

Individual Safety Report



THE FDA MEDICAL PRODUCTS REGISTRATION DIVISION

**McNEIL**

31 CONSUMER PRODUCTS COMPANY  
FORT WASHINGTON, PA 19034

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Approved by FDA on 11/15/98

Mfr report # \_\_\_\_\_

UP/Out report # \_\_\_\_\_

FDA use only

**A. Patient information**

1. Patient identifier Case 229 In confidence	2. Age at time of event: or 63 yrs Date of birth:	3. Sex (X) female ( ) male	4. Weight unk lbs or kgs
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**B. Adverse event or product problem**

1. X Adverse event and/or Product problem (e.g., defects/malfunctions)	2. Outcomes attributed to adverse event (check all that apply)
	<input checked="" type="checkbox"/> death (unknown mo/day/yr) <input type="checkbox"/> life-threatening <input type="checkbox"/> hospitalization - initial or prolonged <input type="checkbox"/> disability <input type="checkbox"/> congenital anomaly <input type="checkbox"/> required intervention to prevent permanent impairment/damage <input type="checkbox"/> other:
3. Date of event (mo/day/yr) unknown	4. Date of this report (mo/day/yr) 11/09/98

5. Describe event or problem

Literature report (Am J Emerg Med 1998;16(5):443-497) from Annual Report of the American Association of Poison Control Centers TESS database of human exposure cases reported by 66 participating centers during 1997. Information provided in line listing indicates Case 229 was a 63 year old who ingested an unknown amount of an acetaminophen product and ethanol and died (DEATH) following an acute-on-chronic ingestion. Acetaminophen blood concentration was reported to be 11 mcg/ml at an unknown interval after exposure.

Addl info rec'd 11/2/98: Case #229 received from the AAPCC 1997 case fatality data. See attached case report form provided by AAPCC.

6. Relevant tests/laboratory data, including dates

acetaminophen blood concentration: 11 mcg/ml, interval after exposure: unknown; see attached case report form provided by AAPCC

7. Other relevant history, including preexisting medical conditions (e.g., allergies, race, pregnancy, smoking and alcohol use, hepatic/renal dysfunction, etc.)

history of alcohol abuse; See attached case report form provided by AAPCC.

**C. Suspect medication(s)**

1. Name (give labeled strength & mfr/labeler, if known)		3. Therapy dates (if unknown, give duration from/to (or best estimate)	
#1 unknown acetaminophen product		#1 unknown	
#2 ethanol		#2 unknown	
2. Dose, frequency & route used		3. Therapy dates (if unknown, give duration from/to (or best estimate)	
#1 unknown dose, po		#1 unknown	
#2 unknown		#2 unknown	
4. Diagnosis for use (indication)		5. Event abated after use stopped or dose reduced	
#1 unknown		#1 ( ) Yes ( ) No (X) N/A	
#2 unknown		#2 ( ) Yes ( ) No (X) N/A	
6. Lot # (if known)		7. Exp. date (if known)	
#1 Unknown		#1 Unknown	
#2 unknown		#2 unknown	
9. NDC # - for product problems only (if known)			
10. Concomitant medical products and therapy dates (exclude treatment of event) See attached case report form provided by AAPCC.			

**G. All manufacturers**

1. Contact office - name/address (& mfring site for devices)		2. Phone number	
McNeil Consumer Products Company Medical Affairs 7050 Camp Hill Road Ft. Washington, PA 19034		215-233-7820	
4. Date received by manufacturer (mo/day/yr) 11/02/98		3. Report source (check all that apply)	
5. (A) NDA # 19-872		<input type="checkbox"/> foreign <input type="checkbox"/> study <input checked="" type="checkbox"/> literature <input type="checkbox"/> consumer <input checked="" type="checkbox"/> health professional <input type="checkbox"/> user facility <input type="checkbox"/> company representative <input type="checkbox"/> distributor <input type="checkbox"/> other:	
6. If IND, protocol #		IND #	
7. Type of report (check all that apply)		PLA #	
<input type="checkbox"/> 5-day (X) 15-day <input type="checkbox"/> 10-day ( ) periodic <input type="checkbox"/> initial (X) follow-up # 1		pre-1938 ( ) Yes	
9. Mfr. report number		OTC product (X) Yes	
1046735A		8. Adverse event term(s)	
		DEATH                      CONFUSION HYPERVENTIL              EDEMA PERIPH HEPATOMEGALY            ASCITES	

**E. Initial reporter**

1. Name, address & phone #		
Toby L. Litovitz, MD Amer Assoc of Poison Control Centers 3201 New Mexico Avenue, Suite 310 Washington, DC 20016		
2. Health professional?	3. Occupation	4. Initial reporter also sent report to FDA
(X) Yes ( ) No	physician	( ) Yes ( ) No (X) Unk

NOV 13 1998



Submission of a report does not constitute an admission that medical personnel, user facility, distributor, manufacturer or product caused or contributed to the event.



## AAPCC TESS FATALITY ABSTRACTS: 1997

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**Case Number:** 229  
**Age:** 63  
**Substances:** Acetaminophen  
Ethanol  
**Chronicity:** Acute on Chronic  
**Route:** Ingestion  
**Reason:** Unknown  
**Pre-Hospital Arrest:** No

**Abstract:**

A 63 year old woman with a history of alcohol abuse presented disoriented, confused, with deep, labored respiration, blood pressure, 100/58 mm Hg; heart rate, 114 beats/min; respirations, 24/min; temperature, 97.2 °F; an enlarged firm nodular liver, and edema of the lower extremities. Pulse oximetry, 89-92% on room air; AS<sub>1</sub>, 255 IU/L; total bilirubin, 3.5 mg/dL; Na, 145 mEq/L; K, 3.9 mEq/L; Cl, 108 mEq/L; CO<sub>2</sub>, 10 (anion gap 27); BUN, 8 mg/dL; creatinine, 1.4 mg/dL; glucose, 72 mg/dL; acetaminophen level, 11 µg/mL; serum ammonia, 128 (?units). CT scan of the abdomen showed a diffusely enlarged liver and ascites. She had a past history of peptic ulcer disease and upper GI hemorrhage 10 months before. She also had a history of acetaminophen abuse in addition to chronic alcohol abuse and had apparently stopped drinking alcohol about 4 days before, and had not had any oral intake since that time. She was treated with intravenous fluids, acetylcysteine, thiamine, and folate but the family requested no further aggressive measures and she died within 24 hours. No autopsy was performed. The death was probably due to a combination of chronic ethanol abuse and excessive acetaminophen ingestion.