

# **Safety Data Sheet**

This safety data sheet was created pursuant to the requirements of: Regulation (EC) No. 1907/2006 and Regulation (EC) No. 1272/2008

Revision Date 2021-02-07 Revision Number 3

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

#### 1.1. Product identifier

Product Code SD5648

Product Name Standard Osteonectin

Contains ProClin 300

#### 1.2. Relevant identified uses of the substance or mixture and uses advised against

Identified uses No information available

Uses advised against No information available

### 1.3. Details of the supplier of the safety data sheet

#### **Supplier**

USA:

Takara Bio USA, Inc. 1290 Terra Bella Avenue Mountain View, CA 94043

Phone: 800.662.2566/888.251.6618

Web: www.takarabio.com

### Europe:

Takara Bio Europe S.A.S. 34, Rue de la Croix de Fer 78100 Saint-Germain-en-Laye France

Phone: +33 1 39 04 68 80 Web: www.takarabio.com

# Europe:

Takara Bio Europe AB Arvid Wallgrens Backe 20, SE-413 46 Goteborg, Sweden Phone: +46 31 758 09 00 Web: www.takarabio.com

India:

DSS Takara Bio India Pvt. Ltd. A-5 Mohan Co-operative Industrial Estate, Mathura Road, New Delhi 110044, India

Phone: +91 11 30886717

For further information, please contact:

# 1.4. Emergency telephone number

Emergency telephone In case of emergency, call PERS (Professional Emergency Resource Services)

1-800-633-8253 (US) or 801-629-0667 (international).

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# **SECTION 2: Hazards identification**

#### 2.1. Classification of the substance or mixture

Regulation (EC) No 1272/2008

Acute toxicity - Oral	Category 4 - (H302)
Acute toxicity - Dermal	Category 2 - (H310)
Acute toxicity - Inhalation (Dusts/Mists)	Category 2 - (H330)
Skin corrosion/irritation	Category 1 Sub-category B - (H314)
Serious eye damage/eye irritation	Category 1 - (H318)
Skin sensitization	Category 1 - (H317)
Acute aquatic toxicity	Category 1 - (H400)
Chronic aquatic toxicity	Category 1 - (H410)

#### 2.2. Label elements





Signal word Danger

#### Hazard statements

H302 - Harmful if swallowed

H310 - Fatal in contact with skin

H314 - Causes severe skin burns and eye damage

H317 - May cause an allergic skin reaction

H330 - Fatal if inhaled

H410 - Very toxic to aquatic life with long lasting effects

### Precautionary Statements - EU (§28, 1272/2008)

P260 - Do not breathe dust/fume/gas/mist/vapors/spray

P262 - Do not get in eyes, on skin, or on clothing

P273 - Avoid release to the environment

P280 - Wear protective gloves/protective clothing and eye/face protection

P303 + P361 + P353 - IF ON SKIN (or hair): Take off immediately all contaminated clothing. Rinse skin with water [or shower]

P304 + P340 - IF INHALED: Remove person to fresh air and keep comfortable for breathing

P305 + P351 + P338 - IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing

P310 - Immediately call a POISON CENTER or doctor

P320 - Specific treatment is urgent (see .? on this label)

P321 - Specific treatment (see .? on this label)

P391 - Collect spillage

P403 + P233 - Store in a well-ventilated place. Keep container tightly closed

### **Additional information**

This product requires child resistant fastenings if supplied to the general public. This product requires tactile warnings if supplied to the general public.

#### 2.3. Other hazards

No information available.

# **SECTION 3: Composition/information on ingredients**

#### 3.1 Substances

Not applicable

#### 3.2 Mixtures

Chemical name	Weight-%	REACH registration number	EC No	Classification according to Regulation (EC) No. 1272/2008 [CLP]	Specific concentration limit (SCL)	M-Factor	M-Factor (long-term)
ProClin 300 55965-84-9	5 - 10	No data available	-	Skin Corr. 1C (H314) Eye Dam. 1 (H318) Skin Sens. 1A (H317) (EUH071) Aquatic Acute 1	Skin Irrit. 2 ::		100

### Full text of H- and EUH-phrases: see section 16

Acute Toxicity Estimate
No information available

This product does not contain candidate substances of very high concern at a concentration >=0.1% (Regulation (EC) No. 1907/2006 (REACH), Article 59)

# **SECTION 4: First aid measures**

#### 4.1. Description of first aid measures

General advice Immediate medical attention is required. Show this safety data sheet to the doctor in

attendance.

