

Revision date : 2015/03/24 Page: 1/12
Version: 3.0 (30605894/SDS\_GEN\_US/EN)

### 1. Identification

# Product identifier used on the label

# MasterSeal CR 195 wht also ULTRA WHITE

# Recommended use of the chemical and restriction on use

Recommended use\*: polyurethane component; for industrial and professional users

# Details of the supplier of the safety data sheet

Company: BASF CORPORATION 100 Park Avenue Florham Park, NJ 07932, USA

Telephone: +1 973 245-6000

# **Emergency telephone number**

CHEMTREC: 1-800-424-9300

BASF HOTLINE: 1-800-832-HELP (4357)

Other means of identification

### 2. Hazards Identification

# According to Regulation 2012 OSHA Hazard Communication Standard; 29 CFR Part 1910.1200

# Classification of the product

Eye Dam./Irrit. 2A Serious eye damage/eye irritation

Resp. Sens. 1 Respiratory sensitization Skin Sens. 1 Skin sensitization

### Label elements

Pictogram:

<sup>\*</sup> The "Recommended use" identified for this product is provided solely to comply with a Federal requirement and is not part of the seller's published specification. The terms of this Safety Data Sheet (SDS) do not create or infer any warranty, express or implied, including by incorporation into or reference in the seller's sales agreement.

Revision date: 2015/03/24 Page: 2/12 Version: 3.0 (30605894/SDS GEN US/EN)



Signal Word: Danger

Hazard Statement:

H319 Causes serious eye irritation.

H334 May cause allergy or asthma symptoms or breathing difficulties if

inhaled.

H317 May cause an allergic skin reaction.

Precautionary Statements (Prevention):

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

protection.

P261 Avoid breathing dust/fume/gas/mist/vapours/spray.

P202 Do not handle until all safety precautions have been read and

understood.

P284 [In case of inadequate ventilation] wear respiratory protection.

P272 Contaminated work clothing should not be allowed out of the workplace.

P264 Wash with plenty of water and soap thoroughly after handling.

Precautionary Statements (Response):

P305 + P351 + P338 IF IN EYES: Rinse cautiously with water for several minutes. Remove

contact lenses, if present and easy to do. Continue rinsing.

P304 + P341 + P311 IF INHALED: If breathing is difficult, remove to fresh air and keep at rest

in a position comfortable for breathing. Call a POISON CENTER or

doctor/physician.

P308 + P311 IF exposed or concerned: Call a POISON CENTER or doctor/physician.

P303 + P352 IF ON SKIN (or hair): Wash with plenty of soap and water.
P333 + P311 If skin irritation or rash occurs: Call a POISON CENTER or

doctor/physician.

P362 + P364 Take off contaminated clothing and wash before reuse.

P337 + P311 If eye irritation persists: Call a POISON CENTER or doctor/physician.

Precautionary Statements (Storage):
P405 Store locked up.

Precautionary Statements (Disposal):

P501 Dispose of contents/container to hazardous or special waste collection

point.

### Hazards not otherwise classified

No specific dangers known, if the regulations/notes for storage and handling are considered.

### Labeling of special preparations (GHS):

CONTAINS ISOCYANATES. INHALATION OF ISOCYANATE MISTS OR VAPORS MAY CAUSE RESPIRATORY IRRITATION, BREATHLESSNESS, CHEST DISCOMFORT AND REDUCED PULMONARY FUNCTION. OVEREXPOSURE WELL ABOVE THE PEL MAY RESULT IN BRONCHITIS, BRONCHIAL SPASMS AND PULMONARY EDEMA. LONG-TERM EXPOSURE TO ISOCYANATES HAS BEEN REPORTED TO CAUSE LUNG DAMAGE, INCLUDING REDUCED LUNG FUNCTION WHICH MAY BE PERMANENT. ACUTE OR CHRONIC OVEREXPOSURE TO ISOCYANATES MAY CAUSE SENSITIZATION IN SOME INDIVIDUALS, RESULTING IN ALLERGIC RESPIRATORY REACTIONS INCLUDING WHEEZING, SHORTNESS OF BREATH AND DIFFICULTY BREATHING. ANIMAL TESTS INDICATE THAT SKIN CONTACT MAY PLAY A

Revision date : 2015/03/24 Page: 3/12 Version: 3.0 (30605894/SDS GEN US/EN)

ROLE IN CAUSING RESPIRATORY SENSITIZATION. ANIMAL TESTS AND OTHER RESEARCH INDICATE THAT SKIN CONTACT WITH MDI MAY PLAY A ROLE IN CAUSING RESPIRATORY SENSITIZATION.

