

SAFETY DATA SHEETS

This SDS packet was issued with item:

078605722

The safety data sheets (SDS) in this packet apply to the individual products listed below. Please refer to invoice for specific item number(s).

078069568 078934021



UPDATED PRODUCT CODE: 022219
VERSION DATE: 7/2007

Page 1 of 4

MATERIAL SAFETY DATA SHEET

----- 1. CHEMICAL PRODUCT and COMPANY IDENTIFICATION -----

Product Name: CHORULON®
Product Family: BOVINE PHARMACETUTICALS

PRODUCT:

CHORULON®
(CHORIONIC GONADOTROPIN FOR INJECTION)

PRODUCT CODE:

022219

SYNONYMS:

NA

PRODUCT USE: Refer to product insert for proper usage.

COMPANY ADDRESS - Intervet Inc - 29160 Intervet Millsboro - Millsboro, DE 19966

----- 2. COMPOSITION / INFORMATION on INGREDIENTS -----

<u>PRODUCT COMPONENT:</u>	<u>CAS NUMBER:</u>	<u>RTECS NUMBER</u>
HUMAN CHORIONIC GONADOTROPIN (HCG)	9002-61-3	MD6953000
D-MANNITOL	69-65-8	OP2060000
MONOSODIUM PHOSPHATE	7558-79-4	WC4500000
DISODIUM PHOSPHATE	7558-80-7	WA1900000

Ingredients are not hazardous in the amounts present in product. See Registry of Toxic Effects of Chemical Substances (RTECS) for information regarding specific ingredients.

EMERGENCY: HUMAN, FIRE, SPILL OR ENVIRONMENTAL: 1-800-228-5635 EXT. 132 24 HRS.
ANIMAL: 1-800-345-4735 EXT. 104 24 HRS.
CHEMTREC® FOR CHEMICAL EMERGENCY SPILL, LEAK, FIRE: 1-800-424-9300

PRODUCT INFORMATION: 1-800-835-0541 OR 1-302-934-8051 9:00 A.M. – 5:00 P.M. EST



UPDATED PRODUCT CODE: 022219
VERSION DATE: 7/2007

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----- 3. HAZARDS IDENTIFICATION-----

ROUTES OF ENTRY: *Dermal, Injection, Inhalation, Ingestion*

ACUTE EFFECTS OF EXPOSURE: *Exposure to powder or reconstituted product may cause irritation or allergic reaction at site of contact. Accidental injection may cause result in menorrhagia.*

CRONIC EFFECTS OF EXPOSURE: *None known*

CARCENOGINIC EFFECTS: *This product is not considered a carcinogen and is not listed by OSHA, IRAC or NTP.*

----- 4. FIRST AID MEASURES -----

SKIN: *Wash immediately affected area with soap and water. Contact a physician.*

EYES: *Immediately flush with plenty of water for fifteen minutes. Contact a physician*

INHALATION: *Remove to fresh air. If not breathing, give artificial respiration and call for medical help immediately.*

INGESTION: *Seek medical attention immediately.*

INJECTION: *Remove needle, wash injection site with soap and water, contact physician immediately.*

----- 5. FIRE FIGHTING MEASURES -----

FLAMMABILITY: *Product is non-flammable*

EXTINGUISHING METHODS: *Use Water, Water Mist, Foam or Dry Chemical to extinguish fire.*

FIRE FIGHTING INSTRUCTIONS: *Wear full bunker gear, including SCBA, for fighting fires involving large quantities of this material. Keep upwind.*

----- 6. ACCIDENTAL RELEASE MEASURES-----

PROCEDURES IN CASE OF SPILL OR LEAK: *Clean up spilled material. Place powder and broken vials in a secure container for disposal.*

EMERGENCY: HUMAN, FIRE, SPILL OR ENVIRONMENTAL: 1-800-228-5635 EXT. 132 24 HRS.
ANIMAL: 1-800-345-4735 EXT. 104 24 HRS.
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UPDATED PRODUCT CODE: 022219
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----- 7. HANDLING and STORAGE -----

STORAGE: *Store at room temperature. Protect containers from damage.*

SHELF LIFE: *See expiration date on product label.*

HANDLING PRECAUTIONS: *Read and follow all package insert instructions. Protect containers from damage.*

----- 8. EXPOSURE CONTROL / PERSONAL PROTECTION -----

EYES: *Prevent eye contact by wearing appropriate eye protection for handling tasks.*

SKIN: *Avoid skin contact. Wear chemical resistant gloves, long-sleeves and trousers to prevent dermal contact.*

RESPIRATOR PROTECTION: *Under normal conditions of use, as stated in the product insert, no respiratory protection is necessary. However, if ventilation is inadequate or aerosol hazard exists; wear a NIOSH approved respirator.*

----- 9. PHYSICAL and CHEMICAL PROPERTIES -----

APPEARANCE: *White amorphous powder plus clear, odorless, sterile aqueous solution.*

PH: *Not Available*

----- 10. STABILITY and REACTIVITY -----

CHEMICAL STABILITY: *Stable*

CONDITIONS TO AVOID: *None known*

INCOMPATIBILITY: *None Known*

HAZARDOUS POLYMERIZATION: *Will not occur*

----- 11. TOXICOLOGICAL INFORMATION -----

Oral LD 50 Rat: *Not available*

Intraperitoneal LD50 (rat): *Not available*

EMERGENCY: HUMAN, FIRE, SPILL OR ENVIRONMENTAL: 1-800-228-5635 EXT. 132 24 HRS.
ANIMAL: 1-800-345-4735 EXT. 104 24 HRS.
CHEMTREC® FOR CHEMICAL EMERGENCY SPILL, LEAK, FIRE: 1-800-424-9300

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UPDATED PRODUCT CODE: 022219
VERSION DATE: 7/2007

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Intraperitoneal LD50 (mouse): *Not available*

----- **12. ECOLOGICAL INFORMATION** -----

This product when used according to the insert direction, poses negligible impact on the environment.

----- **13. DISPOSAL CONSIDERATIONS** -----

Dispose in accordance with all applicable Federal, State and Local regulations.

