



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 2021-02-05

Revision Number 5

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

1.1. Product identifier

Product Code 635089
Product Name DmrA Monoclonal Antibody

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).

SECTION 2: Hazards identification

2.1. Classification of the substance or mixture

Regulation (EC) No 1272/2008

Skin sensitization	Category 1 - (H317)
Chronic aquatic toxicity	Category 2 - (H411)

2.2. Label elements

Contains ProClin 300



Signal word

Warning

Hazard statements

H317 - May cause an allergic skin reaction

H411 - Toxic to aquatic life with long lasting effects

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

P261 - Avoid breathing dust/fume/gas/mist/vapors/spray

P273 - Avoid release to the environment

P280 - Wear protective gloves

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

P333 + P313 - If skin irritation or rash occurs: Get medical advice/attention

P391 - Collect spillage

2.3. Other hazards

Toxic to aquatic life.

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)
Glycerol 56-81-5	10 - 30	No data available	200-289-5	No data available	-	-	-
ProClin 300 55965-84-9	< 0.1	No data available	-	Acute Tox. 3 (H301) Acute Tox. 2 (H310) Acute Tox. 2 (H330) Skin Corr. 1C (H314) Eye Dam. 1 (H318) Skin Sens. 1A (H317) (EUH071) Aquatic Acute 1 (H400) Aquatic Chronic 1	Skin Sens. 1 :: C>=0.0015% Skin Corr. 1B :: C>=0.6% Skin Irrit. 2 :: 0.06%<=C<0.6% % Eye Irrit. 2 :: 0.06%<=C<0.6% %	100	100

				(H410)			
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Full text of H- and EUH-phrases: see section 16Acute Toxicity Estimate

No information available

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

SECTION 4: First aid measures

4.1. Description of first aid measures

General advice	Show this safety data sheet to the doctor in attendance.
Inhalation	Remove to fresh air.
Eye contact	Rinse thoroughly with plenty of water for at least 15 minutes, lifting lower and upper eyelids. Consult a physician.
Skin contact	Wash with soap and water. May cause an allergic skin reaction. In the case of skin irritation or allergic reactions see a physician.
Ingestion	Clean mouth with water and drink afterwards plenty of water.

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

Symptoms Itching. Rashes. Hives.

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

Note to physicians May cause sensitization in susceptible persons. Treat symptomatically.

SECTION 5: Firefighting measures

5.1. Extinguishing media

Suitable Extinguishing Media Use extinguishing measures that are appropriate to local circumstances and the 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 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 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.

For emergency responders Use personal protection recommended in Section 8.

6.2. Environmental precautions

Environmental precautions See Section 12 for additional Ecological Information.

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 Handle in accordance with good industrial hygiene and safety practice. Avoid contact with skin, eyes or clothing. Ensure adequate ventilation. 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 Handle in accordance with good industrial hygiene and safety practice.

7.2. Conditions for safe storage, including any incompatibilities

Storage Conditions 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	European Union	Austria	Belgium	Bulgaria	Croatia
Glycerol 56-81-5	-	-	TWA 10 mg/m ³	-	TWA 10 mg/m ³
ProClin 300 55965-84-9	-	TWA 0.05 mg/m ³ Sh/Sah**	-	-	-
Chemical name	Cyprus	Czech Republic	Denmark	Estonia	Finland
Glycerol 56-81-5	-	-	-	TWA 10 mg/m ³	TWA 20 mg/m ³
Chemical name	France	Germany	Germany MAK	Greece	Hungary
Glycerol 56-81-5	TWA 10 mg/m ³	-	AGW 200 mg/m ³	TWA 10 mg/m ³	-
Chemical name	Ireland	Italy	Italy REL	Latvia	Lithuania

Glycerol 56-81-5	-	200 mg/m ³ TWA AGW (the risk of damage to the embryo or fetus can be excluded when AGW and BGW values are observed, inhalable fraction, exposure factor 2)	-	-	-
Chemical name	Luxembourg	Malta	Netherlands	Norway	Poland
Glycerol 56-81-5	-	-	-	-	TWA 10 mg/m ³
Chemical name	Portugal	Romania	Slovakia	Slovenia	Spain
Glycerol 56-81-5	TWA 10 mg/m ³	-	TWA 11 mg/m ³	STEL 400 mg/m ³ TWA 200 mg/m ³	TWA 10 mg/m ³
Chemical name	Sweden		Switzerland		United Kingdom
Glycerol 56-81-5	-		SS-C** TWA 50 mg/m ³ STEL 100 mg/m ³		STEL 30 mg/m ³ TWA 10 mg/m ³
ProClin 300 55965-84-9	-		SS-C** 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) No information available.

