



19-FEB-1998-0676



McNEIL CONSUMER FORT WASHING



\*3031728-6-00\*

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**A. Patient information**

1. Patient identifier Case 193 In confidence	2. Age at time of event: or 41 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)

(X) death (mo/day/yr) unknown	( ) disability
( ) life-threatening	( ) congenital anomaly
(X) hospitalization - initial or prolonged	( ) required intervention to prevent permanent impairment/damage
	( ) other:

3. Date of event (mo/day/yr) 6/25/96	4. Date of this report (mo/day/yr) 02/06/98
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5. Describe event or problem

Case # 193 received for the case fatality data. See attached case report form provided by [redacted]

6. Relevant tests/laboratory data, including dates

See attached case report form provided by [redacted]

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

See attached case report form provided by [redacted]

**C. Suspect medication(s)**

1. Name (give labeled strength & mfr/labeler, if known)

#1 TYLENOL Analgesic Unknown

#2

2. Dose, frequency & route used	3. Therapy dates (if unknown, give duration) from/to (or best estimate)
#1 #9 TYLENOL, po	#1 unknown
#2	#2

4. Diagnosis for use (indication)

#1 unknown

#2

5. Event abated after use stopped or dose reduced
#1 ( ) Yes ( ) No (X) N/A
#2 ( ) Yes ( ) No ( ) N/A

6. Lot # (if known)	7. Exp. date (if known)
#1 Unknown	#1 Unknown
#2	#2

8. Event reappreciated after reintroduction

#1 ( ) Yes ( ) No (X) N/A

#2 ( ) Yes ( ) No ( ) N/A

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 [redacted]

**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) 01/30/98	3. Report source (check all that apply)
8. If IND, protocol #	( ) foreign ( ) study (X) literature ( ) consumer  (X) health professional ( ) user facility  ( ) company representative ( ) distributor ( ) other:
5. (A) NDA # 17-552 IND # PLA # pre-1938 ( ) Yes OTC product (X) Yes	
7. Type of report (check all that apply) ( ) 5-day (X) 15-day ( ) 10-day ( ) periodic (X) Initial ( ) follow-up #	8. Adverse event term(s)
9. Mfr. report number 0929585A	OVERDOSE SEPSIS HYPOTENSION HEMORRHAGE GI ACIDOSIS HYPOGLYCEMIA LIVER FUNC ABNO DEATH

**E. Initial reporter**

1. Name, address & phone #

[redacted] MD  
[redacted] Centers  
Suite [redacted] Ave.  
[redacted]

2. Health professional?	3. Occupation	4. Initial reporter also sent report to FDA
(X) Yes ( ) No	physician	( ) Yes ( ) No (X) Unk



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[REDACTED] FATALITY: 1996 [REDACTED]

Case Number: 193

Age: 41 yrs

Substances: Acetaminophen

Chronicity: Chronic

Route: Ingestion

Reason: Int Misuse

Pre-Hospital Arrest? No

This 41 year old female was brought into the hospital because of persistent nausea and vomiting with fever for one day on June 25, 1996. The patient reportedly had a history of ethanol abuse and claimed to have taken nine Tylenol. The patient was assessed to have urosepsis, hypotension, gastrointestinal bleed, metabolic acidosis, and hypoglycemia. Initial laboratory evaluation revealed elevated liver functions, a prothrombin time of 31 seconds, and an acetaminophen level of 23mcg/ml approximately nine hours from her stated ingestion. The doctor requested information on IV mucomyst. He then contacted the [REDACTED] Center and 20cc of 3% NAC was started. Despite IV mucomyst, antibiotics, and transfusion of fresh frozen plasma, the patient developed multi organ failure and died shortly thereafter.