**Inhalation** Do not breathe dust. If breathing has stopped, give artificial respiration. Get medical

attention immediately. Do not use mouth-to-mouth method if victim ingested or inhaled the substance; give artificial respiration with the aid of a pocket mask equipped with a one-way valve or other proper respiratory medical device. If breathing is difficult, (trained personnel should) give oxygen. Delayed pulmonary edema may occur. Get immediate medical

advice/attention. Remove to fresh air.

Eye contact Get immediate medical advice/attention. Rinse immediately with plenty of water, also under

the eyelids, for at least 15 minutes. Remove contact lenses, if present and easy to do.

Continue rinsing. Keep eye wide open while rinsing. Do not rub affected area.

**Skin contact**Wash off immediately with soap and plenty of water while removing all contaminated

clothes and shoes. Get immediate medical advice/attention. May cause an allergic skin

reaction.

Ingestion Get immediate medical advice/attention. Clean mouth with water and drink afterwards

plenty of water. Never give anything by mouth to an unconscious person. Do NOT induce

vomiting.

**Self-protection of the first aider**Do not breathe dust. Do not use mouth-to-mouth method if victim ingested or inhaled the

substance; give artificial respiration with the aid of a pocket mask equipped with a one-way valve or other proper respiratory medical device. Use personal protective equipment as required. See section 8 for more information. Ensure that medical personnel are aware of the material(s) involved, take precautions to protect themselves and prevent spread of

contamination. Avoid contact with skin, eyes or clothing.

#### 4.2. Most important symptoms and effects, both acute and delayed

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Symptoms Co

Coughing and/ or wheezing. Difficulty in breathing. Burning sensation. Itching. Rashes.

Hives.

### 4.3. Indication of any immediate medical attention and special treatment needed

Note to physicians Product is a corrosive material. Use of gastric lavage or emesis is contraindicated.

Possible perforation of stomach or esophagus should be investigated. Do not give chemical antidotes. Asphyxia from glottal edema may occur. Marked decrease in blood pressure may occur with moist rales, frothy sputum, and high pulse pressure. May cause

sensitization in susceptible persons. Treat symptomatically.

# **SECTION 5: Firefighting measures**

5.1. Extinguishing media

surrounding environment.

**Large Fire** CAUTION: Use of water spray when fighting fire may be inefficient.

**Unsuitable extinguishing media**Do not scatter spilled material with high pressure water streams.

5.2. Special hazards arising from the substance or mixture

Specific hazards arising from the

chemical

The product causes burns of eyes, skin and mucous membranes. Thermal decomposition can lead to release of irritating gases and vapors. Product is or contains a sensitizer. May

cause sensitization by skin contact.

5.3. Advice for firefighters

Special protective equipment for

fire-fighters

Firefighters should wear self-contained breathing apparatus and full firefighting turnout

gear. Use personal protection equipment.

### **SECTION 6: Accidental release measures**

# 6.1. Personal precautions, protective equipment and emergency procedures

**Personal precautions** Avoid generation of dust. Do not breathe dust. Attention! Corrosive material. Avoid contact

with skin, eyes or clothing. Ensure adequate ventilation. Use personal protective equipment as required. Evacuate personnel to safe areas. Keep people away from and upwind of

spill/leak.

Other information Refer to protective measures listed in Sections 7 and 8.

**For emergency responders**Use personal protection recommended in Section 8.

6.2. Environmental precautions

Environmental precautions Should not be released into the environment. Do not allow to enter into soil/subsoil. Prevent

product from entering drains. Prevent further leakage or spillage if safe to do so.

6.3. Methods and material for containment and cleaning up

**Methods for containment** Prevent further leakage or spillage if safe to do so.

Methods for cleaning up Take up mechanically, placing in appropriate containers for disposal.

