SAFETY DATA SHEET

This safety data sheet was created pursuant to the requirements of: US OSHA Hazard Communication Standard 2024 (29 CFR 1910.1200) and Canada Hazardous Products Act (HPA) and the Hazardous Products Regulation (HPR), as amended

Issuing Date 29-Jul-2026 **Revision date** 29-Jul-2026 **Revision Number** 1

1. Identification

Product identifier

Product Name Ortho™ BioClone™ PLUS Anti-M

Other means of identification

Product Code(s) 6141126

Synonyms None

Recommended use of the chemical and restrictions on use

Recommended use In vitro diagnostic.

Restrictions on use No information available.

Details of the supplier of the safety data sheet

Supplier Address
Ortho-Clinical Diagnostics, Inc.
1001 US Highway 202
Raritan, NJ 08869
USA

Customer Service
1 (800) 828-6316
http://www.quidelortho.com/global/en/contact-us/

Emergency telephone number

Emergency Telephone
CHEMTREC: +1-703-527-3887 (INTERNATIONAL)
1-800-424-9300 (NORTH AMERICA)

2. Hazard(s) identification

Classification of the substance or mixture

This product is not considered hazardous by either the US OSHA Hazard Communication Standard 2024, or Canada Hazardous Products Act (HPA) and Hazardous Products Regulation (HPR), as amended.

Label elements

Hazard statements
Not classified.

Hazards classified under paragraph (d)(1)(ii) of 1910.1200

No information available.

Other information

Harmful to aquatic life with long lasting effects. This product contains blood derivatives. No known test method can offer complete assurance that products derived from blood will not transmit infectious agents. Therefore, all blood derivatives should be considered potentially infectious. It is recommended that these reagents be handled using established good laboratory working practices.

3. Composition/information on ingredients

Substance

Not applicable.

Mixture

Chemical name	CAS No.	Weight-%	Hazardous Material Information Review Act registry number (HMIRA registry #)	Date HMIRA filed and date exemption granted (if applicable)	Trade secret / Unique identifier
Sodium azide	26628-22-8	< 1	-	-	-

4. First-aid measures

Description of first aid measures

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 skin with soap and water.

Ingestion Do NOT induce vomiting. Never give anything by mouth to an unconscious person. Call a physician.

Most important symptoms and effects, both acute and delayed

Symptoms No information available.

Effects of Exposure See Section 11 for additional Toxicological Information.

Indication of any immediate medical attention and special treatment needed

Note to physicians Treat symptomatically.

5. Fire-fighting measures

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

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

Specific hazards arising from the No information available.

chemical

Explosion data
Sensitivity to mechanical impact None.
Sensitivity to static discharge None.

Special protective equipment and precautions for fire-fighters Firefighters should wear self-contained breathing apparatus and full firefighting turnout gear. Use personal protective equipment.

6. Accidental release measures

Personal precautions, protective equipment and emergency procedures

Personal precautions Handle all blood and materials in contact with blood as if capable of transmitting infectious agents. It is recommended that blood and materials in contact with blood be handled using established good laboratory practices. Ensure adequate ventilation.

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 Dam up. Soak up with inert absorbent material. Pick up and transfer to properly labeled containers. Clean contaminated surface thoroughly. Sodium azide has been reported to form lead or copper azides in laboratory plumbing. These azides are potentially explosive. To prevent buildup, flush plumbing with a large volume of water while disposing of these solutions in the sink.

7. Handling and storage

Precautions for safe handling

Advice on safe handling Handle in accordance with good industrial hygiene and safety practice.

General hygiene considerations Do not eat, drink or smoke when using this product. Wash hands before breaks and after work.

Conditions for safe storage, including any incompatibilities

Storage Conditions Keep containers tightly closed in a dry, cool and well-ventilated place. Store according to label instructions.

8. Exposure controls/personal protection

Control Parameters
Exposure Limits

Chemical name	ACGIH TLV	OSHA PEL	NIOSH
Sodium azide 26628-22-8	Ceiling: 0.29 mg/m³ Sodium azide Ceiling: 0.11 ppm Hydrazoic acid vapor	(vacated) Ceiling: 0.1 ppm HN3 (vacated) Ceiling: 0.3 mg/m³ NaN3 Sdv	Ceiling: 0.1 ppm HN3 Ceiling: 0.3 mg/m³ NaN3