----- **14. TRANSPORTATION** -----

DOT SHIPPING INFORMATION: *Not regulated by the DOT*

----- **15. REGULATORY INFORMATION** -----

STATE REGULATIONS: *The following chemicals associated with the product are subject to the Right-To-Know regulations in these states: None known*

US FEDERAL REGULATIONS: SARA 313: *No components listed.*

----- **16. OTHER INFORMATION** -----

DISCLAIMER:

The information contained herein is true and accurate to the best of the knowledge of Intervet Inc. However, all data, instructions and/or recommendations are made without guarantee. The buyer and handler assume all risk and liability of use, storage and/or handling of this product not in accordance with the terms of the product label.

EMERGENCY: HUMAN, FIRE, SPILL OR ENVIRONMENTAL: 1-800-228-5635 EXT. 132 24 HRS.
ANIMAL: 1-800-345-4735 EXT. 104 24 HRS.
CHEMTREC® FOR CHEMICAL EMERGENCY SPILL, LEAK, FIRE: 1-800-424-9300

PRODUCT INFORMATION: 1-800-835-0541 OR 1-302-934-8051 9:00 A.M. – 5:00 P.M. EST

MATERIAL SAFETY DATA SHEET

SECTION I – PRODUCT INFORMATION

PRODUCT NAME: Chorulon
OFFICIAL NAME: Chorionic Gonadotropin for Injection
PRODUCT TYPE: Animal Drug
DIN #: 00781851

MANUFACTURER/SUPPLIER: Intervet International BV
The Netherlands

TELEPHONE: 1-800-268-4257
EMERGENCY #: 1-800-345-4735 (only to be
used after hours between 4:30pm - 8:30am)
FAX: 1-888-498-4444

SECTION II – INGREDIENT INFORMATION

INGREDIENTS	CAS #	RTECS #
Human Chorionic Gonadotropin (HCG)	9002-61-3	MD6953000
D-Mannitol	69-65-8	OP2060000
Monosodium Phosphate	7558-79-4	WC4500000
Disodium Phosphate	7558-80-7	WA1900000

Ingredients are not hazardous in amounts present in product. See Registry of Toxic Effects of Chemical Substances (RTECS) for information regarding specific ingredients.

SECTION III – PHYSICAL DATA

BOILING POINT (°F): N.A.
VAPOR PRESSURE (MM HG): N.A.
VAPOR DENSITY (Air=1): N.A.
SOLUBILITY IN WATER: Soluble
APPEARANCE AND ODOUR: White amorphous powder plus clear, odourless, sterile aqueous solution.

VOLATILE BY VOLUME (%): N.A.
EVAPORATION RATE (=1): N.A.
SPECIFIC GRAVITY (Water=1): N.A.

SECTION IV - FIRE AND EXPLOSION DATA

FLASH POINT (°F): Non-Flammable
Method Used: N.A.
FLAMMABLE LIMITS - Lower: N.A.
Upper: N.A.
EXTINGUISHER MEDIA: Water, extinguishing powder, carbon dioxide, foam.
SPECIAL FIRE FIGHTING PROCEDURES: None
UNUSUAL FIRE AND EXPLOSION HAZARDS: None

SECTION V – HEALTH HAZARD DATA

EXPOSURE LIMITS: None Established
INHALATION: Powder may cause allergic reaction.
EYE CONTACT: Powder or reconstituted product may cause irritation.
SKIN CONTACT: None
INGESTION: None
OTHER (Specify): Accidental injection may result in menorrhagia.
LISTED AS A CARCINOGEN BY: NTP: Yes ____ IARC: Yes ____ OSHA: Yes ____
No X No X No X

SECTION V – HEALTH HAZARD DATA (CONT.)

FIRST AID PROCEDURES:

In case of accidental injection, remove needle, wash injection site with soap and water. Contact physician **IMMEDIATELY**.
In case of contact with eyes, flush eyes for 15 minutes with water; if irritation persists, contact physician.

SECTION VI – REACTIVITY DATA

STABILITY: Stable . X
Unstable:

CONDITIONS TO AVOID: N.A.

INCOMPATIBILITY (Materials to Avoid): None

HAZARDOUS DECOMPOSITION PRODUCTS: None

HAZARDOUS POLYMERIZATION:

CONDITIONS TO AVOID: N.A.

May occur:

Will not occur: X

SECTION VII – SPILL OR LEAK PROCEDURE

STEPS TO BE TAKEN: Sweep area; collect powder and broken vials in appropriate container for disposal, seal effectively and dispose; wash down area.

DISPOSAL METHODS: Incinerate open, used vials and cartons. To destroy outdated product, open vials and incinerate. At all times adhere to applicable local, state, and federal regulations for disposal.

SECTION VIII - SPECIAL PROTECTION INFORMATION

RESPIRATORY PROTECTION: N.A.

Type: N.A.

VENTILATION:

Local: N.A.

Special: N.A.

Mechanical: N.A.

Other: N.A.

EYE PROTECTION: N.A.

PROTECTIVE GLOVES: N.A.

OTHER PROTECTIVE EQUIPMENT: N.A.

SECTION IX - STORAGE AND HANDLING PRECAUTIONS

STORAGE AND HANDLING: Store at or below room temperature, 25°C (77°F). Protect glass vials from breakage.

OTHER PRECAUTIONS: Read and follow all label directions.

SECTION X – ADDITIONAL INFORMATION

Product is not hazardous when used according to label directions. Once reconstituted, product should be used immediately. Unused solution should be disposed of properly and not saved for future use.

Caution: Federal law restricts this product to use by or on the order of a licensed veterinarian.

FOR ANIMAL USE ONLY

**The information contained herein is true and accurate to the best of the knowledge of Intervet Canada Ltd.
However, all data, instructions and/or recommendations are made without guarantee.**

SIGNED: _____

DATE ISSUED: January 2, 2008



Merck & Co., Inc.
One Merck Dr.
Whitehouse Station, NJ 08889

MATERIAL SAFETY DATA SHEET

Merck urges each user or recipient of this MSDS to read the entire data sheet to become aware of the hazards associated with this material.

