Received Date : Jun 4, 2020

Test Completed Date : Jun 6, 2020

Test Method : Refer to the next page(s).

Test Results : Refer to the next page(s).

Test Requested	Conclusion
RoHS Directive (EU)2015/863 amending Annex II to Direxitive 2011/65/EU–Lead(Pb), Cadmium(Cd), Mercury(Hg), Hexavalent Chromium(CrVI), Polybrominated Biphenyls (PBBs), Polybrominated Biphenyl Ethers(PBDEs), Dibutyl phthalate (DBP), Butyl benzyl phthalate(BBP), Bis-(2-ethylhexyl)phthalate(DEHP), Di-iso-butyl ortho-phthalate(DIBP)	PASS

Reviewed by: Lab Senior Engineer

Authorized Signature: Technology Manager

FLION TESTING TECHNOLOGIES
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Pb, Cd, Hg, Cr(VI), PBBs, PBDEs Test Results:

Test Item	Test method/Instrument	MDL (mg/kg)	Result (mg/kg)	Limit (mg/kg)
Lead(Pb)	IEC62321-5:2013/ICP-OES	2	N.D.	1000
Cadmium(Cd)	IEC62321-5:2013/ICP-OES	2	N.D.	100
Mercury(Hg)	IEC62321-4:2013+A1:2017/ICP-OES	2	N.D.	1000
Hexavalent Chromium(CrVI)	IEC62321-7-2:2017 /UV-VIS	8	N.D.	1000
Sum of PBBs	-	-	N.D.	1000
Monobromobiphenyl	IEC62321-6:2015 /GC-MS	5	N.D.	--
Dibromobiphenyl	IEC62321-6:2015 /GC-MS	5	N.D.	--
Tribromobiphenyl	IEC62321-6:2015 /GC-MS	5	N.D.	--
Tetrabromobiphenyl	IEC62321-6:2015 /GC-MS	5	N.D.	--
Pentabromodiphenyl	IEC62321-6:2015 /GC-MS	5	N.D.	--
Hexabromobiphenyl	IEC62321-6:2015 /GC-MS	5	N.D.	--
Heptabromobiphenyl	IEC62321-6:2015 /GC-MS	5	N.D.	--
Octabromobiphenyl	IEC62321-6:2015 /GC-MS	5	N.D.	--
Nonabromobiphenyl	IEC62321-6:2015 /GC-MS	5	N.D.	--
Decabromobiphenyl	IEC62321-6:2015 /GC-MS	5	N.D.	--
Sum of PBDEs	-	-	N.D.	1000
Monobromobiphenyl ether	IEC62321-6:2015 /GC-MS	5	N.D.	--
Dibromobiphenyl ether	IEC62321-6:2015 /GC-MS	5	N.D.	--
Tribromobiphenyl ether	IEC62321-6:2015 /GC-MS	5	N.D.	--
Tetrabromobiphenyl ether	IEC62321-6:2015 /GC-MS	5	N.D.	--
Pentabromobiphenyl ether	IEC62321-6:2015 /GC-MS	5	N.D.	--
Hexabromobiphenyl ether	IEC62321-6:2015 /GC-MS	5	N.D.	--
Heptabromobiphenyl ether	IEC62321-6:2015 /GC-MS	5	N.D.	--
Octabromobiphenyl ether	IEC62321-6:2015 /GC-MS	5	N.D.	--
Nonabromobiphenyl ether	IEC62321-6:2015 /GC-MS	5	N.D.	--
Decabromobiphenyl ether	IEC62321-6:2015 /GC-MS	5	N.D.	--

