

Ortho Clinical Diagnostics

a *Johnson & Johnson* company

SAFETY DATA SHEET

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

Product code: OCDUS8568040
Issuing date: 03-02-2009
Revision date: 08-24-2012

1. IDENTIFICATION OF THE SUBSTANCE/PREPARATION AND OF THE COMPANY/UNDERTAKING

Supplier:
Ortho-Clinical Diagnostics, Inc.
100 Indigo Creek Drive
Rochester, NY 14626-5101

Importer:
OCD ESC
24, Bld Sebastien Brant BP 30335
Illkirch Graffenstaden
67411
France

Customer service telephone: 1-800-421-3311 (USA only)
+1 585-453-3030 (Outside of USA)

Product name: VITROS Chemistry Products Calibrator Kit 9 (Vials 1-3)
Product code: OCDUS8568040
Pure substance/preparation: Preparation

Contact person:
Responsible/Issuing person: No information available
E-mail address: www.orthoclinical.com

Emergency telephone number: (800) 424-9300 ChemTrec (24 hours)
(703) 527-3887 (International - 24 hours)

2. HAZARDS IDENTIFICATION

Classification and labeling: The preparation is classified as dangerous in accordance with Directive 1999/45/EC

Classification: R43
Indication of danger: Xi - Irritant.

**Most important hazards****Risk Phrase** R43 - May cause sensitization by skin contact.**General hazard information:** Avoid contact with skin and eyes.
Product contains animal-derived material.**Carcinogenicity rating:**
Johnson & Johnson: None.
European Union: None.

3. COMPOSITION/INFORMATION ON INGREDIENTS

Chemical nature of the preparation:

Buffer solution

Components	CAS Number	Weight %	REACH No.	EINECS-No.	Synonyms	Classification
Phenytoin	57-41-0	<0.5		2003286 Listed.		
ProClin 300	PRO300	0.05				C;R34 N;R51-53 R43 Xn;R20/21/22
Acetaminophen	103-90-2	<0.1		203-157-5		Xn;R22
Phenobarbital	50-06-6	<0.1				
Digoxin	20830-75-5	<0.1				
Carbamazepine	298-46-4	<0.1				

Components	EINECS-No.	CAS Number	Weight %	REACH Substances of Very High Concern
Phenytoin	2003286 Listed.	57-41-0	<0.5	
Acetaminophen	203-157-5	103-90-2	<0.1	

4. FIRST AID MEASURES

Eye contact: In the case of contact with eyes, rinse immediately with plenty of water for 15 minutes and seek medical attention.

Skin contact: Wash off immediately with soap and plenty of water. If a person feels unwell or symptoms of skin irritation appear, consult a physician.

Ingestion: If ingested, seek medical attention immediately and show the label.

Inhalation: Move to fresh air immediately. If experiencing difficulty breathing, seek medical attention.

Protection of first-aiders: Wear suitable gloves and eye/face protection.

5. FIRE-FIGHTING MEASURES

Suitable extinguishing media: Use any extinguishing media which is suitable for the surrounding fire.

Extinguishing media which must not be used for safety reasons:

None.

Special exposure hazards arising from the substance or preparation itself, combustion products, resulting gases:

None reasonably foreseeable.

Combustion products or resulting gases:

Carbon dioxide, carbon monoxide, oxides of nitrogen. Sulphur oxides.

Special protective equipment for firefighters:

Wear self-contained breathing apparatus and protective suit.

6. ACCIDENTAL RELEASE MEASURES

Personal precautions:

Wear suitable gloves and eye/face protection 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.

Environmental precautions:

Waste disposal must be in accordance with appropriate US, Federal, State and International regulations.

Methods for cleaning up:

Clean contaminated surface thoroughly. Wipe up with absorbent material (e.g. cloth, fleece). Clean with disinfectants.

7. HANDLING AND STORAGE

Handling:

Technical measures/precautions:

Wear protective safety glasses, gloves and clothing.

Safe handling advice:

Wear disposable gloves while handling reagents. Thoroughly wash hands afterwards. Always replace cap after use.

Storage:

Technical measures/storage conditions:

Store at or below -18°C (0°F).

Incompatible products:

No special restrictions on storage with other products.

Specific use(s):

None under normal use.