SECTION 1. IDENTIFICATION OF SUBSTANCE AND CONTACT INFORMATION

MSDS NAME: PREGNYL 1500E/A

SYNONYM(S): AMPUL MET GEVRIESDROOGD POEDER: MENGSEL VAN CHORIONGONADOTROFINE, CMC NA HV OPL. 2G/L, MANNITOL, NATRIUM H₂ FOSFAAT.2AQ EN NATRIUM2 H FOSF.2AQ; PREGNYL 1500E/A

MSDS NUMBER: SP324027

EMERGENCY NUMBER(S): (908) 423-6000 (24/7/365) English Only

Transportation Emergencies - CHEMTREC:
(800) 424-9300 (Inside Continental USA)
(703) 527-3887 (Outside Continental USA)

MERCK MSDS HELPLINE: (800) 770-8878 (US and Canada)
(908) 473-3371 (Worldwide)
Monday to Friday, 9am to 5pm (US Eastern Time)

SECTION 2. HAZARDS IDENTIFICATION

EMERGENCY OVERVIEW

Lyophilized powder, Hygroscopic
White to off-white
Odorless
May cause sensitization by inhalation or skin contact.
Causes effects to:
endocrine system

POTENTIAL HEALTH EFFECTS:

The toxicological properties of this material have not been fully characterized in humans and animals. Therefore, laboratory or process control systems and appropriate work practices should be in place to minimize the potential for inhalation exposure, skin contact, eye contact, or ingestion when working with this material.

Gonadotrophin, Chorionic is a hypothalamic / pituitary hormone. Symptoms of exposure may include headache, tiredness, changes of mood, depression, restlessness, and edema. Overexposure by inhalation may be harmful.

LISTED CARCINOGENS

Not listed as a carcinogen by OSHA, IARC, NTP or ACGIH.

SECTION 3. COMPOSITION AND INFORMATION ON INGREDIENTS

CHEMICAL NAME: AMPUL WITH GONADOTROPHIN, CHORIONIC (APPROX. 15%)

CHEMICAL FAMILY: Hypothalamic and pituitary hormones/ Gonadotrophic

PRODUCT USE: Pharmaceutical production and analysis

CHEMICAL FORMULA: Mixture.

CHEMICAL COMPOSITION

INGREDIENT	CAS NUMBER	PERCENT
Gonadotropin, Chorionic	9002-61-3	15

SECTION 4. FIRST AID MEASURES

INHALATION: Remove to fresh air. If any trouble breathing, get immediate medical attention. Administer artificial respiration if breathing has ceased. If irritation or symptoms occur or persist, consult a physician.

SKIN CONTACT: In case of skin contact, while wearing protective gloves, carefully remove any contaminated clothing, including shoes, and wash skin thoroughly with soap and water. If irritation or symptoms occur or persist, consult a physician.

EYE CONTACT: In case of eye contact, immediately rinse eyes thoroughly with plenty of water. If wearing contact lenses, remove only after initial rinse, and continue rinsing eyes for at least 15 minutes. If irritation occurs or persists, consult a physician.

INGESTION: Rinse mouth and drink a glass of water. Do not induce vomiting unless under the direction of a qualified medical professional or Poison Control Center. If symptoms persist, consult a physician.

SECTION 5. FIRE FIGHTING MEASURES

FLAMMABILITY DATA:

Flash Point: Not determined (liquids) or not applicable (solids).

EXPLOSION HAZARDS:

Under normal conditions of use, this material does not present a significant fire or explosion hazard. However, like most organic compounds, this material may present a dust deflagration hazard if sufficient quantities are suspended in air. This hazard may exist where sufficient quantities of finely divided material are (or may become) suspended in air during typical process operations. An assessment of each operation should be conducted and suitable deflagration prevention and protection techniques employed. The sensitivity of this material to ignition by electrostatic discharges has not been determined. In the absence of testing data, all conductive plant items and operations personnel handling this material should be suitably grounded.

SPECIAL FIRE FIGHTING PROCEDURES:

Wear full protective clothing and self-contained breathing apparatus (SCBA).

SUITABLE EXTINGUISHING MEDIA:

Carbon dioxide (CO₂), extinguishing powder or water spray.

See Section 9 for Physical and Chemical Properties.

SECTION 6. ACCIDENTAL RELEASE MEASURES

PERSONAL PRECAUTIONS:

Wear appropriate personal protective equipment as specified in Section 8. Keep personnel away from the clean-up area.

SPILL RESPONSE / CLEANUP:

All spills should be handled according to site requirements and based on precautions cited in the MSDS. In the case of liquids, use proper absorbent materials. For laboratories and small-scale operations, incidental spills within a hood or enclosure should be cleaned by using a HEPA filtered vacuum or wet cleaning methods as appropriate. For large dry or liquid spills or those spills outside enclosure or hood, appropriate emergency response personnel should be notified. In manufacturing and large-scale operations, HEPA vacuuming prior to wet mopping or cleaning is required.

See Sections 9 and 10 for additional physical, chemical, and hazard information.

SECTION 7. HANDLING AND STORAGE

HANDLING:

Avoid dust generation. Keep containers adequately sealed during material transfer, transport, or when not in use. Wash face, hands, and any exposed skin after handling. Do not eat, drink, or smoke when using this substance or mixture.

Appropriate handling of this material is dependent on many factors, including physical form, duration and frequency of process or task, and effectiveness of engineering controls. Site-specific risk assessments should be conducted to determine the feasibility and the appropriateness of all exposure control measures. See Section 8 (Exposure Controls) for additional guidance.

STORAGE:

Store at 2-8 deg C. Avoid moisture. Store in brown coloured glass bottles which are closed with a screw cap fitted with polyethylene inlay.

See Section 8 for exposure controls and additional safe handling information.

SECTION 8. EXPOSURE CONTROLS AND PERSONAL PROTECTION

The following guidance applies to the handling of the active ingredient(s) in this formulation.

OCCUPATIONAL EXPOSURE BAND (OEB):

OEB 4: 1-10 mcg/m³. Materials in an OEB 4 category are considered high health hazards. The OEB is range of airborne concentrations expressed as an 8-hour Time Weighted Average (8-hr. TWA) and is intended to be used with Industrial Hygiene Risk Assessment to assist with industrial hygiene sampling and selection of proper controls for worker protection. Consult your site safety and industrial hygiene staff for guidance on handling and control strategies.