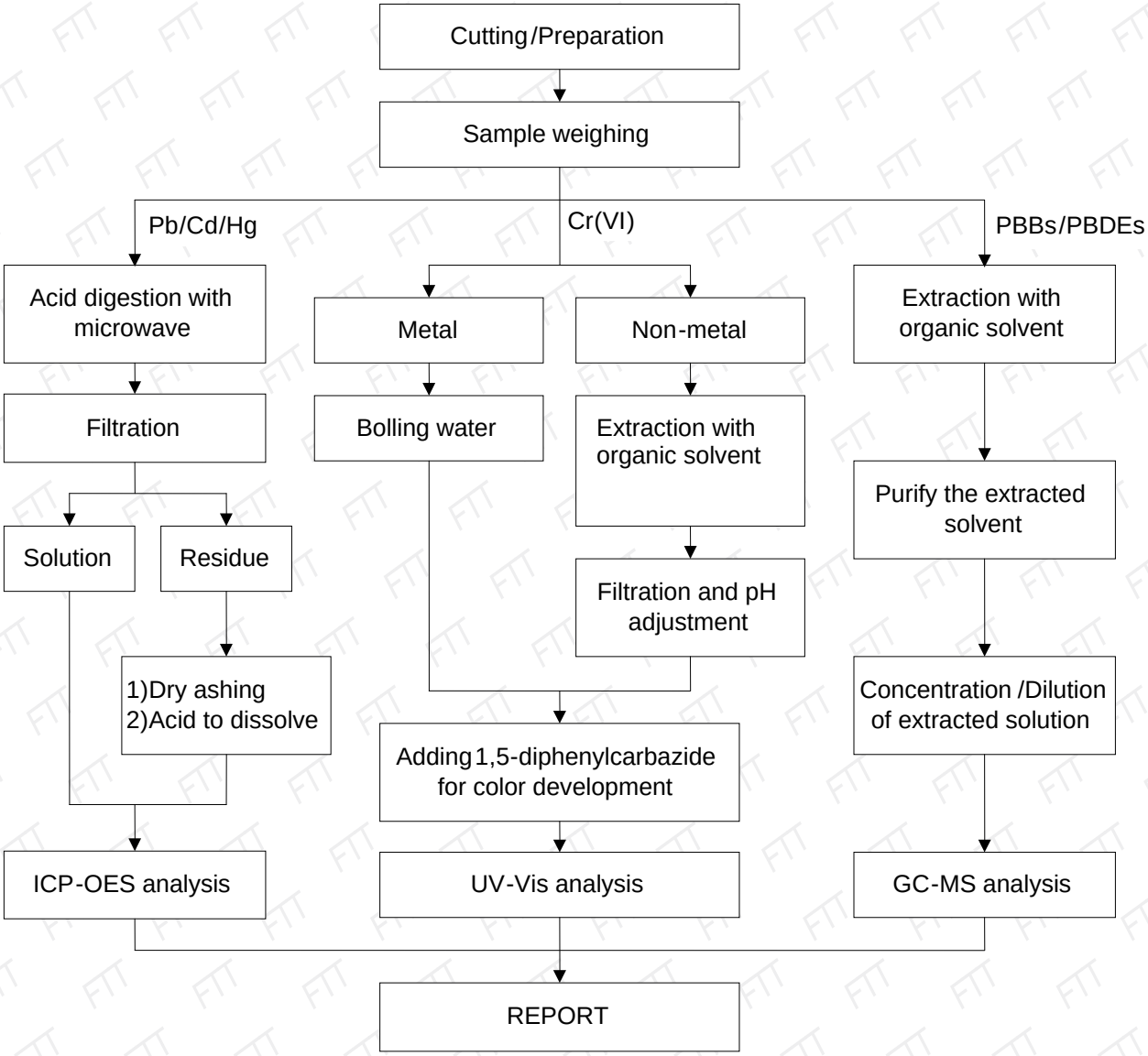
Note:
(1) 1 mg/kg = 1 ppm = 0.0001%
(2) N.D. = Not Detected (less than MDL)
(3) MDL = Method Detection Limit
(4) "--" = Not Regulated

Phthalates Test Results:

Test Item	CAS No.	Test Method / Instrument	MDL (%)	Result (%)	Limit (%)
Dibutyl phthalate (DBP)	84-74-2	IEC 62321-8:2017 / GC-MS	0.005	N.D.	0.1
Butyl benzyl phthalate (BBP)	85-68-7	IEC 62321-8:2017 / GC-MS	0.005	N.D.	0.1
Bis-(2-ethylhexyl)phthalate (DEHP)	117-81-7	IEC 62321-8:2017 / GC-MS	0.005	N.D.	0.1
Di-iso-butyl ortho-phthalate (DIBP)	84-69-5	IEC 62321-8:2017 / GC-MS	0.005	N.D.	0.1

Note:
(1) 1 mg/kg = 1 ppm = 0.0001%
(2) N.D. = Not Detected (less than MDL)
(3) MDL = Method Detection Limit
Remark: The above result(s) was/were only given as the informality value and only for reference

Testing Flow Chart:



Test Part Description: Menstrual Cup

Sample Photo

Note: The results shown in this report refer only to the sample(s) tested.

* * * * * End of Report * * * * *

FLION TESTING TECHNOLOGIES

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检测
TESTING
CNAS L10066

Test Report

Report Number: SSMT-R-2020-03009-03B

Sample Name: Menstrual cup

Study Title: Skin Sensitization Test

Standard: GB/T 16886.10-2017

ISO 10993-10:2010

Test facility

Jiangsu Science Standard Medical Testing Co., Ltd.

C4 Building, No.9 Changyang Road, Wujin District, Changzhou, Jiangsu, China

Sponsor

Xi'an Furuize Biotechnology Co., Ltd.

Room 11131, Building 3, i Duhui, No.11, Tangyan South Road, Zhangba Street Office, High-tech Zone, Xi'an City, Shaanxi, China.

Contents

Explanation

1. Please apply for rechecking within 15 days of receiving the report if there is any objection.
2. Any erasure or without special testing seal renders the report null and void.
3. The report is only valid when signed by the persons who edited, checked and approved it.
4. The result relate only to the articles tested.
5. The report shall not be reproduced except in full without the written approval of the institute.
6. This experiment was carried out in the sub-site and the address is: No. 68, Yaoluo Road, Wujin District, Changzhou City.

Conclusion

The extract of the test article was evaluated for its potential skin sensitization in the Guinea Pig Maximization Test.

The test articles were extracted with 0.9% sodium chloride injection and sesame oil respectively. The test article extract was intradermally injected into guinea pigs and applied topically for induction. Control animals were treated accordingly but with the solvent alone.

The topical challenge with the test article elicited no skin reaction in the test or the control animals. The skin sensitization rates of polar and non-polar group were both determined with 0%.

Study verification and signature

The study was carried out in accordance with the standard operating procedure. The test process was conducted in compliance with the requirements of CNAS-CL01:2018 (ISO/IEC17025:2017, IDT) and RB/T214-2017.

Date Received	2020-10-15
Technical Initiation Date	2020-10-26
Technical Completion Date	2020-11-19
Final Report Completion Date	2020-11-19

Edited by Molly Liu 2020.11.19
Date

Checked by Suri Han 2020.11.19
Date

Approved by Daisy Zhang 2020.11.20
Authorized signatory Date

Jiangsu Science Standard Medical Testing Co., Ltd.

1.0 Purpose

The test was designed to evaluate the potential of a test article to cause skin sensitization using Guinea Pig Maximization Test.