8. EXPOSURE CONTROLS / PERSONAL PROTECTION

Exposure limits:

Components	J&J - OEL (TWA - 8 hr)	J&J - OEL (STEL)	J&J - OEL (Ceiling)	J&J - PBOEL	ASL
ProClin 300 (0.05%) PRO300				Category 4	
Acetaminophen (<0.1%) 103-90-2	3 mg/m ³			Category 1	

Components	European Union	France	Germany	Switzerland	The Netherlands	The United Kingdom
Phenytoin (<0.5%) 57-41-0	N/A	N/A	N/A	N/A	N/A	N/A
ProClin 300 (0.05%) PRO300	N/A	N/A	N/A	N/A	N/A	N/A
Acetaminophen (<0.1%) 103-90-2	N/A	N/A	N/A	N/A	N/A	STEL 30 mg/m ³ TWA 10 mg/m ³
Phenobarbital (<0.1%) 50-06-6	N/A	N/A	N/A	N/A	N/A	N/A
Digoxin (<0.1%) 20830-75-5	N/A	N/A	N/A	N/A	N/A	N/A
Carbamazepine (<0.1%) 298-46-4	N/A	N/A	N/A	N/A	N/A	N/A

Components	Spain	Italy	Portugal	Finland	Denmark	Austria
Phenytoin (<0.5%) 57-41-0	N/A	N/A	N/A	N/A	N/A	N/A
ProClin 300 (0.05%) PRO300	N/A	N/A	N/A	N/A	N/A	N/A
Acetaminophen (<0.1%) 103-90-2	N/A	N/A	N/A	N/A	N/A	N/A

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Product code: OCDUS8568040

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Components	Spain	Italy	Portugal	Finland	Denmark	Austria
Phenobarbital (<0.1%) 50-06-6	N/A	N/A	N/A	N/A	N/A	N/A
Digoxin (<0.1%) 20830-75-5	N/A	N/A	N/A	N/A	N/A	N/A
Carbamazepine (<0.1%) 298-46-4	N/A	N/A	N/A	N/A	N/A	N/A

Components	Norway	Poland	Ireland	Belgium	Bulgaria	Czech Republic
Phenytoin (<0.5%) 57-41-0	N/A	N/A	N/A	N/A	N/A	N/A
ProClin 300 (0.05%) PRO300	N/A	N/A	N/A	N/A	N/A	N/A
Acetaminophen (<0.1%) 103-90-2	N/A	N/A	TWA 10 mg/m ³	N/A	N/A	N/A
Phenobarbital (<0.1%) 50-06-6	N/A	N/A	N/A	N/A	N/A	N/A
Digoxin (<0.1%) 20830-75-5	N/A	N/A	N/A	N/A	N/A	N/A
Carbamazepine (<0.1%) 298-46-4	N/A	N/A	N/A	N/A	N/A	N/A

Components	Estonia	Greece	Hungary	Latvia	Lithuania	Luxembourg
Phenytoin (<0.5%) 57-41-0	N/A	N/A	N/A	N/A	N/A	N/A
ProClin 300 (0.05%) PRO300	N/A	N/A	N/A	N/A	N/A	N/A
Acetaminophen (<0.1%) 103-90-2	N/A	N/A	N/A	N/A	N/A	N/A
Phenobarbital (<0.1%) 50-06-6	N/A	N/A	N/A	N/A	N/A	N/A
Digoxin (<0.1%) 20830-75-5	N/A	N/A	N/A	N/A	N/A	N/A
Carbamazepine (<0.1%) 298-46-4	N/A	N/A	N/A	N/A	N/A	N/A

Components	Slovenia	Slovakia	Sweden	Cyprus	Malta	Romania
Phenytoin (<0.5%) 57-41-0	N/A	N/A	N/A	N/A	N/A	N/A
ProClin 300 (0.05%) PRO300	N/A	N/A	N/A	N/A	N/A	N/A
Acetaminophen (<0.1%) 103-90-2	N/A	N/A	N/A	N/A	N/A	N/A
Phenobarbital (<0.1%) 50-06-6	N/A	N/A	N/A	N/A	N/A	N/A
Digoxin (<0.1%) 20830-75-5	N/A	N/A	N/A	N/A	N/A	N/A
Carbamazepine (<0.1%) 298-46-4	N/A	N/A	N/A	N/A	N/A	N/A

Components	Argentina	Brazil	Chile	Venezuela	Chile Prohibited Substances List
Phenytoin (<0.5%) 57-41-0	N/A	N/A	N/A	N/A	N/A
ProClin 300 (0.05%) PRO300	N/A	N/A	N/A	N/A	N/A
Acetaminophen (<0.1%) 103-90-2	N/A	N/A	N/A	N/A	N/A
Phenobarbital (<0.1%) 50-06-6	N/A	N/A	N/A	N/A	N/A
Digoxin (<0.1%) 20830-75-5	N/A	N/A	N/A	N/A	N/A
Carbamazepine (<0.1%) 298-46-4	N/A	N/A	N/A	N/A	N/A

Exposure controls / personal protection

Engineering controls:	Ensure adequate ventilation. Eye baths, washing facilities, and safety shower.
Respiratory protection:	None required.
Hand protection:	Wear disposable gloves while handling kit reagents. Thoroughly wash hands afterwards..
Eye protection:	Wear eye/face protection
Skin and body protection	Wear suitable protective clothing. Wear suitable gloves and eye/face protection.