Prevention of secondary hazards Clean contaminated objects and areas thoroughly observing environmental regulations.

6.4. Reference to other sections

**Reference to other sections** See section 8 for more information. See section 13 for more information.

# **SECTION 7: Handling and storage**

#### 7.1. Precautions for safe handling

Advice on safe handling Do not breathe dust. Avoid generation of dust. Handle product only in closed system or

provide appropriate exhaust ventilation. Handle in accordance with good industrial hygiene and safety practice. Avoid contact with skin, eyes or clothing. In case of insufficient ventilation, wear suitable respiratory equipment. Do not eat, drink or smoke when using this

product. Take off contaminated clothing and wash before reuse.

General hygiene considerations Do not breathe dust. Take off contaminated clothing and wash before reuse. Remove and

wash contaminated clothing and gloves, including the inside, before re-use. Contaminated work clothing should not be allowed out of the workplace. Regular cleaning of equipment, work area and clothing is recommended. Wash hands before breaks and immediately after handling the product. Avoid contact with skin, eyes or clothing. Wear suitable gloves and

eye/face protection. Do not eat, drink or smoke when using this product.

#### 7.2. Conditions for safe storage, including any incompatibilities

Storage Conditions Protect from moisture. Store away from other materials. Store locked up. Keep out of the

reach of children. Keep containers tightly closed in a dry, cool and well-ventilated place.

7.3. Specific end use(s)

Identified uses

# **SECTION 8: Exposure controls/personal protection**

#### 8.1. Control parameters

#### **Exposure Limits**

Chemical name	Europe	an Union	Austria	Belgium	Bu	Igaria	Croatia
ProClin 300		-	TWA 0.05 mg/m <sup>3</sup>	-		-	-
55965-84-9			Sh/Sah**				
Chemical name		Sv	veden	Switzerland		Uni	ted Kingdom
ProClin 300			-	SS-C**			-
55965-84-9				S+			
				TWA 0.2 mg/m	3		
				STEL 0.4 mg/m	3		

## **Biological occupational exposure limits**

This product, as supplied, does not contain any hazardous materials with biological limits established by the region specific regulatory bodies.

Derived No Effect Level (DNEL)
Predicted No Effect Concentration
(PNEC)

No information available. No information available.

8.2. Exposure controls

**Personal Protective Equipment** 

**Eye/face protection** Face protection shield. Tight sealing safety goggles.

**Hand protection** Impervious gloves. Wear suitable gloves.

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Skin and body protection Impervious clothing. Long sleeved clothing. Chemical resistant apron. Wear suitable

protective clothing.

**Respiratory protection** When workers are facing concentrations above the exposure limit they must use

appropriate certified respirators.

**General hygiene considerations** Do not breathe dust. Take off contaminated clothing and wash before reuse. Remove and

wash contaminated clothing and gloves, including the inside, before re-use. Contaminated work clothing should not be allowed out of the workplace. Regular cleaning of equipment, work area and clothing is recommended. Wash hands before breaks and immediately after handling the product. Avoid contact with skin, eyes or clothing. Wear suitable gloves and

eye/face protection. Do not eat, drink or smoke when using this product.

**Environmental exposure controls** No information available.

# **SECTION 9: Physical and chemical properties**

9.1. Information on basic physical and chemical properties

Physical state Solid

Appearance Lyophilized cake

Color No information available

Odorless.

Odor Threshold No information available

<u>Property</u> <u>Values</u> <u>Remarks • Method</u>

Melting point / freezing pointNo data availableNone knownBoiling point/boiling range (°C)No data availableNone knownFlammability (solid, gas)No data availableNone knownFlammability Limit in AirNone known

Upper flammability limit:No data availableLower flammability limit:No data available

Flash pointNo data availableOpen cupAutoignition temperatureNo data availableNone knownDecomposition temperatureNone known

None known None known

pH (as aqueous solution) No data available No information available

No data available Kinematic viscosity None known No data available **Dynamic Viscosity** None known Water solubility No data available None known Solubility in other solvents No data available None known **Partition coefficient** No data available None known Vapor pressure No data available None known Relative density None known