2.0 Reference

Biological evaluation of medical devices-Part 10:Tests for irritation and skin sensitization(GB/T 16886.10-2017)

Biological evaluation of medical devices-Part 12:Sample preparation and reference materials(GB/T 16886.12-2017)

Biological evaluation of medical devices-Part 2: Animal welfare requirements (GB/T 16886.2-2011)

Biological evaluation of medical devices-Part 10:Tests for irritation and skin sensitization(ISO 10993-10:2010)

Biological evaluation of medical devices-Part 12:Sample preparation and reference materials(ISO 10993-12:2012)

Biological evaluation of medical devices-Part 2: Animal welfare requirements (ISO 10993-2:2006)

3.0 Test and control articles

3.1 Test article (The information about the test article was supplied by the sponsor wherever applicable.)

Test article name: Menstrual cup

Sterilization state: Unsterilized

Model/Size: N/S

Lot/ Batch#: N/S

Physical State: Solid

Color: See the photo

Density: N/S

Stability: N/S

Solubility: N/S

Test Article Material: Silica gel

Packing Material: N/S

Storage Condition: Room temperature

Manufacturer: Xi'an Furuize Biotechnology Co., Ltd.

Manufacturer address: Room 11131, Building 3, i Duhui, No.11, Tangyan South Road, Zhangba Street Office, High-tech Zone, Xi' an City, Shaanxi, China.

Sample photograph:

3.2 Control Articles

3.2.1 Polar Negative Control

Name: 0.9% Sodium chloride injection (SC)

Manufacturer: Chenxin Pharmaceutical Co., Ltd.

Size: 250 ml

Physical State: Liquid

Color: Colourless

Lot/ Batch#: 1906112830

Storage Condition: Room Temperature

3.2.2 Non-polar Negative Control

Name: Sesame Oil (SO)

Manufacturer: Ji'an Ivyuanxiangliao. Co., Ltd.

Size: 20 kg

Physical State: Liquid

Color: Pale yellow

Lot/ Batch#: 20190516

Storage Condition: Room Temperature

4.0 Identification of test system

Species: Hartley Guinea Pig (Cavia Porcellus)

Number: 15 for polar group and 15 for non-polar group (10 for test and 5 for control in each group)

Sex: Male

Health status: Healthy, not previously used in other experimental procedures

Housing: Animals were housed in groups in cages identified by a card indicating the lab number and test code.

Animal identification: Stain with picric acid

The quarantine period: 5 days

5.0 Animal Care and Maintenance

Animal purchase: Provided by Suzhou Genesc Biotechnolongy Co .,Ltd <Permit Code: SCXK (SU) 2020-0001>

Bedding: NA

Feed: Guinea Pig Diet, Beijing Keao Xieli Feed Co., Ltd.

Water: Drinking water met the Standards for Drinking Water Quality GB 5749-2006

Cages: Plastic cage, Suzhou Fengqiao purification equipment Co.,Ltd.

Environment: Temperature 18-29℃, Relative humidity 40%-70%, Lights 12 hours light/dark cycle

Personnel: Associates involved were appropriately qualified and trained

Selection: Only healthy, previously unused animals were selected

Veterinarian: Vet takes care of the whole course

Ethics: Test methods of operation were reviewed and approved by the Commission on Science Standard animal ethics

There were no known contaminants present in the feed, water, or bedding expected to interfere with the test data.

6.0 Justification of the test system

6.1 The guinea pig is believed to be the most sensitive animal model for this type of study. The susceptibility of the guinea pig to a known sensitizing agent, dinitrochlorobenzene (DNCB) has been substantiated at SSMT. The skin sensitized positive control test is conducted every six months. The last allergenic rate is 100%. The data was from the report SSMT-R-2020-00198-03 (Date: 2020-09-27) .

6.2 The test article was extracted and administered in vivo through a medium compatible with the test system, which is considered as the best route of administration.

7.0 Instruments and reagents

7.1 Instruments

Digital oscillation incubator (SSMT-300)

Electronic balance (SSMT-075)

Electronic balance (SSMT-147)

Clean bench (SSMT-187)

7.2 Reagents

Sodium dodecyl sulfate (SDS)

Freund's Adjuvant, Complete liquid

8.0 Experiment design and dose

8.1 Sample preparation

The test article was extracted as Table 1. Extract was checked and used immediately after extraction without the process of filtering, centrifugation, dilution, etc. The pH of the extract was not adjusted prior to testing. The preparation process was aseptic. The control article was prepared under the same condition.

Table 1 Sample Preparation

Aseptic Sampling			Aseptic Agitation Extraction In Inert Container				Final Extract
Sampling Manner	Test phase	Actually Sampling	Extraction solvent	Extraction ratio	Solvent volume	Condition	Clear or Not
Take the whole. One test sample was used in every test phase.	Intradermal induction phase I	14.18 g	0.9% sodium chloride injection	0.2 g : 1 ml	70.9 ml	50 ℃, 72 h	Clear
	Topical induction phase II	12.13 g			60.6 ml	50 ℃, 72 h	Clear
	Challenge phase	16.90 g			84.5 ml	50 ℃, 72 h	Clear
	Intradermal induction phase I	9.60 g	Sesame oil	0.2 g : 1 ml	48.0 ml	50 ℃, 72 h	Clear
	Topical induction phase II	10.88 g			54.4 ml	50 ℃, 72 h	Clear
	Challenge phase	17.07 g			85.3 ml	50 ℃, 72 h	Clear

8.2 Test method

8.2.1 Intradermal induction phase I

A pair of 0.1 ml intradermal injections was made for each animal, at the sites (A, B and C) in the clipped intrascapular region as shown in the following Figure 1.

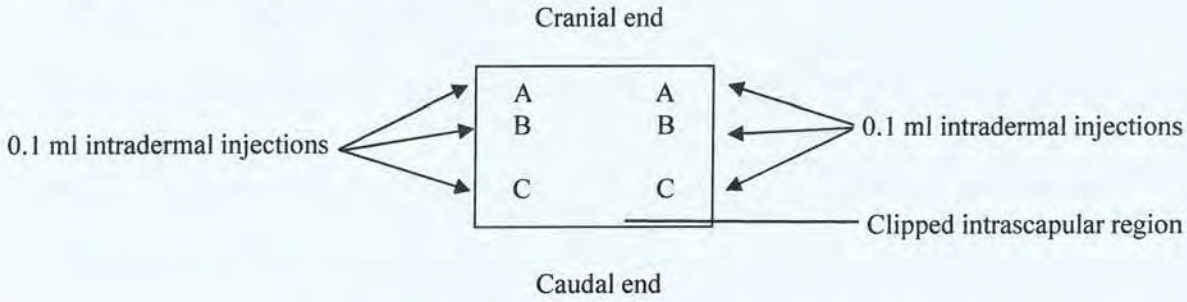

Figure 1 Location of intradermal injection sites

Site A: A 50:50 volume ratio stable emulsion of Freund's complete adjuvant mixed with the solvent.

Site B: The test sample (undiluted extract); inject the control animals with the control articles alone.

Site C: The test sample at the concentration used at site B, emulsified in a 50:50 volume ratio stable emulsion of Freund's complete adjuvant and the solvent (50%); inject the control animals with an emulsion of the blank liquid with adjuvant.

8.2.2 Topical induction phase II

At 6 d after completion of the intradermal induction phase, administer the test sample by topical application to the intrascapular region of each animal, using a patch of area approximately 8 cm^2 (absorbent gauze) soaked with 0.5 ml extract, so as to cover the intradermal injection sites. Use the concentration selected in the intradermal induction phase for site B. If the maximum concentration that can be achieved in Intradermal induction phase I did not produce irritation, animals were pretreated with 10% sodium dodecyl sulfate 24 hours before the topical induction application. Secure the patches with an occlusive dressing. Remove the dressings and patches after 48 h.

Treat the control animals similarly, using the blank liquid alone.

8.2.3 Challenge phase

At 13 d after completion of the topical induction phase, challenge all test and control animals with the test sample. Administer the test sample and a blank by topical application to left and right abdomen of animals respectively, using absorbent gauze (about 8 cm^2) soaked with 0.5ml extracts or solvent control. Secure with an occlusive dressing. Remove the dressings and patches after 24 h.

8.3 Observation of animal

Observe the appearance of the challenge skin sites of the test and control animals 24 h and 48 h after removal of the dressings. Full-spectrum lighting was used to visualize the skin reactions. Describe and grade the skin reactions for erythema and oedema according to the Magnusson and Kligman grading given in Table 2 for each challenge site and at each time interval.

Table 2 Magnusson and Kligman scale

Patch test reaction	Grading scale
No visible change	0
Discrete or patchy erythema	1
Moderate and confluent erythema	2
Intense erythema and/or swelling	3

9.0 Evaluation criteria

Magnusson and Kligman grades of 1 or greater in the test group generally indicate sensitization, provided grades of less than 1 are seen in control animals.

If grades of 1 or greater are noted in control animals, then the reactions of test animals which exceed the most severe reaction in control animals are presumed to be due to sensitization.

If the response is equivocal, rechallenge is recommended to confirm the results from the first challenge.

10.0 Results of the test

The skin response of guinea pigs and body weight change are shown in Table 3.

Table 3 Guinea pig Sensitization Dermal Reactions

Extraction solvent	Group	Animal Number	Excitation patch removed 24 h	Excitation patch removed 48 h	Positive rate after challenge phase	Weight range before injection (g)	Weight range after experiment (g)	Abnormal appearance except dermal reactions
0.9% sodium chloride injection	Control	J1001	0	0	0%	315.4-349.2	462.9-485.4	None
		J1002	0	0				None
		J1003	0	0				None
		J1004	0	0				None
		J1005	0	0				None
	Test	J2001	0	0	0%	310.2-365.1	465.6-528.4	None
		J2002	0	0				None
		J2003	0	0				None
		J2004	0	0				None

		J2005	0	0				None
		J2006	0	0				None
		J2007	0	0				None
		J2008	0	0				None
		J2009	0	0				None
		J2010	0	0				None
Sesame oil	Control	F1001	0	0	0%	309.1-349.2	451.2-490.8	None
		F1002	0	0				None
		F1003	0	0				None
		F1004	0	0				None
		F1005	0	0				None
	Test	F2001	0	0	0%	314.9-373.6	465.4-526.2	None
		F2002	0	0				None
		F2003	0	0				None
		F2004	0	0				None
		F2005	0	0				None
		F2006	0	0				None
		F2007	0	0				None
		F2008	0	0				None
		F2009	0	0				None
		F2010	0	0				None

Under the condition of this study, the test article did not show significant evidence of causing skin sensitization in the guinea pigs. The skin sensitization rates of polar and non-polar test group were both determined with 0%.

11.0 Deviation statement

There was no deviation from the standard operating procedure which were judged to have any impact on the validity of the data.

12.0 Record

All the original data and records related to this test and copies of the final report are retained in the archives of Science Standard Medical Testing.

13.0 Confidentiality agreement

Statements of confidentiality were as agreed upon prior to study initiation.

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TESTING
CNAS L10066

Test Report

Report Number: SSMT-R-2020-03009-02B

Sample Name: Menstrual cup

Study Title: Skin Irritation Test

Standard: ISO 10993-10:2010

GB/T 16886.10-2017

Test facility

Jiangsu Science Standard Medical Testing Co., Ltd.

C4 Building, No.9 Changyang Road, Wujin District, Changzhou, Jiangsu, China

Sponsor

Xi'an Furuize Biotechnology Co., Ltd.

Room 11131, Building 3, i Duhui, No.11, Tangyan South Road, Zhangba Street Office, High-tech Zone, Xi'an City, Shaanxi, China.

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4. The result relate only to the articles tested.
5. The report shall not be reproduced except in full without the written approval of the institute.
6. This experiment was carried out in the sub-site and the address is: No. 68, Yaoluo Road, Wujin District, Changzhou City.

Conclusion

The animal skin irritation test was conducted to assess the potential irritation of the test article or material.

The test sample was extracted with 0.9% sodium chloride injection and sesame oil respectively. The patches (about 2.5 cm×2.5 cm) which moistened by 0.5 ml extract of test article were directly applied to the rabbit skin for 4 hours. Observation for erythema and edema were conducted at 1 h, 24 h, 48 h and 72 h after removal of the patches.

The primary irritation indexes of the polar and non-polar test group were both calculated to be 0. The test result showed that the extract of the test article did not induce skin irritation in rabbit under the test condition.

Study verification and signature

The study was carried out in accordance with the standard operating procedure. The test process was conducted in compliance with the requirements of CNAS-CL01:2018 (ISO/IEC 17025:2017, IDT) and RB/T 214-2017.

Date Received	2020-10-15
Technical Initiation Date	2020-10-26
Technical Completion Date	2020-10-29
Final Report Completion Date	2020-10-30

Edited by Molly Liu 2020.10.30
Date

Checked by Suri Han 2020.10.30
Date

Approved by Daisy Zhang 2020.10.30
Authorized signatory Date

Jiangsu Science Standard Medical Testing Co., Ltd.

1.0 Purpose

New Zealand rabbits were used to evaluate the potential of skin irritation of samples under the condition of this test.

2.0 Reference

Biological evaluation of medical devices-Part 10:Tests for irritation and skin sensitization(ISO 10993-10:2010)

Biological evaluation of medical devices-Part 12:Sample preparation and reference materials(ISO 10993-12:2012)

Biological evaluation of medical devices-Part 2: Animal welfare requirements (ISO 10993-2:2006)

Biological evaluation of medical devices-Part 10:Tests for irritation and skin sensitization(GB/T 16886.10-2017)

Biological evaluation of medical devices-Part 12:Sample preparation and reference materials(GB/T 16886.12-2017)

Biological evaluation of medical devices-Part 2: Animal welfare requirements (GB/T 16886.2-2011)

3.0 Test and control articles

3.1 Test article (The information about the test article was supplied by the sponsor wherever applicable.)

Test article name: Menstrual cup

Sterilization state: Unsterilized

Model/Size: N/S

Lot/ Batch#: N/S

Physical State: Solid

Color: See the photo

Density: N/S

Stability: N/S

Solubility: N/S

Test Article Material: Silica gel

Packing Material: N/S

Storage Condition: Room temperature

Manufacturer: Xi'an Furuize Biotechnology Co., Ltd.

Manufacturer address: Room 11131, Building 3, i Duhui, No.11, Tangyan South Road, Zhangba Street Office, High-tech Zone, Xi' an City, Shaanxi, China.

Sample photograph:

3.2 Control Articles

3.2.1 Polar Negative Control: 0.9% Sodium chloride injection (SC)

Manufacturer: Chenxin Pharmaceutical Co., Ltd.

Size: 250 ml

Physical State: Liquid

Color: Colourless

Lot/ Batch#: 1906112830

Storage Condition: Room Temperature

3.2.2 Non-polar Negative Control: Sesame Oil (SO)

Manufacturer: Ji'an lvyuanxiangliao. Co., Ltd.

Size: 20 kg

Physical State: Liquid

Color: Pale yellow

Lot/ Batch#: 20190516

Storage Condition: Room Temperature

4.0 Identification of test system

Species: New Zealand white rabbit (single strain)

Number: 6 (3 for polar test group and 3 for non-polar group)

Sex: Female

Weight: Initial body weight not less than 2.0 kg

Health status: Healthy, young adult, nulliparous and not pregnant.

Housing: Animals were housed in groups in cages identified by a card indicating the lab number, test code and first treatment date.

Animal identification: Cage card

The quarantine period: 5 days

5.0 Animal Care and Maintenance

Animal purchase: Provided by Tongxiang Yinhai Animal Husbandry Professional Cooperative <Permit Code: SCXK (ZHE) 2018-0002>

Bedding: NA

Feed: Rabbit Diet, Beijing Keao Xieli Feed Co., Ltd.

Water: Drinking water met the Standards for Drinking Water Quality (GB 5749-2006)

Cages: Stainless steel cage, Suzhou Fengqiao purification equipment Co.,Ltd.

Environment: Temperature 16-26℃, Relative humidity 40%-70%, Lights 12 hours light/dark cycle

Personnel: Associates involved were appropriately qualified and trained

Selection: Only healthy animals were selected

Veterinarian: Vet takes care of the whole course

Ethics: Test methods of operation were reviewed and approved by the Commission on Science Standard animal ethics

There were no known contaminants present in the feed, water expected to interfere with the test data.

6.0 Justification of the test system

6.1 The rabbit is specified as an appropriate animal model for evaluating potential skin irritants by the current testing standards. Positive control 15% sodium dodecyl sulfate has been substantiated at SSMT with this method. Positive control tests are conducted every six months. The last irritation index of polar test group was 6.0. The last irritation index of non-polar test group was 5.7. The data was from the report SSMT-R-2020-01262-01 (Date: 2020-05-29).

6.2 The test article extract was directly applied to the rabbit skin, which was suggested by the standard.

7.0 Instruments

Digital oscillation incubator (SSMT-300)

Electronic balance (SSMT-075)

Steel Straight Scale (SSMT-210)

Clean bench (SSMT-187)

8.0 Experiment design and dose

8.1 Sample preparation

The test article was extracted as Table 1. Extract was checked and used immediately after extraction without the process of filtering, centrifugation, dilution, etc. The pH of the extract was not adjusted prior to testing. The preparation process was aseptic. The control article was prepared under the same condition.

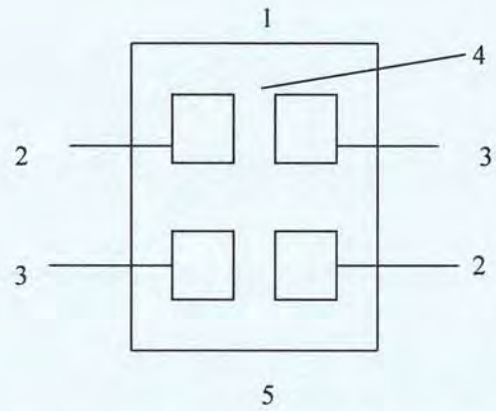
Table 1 Sample Preparation

Aseptic Sampling		Aseptic Agitation Extraction In Inert Container				Final Extract
Sampling Manner	Actually Sampling	Extraction solvent	Extraction ratio	Solvent volume	Condition	Clear or Not
Take the whole. One test sample was used in each group.	14.18 g	0.9% sodium chloride injection	0.2 g : 1 ml	70.9 ml	50 ℃, 72 h	Clear
	12.13 g	Sesame oil	0.2 g : 1 ml	60.6 ml	50 ℃, 72 h	Clear

8.2 Test method

Use the rabbits with healthy intact skin. Fur is generally clipped on the back of the rabbits 16 h before testing, a sufficient distance on both sides of the spine for application and observation of all test sites (approximately 10 × 15 cm).

Apply 0.5 ml extract of test article or control to 2.5 cm × 2.5 cm absorbent gauze patches, and then apply the patch soaked with the extract of test article or control directly to the skin on each side as shown in Figure 1. And then wrap the application site with a bandage (semi-occlusive) for 4 h. At the end of the contact time, remove the dressings.



1- Cranial end, 2- Test site, 3- Control site, 4- Clipped dorsal region, 5- Caudal end

Figure1 Location of skin application sites

8.3 Observation of animal

Describe and score the skin reaction for erythema and oedema according to the scoring system given in Table 2 for each application site at each time interval. Record the appearance of each application site at 1 h, 24 h, 48 h and 72 h following removal of the patches.

Table 2 Classification System for Skin Reaction

Reaction	Irritation score
Erythema and Eschar Formation	
No erythema	0
Very slight erythema (barely perceptible)	1
Well-defined erythema	2
Moderate erythema	3
Severe erythema (beet redness) to eschar formation preventing grading of erythema	4
Oedema Formation	
No oedema	0
Very slight oedema (barely perceptible)	1
Well-defined oedema (edges of area well-defined by definite raising)	2
Moderate oedema (raised approximately 1mm)	3
Severe edema (raised more than 1mm and extending beyond exposure area)	4
Maximal possible score for irritation	**8**

NOTE: Other adverse changes at the skin sites were recorded and are reported.

8.4 Result calculation

Use only 24 h, 48 h and 72 h observations for calculation.

After the 72 h grading, all erythema grades plus oedema grades 24 h, 48 h and 72 h are totalled separately for each test sample and blank for each animal. The primary irritation score for an animal is calculated by dividing the sum of all the scores by 6 (two test/observation sites, three time points).

To obtain the primary irritation index for the test sample add all the primary irritation scores of the individual animals and divide by the number of animals.

Calculate the primary irritation score for the controls and subtract that score from the score using the test material to obtain the primary irritation score.

9.0 Evaluation criteria

The primary irritation index is characterized by number (score) and description (response category) given in Table 3.

Table 3 Primary irritation index categories in a rabbit

Mean score	Response category
0-0.4	Negligible
0.5-1.9	Slight
2.0-4.9	Moderate
5-8	Severe

10.0 Results of the test

According to what observed, the response of skin on testing side did not exceed that on the control side. See Table 4 .

Table 4 Dermal observations

Extraction solvent	Rabbit No.	Group		Interval			
				1h	24h	48h	72h
0.9% sodium chloride injection	J1501	Test Article	Erythema	0	0	0	0
			Oedema	0	0	0	0
		Negative Control	Erythema	0	0	0	0
			Oedema	0	0	0	0
	J1502	Test Article	Erythema	0	0	0	0
			Oedema	0	0	0	0
		Negative Control	Erythema	0	0	0	0
			Oedema	0	0	0	0
	J1503	Test Article	Erythema	0	0	0	0
			Oedema	0	0	0	0
		Negative Control	Erythema	0	0	0	0
			Oedema	0	0	0	0
Sesame oil	F1501	Test Article	Erythema	0	0	0	0
			Oedema	0	0	0	0
		Negative Control	Erythema	0	0	0	0
			Oedema	0	0	0	0

	F1502	Test Article	Erythema	0	0	0	0
			Oedema	0	0	0	0
		Negative Control	Erythema	0	0	0	0
			Oedema	0	0	0	0
	F1503	Test Article	Erythema	0	0	0	0
			Oedema	0	0	0	0
		Negative Control	Erythema	0	0	0	0
			Oedema	0	0	0	0

The primary irritation indexes of the polar and non-polar test group were both calculated to be 0. Under the conditions of this study, the extract of the test article did not induce skin irritation.

11.0 Deviation statement

There was no deviation from the standard operating procedure which were judged to have any impact on the validity of the data.

12.0 Record

All the original data and records related to this test and copies of the final report are retained in the archives of Science Standard Medical Testing.

13.0 Confidentiality agreement

Statements of confidentiality were as agreed upon prior to study initiation.

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TESTING
CNAS L10066

Test Report

Report Number: SSMT-R-2020-03009-01B

Sample Name: menstrual cup

Study Title: In Vitro Cytotoxicity Test

Standard: ISO 10993-5:2009

GB/T 16886.5-2017

Test facility

Jiangsu Science Standard Medical Testing Co., Ltd.

C4 Building, No.9 Changyang Road, Wujin District, Changzhou, Jiangsu, China

Sponsor

Xi'an Furuize Biotechnology Co., Ltd.

Room 11131 , Building 3,i Duhui, No.11 ,Tangyan South Road ,Zhangba Street Office ,High-tech Zone ,Xi'an City, Shaanxi, China.

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2. Any erasure or without special testing seal renders the report null and void.
3. The report is only valid when signed by the persons who edited, checked and approved it.
4. The result relate only to the articles tested.
5. The report shall not be reproduced except in full, without approval of the laboratory.

Conclusion

The study was to investigate the potential cytotoxicity of the test sample. The extract of the test article was added to L-929 cells and then incubated at 37℃ in 5% CO_2 for 24 hours. After the incubation, observe the cell morphology. The results were detected with MTT method. The results showed that the cytotoxicity ratio of the 100 % test article extract was 85.9% and the results of control groups showed the test was valid.

Under the conditions of this study, the extract of the test article did not show potential toxicity to L-929 cells.

Study verification and signature

The study was carried out in accordance with the standard operating procedure. The test process was conducted in compliance with the requirements of CNAS-CL01:2018 (IDT ISO/IEC 17025:2017) and RB/T 214-2017.

Date Received	2020-10-15
Technical Initiation Date	2020-10-21
Technical Completion Date	2020-10-23
Final Report Completion Date	2020-10-26

Edited by Cindy Zhu 2020.10.26
Date

Checked by Bella Pi 2020.10.26
Date

Approved by Daisy Zhang 2020.10.28
Authorized signatory
Date

Jiangsu Science Standard Medical Testing Co., Ltd.

1.0 Purpose

The purpose of the test is to determine the potential cytotoxicity toxicity of a mammalian cell culture (mouse fibroblast L-929 cells) in response to the test article.

2.0 Standard

Biological evaluation of medical devices Part 5: Tests for In Vitro Cytotoxicity (ISO 10993-5:2009)

Biological evaluation of medical devices Part 12: Sample preparation and reference materials (ISO 10993-12:2012)

Biological evaluation of medical devices Part 5: Tests for In Vitro Cytotoxicity (GB/T 16886.5-2017)

Biological evaluation of medical devices Part 12: Sample preparation and reference materials (GB/T 16886.12-2017)

3.0 Test and control articles

3.1 Test article (The information about the test article was supplied by the sponsor wherever applicable.)

Test article name: menstrual cup

Sterilization state: Not sterilized

Model/Size: N/S

Lot/ Batch#: N/S

Physical State: Solid

Color: See the photo

Density: N/S

Stability: N/S

Solubility: N/S

Test Article Material: silica gel

Packing Material: N/S

Storage Condition: Room temperature

Manufacturers: Xi'an Furuize Biotechnology Co., Ltd.

Manufacturer address: Room 11131 , Building 3,i Duhui, No.11 ,Tangyan South Road ,Zhangba Street Office ,High-tech Zone ,Xi'an City, Shaanxi, China.

Sample photograph:

3.2 Control Articles

3.2.1 Negative Control Article Name: High Density Polyethylene

Manufacturer: Jiangsu haiaosihui biotechnology co., LTD.

Size: 1.6 mm thick, 300*300 mm

Lot/ Batch#: M02F017

Physical State: Solid

Color: White

Storage Conditions: Room temperature

3.2.2 Positive Control Article Name: ZDEC

Manufacturer: Tokyo Into Industrial Co., Ltd.

Size: 25 g

Lot/ Batch#: DUDQG-JF

Physical State: Solid

Color: White

Storage Condition: Room temperature

Concentration: 0.1%

3.2.3 Blank Control Name: MEM medium, with addition 10% FBS

Physical State: Liquid

Color: Pink

Storage Condition: 4 ℃

4.0 Identification of test system

Mouse fibroblast L-929 cells obtained from ATCC CCL1 (NCTC clone 929).

5.0 Justification of test system

5.1 Historically, mouse fibroblast L-929 cells have been used for cytotoxicity studies because they demonstrate sensitivity to extractable cytotoxic articles.

5.2 The test article was extracted and administered in vitro to mouse fibroblast L-929 cells through a solvent compatible with the test system. This was the optimal route of administration available in this test system as recommended in the standard.

6.0 Instruments and Reagents

6.1Instruments

Vertical pressure steam sterilizer (SSMT-281)

CO_2 Incubator (SSMT-279)

Biological microscope（SSMT-278）

Clean bench (SSMT-028)

Bench type low speed centrifuge (SSMT-048)

Vapour-bathing Constant Temperature Vibrator (SSMT-004)

Electronic Balance (SSMT-015)

Multiskan Spectrum Microplate Spectrophotometer (SSMT-139)

Mini Vibrator (SSMT-311)

6.2 Reagents

FBS

MEM

Trypsin

Penicillin, Streptomycin sulfate

PBS

MTT (3-(4,5-Dimethylthiazol-2-yl)-2,5-diphenyletrazolium bromide)

Isopropyl alcohol

7.0 Experiment design and dose

7.1 Sample preparation

Aseptic extracting the test article (test article to volume of vehicle) according to the table below. Sealed and incubated in Vapour-bathing Constant Temperature Vibrator at 37 ℃ and 60 rpm for 24 hours. After the extraction, check the extraction changes, and immediately use for the experiment, the leach was not filtered, centrifuged or diluted. No pH adjustment.

Table 1 Sample preparation

Sampling		Aseptic Agitation Extraction In Inert Container				Final Extract
Sampling Manner	Actually sampling	Extraction solvent	Extraction ratio	Solvent volume	Condition	Clear or Not
Take the whole	12.08 g	MEM medium (10% FBS)	0.2 g : 1 ml	60.4 ml	37 ℃, 24 h	Clear

The blank control (MEM medium, with addition 10% FBS) and negative/positive controls were prepared in the same condition.

7.2 Test method

Aseptic procedures were used for handling cell cultures.

L-929 cells were cultured in MEM medium (10% FBS, Penicillin 100 U/ml, Streptomycin sulfate 100 μg/ml) at 37℃ in a humidified atmosphere of 5% CO_2, then digested by 0.25% trypsin containing EDTA to get single cell suspension. And obtain a 1×10^5 cells/ml suspension by centrifuging (200 g, 3 min) and re-dispersing in MEM medium finally.

The suspended cells were dispensed at 100 μl per well in 96-well plate, and cultured in cell incubator (5% CO_2, 37℃, >90%humidity). Cell morphology was evaluated to verify that the monolayer was satisfactory.

After the cells grew to form a monolayer, original culture medium was discarded. The 96-well plates were then treated with 100 μl of extract of test article (100%, 75%, 50%, 25%), control article, negative article (100%) and positive article (100%) respectively. The 96-well plate was incubated at 37℃ in cell incubator of 5% CO_2 for 24 h. Six replicates of each test were tested.

After 24 h incubation, observe the cell morphology first and then discard the culture medium. A 50 μl aliquot of MTT (1 mg/ml) was added to each well and then incubated at 37℃ in a humidified atmosphere of 5% CO_2 for 2

hours. The liquid in each well was tipped out and 100 μl isopropanol was added to each well to suspend the cell layer. The microporous plate was vibrated for 10 min and monitored by the optical density at 570 nm on the microplate analyzer.

7.3 Statistical method

Mean±standard deviation ($\bar{x}$ ±s)

Viab. %=100×OD_{570e}/OD_{570b}

Where: OD_{570e}——is the mean value of the measured optical density of test sample/negative control/positive control;

OD_{570b}——is the mean value of the measured optical density of the blanks.

7.4 Observation of the cell morphology

Table 2 Observation of the cell morphology

Grade	Conditions of all cultures
0	Discrete intracytoplasmatic granules, no cell lysis, no reduction of cell growth.
1	Not more than 20 % of the cells are round, loosely attached and without intracytoplasmatic granules, or show changes in morphology; occasional lysed cells are present; only slight growth inhibition observable.
2	Not more than 50 % of the cells are round, devoid of intracytoplasmatic granules, no extensive cell lysis; not more than 50 % growth inhibition observable.
3	Not more than 70 % of the cell layers contain rounded cells or are lysed; cell layers not completly destroyed, but more than 50 % growth inhibition observable.
4	Nearly complete or complete destruction of the cell layers.

8.0 Evaluation criteria

8.1 The 50% extract of the test article should have at least the same or a higher viability than the 100% extract. Otherwise the test should be repeated.

8.2 The lower the Viab.% value, the higher the cytotoxic potential of the test article is.

8.3 If viability is reduced to < 70% of the blank, it has a cytotoxic potential.

8.4 The Viab.% of the 100% extract of the test article is the final result.

9.0 Results of the test

Table 3 Results of the cell vitality

Group	$\bar{x}$ ±s	Viability%	The morphology of the extracted cells was observed under the microscope
Blank control	0.875±0.090	100.0	0

Negative control	0.878±0.043	100.3	0
Positive control	0.074±0.012	8.5	4
100% test article extract	0.752±0.035	85.9	0
75% test article extract	0.858±0.033	98.0	0
50% test article extract	0.839±0.012	95.9	0
25% test article extract	0.874±0.043	99.9	0
Quality check	The mean OD_{570} of blanks is ≥ 0.2. The left (row2) and the right (row11) mean of the blanks do not differ by more than 15 %. The test meets the acceptance criteria.		
Conclusion	Under the conditions of this study, the test article did not show potential toxicity to L-929 cells.		

10.0 Deviation statement

There was no deviation from the approved standard operating procedure which were judged to have any impact on the validity of the data.

11.0 Record

All the original data and records related to this test and copies of the final report are retained in the archives of Science Standard Medical Testing.

12.0 Confidentiality agreement

Statements of confidentiality were as agreed upon prior to study initiation.