Environmental exposure controls No information available

9. PHYSICAL AND CHEMICAL PROPERTIES

General Information

Physical state:	Refrigerated, Liquid
Appearance:	Transparent
Color:	Gold
Odor:	Odorless

Important Health Safety and Environmental Information

Flash point:	Not determined.	Boiling point/range:	No information available.
pH:	7.8		
Flammability (solid, gas):	No information available		
Explosivity:	No information available		
Oxidizing properties:	No information available		
Vapor pressure:	No information available		
Specific gravity:	~1		
Density (20/4):	No information available		
Water solubility:	No information available		
Solubility in other solvents:	No information available		
Partition coefficient (n-octanol/water):	No information available		
Viscosity:	No information available		
Vapor density:	No information available		
Evaporation rate:	No information available		

Other information

Autoignition temperature:	No information available	Melting point/range:	No information available
Miscibility	No information available		
Fat solubility (g/l)	No information available		
Volume resistivity or conductivity:	No information available		
Gas Group	No information available		

10. STABILITY AND REACTIVITY

Chemical stability:	Stable under recommended storage conditions.
Materials to avoid:	No data available.
Conditions to avoid:	Do not freeze.
Hazardous polymerization:	Hazardous polymerization does not occur.
Possibility of hazardous reactions:	No information available
Hazardous decomposition products:	None known.

11. TOXICOLOGICAL INFORMATION

Acute toxicity

- Eye contact** May cause eye irritation.
- Skin contact** May cause sensitization by skin contact.
- Ingestion** Not available. Not expected to be toxic if swallowed.
- Inhalation** Not expected to be toxic if inhaled.

Components	LD50 Oral	LD50 Dermal	LC50 (mg/m ³) Inhalation	LC50 (ppm) Inhalation
Phenytoin (<0.5%) 57-41-0	1635			
ProClin 300 (0.05%) PRO300	3600 mg/kg	>3500 mg/kg	37	
Acetaminophen (<0.1%) 103-90-2	1944			

Sub-Chronic/Chronic Toxicity

No repeat dose data available.

- Target Organ(s)** skin
- Reproductive effects** Not available.
- Developmental effects** Not available.
- Carcinogenic effects** Not available.

Components	ACGIH	IARC	OSHA	NTP
Phenytoin (<0.5%) 57-41-0		2B		A

- Genotoxic effects** Not available.

12. ECOLOGICAL INFORMATION

Ecotoxicity

- Ecotoxicity effects:** This product has no known eco-toxicological effects.
- Aquatic toxicity effects:** This product has no known aquatic toxicological effects.

- Mobility:** No data available.
- Persistence / degradability:** No data available.
- Bioaccumulation:** No data available.
- Degradation:** No data available.

13. DISPOSAL CONSIDERATIONS

Waste from residues / unused products:

Waste disposal must be in accordance with appropriate US, Federal, State and International regulations.

Contaminated packaging:

Waste disposal must be in accordance with appropriate US, Federal, State and International regulations.

14. TRANSPORT INFORMATION

Product not regulated by DOT, IATA/ICAO, IMO/IMDG, ADR/RID, or TDG.

15. REGULATORY INFORMATION

The preparation is classified as dangerous in accordance with Directive 1999/45/EC

Indication of danger:

Xi - Irritant.

Contains:

ProClin 300



R -phrase(s)

R43 - May cause sensitization by skin contact.

S -phrase(s)

S24 - Avoid contact with skin.

S37 - Wear suitable gloves.

16. OTHER INFORMATION

This data sheet contains changes from the previous version in section(s):

Changes since the last publication are highlighted in red followed by three asterisks (***)

Restrictions on use:

No information available

Additional advice:

Consult your supplier if the material is to be used for special applications such as in the food industry or for hygiene, medical or surgical end-use

Full text of R-phrases referred to under sections 2 and 3

MSDS Format:

European Format

Regulation

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

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End of Safety Data Sheet