

# Material Safety Data Sheet



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

**Product name:** DAT Validity Test Calibrator pH  
**Product number:** 04712463190  
**Business area:** Centralized Diagnostics  
**Product line:** Roche/Hitachi  
**Supplier:** Roche Diagnostics Corporation  
9115 Hague Road  
Indianapolis, IN 46250  
Site Phone Number: 1-800-428-5074  
**Emergency telephone number:**  
CHEMTREC:  
1-800-424-9300 (U.S. or Canada)  
1-703-527-3887 (International)

## 2. COMPOSITION/INFORMATION ON INGREDIENTS

### Description 1: pH 3.0 Calibrator

Components	CAS Number	Weight %	OSHA PEL:	OSHA STEL:	ACGIH TLV:	ACGIH STEL:
Potassium Hydrogen Phthalate	877-24-7	0.1-<1	NA	NA	NA	NA
Chloramphenicol	56-75-7	<0.01	NA	NA	NA	NA

### Description 2: pH 11.0 Calibrator

Components	CAS Number	Weight %	OSHA PEL:	OSHA STEL:	ACGIH TLV:	ACGIH STEL:
Chloramphenicol	56-75-7	<0.01	NA	NA	NA	NA
Sodium carbonate	497-19-8	0.1-<1	NA	NA	NA	NA
Borax	1303-96-4	0.1-<1	NA	NA	2 mg/m <sup>3</sup>	6 mg/m <sup>3</sup>

## 3. HAZARDS IDENTIFICATION

### Emergency Overview

**NFPA Ratings:** Health= 2 Flammability= 0 Reactivity= 0 Special= CA , I

**Special Definitions:** A=Allergen CA=Carcinogen CO=Corrosive F=Flammable H=Harmful I=Irritant Ox=Oxidizer PB=Potential Biohazard R=Reproductive S=Sensitizer T=Toxic T+=Highly Toxic W=Water Reactive

**Principle routes of exposure:** Ingestion, skin and/or eye contact

**Inhalation:** None

**Ingestion:** Harmful if swallowed. Ingestion may cause gastrointestinal irritation, nausea, vomiting and diarrhea.

**Skin contact:** Harmful in contact with skin. May cause irritation in contact with skin.

**Eye contact:** Avoid contact with eyes. Contact with eyes may cause irritation.

**Sensitization or Odor threshold:** The following chemical(s) may cause sensitization, be absorbed via skin, and/or has an odor threshold for detection:

**Medical conditions aggravated by exposure:** None known

**Additional information:** Chloramphenicol induces aplastic anaemia, and this condition is related to the occurrence of leukaemia. Chloramphenicol is probably carcinogenic to humans (IARC Group 2A). (Reference: IARC Summary of Data Reported and Evaluation for Chloramphenicol, VOL.: 50 (1990) (p. 169) Sections 5.3 Human carcinogenicity data and 5.5 General Summary). Although the concentration of chloramphenicol is very low in this product, it is recommended to take conservative protective measures and proper precautions to prevent exposure.

## 4. FIRST AID MEASURES

**Inhalation:** Consult a physician. Move to fresh air. If not breathing, give artificial respiration. If breathing is difficult, give oxygen

**Skin contact:** Rinse with plenty of water. If skin irritation persists, call a physician. Remove and wash contaminated clothing before re-use

**Ingestion:** Consult a physician. Do not induce vomiting without medical advice

**Eye contact:** In the case of contact with eyes, rinse immediately with plenty of water and seek medical advice

**Notes to physician:** None determined

## 5. FIRE-FIGHTING MEASURES

**Suitable extinguishing media:** Use dry chemical, CO<sub>2</sub>, water spray or 'alcohol' foam

**Unusual hazards:** None known

**Special protective equipment for firefighters:** Wear self contained breathing apparatus for fire fighting if necessary

## 6. ACCIDENTAL RELEASE MEASURES

**Personal precautions:** Use personal protective equipment. Evacuate personnel to safe areas

**Environmental precautions:** Prevent further leakage or spillage if safe to do so. Prevent product from entering drains.

**Methods for cleaning up:** Never return spills in original containers for re-use. Sweep up or vacuum (if powder) or soak up with inert absorbent material (if liquid), then place into a suitable clean, dry, closed container, and label for disposal

## 7. HANDLING AND STORAGE

**Handling:** Protect from contamination. Wear personal protective equipment

**Storage:** No special precautions required

## 8. EXPOSURE CONTROLS / PERSONAL PROTECTION

**Engineering measures:** Not applicable

### Personal Protective Equipment

**Respiratory protection:** Respiratory protection is not required under normal use of this product. If respiratory protection is needed, follow the OSHA regulation, 29CFR1910.134. Always use a NIOSH approved respirator when necessary

**Hand protection:** Wear appropriate protective gloves to prevent skin contact. Replace torn or punctured gloves promptly

**Skin and body protection:** Wear appropriate body protection to prevent skin contact

**Eye protection:** Wear appropriate eye protection to prevent eye contact

**Hygiene measures:** Avoid contact with skin, eyes and clothing

## 9. PHYSICAL AND CHEMICAL PROPERTIES

**Color:** Colorless.

**Odor:** None.

**pH:** pH 11.0 Calibrator pH = 11.0, pH 3.0 Calibrator pH = 3.0

**Physical state:** Liquid.

## 10. STABILITY AND REACTIVITY

**Stability:** Stable under recommended storage conditions

**Polymerization:** Not applicable

**Hazardous decomposition products:** Carbon oxides

**Materials to avoid:** Strong acids and strong bases. Strong oxidising agents

## 11. TOXICOLOGICAL INFORMATION

Components	NIOSH - Selected LD50s and LC50s:	NIOSH Pocket Guide - Target Organs:
Potassium Hydrogen Phthalate	>3200 mg/kg Oral LD50 Rat	
Chloramphenicol	=2500 mg/kg Oral LD50 Rat	