# 3. Composition / Information on Ingredients

### According to Regulation 2012 OSHA Hazard Communication Standard; 29 CFR Part 1910.1200

<b>CAS Number</b>	Content (W/W)	Chemical name
1317-65-3	>= 15.0 - < 50.0 %	Limestone
8052-41-3	>= 7.0 - < 10.0 %	Stoddard solvent
13463-67-7	>= 3.0 - < 10.0 %	Titanium dioxide
14807-96-6	>= 1.0 - < 3.0 %	talc
1305-78-8	>= 1.0 - < 3.0 %	calcium oxide
14808-60-7	>= 0.3 - < 1.0 %	crystalline silica
5124-30-1	>= 0.3 - < 1.0 %	4,4'-methylenedicyclohexyl diisoncyanate
77-58-7	>= 0.1 - < 0.2 %	dibutyltin dilaurate

### 4. First-Aid Measures

# **Description of first aid measures**

### General advice:

Remove contaminated clothing.

# If inhaled:

Remove the affected individual into fresh air and keep the person calm. Assist in breathing if necessary. Immediate medical attention required.

### If on skin:

Wash affected areas thoroughly with soap and water. If irritation develops, seek medical attention.

### If in eyes:

In case of contact with the eyes, rinse immediately for at least 15 minutes with plenty of water. Immediate medical attention required.

#### If swallowed:

Rinse mouth and then drink plenty of water. Do not induce vomiting. Never induce vomiting or give anything by mouth if the victim is unconscious or having convulsions. Immediate medical attention required.

# Most important symptoms and effects, both acute and delayed

Symptoms: The most important known symptoms and effects are described in the labelling (see section 2) and/or in section 11., Eye irritation, skin irritation, allergic symptoms Hazards: Symptoms can appear later.

# Indication of any immediate medical attention and special treatment needed

### Note to physician

Antidote: Specific antidotes or neutralizers to isocyanates do not exist.

Treatment: Treatment should be supportive and based on the judgement of the

physician in response to the reaction of the patient.

Revision date: 2015/03/24 Page: 4/12 Version: 3.0 (30605894/SDS GEN US/EN)

# 5. Fire-Fighting Measures

# **Extinguishing media**

Suitable extinguishing media: water spray, dry powder, carbon dioxide, foam

# Special hazards arising from the substance or mixture

Hazards during fire-fighting: nitrous gases, fumes/smoke, isocyanate, vapour

# Advice for fire-fighters

Protective equipment for fire-fighting:

Firefighters should be equipped with self-contained breathing apparatus and turn-out gear.

### Further information:

Keep containers cool by spraying with water if exposed to fire. Dispose of fire debris and contaminated extinguishing water in accordance with official regulations.

### 6. Accidental release measures

### Personal precautions, protective equipment and emergency procedures

Clear area. Ensure adequate ventilation. Wear suitable personal protective clothing and equipment.

### **Environmental precautions**

Do not discharge into drains/surface waters/groundwater.

### Methods and material for containment and cleaning up

For small amounts: Absorb isocyanate with suitable absorbent material (see § 40 CFR, sections 260, 264 and 265 for further information). Shovel into open container. Do not make container pressure tight. Move container to a well-ventilated area (outside). Spill area can be decontaminated with the following recommended decontamination solution: Mixture of 90 % water, 8 % concentrated ammonia, 2 % detergent. Add at a 10 to 1 ratio. Allow to stand for at least 48 hours to allow escape of evolved carbon dioxide.

For large amounts: If temporary control of isocyanate vapor is required, a blanket of protein foam or other suitable foam (available from most fire departments) may be placed over the spill. Transfer as much liquid as possible via pump or vacuum device into closed but not sealed containers for disposal.

For residues: The following measures should be taken for final cleanup: Wash down spill area with decontamination solution. Allow solution to stand for at least 10 minutes. Dike spillage.