Predicted No Effect Concentration (PNEC) No information available.

8.2. Exposure controls**Personal Protective Equipment**

Eye/face protection Wear safety glasses with side shields (or goggles).

Hand protection Wear suitable gloves.

Skin and body protection Wear suitable protective clothing.

Respiratory protection No protective equipment is needed under normal use conditions. If exposure limits are exceeded or irritation is experienced, ventilation and evacuation may be required.

General hygiene considerations Handle in accordance with good industrial hygiene and safety practice.

Environmental exposure controls No information available.

SECTION 9: Physical and chemical properties

9.1. Information on basic physical and chemical properties

Physical state	Liquid
Appearance	Clear, colorless
Color	Clear
Odor	Odorless.
Odor Threshold	No information available

<u>Property</u>	<u>Values</u>	<u>Remarks • Method</u>
Melting point / freezing point	No data available	None known
Boiling point/boiling range (°C)	No data available	None known
Flammability (solid, gas)	No data available	None known
Flammability Limit in Air		None known
Upper flammability limit:	No data available	
Lower flammability limit:	No data available	
Flash point	No data available	Open cup
Autoignition temperature	392.8 °C	None known
Decomposition temperature		None known
pH		None known
pH (as aqueous solution)	No data available	No information available
Kinematic viscosity	No data available	None known
Dynamic Viscosity	No data available	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 density	No data available	None 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 None known based on information supplied.

10.5. Incompatible materials

Incompatible materials None known based on information supplied.

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	Specific test data for the substance or mixture is not available.
Eye contact	Specific test data for the substance or mixture is not available.
Skin contact	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	Specific test data for the substance or mixture is not available.

Symptoms related to the physical, chemical and toxicological characteristics

Symptoms 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)	63,000.00 mg/kg
ATEmix (dermal)	50,050.00 mg/kg
ATEmix (inhalation-dust/mist)	13.764 mg/l

Component Information

Chemical name	Oral LD50	Dermal LD50	Inhalation LC50
Glycerol	= 12600 mg/kg (Rat)	> 10 g/kg (Rabbit)	> 2.75 mg/L (Rat) 4 h
ProClin 300	= 53 mg/kg (Rat)	-	-

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

Skin corrosion/irritation	No information available.
Serious eye damage/eye irritation	No information available.
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 Toxic to aquatic life. Toxic to aquatic life with long lasting effects.

Unknown aquatic toxicity Contains 0.8092 % of components with unknown hazards to the aquatic environment.

Chemical name	Algae/aquatic plants	Fish	Toxicity to microorganisms	Crustacea
Glycerol	-	51 - 57: 96 h Oncorhynchus mykiss mL/L LC50 static	-	-
ProClin 300	0.03 - 0.13: 96 h Pseudokirchneriella subcapitata mg/L EC50 static 0.11 - 0.16: 72 h Pseudokirchneriella subcapitata mg/L EC50 static	1.6: 96 h Oncorhynchus mykiss mg/L LC50 semi-static	-	0.12 - 0.3: 48 h Daphnia magna mg/L EC50 Flow through 0.71 - 0.99: 48 h Daphnia magna mg/L EC50 Static 4.71: 48 h Daphnia magna mg/L 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
Glycerol	-1.76
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

IATA

14.1 UN number or ID number Not regulated
 14.2 UN proper shipping name No information available
 14.3 Transport hazard class(es) Not regulated
 14.4 Packing group Not regulated
 14.5 Environmental hazards 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) Not regulated
 14.4 Packing group Not regulated
 14.5 Environmental hazards Not applicable
 14.6 Special precautions for user
 Special Provisions None
 14.7 Maritime transport in bulk according to IMO instruments No information available

RID

14.1 UN number or ID number Not regulated
 14.2 UN proper shipping name No information available
 14.3 Transport hazard class(es) Not regulated
 14.4 Packing group Not regulated
 14.5 Environmental hazards 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) Not regulated
 14.4 Packing group Not regulated
 14.5 Environmental hazards 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)

E2 - Hazardous to the Aquatic Environment in Category Chronic 2

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
**	Hazard Designation	+	Sensitizers

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 2021-02-05

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

Disclaimer

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specified in the text.

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End of Safety Data Sheet