OCCUPATIONAL EXPOSURE GUIDELINE (OEG):

Internal Occupational Exposure Limit of 1.3 mcg/m³ for Gonadotropin, chorionic.

EXPOSURE CONTROLS

The health hazard risks of handling this material are dependent on many factors, including physical form, duration and frequency of process or task, and effectiveness of engineering controls. Site-specific risk assessments should be conducted to determine the feasibility and the appropriateness of all exposure control measures. Exposure controls for normal operating or routine procedures follow a tiered strategy. Engineering controls are the preferred means of long-term or permanent exposure control. If engineering controls are not feasible, appropriate use of personal protective equipment (PPE) may be considered as alternative control measures. Exposure controls for non-routine operations must be evaluated and addressed as part of the site-specific risk assessment.

RECOMMENDED PERSONAL PROTECTIVE EQUIPMENT (PPE):

Respiratory Protection:	Respiratory protective equipment (RPE) may be required for certain laboratory and large-scale manufacturing tasks if potential airborne breathing zone concentrations of substances exceed the relevant exposure limit(s). Workplace risk assessment should be completed before specifying and implementing RPE usage. Potential exposure points and pathways, task duration and frequency, potential employee contact with the substance, and the ability of the substance to be rendered airborne during specific tasks should be evaluated. Initial and ongoing strategies of quantitative exposure measurement should be obtained as required by the workplace risk assessment. All RPE must conform to local and regional specifications for efficacy and performance. Consult your site or corporate health and safety professional for additional guidance.
Skin Protection:	Gloves that provide an appropriate barrier to the skin are recommended if there is potential for contact with this material. Consult your site safety staff for guidance.
Eye Protection:	Safety glasses with side shields. Use of goggles or full face protection may be required based on hazard, potential for contact, or level of exposure. Consult your site safety staff for guidance.
Body Protection:	<p>In small-scale or laboratory operations, lab coats or equivalent protection is required. Disposable Tyvek or other dust impermeable suit should be considered based on procedure or level of exposure. Use of additional PPE such as shoe coverings, gauntlets, hood, or head covering may be necessary. Consult your site safety staff for guidance.</p> <p>In large-scale or manufacturing operations, disposable Tyvek or other dust impermeable suit is recommended and based on level of exposure. Use of additional PPE such as shoe coverings, gauntlets, hood, or head covering may be necessary. Consult your site safety staff for guidance.</p>

EXPOSURE LIMIT VALUES

See Internal Occupational Exposure Limit listed above.

SECTION 9. PHYSICAL AND CHEMICAL PROPERTIES

FORM: Lyophilized powder, Hygroscopic
COLOR: White to off-white
ODOR: Odorless
SOLUBILITY:
Water: Insoluble

See Section 5 for flammability/explosivity information.

SECTION 10. STABILITY AND REACTIVITY

STABILITY/ REACTIVITY:
Stable under normal conditions.

INCOMPATIBLE MATERIALS / CONDITIONS TO AVOID:
None known.

HAZARDOUS DECOMPOSITION PRODUCTS / REACTIONS:
No dangerous decomposition is expected if used according to manufacturer's specifications.

SECTION 12. ECOLOGICAL INFORMATION

ECOTOXICITY DATA

INGREDIENT ECOTOXICITY Gonadotrophin, Chorionic:
LOEC (21 days): 3ug/L (Fish, Anguilla anguilla) Endpoint: hormone change.

ENVIRONMENTAL DATA

There are no environmental data available for this material.

SECTION 11. TOXICOLOGICAL INFORMATION

ACUTE TOXICITY DATA

INHALATION:
No data available.

SKIN:
No data available.

EYE:
No data available.

ORAL:
No data available.

DERMAL AND RESPIRATORY SENSITIZATION:
No data available.

REPEAT DOSE TOXICITY DATA

SUBCHRONIC / CHRONIC TOXICITY:
No data available.

REPRODUCTIVE / DEVELOPMENTAL TOXICITY:
Gonadotrophin, Chorionic showed reproductive disorders in humans and animal studies, and impairment of pre- and post-implantation development in mice. Female pigs dosed intravenously with 0.883 mg/kg 2 days pre-mating showed effects on fertility. Female monkeys dosed intramuscularly with 0.224 mg/kg 18 - 36 days after conception showed maternal effects. Rats dosed intravenously at 8.89 mg/kg 1 day pre-mating showed effects on fertility.

MUTAGENICITY / GENOTOXICITY:
No data available.

CARCINOGENICITY:
This material or product has not been evaluated for carcinogenicity.

MSDS NAME: PREGNYL 1500E/A

MSDS NUMBER: SP324027

Latest Revision Date: 26-Jan-2012

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SECTION 13. DISPOSAL CONSIDERATIONS

MATERIAL WASTE:

Disposal must be in accordance with applicable federal, state/provincial, and/or local regulations. Incineration is the preferred method of disposal, when appropriate. Operations that involve the crushing or shredding of waste materials or returned goods must be handled to meet the recommended exposure limit(s).

PACKAGING AND CONTAINERS:

Disposal must be in accordance with applicable federal, state/provincial, and/or local regulations.

SECTION 14. TRANSPORT INFORMATION

This material is not subject to the transportation regulations of DOT, IATA, IMO, and the ADR.

SECTION 15. REGULATORY INFORMATION

TSCA LISTING

This material or product is not subject to TSCA requirements.

U.S. STATE REGULATIONS

Check state requirements for ingredient listing.

SECTION 16. OTHER INFORMATION

Although reasonable care has been taken in the preparation of this document, we extend no warranties and make no representations as to the accuracy or completeness of the information contained therein, and assume no responsibility regarding the suitability of this information for the user's intended purposes or for the consequence of its use. Each individual should make a determination as to the suitability of the information for their particular purpose(s).