Bulk Density
No data available
Liquid Density
No data available

Vapor densityNo data availableNone known

Particle characteristics

Particle Size No information available Particle Size Distribution No information available

#### 9.2. Other information

9.2.1. Information with regard to physical hazard classes Not applicable

9.2.2. Other safety characteristics No information available

# **SECTION 10: Stability and reactivity**

10.1. Reactivity

**Reactivity** No information available.

10.2. Chemical stability

**Stability** Stable under normal conditions.

**Explosion Data** 

**Sensitivity to mechanical impact** None. **Sensitivity to static discharge** None.

10.3. Possibility of hazardous reactions

Possibility of hazardous reactions None under normal processing.

10.4. Conditions to avoid

**Conditions to avoid** Excessive heat. Exposure to air or moisture over prolonged periods.

10.5. Incompatible materials

Incompatible materials Acids. Bases. Oxidizing agent.

10.6. Hazardous decomposition products

Hazardous Decomposition Products None known based on information supplied.

# **SECTION 11: Toxicological information**

#### 11.1. Information on hazard classes as defined in Regulation (EC) No 1272/2008

### Information on likely routes of exposure

#### **Product Information**

**Inhalation** Fatal if inhaled. Corrosive by inhalation. (based on components). Inhalation of corrosive

fumes/gases may cause coughing, choking, headache, dizziness, and weakness for several hours. Pulmonary edema may occur with tightness in the chest, shortness of breath, bluish skin, decreased blood pressure, and increased heart rate. Inhaled corrosive substances can lead to a toxic edema of the lungs. Pulmonary edema can be fatal. Specific test data for

the substance or mixture is not available.

Eye contact (based on components). Corrosive to the eyes and may cause severe damage including

blindness. Specific test data for the substance or mixture is not available. Causes serious

eye damage. May cause irreversible damage to eyes.

**Skin contact** Fatal in contact with skin. Corrosive. Causes burns. May cause sensitization by skin

contact. Specific test data for the substance or mixture is not available. Repeated or prolonged skin contact may cause allergic reactions with susceptible persons. (based on

components).

**Ingestion** Causes burns. Ingestion causes burns of the upper digestive and respiratory tracts. May

cause severe burning pain in the mouth and stomach with vomiting and diarrhea of dark blood. Blood pressure may decrease. Brownish or yellowish stains may be seen around the mouth. Swelling of the throat may cause shortness of breath and choking. May cause lung damage if swallowed. May be fatal if swallowed and enters airways. Specific test data for

the substance or mixture is not available. (based on components).

Symptoms related to the physical, chemical and toxicological characteristics

Symptoms Difficulty in breathing. Coughing and/ or wheezing. Redness. Burning. May cause

blindness. Itching. Rashes. Hives.

### Numerical measures of toxicity

#### **Acute toxicity**

The following values are calculated based on chapter 3.1 of the GHS document

 ATEmix (oral)
 782.20 mg/kg

 ATEmix (dermal)
 65.00 mg/kg

 ATEmix (inhalation-dust/mist)
 0.065 mg/l

#### Unknown acute toxicity

51.3292 % of the mixture consists of ingredient(s) of unknown acute oral toxicity.

93.3292 % of the mixture consists of ingredient(s) of unknown acute dermal toxicity.

93.3292 % of the mixture consists of ingredient(s) of unknown acute inhalation toxicity (dust/mist).

# **Component Information**

Chemical name	Oral LD50	Dermal LD50	Inhalation LC50
ProClin 300	= 53 mg/kg (Rat)	-	-

# Delayed and immediate effects as well as chronic effects from short and long-term exposure

**Skin corrosion/irritation** Classification based on data available for ingredients. Causes burns.

Serious eye damage/eye irritation Classification based on data available for ingredients. Causes burns. Risk of serious

damage to eyes.

**Respiratory or skin sensitization** May cause sensitization by skin contact.

Germ cell mutagenicity No information available.

**Carcinogenicity** No information available.

Reproductive toxicity No information available.

