



**McNeil**  
 Consumer Healthcare  
 Jell Consumer Healthcare  
 Washington, PA 19034-2299

Approved by FDA on 11/15/93

Mfr report # \_\_\_\_\_  
 UF/Dist report # \_\_\_\_\_  
 FDA use only

Page \_\_\_\_ of \_\_\_\_

**A. Patient information**

1. Patient identifier  In confidence	2. Age at time of event: 4 yrs or Date of birth:	3. Sex (X) female  ( ) male	4. Weight 40 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)

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

3. Date of event (mo/day/yr) 4/29/00	4. Date of this report (mo/day/yr) 05/04/00
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5. Describe event or problem

Consumer report received via the Internet of ACCIDENTAL OVERDOSE (daughter drank about a half a bottle) allegedly associated with one of our TYLENOL® acetaminophen Suspension products. According to mother, her 4 year-old daughter drank approximately one-half bottle (1920 mg) of "stage 2-oral suspension childrens tylenol" while her baby sitter as sleeping. Consumer does not know time frame from ingestion to time of presentation because babysitter was sleeping. Consumer reports that daughter was subsequently admitted to the hospital for 2 days and received "nucomist" treatment. Approximately 10 hours after ingestion, consumer reports that "she had 9 ml still in her system". Consumer reports that "her enzyme counts are good now and she is okay". Addl info rec'd 5/5/00: Phone call to mother revealed that the ingestion occurred on 4/29/00. Acetaminophen level on arrival to ER was reportedly 9 and unspecified liver tests were "high" (LIVER FUNCTION TESTS ABNORMAL). Mother reports that child had 5 (See Sect B7)

6. Relevant tests/laboratory data, including dates

approximately 10 hrs post-ingestion (on admission): acetaminophen level was reportedly 9 and unspecified liver tests were reportedly high; 5/1/00: AST was reportedly 29 and ALT was 14

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

no known conditions; NKDA

(Sect B5 cont) treatments with MUCOMYST® via an NG tube & child was given IV fluids. Daughter was reportedly discharged on 4/30/00. Follow-up AST and ALT levels on 5/1/00 were reportedly 29 and 14. Child is reportedly doing fine.

**C. Suspect medication(s)**

1. Name (give labeled strength & mfr/labeler, if known)		3. Therapy dates (if unknown, give duration) from/to for best estimate	
#1 Children's TYLENOL Suspension Product		#1 4/29/00; 1 day	
#2		#2	
2. Dose, frequency & route used		5. Event abated after use stopped or dose reduced	
#1 approx 1920 mg, once, po		#1 (X) Yes ( ) No ( ) N/A	
#2		#2 ( ) Yes ( ) No ( ) N/A	
4. Diagnosis for use (indication)		8. Event reappeared after reintroduction	
#1 accidental ingestion		#1 ( ) Yes ( ) No (X) N/A	
#2		#2 ( ) Yes ( ) No ( ) N/A	
6. Lot # (if known)	7. Exp. date (if known)		
#1 Unknown	#1 Unknown		
#2	#2		
9. NDC # - for product problems only (if known)			
10. Concomitant medical products and therapy dates (exclude treatment of event) none			

MAY 16 2000

**G. All manufacturers**

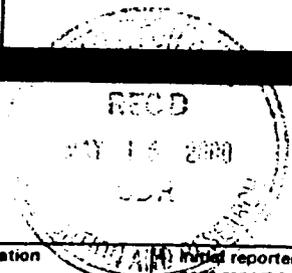
1. Contact office - name/address (& mfring site for devices)		2. Phone number
McNeil Consumer Healthcare Medical Affairs 7050 Camp Hill Road Ft. Washington, PA 19034		215-273-7303
4. Date received by manufacturer (mo/day/yr) 05/04/00		3. Report source (check all that apply)
6. If IND, protocol #		( ) foreign
7. Type of report (check all that apply)		( ) study
( ) 5-day (X) 15-day		( ) literature
( ) 10-day ( ) periodic		(X) consumer
(X) Initial ( ) follow-up #		( ) health professional
9. Mfr. report number		( ) user facility
1357408A		( ) company representative
5. (A) NDA # 19-872		( ) distributor
IND #		( ) other:
PLA #		
pre-1938 ( ) Yes		
OTC product (X) Yes		
8. Adverse event term(s)		
OVERDOSE ACCID LIVER FUNC ABNO		

DSS

MAY 17 2000

**E. Initial reporter**

1. Name, address & phone #		3. Occupation	
2. Health professional?		Initial reporter also sent report to FDA	
( ) Yes ( ) No		( ) Yes ( ) No ( ) Unk	



Submission of a report does not constitute an admission that medical personnel, user facility, or manufacturer or product caused or