Components	NIOSH - Selected LD50s and LC50s:	NIOSH Pocket Guide - Target Organs:
Chloramphenicol	=2500 mg/kg Oral LD50 Rat	
Sodium carbonate	=4090 mg/kg Oral LD50 Rat	
Borax	=2660 mg/kg Oral LD50 Rat	respiratory system skin eyes

**Inhalation:** No additional data available  
**Skin:** No additional data available  
**Oral:** No additional data available  
**Mutagenic effects:** No data is available on the product itself  
**Reproductive toxicity:** No data is available on the product itself

Components	IARC Group 1	IARC Group 2A or 2B	IARC Group 3 or 4	NTP	OSHA Select Carcinogens
Chloramphenicol		Monograph 50 [1990] (overall evaluation upgraded from 2B to 2A with supporting evidence from other relevant data) Supplement 7 [1987]		Reasonably Anticipated To Be A Human Carcinogen	Present

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Chloramphenicol		Monograph 50 [1990] (overall evaluation upgraded from 2B to 2A with supporting evidence from other relevant data) Supplement 7 [1987]		Reasonably Anticipated To Be A Human Carcinogen	Present

## 12. ECOLOGICAL INFORMATION

**Bioaccumulation:** Not determined  
**Aquatic toxicity:** No data is available on the product itself  
**Ecotoxicity effects:** No data is available on the product itself

**U.S. EPA, RCRA, CERCLA, SARA, or DGC information on persistent, bioaccumulative, and toxic chemicals (PBTs):**  
 The following chemicals are listed under the U.S. EPA regulations of RCRA, CERCLA, SARA, or DGC:

## 13. DISPOSAL CONSIDERATIONS

**Waste from residues / unused products:** Waste disposal must be in accordance with appropriate Federal, State, and local regulations. This product, if unaltered by use, may be disposed of by treatment at a permitted facility or as advised by your local hazardous waste regulatory authority. Residue from fires extinguished with this material may be hazardous

## 14. TRANSPORT INFORMATION

**Is product hazardous to ship?** No  
**DOT**

<b>Proper shipping name:</b> None			
<b>UN Number:</b> Not applicable	<b>Hazard class:</b> Not applicable	<b>Subsidiary risk:</b> Not applicable	<b>Packing group:</b> Not applicable

### ICAO/IATA

<b>Proper shipping name:</b> None			
<b>UN Number:</b> Not applicable	<b>Hazard class:</b> Not applicable	<b>Subsidiary risk:</b> Not applicable	<b>Packing group:</b> Not applicable

## 15. REGULATORY INFORMATION

### U.S. Regulations:

**Product number:** 04712463190

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**Product name:** DAT Validity Test Calibrator pH

**U.S. CERCLA/SARA/TSCA Regulatory Information:** The following chemicals are listed under the following TSCA/SARA/CERCLA lists. Refer to TSCA regulation if you need a definition for acronyms that may be shown in the TSCA Inventory field in the table below

Components	CERCLA/SARA 302 RQ and TPQ (40 CFR 355, App.A)	CERCLA/SARA 304 RQ (40 CFR Table 302.4)	SARA 313 Emission reporting	TSCA Inventory
Potassium Hydrogen Phthalate				Present
Chloramphenicol				Present

Components	CERCLA/SARA 302 RQ and TPQ (40 CFR 355, App.A)	CERCLA/SARA 304 RQ (40 CFR Table 302.4)	SARA 313 Emission reporting	TSCA Inventory
Chloramphenicol				Present
Sodium carbonate				Present
Borax				Present

**U.S. Clean Water Act (CWA)/ California Proposition 65:** The following chemicals are listed under the CWA and/or California Proposition 65:

Components	Clean Water Act Hazardous Substances	Clean Water Act Priority Pollutants	California Proposition 65
Chloramphenicol			carcinogen

Components	Clean Water Act Hazardous Substances	Clean Water Act Priority Pollutants	California Proposition 65
Chloramphenicol			carcinogen

#### Canadian Regulations:

This product has been classified in accordance with the hazard criteria of the Controlled Products Regulations and the MSDS contains all the information required by the Controlled Products Regulations.

Components	Canada - WHMIS: Classifications of Substances:
Potassium Hydrogen Phthalate	Uncontrolled product according to WHMIS classification criteria
Chloramphenicol	D2A

Components	Canada - WHMIS: Classifications of Substances:
Chloramphenicol	D2A
Sodium carbonate	D2B E
Borax	D2B

## 16. OTHER INFORMATION

**Reason for revision:** Not applicable  
**References:** None  
**Additional advice:** None  
**Prepared by:** Roche Diagnostics, Health & Safety Department, MSDS Contact: 317-521-7425 or 317-521-7505

The information, data and recommendations contained herein are based upon information believed by Roche Diagnostics Operations after reasonable investigation and research, to be accurate; however, Roche Diagnostics Operations does not warrant the accuracy of this information. All materials and mixtures may present unknown hazards and should be used with caution. When necessary or appropriate, independent opinions regarding the risk of handling or exposure should be obtained from trained professionals. Roche Diagnostics Operations disclaims any warranty against patent infringement and the implied warranties of merchantability and fitness for a particular purpose. Customer's sole and exclusive remedy shall be replacement of the product or return of the product and refund of the purchase price, at Roche Diagnostics Operations's option. In no case shall Roche Diagnostics Operations be liable for incidental or consequential damages, including lost profits.

**End of Safety Data Sheet**