**STOT - single exposure**No information available.

**STOT - repeated exposure**No information available.

**Aspiration hazard** No information available.

#### 11.2. Information on other hazards

# 11.2.1. Endocrine disrupting properties

**Endocrine disrupting properties** No information available.

11.2.2. Other information

Other adverse effects No information available.

# **SECTION 12: Ecological information**

12.1. Toxicity

**Ecotoxicity** Very toxic to aquatic life with long lasting effects.

**Unknown aquatic toxicity**Contains 0.0292 % of components with unknown hazards to the aquatic environment.

Chemical name	Algae/aquatic plants	Fish	Toxicity to	Crustacea
			microorganisms	
ProClin 300	0.03 - 0.13: 96 h	1.6: 96 h Oncorhynchus	-	0.12 - 0.3: 48 h Daphnia
	Pseudokirchneriella	mykiss mg/L LC50		magna mg/L EC50 Flow
	subcapitata mg/L EC50	semi-static		through 0.71 - 0.99: 48 h
	static 0.11 - 0.16: 72 h			Daphnia magna mg/L
	Pseudokirchneriella			EC50 Static 4.71: 48 h
	subcapitata mg/L EC50			Daphnia magna mg/L
	static			EC50

# 12.2. Persistence and degradability

Persistence and degradability No information available.

12.3. Bioaccumulative potential

**Bioaccumulation** There is no data for this product.

**Component Information** 

Chemical name	Partition coefficient
ProClin 300	0.75

### 12.4. Mobility in soil

Mobility in soil No information available.

# 12.5. Results of PBT and vPvB assessment

PBT and vPvB assessment No information available.

### 12.6. Endocrine disrupting properties

**Endocrine disrupting properties** No information available.

# 12.7. Other adverse effects

No information available.

# **SECTION 13: Disposal considerations**

### 13.1. Waste treatment methods

Waste from residues/unused products

Dispose of in accordance with local regulations. Dispose of waste in accordance with

environmental legislation.

**Contaminated packaging** Do not reuse empty containers.

# **SECTION 14: Transport information**

<u>IATA</u>

14.1 UN number or ID number Not regulated

**14.2 UN proper shipping name 14.3 Transport hazard class(es)**No information available Not regulated

14.4 Packing group
Not regulated
Not applicable

14.6 Special precautions for user

Special Provisions None

**IMDG** 

14.1 UN number or ID number Not regulated

**14.2 UN proper shipping name** No information available

14.3 Transport hazard class(es)
14.4 Packing group
14.5 Environmental hazards
Not regulated Not applicable

14.6 Special precautions for user Special Provisions

**14.7** Maritime transport in bulk No information available

None

according to IMO instruments

<u>RID</u>

14.1 UN number or ID number Not regulated

**14.2 UN proper shipping name** No information available

14.3 Transport hazard class(es)
 14.4 Packing group
 14.5 Environmental hazards
 Not regulated Not regulated Not applicable

14.6 Special precautions for user

Special Provisions None

**ADR** 

14.1 UN number or ID number Not regulated

**14.2 UN proper shipping name** No information available

14.3 Transport hazard class(es)
 14.4 Packing group
 14.5 Environmental hazards
 Not regulated Not regulated Not applicable

14.6 Special precautions for user

Special Provisions None

# **SECTION 15: Regulatory information**

15.1. Safety, health and environmental regulations/legislation specific for the substance or mixture

### **European Union**

Take note of Directive 98/24/EC on the protection of the health and safety of workers from the risks related to chemical agents at work.

### Authorizations and/or restrictions on use:

This product does not contain substances subject to authorization (Regulation (EC) No. 1907/2006 (REACH), Annex XIV) This product does not contain substances subject to restriction (Regulation (EC) No. 1907/2006 (REACH), Annex XVII)

### **Persistent Organic Pollutants**

Not applicable

### Dangerous substance category per Seveso Directive (2012/18/EU)

H2 - ACUTE TOXIC

E1 - Hazardous to the Aquatic Environment in Category Acute 1 or Chronic 1

### Ozone-depleting substances (ODS) regulation (EC) 1005/2009

Not applicable

#### International Inventories

TSCA DSL/NDSL EINECS/ELINCS ENCS IECSC KECL PICCS AICS -

#### Legend:

TSCA - United States Toxic Substances Control Act Section 8(b) Inventory

DSL/NDSL - Canadian Domestic Substances List/Non-Domestic Substances List

EINECS/ELINCS - European Inventory of Existing Chemical Substances/European List of Notified Chemical Substances