DEPARTMENT ISSUING MSDS:

Global Safety & the Environment
Merck & Co., Inc.
One Merck Drive
Whitehouse Station, NJ 08889

MERCK MSDS HELPLINE:

(800) 770-8878 (US and Canada)
(908) 473-3371 (Worldwide)
Monday to Friday, 9am to 5pm (US Eastern Time)

MSDS CREATION DATE:

07-Jul-2008

SUPERSEDES DATE:

16-Dec-2010

SIGNIFICANT CHANGES (US SUBFORMAT):

Conversion, OEB

----- MATERIAL SAFETY DATA SHEET -----

Intervet

CHORULON(R) (CHORIONIC GONADOTROPIN FOR INJECTION)

1. CHEMICAL PRODUCT and COMPANY IDENTIFICATION

Product Name: CHORULON(R)
 Product Family: BOVINE PHARMACEUTICALS
 PRODUCT: PRODUCT CODE:
 CHORULON(R) CH-475-1
 (CHORIONIC GONADOTROPIN FOR INJECTION)
 SYNONYMS: NA
 PRODUCT USE: Refer to product insert for proper usage.
 COMPANY ADDRESS- Intervet Inc - 405 State Street -
 Millsboro, DE. 19966

2. COMPOSITION / INFORMATION on INGREDIENTS

PRODUCT COMPONENT:	CAS NUMBER:	RTECS NUMBER
HUMAN CHORIONIC GONADOTROPIN (HCG)	9002-61-3	MD6953000
D-MANNITOL	69-65-8	OP2060000
MONOSODIUM PHOSPHATE	7558-79-4	WC4500000
DISODIUM PHOSPHATE	7558-80-7	WA1900000

Ingredients are not hazardous in the amounts present in product. See Registry of Toxic Effects of Chemical Substances (RTECS) for information regarding specific ingredients.

3. HAZARDS IDENTIFICATION

ROUTES OF ENTRY: Dermal, Injection, Inhalation, Ingestion
 ACUTE EFFECTS OF EXPOSURE: Exposure to powder or reconstituted product may cause irritation or allergic reaction at site of contact. Accidental injection may cause result in menorrhagia.
 CHRONIC EFFECTS OF EXPOSURE: None known
 CARCINOGENIC EFFECTS: This product is not considered a carcinogen and is not listed by OSHA, IARC or NTP.

4. FIRST AID MEASURES

SKIN: Wash immediately affected area with soap and water. Contact a physician.
 EYES: Immediately flush with plenty of water for fifteen minutes. Contact a physician
 INHALATION: Remove to fresh air. If not breathing, give artificial respiration and call for medical help immediately.
 INGESTION: Seek medical attention immediately.
 INJECTION: Remove needle, wash injection site with soap and water, contact physician immediately.

5. FIRE FIGHTING MEASURES

EXTINGUISHING METHODS: Use Water, Water Mist, Foam or Dry Chemical to extinguish fire.
 FIRE FIGHTING INSTRUCTIONS: Wear full bunker gear, including SCBA, for fighting fires involving large quantities of this material. Keep upwind.

6. ACCIDENTAL RELEASE MEASURES

PROCEDURES IN CASE OF SPILL OR LEAK: Clean up spilled material. Place powder and broken vials in a secure container for disposal.

7. HANDLING and STORAGE

STORAGE: Store at room temperature. Protect containers from damage.
 SHELF LIFE: See expiration date on product label.
 HANDLING PRECAUTIONS: Read and follow all package insert instructions. Protect containers from damage.

8. EXPOSURE CONTROL / PERSONAL PROTECTION

EYES: Prevent eye contact by wearing appropriate eye protection for handling tasks.
 SKIN: Avoid skin contact. Wear chemical resistant gloves, long-sleeves and trousers to prevent dermal contact.
 RESPIRATOR PROTECTION: Under normal conditions of use, as stated in the product insert, no respiratory protection is necessary. However, if ventilation is inadequate or aerosol hazard exists; wear a NIOSH approved respirator.

9. PHYSICAL and CHEMICAL PROPERTIES

APPEARANCE: White amorphous powder plus clear, odorless, sterile aqueous solution.
 pH: Not Available

10. STABILITY and REACTIVITY

CHEMICAL STABILITY: Stable
 CONDITIONS TO AVOID: None known
 INCOMPATIBILITY: None Known
 HAZARDOUS POLYMERIZATION: Will not occur

11. TOXICOLOGICAL INFORMATION

Oral LD 50 Rat: Not available
 Intraperitoneal LD50 (rat): Not available
 Intraperitoneal LD50 (mouse): Not available

12. ECOLOGICAL INFORMATION

This product when used according to the insert direction, poses negligible impact on the environment.

13. DISPOSAL CONSIDERATIONS

Dispose in accordance with all applicable Federal, State and Local regulations.

14. TRANSPORTATION

DOT SHIPPING INFORMATION: Not regulated by the DOT

15. REGULATORY INFORMATION

STATE REGULATIONS: The following chemicals associated with the product are subject to the Right-To-Know regulations in these states: None known
 US FEDERAL REGULATIONS: SARA 313: No components listed.

16. OTHER INFORMATION

DISCLAIMER: The information contained herein is true and accurate to the best of the knowledge of Intervet Inc. However, all data, instructions and/or recommendations are made without guarantee. The buyer and handler assume all risk and liability of use, storage and/or handling of this product not in accordance with the terms of the product label.

EMERGENCY:

HUMAN, FIRE, SPILL OR ENVIRONMENTAL: 1-800-680-9206
 ANIMAL: 1-800-345-4735 EXT. 104 24 HRS.
 CHEMTREC(R) FOR CHEMICAL EMERGENCY SPILL, LEAK, FIRE:
 1-800-424-9300
 PRODUCT INFORMATION: 1-800-441-8272 OR 1-302-934-805
 8:00 A.M. - 5:00 P.M. EST

Intervet

CHORULON(R) (CHORIONIC GONADOTROPIN FOR INJECTION)

 DISCLAIMER OF EXPRESSED AND IMPLIED WARRANTIES: although preparer and owner have taken reasonable care in the preparation of this document, we extend no warranties and make no representation as to the accuracy or completeness of the information contained herein, and assume no responsibility regarding the suitability of this information for the user's intended purposes or for the consequences of its use. Each user should make a determination as to the suitability of the information for their particular purpose(s). A request has been made to the manufacturer to approve the contents of this material safety data sheet. Upon receipt of any changes a new MSDS will be made available.