# 7. Handling and Storage

### Precautions for safe handling

Provide suitable exhaust ventilation at the processing machines. Ensure thorough ventilation of stores and work areas. Avoid aerosol formation. When handling heated product, vapours of the product should be ventilated, and respiratory protection used. Wear respiratory protection when spraying. Danger of bursting when sealed gastight. Protect against moisture. If bulging of drum occurs, transfer to well ventilated area, puncture to relieve pressure, open vent and let stand for 48 hours before resealing.

Revision date: 2015/03/24 Page: 5/12 Version: 3.0 (30605894/SDS GEN US/EN)

Protection against fire and explosion: No explosion proofing necessary.

# Conditions for safe storage, including any incompatibilities

No applicable information available.

Suitable materials for containers: High density polyethylene (HDPE)

**ACGIH TLV** 

# 8. Exposure Controls/Personal Protection

# Components with occupational exposure limits

dibutyltin dilaurate OSHA PEL PEL 0.1 mg/m3 (tin (Sn)); TWA value 0.1 mg/m3 (tin (Sn)); SKIN\_FINAL (tin (Sn)); The substance can be absorbed through the skin. **ACGIH TLV** TWA value 0.1 mg/m3 (tin (Sn)); STEL value 0.2 mg/m3 (tin (Sn)); Skin Designation (tin (Sn)); The substance can be absorbed through the skin. OSHA PEL PEL 5 mg/m3; TWA value 5 mg/m3; calcium oxide **ACGIH TLV** TWA value 2 mg/m3; Limestone OSHA PEL PEL 5 mg/m3 Respirable fraction; PEL 15 mg/m3 Total dust; TWA value 15 mg/m3 Total dust; TWA value 5 mg/m3 Respirable fraction 4,4'-methylenedicyclohexyl CLV 0.01 ppm 0.11 mg/m3; OSHA PEL diisoncyanate TWA value 0.005 ppm; **ACGIH TLV** Titanium dioxide OSHA PEL PEL 15 mg/m3 Total dust; TWA value 10 mg/m3 Total dust;

TWA value 10 mg/m3;

Revision date : 2015/03/24 Page: 6/12 Version: 3.0 (30605894/SDS GEN US/EN)

talc

### OSHA PEL

TWA value 20 millions of particles per cubic foot of air; TWA value 2.4 millions of particles per cubic foot of air Respirable;

The exposure limit is calculated from the equation, 250/(%SiO2+5), using a value of 100% SiO2. Lower percentages of SiO2 will yield higher exposure limits.

TWA value 0.1 mg/m3 Respirable; The exposure limit is calculated from the equation, 10/(%SiO2+2), using a value of 100% SiO2. Lower percentages of SiO2 will yield higher exposure limits.

TWA value 0.3 mg/m3 Total dust; The exposure limit is calculated from the equation, 30/(%SiO2+2), using a value of 100% SiO2. Lower percentages of SiO2 will yield higher exposure limits.

TWA value 2 mg/m3 Respirable dust; TWA value 0.3 mg/m3 Total dust;

The exposure limit is calculated from the equation, 30/(%SiO2+2), using a value of 100% SiO2. Lower percentages of SiO2 will yield higher exposure limits.

TWA value 0.1 mg/m3 Respirable; The exposure limit is calculated from the equation, 10/(%SiO2+2), using a value of 100% SiO2. Lower percentages of SiO2 will yield higher exposure limits.

TWA value 2.4 millions of particles per cubic foot of air Respirable;

The exposure limit is calculated from the equation, 250/(%SiO2+5), using a value of 100% SiO2. Lower percentages of SiO2 will yield higher exposure limits.

TWA value 20 millions of particles per cubic foot of air :

**ACGIH TLV** 

TWA value 2 mg/m3 Respirable fraction; The value is for particulate matter containing no asbestos and <1% crystalline silica.

crystalline silica

**OSHA PEL** 

TWA value 2.4 millions of particles per cubic foot of air Respirable;

The exposure limit is calculated from the equation, 250/(%SiO2+5), using a value of 100% SiO2. Lower percentages of SiO2 will yield higher exposure limits.

TWA value 0.1 mg/m3 Respirable; The exposure limit is calculated from the equation, 10/(%SiO2+2), using a value of 100% SiO2. Lower percentages of SiO2 will yield higher exposure limits.

TWA value 0.3 mg/m3 Total dust; The exposure limit is calculated from the equation, 30/(%SiO2+2), using a value of 100% SiO2. Lower percentages of SiO2 will yield higher exposure limits.

