

SAFETY DATA SHEET

1 PRODUCT AND COMPANY IDENTIFICATION

Product name: Porcine Circovirus, Type 2**SDS No:** P00000020326**Synonyms, Trade Names:**

Circumvent PCV G2, Circumvent PCV

Manufacturer:Merck
One Merck Drive P.O. Box 100
Whitehouse Station, NJ, USA 08889-0100**Telephone:** 908-423-1000 (General Information Only)**Fax:** 908-735-1496**Contact Person:** EHS Data Steward**e-mail:** MSDS@merck.com**Emergency telephone:** 1-908-423-6000
(24/7/365) English Only**Intended Use:** Vaccine Intermediate.

2 HAZARDS IDENTIFICATION

Emergency Overview:**Appearance:****Color:** Almost white
Form : Emulsion**Signal words** WARNING!**Potential Health Effects:****General** Exposure to solution may cause irritaiton. Avoid breathing mist or vapor. Avoid contact with eyes, skin, and clothing. Wash thoroughly after handling.**Potential Physical / Chemical Effects:**

None under normal conditions.

Inhalation:

May cause irritation. Avoid breathing substance.

skin:

May cause skin irritation.

eye:

May cause irritation.

Ingestion:

No data available.

Routes of Exposure:

Inhalation, eye

Target Organs:

Not Applicable

Environment:

The environmental hazards and fate of this material have not been characterized.

OTHER INFORMATION

The toxicological properties of this material have not been evaluated.The

vaccine is produced by growing bacteria. The bacteria are killed chemically. The vaccine does not contain live bacteria; therefore it is not infectious to humans or animals.

3 COMPOSITION / INFORMATION ON INGREDIENTS

General information: The formulation for this product is proprietary information. Only hazardous ingredients in concentrations of 1% or greater and/or carcinogenic ingredients in concentrations of 0.1% or greater are listed in the composition table. Active ingredients in any concentration are listed. The safety and health characteristics of these biological materials have not been fully characterized.

Hazardous Component(s):

Chemical name	CAS-No.	Concentration
Mineral Oil	8012-95-1	
Porcine Circovirus Type 2 antigen		

* All concentrations are percent by weight unless ingredient is a gas. Gas concentrations are in percent by volume.

4 FIRST AID MEASURES

Inhalation: Move into fresh air and keep at rest. For breathing difficulties, oxygen may be necessary. Get medical attention. If breathing stops, provide artificial respiration.

Skin contact: Wash skin thoroughly with soap and water. Get medical attention if irritation persists after washing. Remove contaminated clothing and shoes. Wash contaminated clothing before reuse. Destroy or thoroughly clean contaminated shoes.

Eye contact: Immediately flush with plenty of water for at least 15 minutes. If easy to do, remove contact lenses. Get medical attention.

Ingestion: Do not induce vomiting unless directed to do so by medical personnel. Never give liquid to an unconscious person. Get medical attention.

Notes to the physician:

Hazards: See Sections 2 and 11.

Treatment: Treat supportively and symptomatically.

5 FIRE-FIGHTING MEASURES

Extinguishing media: Water spray, fog, CO₂, dry chemical, or alcohol resistant foam.

Unsuitable extinguishing media: None known.

Unusual Fire & Explosion Hazards: Emits toxic fumes under fire conditions.

Special Fire Fighting Procedures: Self-contained breathing apparatus and full protective clothing must be worn in case of fire.

Protective Measures: Prevent runoff from fire control or dilution from entering streams, sewers, or drinking water supply.

6 ACCIDENTAL RELEASE MEASURES

Personal precautions: Use personal protective equipment. Immediately contact emergency personnel. Keep unnecessary personnel away. Follow all fire fighting procedures.

Environmental precautions: Do not release into the environment.

Spill Cleanup Methods: Small Liquid Spills: Absorb up with sand or other non-combustible absorbent material. Large quantities should not be discharged into the drain but removed with absorbing material. For waste disposal, see section 13 of the MSDS. Prevent runoff from entering drains, sewers, or streams.

7 HANDLING AND STORAGE

Handling: Avoid breathing mists or vapors. Avoid contact with eyes, skin, and clothing. Wash thoroughly after handling.

Storage: Keep container tightly closed in a cool, well-ventilated place.

8 EXPOSURE CONTROLS / PERSONAL PROTECTION
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Exposure limits:

Chemical name	Type	Exposure Limit values	Source
Mineral Oil - Inhalable fraction.	TWA	5 mg/m ³	US. ACGIH Threshold Limit Values (01 2010)
Mineral Oil - Mist.	PEL	5 mg/m ³	US. OSHA Table Z-1 Limits for Air Contaminants (29 CFR 1910.1000) (02 2006)
Porcine Circovirus Type 2 antigen	TWA	OEB 3 (10 - 100 ug/m ³)	Merck

OEB (Occupational Exposure Band) is an internal Merck control band.

Protective Measures: Observe occupational exposure limits and minimize the risk of inhalation of vapors and mist. Minimize open handling. Containment technologies suitable for controlling compounds are required to control at source and to prevent migration of the compound to uncontrolled areas (e.g., open-face containment devices).

Respiratory Protection: Use an appropriate approved air-purifying respirator equipped with HEPA cartridges/canisters where there is the potential for exceeding established occupational exposure limits or occupational exposure bands. Powered air filter respirator. Use a positive pressure, air-supplied, pressure demand tight fitting respirator (e.g., SCBA or airline equipped with emergency escape bottle) where there is a potential for uncontrolled releases in excess of the respirator's capabilities, where exposure levels are unknown or where air-purifying respirators may not provide adequate protection.