COMPAS Code: 46500020

Human Chorionic Gonadotropin Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 04/28/2017
5.2	06/12/2017	22144-00008	Date of first issue: 10/15/2014

SECTION 1. IDENTIFICATION

Product name : Human Chorionic Gonadotropin Formulation

Product code : PREGNYL

Manufacturer or supplier's details

Company name of supplier : Merck & Co., Inc

Address : 2000 Galloping Hill Road
Kenilworth - New Jersey - USA 1685

Telephone : 908-740-4000

Telefax : 908-735-1496

Emergency telephone : 1-908-423-6000

E-mail address : EHSDATASTEWARD@merck.com

Recommended use of the chemical and restrictions on use

Recommended use : Pharmaceutical

SECTION 2. HAZARDS IDENTIFICATION

GHS classification in accordance with 29 CFR 1910.1200

Combustible dust

Reproductive toxicity : Category 1A

Specific target organ
systemic toxicity - repeated
exposure : Category 1 (ovaries)

GHS label elements

Hazard pictograms :



Signal Word : Danger

Hazard Statements : If small particles are generated during further processing, handling or by other means, may form combustible dust concentrations in air.
H360Fd May damage fertility. Suspected of damaging the unborn child.
H372 Causes damage to organs (ovaries) through prolonged or repeated exposure.

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Other hazards

Dust contact with the eyes can lead to mechanical irritation.
Contact with dust can cause mechanical irritation or drying of the skin.

Substance / Mixture : Mixture

Chemical name	CAS-No.	Concentration (% w/w)
Gonadotropin, chorionic	9002-61-3	>= 90 -< 100

General advice	: In the case of accident or if you feel unwell, seek medical advice immediately. When symptoms persist or in all cases of doubt seek medical advice.
If inhaled	: If inhaled, remove to fresh air. Get medical attention.
In case of skin contact	: In case of contact, immediately flush skin with soap and plenty of water. Remove contaminated clothing and shoes. Get medical attention. Wash clothing before reuse. Thoroughly clean shoes before reuse.
In case of eye contact	: If in eyes, rinse well with water. Get medical attention if irritation develops and persists.

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- | | | |
|---|---|---|
| If swallowed | : | If swallowed, DO NOT induce vomiting.
Get medical attention.
Rinse mouth thoroughly with water. |
| Most important symptoms and effects, both acute and delayed | : | Contact with dust can cause mechanical irritation or drying of the skin.
Dust contact with the eyes can lead to mechanical irritation.
May damage fertility. Suspected of damaging the unborn child.
Causes damage to organs through prolonged or repeated exposure. |
| Protection of first-aiders | : | First Aid responders should pay attention to self-protection, and use the recommended personal protective equipment when the potential for exposure exists. |
| Notes to physician | : | Treat symptomatically and supportively. |

SECTION 5. FIRE-FIGHTING MEASURES

- | | | |
|--|---|---|
| Suitable extinguishing media | : | Water spray
Alcohol-resistant foam
Carbon dioxide (CO ₂)
Dry chemical |
| Unsuitable extinguishing media | : | None known. |
| Specific hazards during fire fighting | : | Exposure to combustion products may be a hazard to health. |
| Hazardous combustion products | : | Carbon oxides
Nitrogen oxides (NO _x)
Sulfur oxides |
| Specific extinguishing methods | : | Use extinguishing measures that are appropriate to local circumstances and the surrounding environment.
Use water spray to cool unopened containers.
Remove undamaged containers from fire area if it is safe to do so.
Evacuate area. |
| Special protective equipment for fire-fighters | : | In the event of fire, wear self-contained breathing apparatus.
Use personal protective equipment. |

SECTION 6. ACCIDENTAL RELEASE MEASURES

- | | | |
|---|---|--|
| Personal precautions, protective equipment and emergency procedures | : | Use personal protective equipment.
Follow safe handling advice and personal protective equipment recommendations. |
| Environmental precautions | : | Discharge into the environment must be avoided.
Prevent further leakage or spillage if safe to do so. |

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Retain and dispose of contaminated wash water.
Local authorities should be advised if significant spillages cannot be contained.

Methods and materials for containment and cleaning up : Sweep up or vacuum up spillage and collect in suitable container for disposal.
Avoid dispersal of dust in the air (i.e., clearing dust surfaces with compressed air).
Dust deposits should not be allowed to accumulate on surfaces, as these may form an explosive mixture if they are released into the atmosphere in sufficient concentration.
Local or national regulations may apply to releases and disposal of this material, as well as those materials and items employed in the cleanup of releases. You will need to determine which regulations are applicable.
Sections 13 and 15 of this SDS provide information regarding certain local or national requirements.

SECTION 7. HANDLING AND STORAGE

Technical measures : Static electricity may accumulate and ignite suspended dust causing an explosion.
Provide adequate precautions, such as electrical grounding and bonding, or inert atmospheres.

Local/Total ventilation : Use with local exhaust ventilation.

Advice on safe handling : Do not get on skin or clothing.
Do not breathe dust.
Do not swallow.
Avoid contact with eyes.
Handle in accordance with good industrial hygiene and safety practice.
Keep container tightly closed.
Minimize dust generation and accumulation.
Keep container closed when not in use.
Keep away from heat and sources of ignition.
Take precautionary measures against static discharges.
Take care to prevent spills, waste and minimize release to the environment.

Conditions for safe storage : Keep in properly labeled containers.
Store locked up.
Keep tightly closed.
Store in accordance with the particular national regulations.

Materials to avoid : Do not store with the following product types:
Strong oxidizing agents
Organic peroxides
Explosives
Gases

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SECTION 8. EXPOSURE CONTROLS/PERSONAL PROTECTION

Ingredients with workplace control parameters

Ingredients	CAS-No.	Value type (Form of exposure)	Control parameters / Permissible concentration	Basis
Gonadotropin, chorionic	9002-61-3	TWA	3 µg/m ³	Merck
		Wipe limit	25 µg/100 cm ²	Merck
		TWA	OEB 4	Merck

Engineering measures : Minimize workplace exposure concentrations.
 Apply measures to prevent dust explosions.
 Ensure that dust-handling systems (such as exhaust ducts, dust collectors, vessels, and processing equipment) are designed in a manner to prevent the escape of dust into the work area (i.e., there is no leakage from the equipment).
 Use with local exhaust ventilation.
 Dust formation may be relevant in the processing of this product. In addition to substance-specific OELs, general limitations of concentrations of particulates in the air at workplaces have to be considered in workplace risk assessment. Relevant limits include: OSHA PEL for Particulates Not Otherwise Regulated of 15 mg/m³ - total dust, 5 mg/m³ - respirable fraction; and ACGIH TWA for Particles (insoluble or poorly soluble) Not Otherwise Specified of 3 mg/m³ - respirable particles, 10 mg/m³ - inhalable particles.

Personal protective equipment

Respiratory protection : General and local exhaust ventilation is recommended to maintain vapor exposures below recommended limits. Where concentrations are above recommended limits or are unknown, appropriate respiratory protection should be worn. Follow OSHA respirator regulations (29 CFR 1910.134) and use NIOSH/MSHA approved respirators. Protection provided by air purifying respirators against exposure to any hazardous chemical is limited. Use a positive pressure air supplied respirator if there is any potential for uncontrolled release, exposure levels are unknown, or any other circumstance where air purifying respirators may not provide adequate protection.

Hand protection
Material

: Chemical-resistant gloves

Remarks

: Choose gloves to protect hands against chemicals depending on the concentration specific to place of work. Breakthrough time is not determined for the product. Change gloves often! For special applications, we recommend clarifying the

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- resistance to chemicals of the aforementioned protective gloves with the glove manufacturer. Wash hands before breaks and at the end of workday.
- Eye protection : Wear the following personal protective equipment:
Safety goggles
- Skin and body protection : Select appropriate protective clothing based on chemical resistance data and an assessment of the local exposure potential.
Skin contact must be avoided by using impervious protective clothing (gloves, aprons, boots, etc).
- Hygiene measures : Ensure that eye flushing systems and safety showers are located close to the working place.
When using do not eat, drink or smoke.
Wash contaminated clothing before re-use.

SECTION 9. PHYSICAL AND CHEMICAL PROPERTIES

- Appearance : powder
- Color : off-white
- Odor : odorless
- Odor Threshold : No data available
- pH : No data available
- Melting point/freezing point : No data available
- Initial boiling point and boiling range : No data available
- Flash point : Not applicable
- Evaporation rate : No data available
- Flammability (solid, gas) : May form explosive dust-air mixture during processing, handling or other means.
- Flammability (liquids) : No data available
- Upper explosion limit / Upper flammability limit : No data available
- Lower explosion limit / Lower flammability limit : No data available
- Vapor pressure : No data available
- Relative vapor density : No data available

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Relative density	:	No data available
Solubility(ies)	:	
Water solubility	:	soluble
Partition coefficient: n-octanol/water	:	No data available
Autoignition temperature	:	No data available
Decomposition temperature	:	No data available
Viscosity	:	
Viscosity, kinematic	:	No data available
Explosive properties	:	Not explosive
Oxidizing properties	:	The substance or mixture is not classified as oxidizing.
Molecular weight	:	No data available
Particle size	:	No data available

SECTION 10. STABILITY AND REACTIVITY

Reactivity	:	Not classified as a reactivity hazard.
Chemical stability	:	Stable under normal conditions.
Possibility of hazardous reactions	:	Dust can form an explosive mixture in air. Can react with strong oxidizing agents.
Conditions to avoid	:	None known.
Incompatible materials	:	Oxidizing agents
Hazardous decomposition products	:	No hazardous decomposition products are known.

SECTION 11. TOXICOLOGICAL INFORMATION**Information on likely routes of exposure**

Inhalation
Skin contact
Ingestion
Eye contact

Acute toxicity

Not classified based on available information.

Skin corrosion/irritation

Not classified based on available information.

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Serious eye damage/eye irritation

Not classified based on available information.

Respiratory or skin sensitization**Skin sensitization**

Not classified based on available information.

Respiratory sensitization

Not classified based on available information.

Germ cell mutagenicity

Not classified based on available information.

Carcinogenicity

Not classified based on available information.

IARC

No ingredient of this product present at levels greater than or equal to 0.1% is identified as probable, possible or confirmed human carcinogen by IARC.

OSHA

No component of this product present at levels greater than or equal to 0.1% is on OSHA's list of regulated carcinogens.

NTP

No ingredient of this product present at levels greater than or equal to 0.1% is identified as a known or anticipated carcinogen by NTP.

Reproductive toxicity

May damage fertility. Suspected of damaging the unborn child.

Ingredients:**Gonadotropin, chorionic:**

Effects on fertility

: Test Type: Fertility
Species: Rat
Application Route: Intravenous injection
Fertility: LOAEL: 8.89 mg/kg body weight
Result: Effects on fertility.

Test Type: Fertility
Application Route: Intraperitoneal injection
Fertility: LOAEL: 0.883 mg/kg body weight
Result: Effects on fertility.

Test Type: Fertility
Species: Monkey
Fertility: LOAEL: 0.224 mg/kg body weight
Result: Effects on fertility.

Effects on fetal development

: Test Type: Embryo-fetal development
Species: Hamster
Application Route: Intraperitoneal injection
Embryo-fetal toxicity: LOAEL: 60 mg/kg body weight
Result: Embryo-fetal toxicity.

Reproductive toxicity - As-

: Positive evidence of adverse effects on sexual function and

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assessment fertility from human epidemiological studies., Some evidence of adverse effects on development, based on animal experiments.

STOT-single exposure

Not classified based on available information.

STOT-repeated exposure

Causes damage to organs (ovaries) through prolonged or repeated exposure.

Ingredients:**Gonadotropin, chorionic:**

Target Organs: ovaries

Assessment: Causes damage to organs through prolonged or repeated exposure.

Aspiration toxicity

Not classified based on available information.