Chemical name	Alberta	British Columbia	Ontario	Quebec
Sodium azide 26628-22-8	STEL: 0.3 mg/m³; Ceiling: 0.11 ppm; Ceiling: 0.29 mg/m³;	Ceiling: 0.29 mg/m³; Ceiling: 0.11 ppm;	Ceiling: 0.29 mg/m³; Ceiling: 0.11 ppm;	Ceiling: 0.29 mg/m³; Ceiling: 0.11 ppm; vapour

Chemical name	Manitoba	New Brunswick	Newfoundland and Labrador	Nova Scotia
Sodium azide	Ceiling: 0.29 mg/m³; Ceiling: 0.11 ppm;	Ceiling: 0.11 ppm; vapor Ceiling: 0.29 mg/m³;	Ceiling: 0.29 mg/m³; Ceiling: 0.11 ppm;	Ceiling: 0.29 mg/m³; Ceiling: 0.11 ppm;

Chemical name	Nunavut	Prince Edward Island	Saskatchewan	Yukon
Sodium azide	Ceiling: 0.29 mg/m³; Ceiling: 0.11 ppm;	Ceiling: 0.29 mg/m³; Ceiling: 0.11 ppm;	Ceiling: 0.29 mg/m³; Ceiling: 0.11 ppm;	Ceiling: 0.1 ppm; Ceiling: 0.3 mg/m³;

Note See section 16 for terms and abbreviations.

Other information on limit values Vacated limits revoked by the Court of Appeals decision in AFL-CIO v. OSHA, 965 F.2d 962 (11th Cir., 1992).

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

Appropriate engineering controls

Engineering controls Showers
Eyewash stations
Ventilation systems.

Individual protection measures, such as 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.

9. Physical and chemical properties

Information on basic physical and chemical properties

Appearance Clear, Straw-colored, liquid
Physical state Liquid
Color Straw-colored
Odor (includes odor threshold) Odorless

Property	Values	Remarks • Method
Melting point / freezing point	No data available	None known
Boiling point (or initial boiling point or boiling range)	No data available	None known
Flammability	No data available	None known

Flammability Limit in Air		None known
Upper flammability or explosive limits	No data available	
Flash point	No data available	None known
Autoignition temperature	No data available	None known
Decomposition temperature	No data available	None known
SADT (°C)		None known
pH	8.45 - 8.55	None known
pH (as aqueous solution)	No data available	None known
Kinematic viscosity	No data available	None known
Dynamic viscosity	No data available	None known
Solubility	No data available	None known
Water solubility	No data available	None known
Partition coefficient n-octanol/water (log value)	No data available	None known
Vapor pressure (includes evaporation rate)	No data available	None known
Evaporation rate	No data available	None known
Density and/or relative density	No data available	None known
Bulk density	No data available	
Liquid Density	No data available	
Relative vapor density	No data available	None known
Particle characteristics		None known
Particle Size	No data available	
Particle Size Distribution	No data available	

Other information

Molecular weight	No information available
VOC content	No information available
Softening point	No information available

Information with regard to physical hazard classes

Explosives	
Explosive properties	No information available
Oxidizing properties	No information available

10. Stability and reactivity

Reactivity None under normal use conditions.

Chemical stability Stable under normal conditions.

Possibility of hazardous reactions None under normal processing.

Conditions to avoid Sodium azide has been reported to form lead or copper azides in laboratory plumbing. These azides are potentially explosive. To prevent buildup, flush plumbing with a large volume of water while disposing of these solutions in the sink. Heat.

Incompatible materials None known based on information supplied.

Hazardous decomposition products None known based on information supplied.

11. Toxicological information

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

Ingestion Specific test data for the substance or mixture is not available.

Symptoms related to the physical, chemical and toxicological characteristics

Symptoms No information available.

Acute toxicity

Numerical measures of toxicity

Based on available data, the classification criteria are not met

Component Information

Chemical name	Oral LD50	Dermal LD50	Inhalation LC50
Sodium azide	= 27 mg/kg (Rat)	= 20 mg/kg (Rabbit)	0.054 - 0.52 mg/L (Rat) 4 h

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 No information available.

Germ cell mutagenicity No information available.

Carcinogenicity Based on available data, the classification criteria are not met.

The table below indicates whether each agency has listed any ingredient as a carcinogen.

Chemical name	ACGIH	IARC	NTP	OSHA
Sodium azide	A4 - Not classifiable as a human carcinogen	-	-	-

Reproductive toxicity No information available.

STOT - single exposure No information available.

STOT - repeated exposure No information available.

Aspiration hazard No information available.

12. Ecological information

Ecotoxicity Harmful to aquatic life with long lasting effects.