Hand protection: Chemical resistant gloves. Consider double gloving.

Eye protection: Wear safety glasses with side shields (or goggles). Wear appropriate splash goggles if there is a potential for direct contact with liquid splash, mists or aerosols.

Skin and Body Protection: Additional body garments should be used based upon the task being performed (e.g., sleevelets, apron, gauntlets, disposable suits) to avoid exposed skin surfaces. Use appropriate degowning techniques to remove potentially contaminated clothing.

Hygiene measures: Wash skin thoroughly with soap and water.

9 PHYSICAL AND CHEMICAL PROPERTIES

Information on basic physical and chemical properties

Appearance:

Physical State:	Liquid
Form:	Emulsion
Color:	Almost white
pH:	7.0 - 7.6 (25 °C)

10 STABILITY AND REACTIVITY

Stability:	Stable
Possibility of hazardous reactions:	Stable
Conditions to avoid:	None at ambient temperatures.
Incompatible materials:	No data available.
Hazardous decomposition products:	Thermal decomposition or combustion may liberate carbon oxides and other toxic gases or vapors.

11 TOXICOLOGICAL INFORMATION

Specified substance(s):

Acute Toxicity (Oral);

Name Mineral Oil	Test results LD50 (Rat): 24 g/kg LD50 (Mouse): 22 g/kg
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Acute Toxicity (Dermal):

Name Mineral Oil	Test results No data available.
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Acute Toxicity (Inhalation):

Name Mineral Oil	Test results LC50 (Rat, 4 h): 2062 ppm
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Repeated dose toxicity:

Name Mineral Oil	Test results LOAEL (Dog, Inhalation, 24 Months, 6 h/day, 5d/week): 100 mg/m ³ (Target Organ(s): lung) NOAEL (Rat, Oral, 3 Months): 2 mL/kg No significant adverse effects were reported.
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Inhalation: May cause lipid pneumonia. Aspiration hazard.

Ingestion:	Practically non-toxic if swallowed.
Skin corrosion/irritation:	Slightly irritating to the skin.
Serious eye damage/eye irritation:	Mildly to moderately irritating to the eyes.
Respiratory sensitizer/Skin sensitizer:	No data available.
Carcinogenicity:	No data available.
Mutagenesis:	No data available.
Reproductive toxicity:	No data available.

12 ECOLOGICAL INFORMATION

Ecotoxicity:

Specified substance(s):

Acute toxicity(Fish):

Name	Test results
Mineral Oil	No data available.

Chronic Toxicity(Fish):

Name	Test results
Mineral Oil	No data available.

Acute toxicity(Aquatic invertebrates):

Name	Test results
Mineral Oil	No data available.

Chronic Toxicity(Aquatic invertebrates):

Name	Test results
Mineral Oil	No data available.

Acute toxicity(Aquatic plants):

Name	Test results
Mineral Oil	No data available.

Persistence and degradability: No data available.

Bioaccumulative potential: No data available.

Mobility:

13 DISPOSAL CONSIDERATIONS

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

Measures for Avoidance and Recovery:

Incineration is the most effective method of disposal in most instances. Do not allow runoff to sewer, waterway or ground. Operations that involve the crushing or shredding of waste materials or returned goods should take into account recommended exposure limits where they exist.

14 TRANSPORT INFORMATION

DOT

Not regulated.

IMDG - International Maritime Dangerous Goods Code

Not regulated.

IATA - International Air Transport Association

Not regulated.

15 REGULATORY INFORMATION

US Regulations

● **CERCLA Hazardous Substance List (40 CFR 302.4):**

None

● **Clean Water Act Section 311 Hazardous Substances (40 CFR 117.3):**

None

● **Clean Air Act (CAA) Section 112(r) Accidental Release Prevention (40 CFR 68.130):**

None

SARA Title III

● **Section 302 Extremely Hazardous Substance (40 CFR 355, Appendix A):**

None

● **Section 313 Toxic Release Inventory (40 CFR 372):**

None present or none present in regulated quantities.

State Regulations

● **California Safe Drinking Water and Toxic Enforcement Act of 1986 (Proposition 65):**

No ingredient regulated by CA Prop 65 present.

● **Massachusetts Right-To-Know List:**

Mineral Oil Listed

● **New Jersey Right-To-Know List:**

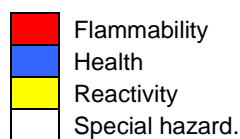
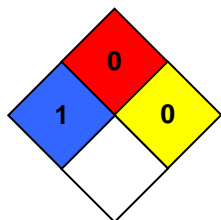
Mineral Oil Listed

● **Pennsylvania Right-To-Know List:**

Mineral Oil Listed

16 OTHER INFORMATION**OTHER INFORMATION**

Experimental research and development material. Health hazard data above is estimated based on best available information.

NFPA Hazard ID

Hazard rating: 0 - Minimal; 1 - Slight; 2 - Moderate; 3 - Serious; 4 - Severe

Revision Information:

Not relevant.

Issue Date:

06.09.2013

Disclaimer:

This information is provided without warranty. The information is believed to be correct. This information should be used to make an independent determination of the methods to safeguard workers and the environment.