Revision date: 2015/03/24 Page: 7/12 Version: 3.0 (30605894/SDS GEN US/EN)

> **ACGIH TLV** TWA value 0.025 mg/m3 Respirable fraction;

OSHA PEL PEL 500 ppm 2,900 mg/m3; Stoddard solvent

> ACGIH TLV TWA value 100 ppm;

Stoddard solvent OSHA PEL PEL 500 ppm 2,900 mg/m3;

> **ACGIH TLV** TWA value 100 ppm;

# Advice on system design:

Provide local exhaust ventilation to maintain recommended P.E.L.

### Personal protective equipment

### Respiratory protection:

When workers are facing concentrations above the occupational exposure limits they must use appropriate certified respirators. When atmospheric levels may exceed the occupational exposure limit (PEL or TLV) NIOSH-certified air-purifying respirators equipped with an organic vapor sorbent and particulate filter can be used as long as appropriate precautions and change out schedules are in place. For emergency or non-routine, high exposure situations, including confined space entry, use a NIOSH-certified full facepiece pressure demand self-contained breathing apparatus (SCBA) or a full facepiece pressure demand supplied-air respirator (SAR) with escape provisions.

### Hand protection:

Chemical resistant protective gloves should be worn to prevent all skin contact.. Suitable materials may include, chloroprene rubber (Neoprene), nitrile rubber (Buna N), chlorinated polyethylene, polyvinylchloride (Pylox), butyl rubber, depending upon conditions of use.

# Eye protection:

Tightly fitting safety goggles (chemical goggles). Wear face shield if splashing hazard exists.

#### **Body protection:**

Cover as much of the exposed skin as possible to prevent all skin contact., Suitable materials may include, saran-coated material, depending upon conditions of use.

### General safety and hygiene measures:

Wear protective clothing as necessary to prevent contact. Eye wash fountains and safety showers must be easily accessible. Observe the appropriate PEL or TLV value. Wash soiled clothing immediately. Contaminated equipment or clothing should be cleaned after each use or disposed of.

# 9. Physical and Chemical Properties

Form: paste Odour: solvent-like

Odour threshold:

Vapour pressure:

Colour: various colours

pH value:

Melting point:

Boiling point: approx. 156 °C

Sublimation point:

No applicable information available. Flash point: Substance/product is non-flammable. The product does not burn self-

sustainingly.

not applicable

Flammability: Not flammable.

Lower explosion limit: Upper explosion limit:

No applicable information available. No applicable information available. No applicable information available.

No applicable information available.

No applicable information available.

Revision date: 2015/03/24 Page: 8/12 Version: 3.0 (30605894/SDS GEN US/EN)

Density: approx. 1.10 (20 °C)

g/cm3

Relative density: No applicable information available.

Vapour density: Heavier than air.

Partitioning coefficient nootanol/water (log Pow):

No applicable information available.

Thermal decomposition: No decomposition if stored and handled as

prescribed/indicated.

Viscosity, dynamic: approx. 4,000 - (20 °C)

8,000 poise

Viscosity, kinematic: No applicable information available.

Solubility in water: (20 °C) slightly soluble Miscibility with water: (20 °C) not soluble

Solubility (quantitative): No applicable information available.

Solubility (qualitative): No applicable information available.

Evaporation rate: No applicable information available.

# 10. Stability and Reactivity

# Reactivity

No applicable information available.

Corrosion to metals:

Corrosive effects to metal are not anticipated.

# **Chemical stability**

The product is stable if stored and handled as prescribed/indicated.

# Possibility of hazardous reactions

Reacts with water, with formation of carbon dioxide. Risk of bursting. Reacts with alcohols. Reacts with acids. Reacts with alkalies. Reacts with amines. Risk of exothermic reaction. Risk of polymerization. Contact with certain rubbers and plastics can cause brittleness of the substance/product with subsequent loss in strength.

# Conditions to avoid

Avoid moisture.

### Incompatible materials

acids, amines, alcohols, water, Alkalines, strong bases, Substances/products that react with isocyanates.

# Hazardous decomposition products

Decomposition products:

Hazardous decomposition products: carbon monoxide, carbon dioxide, nitrogen oxide, hydrogen cyanide, nitrogen oxides, aromatic isocyanates, gases/vapours

Thermal decomposition:

No decomposition if stored and handled as prescribed/indicated.

# 11. Toxicological information

### Primary routes of exposure

Revision date: 2015/03/24 Page: 9/12 Version: 3.0 (30605894/SDS GEN US/EN)

Routes of entry for solids and liquids are ingestion and inhalation, but may include eye or skin contact. Routes of entry for gases include inhalation and eye contact. Skin contact may be a route of entry for liquefied gases.

# **Acute Toxicity/Effects**

#### **Acute toxicity**

Assessment of acute toxicity: No applicable information available.

#### Oral

No applicable information available.

### Inhalation

No applicable information available.

#### Dermal

No applicable information available.

### Assessment other acute effects

No applicable information available.

### Irritation / corrosion

Assessment of irritating effects: Eye contact causes irritation.

# Sensitization

Assessment of sensitization: The substance may cause sensitization of the respiratory tract. Sensitization after skin contact possible.

### **Chronic Toxicity/Effects**

### Repeated dose toxicity

Assessment of repeated dose toxicity: No applicable information available.

### Genetic toxicity

Assessment of mutagenicity: No applicable information available.

#### Carcinogenicity

#### Information on: Titanium dioxide

Assessment of carcinogenicity: IARC (International Agency for Research on Cancer) has classified this substance as group 2B (The agent is possibly carcinogenic to humans). In long-term studies in rats in which the substance was given by inhalation, a carcinogenic effect was observed. Tumors were only observed in rats after chronic inhalative exposure to high concentrations which caused sustained lung inflammation. In long-term studies in rats and mice in which the substance was given by feed, a carcinogenic effect was not observed. Dermal exposure is not expected to be carcinogenic.

# Information on: crystalline silica

Assessment of carcinogenicity: In long-term studies in rats and mice in which the substance was given by feed, a carcinogenic effect was not observed. In long-term animal studies in which the substance was given by inhalation in high doses, a carcinogenic effect was observed. The substance and its compounds in the form of respirable dusts/aerosolsis classified by the German MAK commision as a category 1 carcinogen (substances that cause cancer to humans). A carcinogenic effect cannot safely be ruled out. The inhalation uptake of the alveolar fraction of the fine dust may cause damage to the lungs. The International Agency for Research on Cancer (IARC) has classified this substance as a Group 1 (known) human carcinogen.

-----

Revision date: 2015/03/24 Page: 10/12 Version: 3.0 (30605894/SDS GEN US/EN)

#### Reproductive toxicity

Assessment of reproduction toxicity: No applicable information available.

### Other Information

The product has not been tested. The statement has been derived from the properties of the individual components.

### **Symptoms of Exposure**

The most important known symptoms and effects are described in the labelling (see section 2) and/or in section 11.. Eye irritation, skin irritation, allergic symptoms

### Medical conditions aggravated by overexposure

The isocyanate component is a respiratory sensitizer. It may cause allergic reaction leading to asthma-like spasms of the bronchial tubes and difficulty in breathing. Medical supervision of all employees who handle or come into contact with isocyanates is recommended. Contact may aggravate pulmonary disorders. Persons with history of respiratory disease or hypersensitivity should not be exposed to this product. Preemployment and periodic medical examinations with respiratory function tests (FEV, FVC as a minimum) are suggested. Persons with asthmatic conditions, chronic bronchitis, other chronic respiratory diseases, recurrent eczema or pulmonary sensitization should be excluded from working with isocyanates. Once a person is diagnosed as having pulmonary sensitization (allergic asthma) to isocyanates, further exposure is not recommended.

# 12. Ecological Information

### **Toxicity**

Aquatic toxicity

Assessment of aquatic toxicity:

There is a high probability that the product is not acutely harmful to aquatic organisms.

### **Additional information**

# Other ecotoxicological advice:

Do not discharge product into the environment without control. The product has not been tested. The statements on ecotoxicology have been derived from the properties of the individual components.

# 13. Disposal considerations

### Waste disposal of substance:

Incinerate or dispose of in a licensed facility. Do not discharge substance/product into sewer system.

# Container disposal:

DRUMS:

Steel drums must be emptied and can be sent to a licensed drum reconditioner for reuse, a scrap metal dealer or an approved landfill. Do not attempt to refill or clean containers since residue is difficult to remove. Under no circumstances should empty drums be burned or cut open with gas or electric torch as toxic decomposition products may be liberated. Do not reuse empty containers.

# 14. Transport Information

### Land transport

Revision date: 2015/03/24 Page: 11/12 Version: 3.0 (30605894/SDS GEN US/EN)

USDOT

Not classified as a dangerous good under transport regulations

Sea transport

**IMDG** 

Not classified as a dangerous good under transport regulations

Air transport IATA/ICAO

Not classified as a dangerous good under transport regulations

# 15. Regulatory Information

# **Federal Regulations**

Registration status:

Chemical TSCA, US released / listed

EPCRA 311/312 (Hazard categories): Acute; Chronic

**CERCLA RQ** CAS Number **Chemical name** 5000 LBS 7664-38-2 phosphoric acid

108-88-3 1000 LBS Toluene

100 LBS 108-90-7; 78-84-2 chlorobenzene; isobutyraldehyde

### State regulations

**CA Prop. 65:** 

WARNING: THIS PRODUCT CONTAINS A CHEMICAL(S) KNOWN TO THE STATE OF CALIFORNIA TO CAUSE CANCER AND BIRTH DEFECTS OR OTHER REPRODUCTIVE HARM.

**NFPA Hazard codes:** 

Health: 2 Fire: 0 Reactivity: 0 Special:

**HMIS III rating** 

Health: 2¤ Flammability: 0 Physical hazard: 0

### 16. Other Information

### SDS Prepared by:

**BASF NA Product Regulations** SDS Prepared on: 2015/03/24

We support worldwide Responsible Care® initiatives. We value the health and safety of our employees, customers, suppliers and neighbors, and the protection of the environment. Our commitment to Responsible Care is integral to conducting our business and operating our facilities in a safe and environmentally responsible fashion, supporting our customers and suppliers in ensuring the safe and environmentally sound handling of our products, and minimizing the impact of our operations on society and the environment during production, storage, transport, use and disposal of our products.

Revision date: 2015/03/24 Page: 12/12 Version: 3.0 (30605894/SDS GEN US/EN)

IMPORTANT: WHILE THE DESCRIPTIONS, DESIGNS, DATA AND INFORMATION CONTAINED HEREIN ARE PRESENTED IN GOOD FAITH AND BELIEVED TO BE ACCURATE, IT IS PROVIDED FOR YOUR GUIDANCE ONLY. BECAUSE MANY FACTORS MAY AFFECT PROCESSING OR APPLICATION/USE, WE RECOMMEND THAT YOU MAKE TESTS TO DETERMINE THE SUITABILITY OF A PRODUCT FOR YOUR PARTICULAR PURPOSE PRIOR TO USE. NO WARRANTIES OF ANY KIND, EITHER EXPRESSED OR IMPLIED, INCLUDING WARRANTIES OF MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE. ARE MADE REGARDING PRODUCTS DESCRIBED OR DESIGNS, DATA OR INFORMATION SET FORTH, OR THAT THE PRODUCTS, DESIGNS, DATA OR INFORMATION MAY BE USED WITHOUT INFRINGING THE INTELLECTUAL PROPERTY RIGHTS OF OTHERS. IN NO CASE SHALL THE DESCRIPTIONS, INFORMATION, DATA OR DESIGNS PROVIDED BE CONSIDERED A PART OF OUR TERMS AND CONDITIONS OF SALE. FURTHER, YOU EXPRESSLY UNDERSTAND AND AGREE THAT THE DESCRIPTIONS, DESIGNS, DATA, AND INFORMATION FURNISHED BY OUR COMPANY HEREUNDER ARE GIVEN GRATIS AND WE ASSUME NO OBLIGATION OR LIABILITY FOR THE DESCRIPTION, DESIGNS, DATA AND INFORMATION GIVEN OR RESULTS OBTAINED, ALL SUCH BEING GIVEN AND ACCEPTED AT YOUR RISK. BASF CORPORATION WILL NOT MAKE ITS PRODUCTS AVAILABLE TO CUSTOMERS FOR USE IN THE MANUFACTURE OF MEDICAL DEVICES WHICH ARE INTENDED FOR PERMANENT IMPLANTATION IN THE HUMAN BODY OR IN PERMANENT CONTACT WITH INTERNAL BODILY TISSUES OR FLUIDS.

**END OF DATA SHEET**