

**United States Food and Drug Administration
Consumer Complaint / Injury Report**

This is an accurate reproduction of the original electronic record as of 02/10/2020

COMPLAINT # 160040

Complaint Date	Receiving Organization	Accomplishing District	How Received	Complaint Source	Complaint Received By	Complaint Status
12/10/2019	PHI-DO	PHI-DO	Telephone	Consumer	Gess,Jacquelyn	Closed

Complainant Identification

Name	Address
(b) (4)	(b) (4)

Phone (W)	Phone (H)	Source POC Name	Source Phone
(b) (4)	(b) (4)		

Complaint/Injury

Complaint Description	Adverse Event Result	Adverse Event Date	Injury / Illness
Complainant is a Veterinary Technician and purchased Special Kitty rather than their normal Purina canned food just to get them through because Purina was out of stock. After the third can of the food, Special Kitty Mixed Grill (They only give each cat 1 tbs. am and pm) 4 of their cats tested positive for ethylene glycol toxicity. One of the cats started exhibiting symptoms of vomiting, vocalizing, hypersalivation, wobbling/ataxia, tremors/seizure-like activity less than 12 hours after the morning ingestion of cat food. Complainant rushed her to the clinic to meet their on-call Dr. and the cat tested positive on their in-house ethylene tests. When she returned home, 1 of the other 3 cats was exhibiting similar symptoms. She returned to the clinic to test all remaining cats and they also confirmed positive for ethylene glycol toxicity. After 3 days of TCU care, all cats survived.PET FOOD QUESTIONNAIRE Animal illness severe enough that owner sought advice or intervention from a veterinary professional yielding documented vet records: YES Consumer has packaging for the suspect product and packaging identities a production lot number ; regardless of whether any product remains: YES Pet ill ness occurred within the past 14 days: YES Diagnostic specimens are available or have been provided to pet 's veterinarian: YES Species: 4 Cats Age: 5y, 3y, 21m, 18m Weight: 13.8, 11.4, 8.6, 8.6 Sex: F/M/M/F spayed/neutered: YES Breed: DSH Previous health status of pets: Healthy Date/time of last feeding of this pet food: 8 am morning of treatment (I 1 -30-19) How much food was consumed at that feeding? 1Tb.What i s date/time of illness on-set? 6 pm What symptoms did your pet have? Nausea, vomiting, hypersalivation, vocalization, tremors/seizure like activity, wobbling/ataxia. Why do you suspect the product caused the illness? It i s the only change that a ll 4 cats could have been exposed to. (Continued in Remarks)	Life Threatening Injury/Illness	11/30/19	Gastrointestinal distress

QUESTIONNAIRE

Animal illness severe enough that owner sought advice or intervention from a veterinary professional yielding documented vet records: YES

Consumer has packaging for the suspect product and packaging identities a production lot number ; regardless of whether any product remains: YES

Pet ill ness occurred within the past 14 days: YES Diagnostic specimens are available or have been provided to pet 's veterinarian: YES

Species: 4 Cats Age: 5y, 3y, 21m, 18m Weight: 13.8, 11.4, 8.6, 8.6 Sex: F/M/M/F spayed/neutered: YES Breed: DSH Previous health status of pets: Healthy Date/time of last feeding of this pet food: 8 am morning of treatment (I 1 -30-19) How much food was consumed at that feeding? 1Tb.What i s date/time of illness on-set? 6 pm What symptoms did your pet have? Nausea, vomiting, hypersalivation, vocalization, tremors/seizure like activity, wobbling/ataxia. Why do you suspect the product caused the illness? It i s the only change that a ll 4 cats could have been exposed to. (Continued in Remarks)

Notify DEIO/EMOPS?	Notification Date	Attended Health Professional?	Required Hospitalization?	Emergency Room / