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Date of Issue: 2017.06.12

RE: Material Safety Data Sheet (MSDS) for Biotex Non-absorbable Suture

Biotex Non-absorbable Suture is not considered to be or to contain hazardous chemicals based on evaluations made by Purgo Biologics Inc. with following MSDS of each raw material.

- Stainless Steel Wire
- Polytetrafluoroethylene

Sincerely,

Completed by / Date



Hana Jung/2017.06.12

Safety Data Sheet

1. Chemical Product & Our Company Identification

Product Name: Iron-Based Wire Product

JIS G 4309 Stainless steel wires

JIS G 4314 Stainless steel wires for spring

JIS G 4315 Stainless steel wires for cold heading and cold forging

JIS G 4318 Cold finished stainless steel bars

Others: Nippon Seisen's standard products and stainless steel and alloy wires equivalent to the above products

Creation/Revision: Creation date January 15, 2013 Date of revision June 8, 2015 Date of issue : January 6, 2017

2. Hazards Identification

GHS classification and GHS label element

GHS classification

Health hazards

Skin corrosion/skin irritation	Category 3
Serious eye damage/eye irritation	Category 2B
Respiratory sensitization	Category 1
Skin sensitization	Category 1
Germ cell mutagenicity	Category 2
Carcinogenicity	Category 2
Reproductive toxicity	Category 1B
Specific target organ systemic toxicity (single exposure)	Category 1 (Respiratory organs, kidney) Category 2 (Systemic toxicity) Category 3 (Respiratory tract irritation)
Specific target organ systemic toxicity (repeated exposure)	Category 1 (Nervous system, respiratory organs, liver)

Environmental hazards

Hazardous to the aquatic environment (chronic) Category 4

*Other hazards than above are not classified, or no classification or classification not possible.

Label element

Hazard pictogram or symbol



Signal words

Hazard Warning

Hazard and Toxicity Statement

Causes mild skin irritation
 Causes eye irritation
 Inhalation may cause allergy, asthma, or shortness of breath.
 May cause allergic skin reaction.
 Suspected of causing genetic disease.
 Suspected of being carcinogenic.
 May influence adversely on reproductivity or unborn child.
 Causes damage to organs (respiratory organs, kidney).
 May cause damage to organs (systemic toxicity).
 May cause respiratory organs (respiratory tract irritation).
 Prolonged or repeated exposure causes damage to organs (nervous system, respiratory organs, liver).
 May be harmful on aquatic organism due to a long-term influence.

Precautionary Statement

Safety Measures

Read all precautions before handling the product.
 Protect from exposure by using personal protective equipment and ventilator.
 Do not inhale dust, fume, vapor, spray, etc.
 Do not take contaminated clothing out of the workplace.
 Wash contaminated clothing before reusing.
 Do not eat, drink or smoke when handling the product.
 Wash your hands after handling the product.
 Do not release dust, fume, spray, etc. into the external environment.

First Aid Measures

Inhalation: Move to fresh air and rest afflicted person in the comfortable posture for easy breathing.
 If a breathing problem develops, contact a doctor.
 If sickness develops, seek medical attention.
 Eye contact: Irrigate eyes carefully with water for several minutes. Remove contact lenses, if possible, and continue to wash eyes.
 If eye irritation persists, seek medical attention.
 Skin contact: Wash exposed areas of the body with soap and copious amount of water.
 If skin irritation develops, seek medical attention.
 If exposed or possibly exposed, seek medical attention.
 Product leakage must be recovered.

Storage

Keep the product under lock and key.

Disposal Considerations

The content and vessel must be disposed of by observing municipal, national and international regulations.

3. Composition/Information on Ingredients Classification of individual elements/mixtures: Mixture (Alloy)

«Major ingredients»

Ingredients		Content (Wt%)	CAS No.
Iron	[Fe]	—	Remainder
Chrome	[Cr]	*1),*3)	7 ~ 35
Nickel	[Ni]	*1),*3)	0 ~ 30
Manganese	[Mn]	*1),*3)	0 ~ 20
Molybdenum	[Mo]	*1),*3)	0 ~ 10
Copper	[Cu]	*3)	0 ~ 5
Cobalt	[Co]	*1),*2)	0 ~ 50

*1) means substances designated in the PRTR Law (Class 1 Designated Chemical Substance).

*2) means substances subject to notify their names under the Industrial Safety and Health Act.

*3) means substances subject to reporting under the Industrial Safety and Health Act.

Although the product is metallic solid material, refer to Item 7 "Handling and Storage."

	<p>Note 1) The above ingredients differ in component value according to the type of stainless steel standard.</p> <p>Note 2) Depending on the usage, some products contain trace elements other than above ingredients.</p> <p>Note 3) The detail is listed on the mill sheet. Even if not listed on it, the product sometimes contains minimal trace elements.</p>
4. First Aid Measures	Refer to Item 2.
5. Fire Fighting Measures	The product is non-inflammable. Normal water spray or fire extinguishers can be used even if the surrounding area is in a fire.
6. Measures in case of Leakage	The product is solid-state and leakage will not occur. If the product scatters in a powdery state, it must be shrouded by a suitable cover to prevent scattering.
7. Handling and Storage	<p>(1) When handling the product, wear personal protective equipment in order to protect respiratory organs, skin, eye and body.</p> <p>(2) When dust, fume etc. generate during the product processing, such as heating, melting, cutting, grinding, etc., the equipment used must be kept airtight or the place ventilated to protect operators from exposure.</p> <p>(3) When the product deforms or byproduct generates by heat, take appropriate measures and use extreme care during the work.</p> <p>(4) Keep the product under lock and key. The product in a powdery state must be covered to avoid scattering.</p>
8. Exposure Control/Personal Protection	Use appropriate personal protective equipment/ventilator to avoid exposure.
9. Physical and Chemical Properties	<p>Appearance: Special steel (solid-state)</p> <p>Flash point: N/A. However, fine powder produced by processing might be inflammable/explosive.</p> <p>Melting point: $\geq 1400^{\circ}\text{C}$</p> <p>Specific gravity: 7 - 9</p> <p>Chemical property: Insoluble in water. Corrosion resistant to mild acid and alkali.</p> <ul style="list-style-type: none"> · Soluble in strong acid (hydrochloric acid, sulfuric acid) and hot alkali. The product forms passivation film in oxidizing acid.
10. Stability and Reactivity	<p>Stability: Chemically stable in the normal state.</p> <p>Hazardous decomposition products: heating, dissolution, melting, welding, cutting, metal compounds during processing such as polishing, there are times when dust, fumes, etc. are generated.</p> <p>In that case, you might need to take measures in accordance with the law.</p>
11. Hazard Information	Refer to Item 2.
12. Ecological Information	Refer to Item 2.
13. Disposal Consideration	When disposing of the product or cutting chips or packing materials, follow municipal, national and international regulations.
14. Transport Information	As for stainless steel, N/A.
15. Regulatory Information	Industrial Safety and Health Act, and Pollutant Release and Transfer Register Law (PRTR Law)
16. Other Information	(1) Hazardous Chemical Data Book (The Vigilance and Protection Study Group in the Tokyo Fire Department,)

- (2) Special Investigation Report on Major 1000 Types of Data (Overseas Technical Materials Research Institute, Ltd.)
- (3) Metallic Alloys and Harmonization of Classification Criteria (OECD)
- (4) Material Safety Data Sheet (ISO 11014-1)
- (5) JAIH-recommended value, ACGIH (American Conference of Governmental Industrial Hygienists) recommended value
- (6) Handbook on the Dangers and Hazards (Edited by the Labour Standards Information, Ministry of Health, Labour and welfare: Japan Industrial Safety and Health Association)
- (7) Webpage of the National Institute of Technology and Evaluation

◆ Note

- (1) This information relates only to the specific product designated. For any other way of the product processing, appropriate safety measures should be taken according to usage and application.
- (2) The danger, toxicity, and environmental impacts described here are for an information purpose only, and no warranty or guarantee is provided.
- (3) This English translation is for your reference. The Japanese edition is the official version. If there is any questionable points or problems, we will discuss based on the Japanese edition.

JAMP MSDSplus

MSDSplus Information

Format Version		Ver.4.1
Substance List Version		4.060
GP(Global Portal) Sheet ID		999999999999999
Sheet Reference Number		MSDSplus 304
Original	Issued Date	2013-07-24
Revision	Latest Issued Date	2016-08-02
	Revision History	6

1.Product Information

Manufacturer Name		
Product name		SUS 304 Stainless Steel Wire
Issuing Company Item Number	Alphanumeric	SUS 304 Stainless Steel Wire
	Mother Language	SUS 304 ステンレス鋼線
Common Product Name		SUS 304 Stainless Steel Wire

2. Issuing company Information

Company Name	Alphanumeric	
	Mother Language	
Company ID	ID Organizer	
	Entity ID	
Issuing Department	Department Name	Quality Assurance Department
	Address	
	Telephone Number	
	FAX Number	
Department in Charge of Preparing AIS	Email Address	
	Department Name	Quality Assurance Department
	Telephone Number	
Remarks		

3.Substance Information

Declaration Concerning Substance Information	1.This product contains the following substance(s) listed in the relevant standard and to be notified
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*1 "1 (or symbols that mean to be contained)" is marked if a substance listed in the relevant standard and to be notified is intentionally added
 "1 (or symbols that mean to be contained)" does not directly mean legally regulated. It depends on use and other conditions.

*2 Notified if there is additional information

*3 For more information please refer to "The List of JAMP Declarable Substances: Instruction Manual".

*4 The information herein is given in good faith, but no warranty, express or implied, is made.
 It is the user's responsibility and completeness of this information for his own particular use.

Substance Name	CAS Number	Max. Concentration	Remarks *2	Relevant Standard *1																					
				JP 01	JP 02	JP 03	EU 01	EU 02	EU 03	EU 04	EU 05	EU 06	OT 01	IA 01	IA 02										
Nickel	7440-02-0	10.5%																							
Copper	7440-50-8	1.0%																							D
Cobalt and its compounds; Cobalt, elemental	7440-48-4	1.0%																							D
Diantimony trioxide; Antimony trioxide	1309-64-4	0.025%																							D
Disodium tetraborate, anhydrous; boric acid, disodium salt	1330-43-4	0.025%																							D/P
Boric acid; Orthoboric acid	10043-35-3	0.025%																							D/P
Alkanes, chloro; chloroparaffins	61788-76-9	0.01%																							P

4.Relevant Standard Information

Relevant Standard		Issued or revised
JP01	Japanese Chemical Substances Control Law (Class I Specified Chemical Substances)	2016/04/01
JP02	Industrial Safety and Health Act (Substances Prohibited of Manufacturing etc.)	2007/09/07
JP03	Poisonous and Deleterious Substances Control Law (Specified Poisonous Substances)	2007/08/15
EU01	RoHS Directive	2011/65/EU
EU02	ELV Directive	2011/37/EU
EU03	CLP [Annex VI Table 3.2 CMR-cat. 1,2]	(EU)2015/1221
EU04	REACH Annex XVII [Except EU03]	(EU)2016/217
EU05	REACH SVHC on the Candidate List	2016/06/20
EU06	POPs Annex I	(EU)2016/293
OT01	ESIS PBT [Fulfilled]	2008-10-28
IA01	GADSL	2016 GADSL Reference List Version 1.1
IA02	IEC62474/JIG	IEC62474 D12.00

1. IDENTIFICATION OF THE SUBSTANCE / PREPARATION AND COMPANY:

PRODUCT DETAILS – TRADE NAME:

Lenzing Profilen®:
Weaving yarn
Sewing thread
Staple fibre
Film
Dental floss

SUPPLIER DETAILS:

EMERGENCY TELEPHONE NUMBER:

2. COMPOSITION / INFORMATION ON INGREDIENTS:

CHEMICAL CHARACTERIZATION:

Polytetrafluoroethylene
- pure PTFE, without additives
9002-84-0

CAS-No.:

FORM:

Fibre, yarn, thread, film
solid, flexible

COLOUR:

natural white to opaque

ODOUR:

odourless

HAZARDOUS INGREDIENTS:

none

3. HAZARDS IDENTIFICATION:

GENERAL INFORMATION:

Lenzing Profilen® products are not injurious to health in state of delivery. The major health hazard associated with this material occurs, if the product is heated beyond the temperature of thermal decomposition (see sections 5 and 10) and decomposition products may be inhaled.

If the material is heated over 280°C, take care for sufficient ventilation. The installation of exhaust ventilators is recommended urgently.

Contamination of tobacco products **must** be avoided.

FIRE HAZARD:

Toxic gases are produced during burning (see also sections 5 and 10).

DANGER OF SLIPPING:

Product lying on the floor can cause a danger of slipping.

4. FIRST-AID MEASURES:

INHALATION:

Inhalation of fumes: Remove patient from exposure, keep warm and at rest. Obtain medical attention.

EYE CONTACT:

Remove particles by irrigating with eye wash solution or clean water, holding the eyelids apart. Obtain medical attention.

SKIN CONTACT:

If symptoms persist, clean with soap and water. Obtain medical attention.

INGESTION:

Do not induce vomiting. Wash out mouth with water and give 200-300 ml of water (half a pint) to drink. Obtain medical attention.

HINTS FOR THE PHYSICIAN:

Symptoms: Shortness of breath
Fever
Cyanosis

5. FIRE-FIGHTING MEASURES:

GENERAL INFORMATION:

Low fire hazard.

If a flame is applied to the material, it will ignite but if the flame is removed, combustion ceases.

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HAZARDOUS GASES:	Combustion or thermal decomposition will involve toxic and corrosive vapours: Carbon monoxide (CO) Hydrogen fluoride (HF) Carbonyl fluoride Tetrafluoroethylene Hexafluoropropylene Perfluoroisobutylene
EXTINGUISHING MEDIA:	Water Foam Dry powder Carbon dioxide
FIRE FIGHTING PROTECTIVE EQUIPMENT:	In the presence of combustion or carbonisation gases, any fire fighting, rescue and clearing up activities should be undertaken only with heavy-duty respiratory protection.

6. ACCIDENTAL RELEASE MEASURES:

GENERAL INFORMATION:	No special measures required. Pick up mechanically and dispose of according to regulations. Caution: product lying on the floor may be slippery.
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7. HANDLING AND STORAGE:

HANDLING:	Avoid contact with naked flames and hot surfaces as irritant and toxic decomposition products can be formed. When using do not smoke. Fire class: A
STORAGE:	Do not store great quantities together with flammable products. Storage class: 13

8. EXPOSURE CONTROLS / PERSONAL PROTECTION:

GENERAL PROTECTION AND HYGIENE MEASURES:	Do not smoke during work time. Keep away from tobacco.
RESPIRATORY PROTECTION:	Not required.
HAND PROTECTION:	Not required. Wash your hands after contact with the material.
EYE PROTECTION:	Wear face protection when working with equipment under high pressure.

9. PHYSICAL AND CHEMICAL PROPERTIES:

FORM:	solid	
COLOUR:	natural white to opaque	(see 2.)
ODOUR:	odourless	
CRYSTALLINE MELTING POINT:	320 ÷ 345 °C	(PTFE, ASTM D 4894)
FLASH POINT:	not applicable	
IGNITION TEMPERATURE:	450 °C	(PTFE, ASTM D 1929)
LOWER EXPLOSION LIMIT:	not applicable	
VAPOUR PRESSURE:	not applicable	
DENSITY:	0,5 – 2,2 g/cm ³	(approx., at 23 °C)
SOLUBILITY IN WATER:	insoluble	
PH-VALUE:	not applicable	
VISCOSITY:	not applicable	
LIMITING OXYGEN INDEX:	95 %O ₂	(PTFE)
UNDERWRITERS LABORATORY RATING:	94 V-0	(PTFE)

10. STABILITY AND REACTIVITY:

CHEMICAL STABILITY:	stable between – 240 °C and + 280 °C
THERMAL DECOMPOSITION:	thermal decomposition at long term temperatures above 280 °C
HAZARDOUS REACTIONS:	Reactions with metals in powder form, molten alkali metals or interhalogen compounds from 370 °C onwards.
HAZARDOUS DECOMPOSITION PRODUCTS:	Thermal decomposition products are toxic and corrosive:

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Carbon monoxide (CO)
Hydrogen fluoride (HF)
Carbonyl fluoride
Tetrafluoroethylene
Hexafluoropropylene
Perfluoroisobutylene

11. TOXICOLOGICAL INFORMATION:

GENERAL INFORMATION:

According to present experience, the material is physiologically compatible. According to present experience, the material is neither mutagenic, carcinogenic nor teratogenic.

12. ECOLOGICAL INFORMATION:

GENERAL INFORMATION:

Product is insoluble in water
The material has no harmful effect on the environment

13. DISPOSAL CONSIDERATIONS:

PRODUCT:

In accordance with the necessary technical regulations may be dumped or incinerated with household waste, after consultation with site operator and with the responsible authority.
HF must be removed by flue gas scrubbing.

WASTE CODE (GERMANY):

20 01 06 "andere Kunststoffe"
02 03 01 "gemischte Siedlungsabfälle"

NAME OF WASTE:

Plastic wastes containing fluoride compounds

14. NOTES ON TRANSPORT:

LAND TRANSPORT:

GGVS / GGVE: non-hazardous material

INLAND NAVIGATION:

ADR / RID: non-hazardous material

TRANSPORT BY SEA:

ADN / ADN: non-hazardous material

AIR TRANSPORT:

IMDG / UN: non-hazardous material

DISPATCH BY POST:

ICAO-TI / IATA-DGR: non-hazardous material
Air mail transport: permitted

15. REGULATORY INFORMATION:

LABELLING IN ACCORDANCE WITH GEFSTOFFV/EC: Hazard warning labelling not compulsory

NATIONAL REGULATIONS:

TA-Luft (Ger.) Class I

WATER HAZARD CLASS (GERMANY):

0 (self-classification)

OTHER REGULATIONS:

not applicable

16. OTHER INFORMATION:

This data sheet was prepared in accordance with the Guideline 93/112/EC.

The above information describes exclusively the safety requirements of the product(s) and is based on our present state of knowledge. It does not represent a guarantee for the properties of the product(s) described in terms of the legal warranty regulations. Properties of the product(s) are to be found in the respective product leaflets.

The responsibility for the compliance with the existing laws and regulations lies with the receiver of the product.