Aquatic ecotoxicity

Component Information

Chemical name	Fish	Crustacea	Algae/aquatic plants	Toxicity to microorganisms
Sodium azide	LC50: =0.8mg/L (96h, Oncorhynchus mykiss) LC50: =0.7mg/L (96h, Lepomis macrochirus) LC50: =5.46mg/L (96h, Pimephales promelas)	-	-	-

Persistence and degradability No information available.

Bioaccumulative potential No information available.

Mobility in soil No information available.

Other adverse effects No information available.

13. Disposal considerations

Disposal 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.

California waste information This product contains one or more substances that are listed with the State of California as a hazardous waste.

14. Transport information

DOT Not regulated

TDG Not regulated

IATA Not regulated

IMDG Not regulated

15. Regulatory information

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

International Regulations

The Montreal Protocol on Substances that Deplete the Ozone Layer Not applicable

The Stockholm Convention on Persistent Organic Pollutants Not applicable

The Rotterdam Convention Not applicable

International Inventories

TSCA Exempt.

DSL/NDSL Exempt.

US Federal Regulations

SARA 313
Section 313 of Title III of the Superfund Amendments and Reauthorization Act of 1986 (SARA). This product contains a chemical or chemicals which are subject to the reporting requirements of the Act and Title 40 of the Code of Federal Regulations, Part 372.

SARA 311/312 Hazard Categories
Should this product meet EPCRA 311/312 Tier reporting criteria at 40 CFR 370, refer to Section 2 of this SDS for appropriate classifications.

CWA (Clean Water Act)
This product does not contain any substances regulated as pollutants pursuant to the Clean Water Act (40 CFR 122.21 and 40 CFR 122.42).

CAA (Clean Air Act)
This product does not contain any substances regulated as pollutants pursuant to Clean Air Act (CAA).

CERCLA
This material, as supplied, contains one or more substances regulated as a hazardous substance under the Comprehensive Environmental Response Compensation and Liability Act (CERCLA) (40 CFR 302).

Chemical name	Hazardous Substances RQs	Extremely Hazardous Substances RQs
Sodium azide	1000 lb / 454 kg (final RQ)	1000 lb

US State Regulations

California Proposition 65
This product does not contain any Proposition 65 chemicals

U.S. State Right-to-Know Regulations

Chemical name	New Jersey	Massachusetts	Pennsylvania
Sodium azide	X	X	X

16. Other information

NFPA	**Health hazards** 0	**Flammability** 0	**Instability** 0	**Special hazards** -
HMIS	**Health hazards** 0	**Flammability** 0	**Physical hazards** 0	**Personal protection** X

Key or legend to abbreviations and acronyms used in the safety data sheet
List may include phrases which are not applicable to this product

ACGIH	American Conference of Governmental Industrial Hygienists
ADN	Agreement concerning the International Carriage of Dangerous Goods by Inland Waterways (Europe)
ADR	Agreement concerning the International Carriage of Dangerous Goods by Road (Europe)
AIIC	Australian Inventory of Industrial Chemicals
ATE	Acute Toxicity Estimate
ASTM	American Society for the Testing of Materials
bar	Biological Reference Values for Chemical Compounds in the Work Area
BAT	Biological tolerance values for occupational exposure
BEL	Biological exposure limits
bw	Body weight
Ceiling	Maximum limit value