**ENCS** - Japan Existing and New Chemical Substances

IECSC - China Inventory of Existing Chemical Substances

**KECL** - Korean Existing and Evaluated Chemical Substances

PICCS - Philippines Inventory of Chemicals and Chemical Substances

AICS - Australian Inventory of Chemical Substances

#### 15.2. Chemical safety assessment

Chemical Safety Assessment No information available

# **SECTION 16: Other information**

#### Key or legend to abbreviations and acronyms used in the safety data sheet

# Full text of H-Statements referred to under section 3

EUH071 - Corrosive to the respiratory tract

H301 - Toxic if swallowed

H310 - Fatal in contact with skin

H314 - Causes severe skin burns and eye damage

H317 - May cause an allergic skin reaction

H318 - Causes serious eye damage

H330 - Fatal if inhaled

H400 - Very toxic to aquatic life

H410 - Very toxic to aquatic life with long lasting effects

### Legend

SVHC: Substances of Very High Concern for Authorization:

### Legend Section 8: EXPOSURE CONTROLS/PERSONAL PROTECTION

TWA Time weighted average STEL Short term exposure limit

Ceiling Maximum limit value \* Skin designation

Classification procedure	
Classification according to Regulation (EC) No. 1272/2008 [CLP]	Method Used
Acute oral toxicity	Calculation method
Acute dermal toxicity	Calculation method
Acute inhalation toxicity - gas	Calculation method
Acute inhalation toxicity - vapor	Calculation method
Acute inhalation toxicity - dust/mist	Calculation method
Skin corrosion/irritation	Calculation method
Serious eye damage/eye irritation	Calculation method
Respiratory sensitization	Calculation method
Mutagenicity	Calculation method

Carcinogenicity	Calculation method
Reproductive toxicity	Calculation method
STOT - single exposure	Calculation method
STOT - repeated exposure	Calculation method
Acute aquatic toxicity	Calculation method
Chronic aquatic toxicity	Calculation method
Aspiration hazard	Calculation method
Ozone	Calculation method

### Key literature references and sources for data used to compile the SDS

Agency for Toxic Substances and Disease Registry (ATSDR)

U.S. Environmental Protection Agency ChemView Database

European Food Safety Authority (EFSA)

EPA (Environmental Protection Agency)

Acute Exposure Guideline Level(s) (AEGL(s))

U.S. Environmental Protection Agency Federal Insecticide, Fungicide, and Rodenticide Act

U.S. Environmental Protection Agency High Production Volume Chemicals

Food Research Journal

Hazardous Substance Database

International Uniform Chemical Information Database (IUCLID)

Japan GHS Classification

Australia National Industrial Chemicals Notification and Assessment Scheme (NICNAS)

NIOSH (National Institute for Occupational Safety and Health)

National Library of Medicine's ChemID Plus (NLM CIP)

National Library of Medicine's PubMed database (NLM PUBMED)

National Toxicology Program (NTP)

New Zealand's Chemical Classification and Information Database (CCID)

Organization for Economic Co-operation and Development Environment, Health, and Safety Publications

Organization for Economic Co-operation and Development High Production Volume Chemicals Program

Organization for Economic Co-operation and Development Screening Information Data Set

World Health Organization

Revision Date 2021-02-07

### This safety data sheet complies with the requirements of Regulation (EC) No. 1907/2006

#### **Disclaimer**

The information provided in this Safety Data Sheet is correct to the best of our knowledge, information and belief at the date of its publication. The information given is designed only as a guidance for safe handling, use, processing, storage, transportation, disposal and release and is not to be considered a warranty or quality specification. The information relates only to the specific material designated and may not be valid for such material used in combination with any other materials or in any process, unless specified in the text.

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**End of Safety Data Sheet**