Experience with human exposure**Ingredients:****Gonadotropin, chorionic:**

Inhalation : Target Organs: ovaries
Symptoms: effects on menstruation, gynecomastia, Head-ache, mental depression, Irritability, restlessness, Fatigue

SECTION 12. ECOLOGICAL INFORMATION**Ecotoxicity**

No data available

Persistence and degradability

No data available

Bioaccumulative potential

No data available

Mobility in soil

No data available

Other adverse effects

No data available

SECTION 13. DISPOSAL CONSIDERATIONS**Disposal methods**

Waste from residues : Dispose of in accordance with local regulations.

Contaminated packaging : Empty containers should be taken to an approved waste handling site for recycling or disposal.
If not otherwise specified: Dispose of as unused product.

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SECTION 14. TRANSPORT INFORMATION**International Regulations****UNRTDG**

Not regulated as a dangerous good

IATA-DGR

Not regulated as a dangerous good

IMDG-Code

Not regulated as a dangerous good

Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code

Not applicable for product as supplied.

Domestic regulation**49 CFR**

Not regulated as a dangerous good

SECTION 15. REGULATORY INFORMATION**EPCRA - Emergency Planning and Community Right-to-Know****CERCLA Reportable Quantity**

Ingredients	CAS-No.	Component RQ (lbs)	Calculated product RQ (lbs)
Sodium phosphate, dihydrate	10028-24-7	5000	*

*: Calculated RQ exceeds reasonably attainable upper limit.

SARA 304 Extremely Hazardous Substances Reportable Quantity

This material does not contain any components with a section 304 EHS RQ.

SARA 302 Extremely Hazardous Substances Threshold Planning Quantity

This material does not contain any components with a section 302 EHS TPQ.

SARA 311/312 Hazards : Fire Hazard
Chronic Health Hazard

SARA 313 : This material does not contain any chemical components with known CAS numbers that exceed the threshold (De Minimis) reporting levels established by SARA Title III, Section 313.

US State Regulations**Pennsylvania Right To Know**

Gonadotropin, chorionic	9002-61-3
Sodium phosphate, dihydrate	10028-24-7

California Prop. 65

This product does not contain any chemicals known to the State of California to cause cancer, birth, or any other reproductive defects.

The ingredients of this product are reported in the following inventories:

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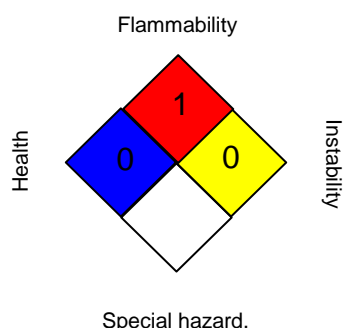
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AICS	:	not determined
DSL	:	not determined
IECSC	:	not determined

SECTION 16. OTHER INFORMATION

Further information

NFPA:



HMIS® IV:

HEALTH	*	3
FLAMMABILITY		3
PHYSICAL HAZARD		0

HMIS® ratings are based on a 0-4 rating scale, with 0 representing minimal hazards or risks, and 4 representing significant hazards or risks. The "*" represents a chronic hazard, while the "/" represents the absence of a chronic hazard.

Full text of other abbreviations

AICS - Australian Inventory of Chemical Substances; ASTM - American Society for the Testing of Materials; bw - Body weight; CERCLA - Comprehensive Environmental Response, Compensation, and Liability Act; CMR - Carcinogen, Mutagen or Reproductive Toxicant; DIN - Standard of the German Institute for Standardisation; DOT - Department of Transportation; DSL - Domestic Substances List (Canada); ECx - Concentration associated with x% response; EHS - Extremely Hazardous Substance; ELx - Loading rate associated with x% response; EmS - Emergency Schedule; ENCS - Existing and New Chemical Substances (Japan); ErCx - Concentration associated with x% growth rate response; ERG - Emergency Response Guide; GHS - Globally Harmonized System; GLP - Good Laboratory Practice; 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; IC50 - Half maximal inhibitory concentration; ICAO - International Civil Aviation Organization; IECSC - Inventory of Existing Chemical Substances in China; IMDG - International Maritime Dangerous Goods; IMO - International Maritime Organization; ISHL - Industrial Safety and Health Law (Japan); ISO - International Organisation for Standardization; KECI - Korea 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; MSHA - Mine Safety and Health Administration; n.o.s. - Not Otherwise Specified; NFPA - National Fire Protection Association; NO(A)EC - No Observed (Adverse) Effect Concentration; NO(A)EL - No Observed (Adverse) Effect Level; NOELR - No Observable Effect Loading Rate; NTP - National Toxicology Program; NZIoC - New Zealand Inventory of Chemicals; OECD - Organization for Economic Co-operation and Development; OPPTS - Office of Chemical Safety and Pollution Prevention; PBT - Persistent, Bioaccumulative and Toxic sub-

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stance; PICCS - Philippines Inventory of Chemicals and Chemical Substances; (Q)SAR - (Quantitative) Structure Activity Relationship; RCRA - Resource Conservation and Recovery Act; REACH - Regulation (EC) No 1907/2006 of the European Parliament and of the Council concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals; RQ - Reportable Quantity; SADT - Self-Accelerating Decomposition Temperature; SARA - Superfund Amendments and Reauthorization Act; SDS - Safety Data Sheet; TCSI - Taiwan Chemical Substance Inventory; TSCA - Toxic Substances Control Act (United States); UN - United Nations; UNRTDG - United Nations Recommendations on the Transport of Dangerous Goods; vPvB - Very Persistent and Very Bioaccumulative

Sources of key data used to compile the Material Safety Data Sheet : Internal technical data, data from raw material SDSs, OECD eChem Portal search results and European Chemicals Agency, <http://echa.europa.eu/>

Revision Date : 06/12/2017

Items where changes have been made to the previous version are highlighted in the body of this document by two vertical lines.

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 is designed only as a guidance for safe handling, use, processing, storage, transportation, disposal and release and shall not be considered a warranty or quality specification of any type. The information provided relates only to the specific material identified at the top of this SDS and may not be valid when the SDS material is used in combination with any other materials or in any process, unless specified in the text. Material users should review the information and recommendations in the specific context of their intended manner of handling, use, processing and storage, including an assessment of the appropriateness of the SDS material in the user's end product, if applicable.

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