CMR	Carcinogen, Mutagen or Reproductive Toxicant
DOT	Department of Transportation (United States)
DSL	Domestic Substances List (Canada)
EINECS	European Inventory of Existing Chemical Substances
ELINCS	European List of Notified Chemical Substances
ECEL	Existing Chemical Exposure Limit
EmS	Emergency Schedule
ENCS	Existing and New Chemical Substances (Japan)
EPA	U.S. Environmental Protection Agency
GHS	Globally Harmonized System
HMIS	Hazardous Materials Identification System
IARC	International Agency for Research on Cancer
IATA	International Air Transport Association
IBC	International Code for the Construction and Equipment of Ships carrying Dangerous Chemicals in Bulk
ICAO	International Civil Aviation Organization
IECSC	Inventory of Existing Chemical Substances in China
IMDG	International Maritime Dangerous Goods
IMO	International Maritime Organization
ISO	International Organization for Standardization
KECI	Korean Existing Chemicals Inventory
LC50	Lethal Concentration to 50% of a test population
LD50	Lethal Dose to 50% of a test population (Median Lethal Dose)
MARPOL	International Convention for the Prevention of Pollution from Ships
NDSL	Non-Domestic Substances List (Canada)
NFPA	National Fire Protection Association
NIOSH	National Institute for Occupational Safety and Health
n.o.s.	Not Otherwise Specified
NOAEC	No Observed Adverse Effect Concentration
NOAEL	No Observed Adverse Effect Level
NOELR	No Observable Effect Loading Rate
NTP	National Toxicology Program (United States)
NZIoC	New Zealand Inventory of Chemicals
OECD	Organization for Economic Cooperation and Development
OEL	Occupational exposure limits
OSHA	Occupational Safety and Health Administration of the US Department of Labor
PBT	Persistent, Bioaccumulative and Toxic substance
PICCS	Philippines Inventory of Chemicals and Chemical Substances
PMT	Persistent, Mobile and Toxic
PPE	Personal protective equipment
QSAR	Quantitative Structure Activity Relationship
RID	Agreement concerning the International Carriage of Dangerous Goods by Rail (Europe)
SADT	Self-Accelerating Decomposition Temperature
SAR	Structure-activity relationship
SARA	Superfund Amendments and Reauthorization Act
SDS	Safety Data Sheet
SL	Surface Limit
STEL	Short Term Exposure Limit
STOT RE	Specific target organ toxicity - Repeated exposure
STOT SE	Specific target organ toxicity - Single exposure
TCSI	Taiwan Chemical Substance Inventory
TDG	Transport of Dangerous Goods (Canada)
TSCA	Toxic Substances Control Act (United States)
TWA	Time-Weighted Average
UN	United Nations
VOC	Volatile organic compounds
vPvB	Very Persistent and Very Bioaccumulative
vPvM	Very Persistent and Very Mobile

As	Allergenic substance
DS	Dermal Sensitizer
Ot	Ototoxicant
pOt	Ototoxicant - potential to cause hearing disorders
PS	Photosensitizer
RS	Respiratory Sensitizer
S	Sensitizer
poS	Sensitizer - capable of causing occupational asthma
Sa	Simple asphyxiant
Sd	Skin designation
pSd	Skin designation - potential for cutaneous absorption
Sdv	Skin designation - vacated
Sk	Skin notation
dSk	Skin notation - danger of cutaneous absorption
pSk	Skin notation - potential for cutaneous absorption

Key literature references and sources for data used to compile the SDS
U.S. Agency for Toxic Substances and Disease Registry (ATSDR)
U.S. Environmental Protection Agency ChemView Database
European Food Safety Authority (EFSA)
U.S. Environmental Protection Agency
U.S. EPA 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
U.S. Hazardous Substance Data Bank (HSDB)
International Uniform Chemical Information Database (IUCLID)
Japan GHS Classification
Australia National Industrial Chemicals Notification and Assessment Scheme (NICNAS)
U.S. National Institute for Occupational Safety and Health (NIOSH)
National Library of Medicine's ChemID Plus (NLM CIP)
National Library of Medicine’s PubMed database (NLM PUBMED)
U.S. National Toxicology Program (NTP)
New Zealand's Chemical Classification and Information Database (CCID)
International Organization for Economic Co-operation and Development (OECD) Environment, Health, and Safety Publications
International Organization for Economic Co-operation and Development (OECD) High Production Volume Chemicals Program
International Organization for Economic Co-operation and Development (OECD) Screening Information Data Set
United Nations World Health Organization (WHO)

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Revision Note Initial Release.

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.

End of Safety Data Sheet

Ortho PRODUCT Category Transfusion Medicine

North America SDS version information - NGHS
UL release:
GHS Revision 7 2026 Q2

North America Partial process, including GHS Wizard, NO TW

STOT: Specific Target Organ Toxicity

Input(s):

Output(s):

Section 2

Section 11
Specific target organ toxicity (single exposure):

Specific target organ toxicity (repeated exposure)

Chemical name	RCRA - U Series Wastes	RCRA - P Series Wastes
Sodium azide	-	P105

Chemical name	California Hazardous Waste Status
Sodium azide	Ignitable Reactive

Supplier Address
Ortho-Clinical Diagnostics, Inc.
1001 US Highway 202
Raritan, NJ 08869
USA

Customer Service
1 (800) 828-6316

Chemical name	GHS Classification	Specific concentration limit (SCL)	Classification according to Regulation (EC) No. 1272/2008 [CLP]	Specific concentration limit (SCL)
Sodium azide	-	-	Acute Tox. 2 (H300) Aquatic Acute 1 (H400) Aquatic Chronic 1 (H410) (EUH032)	-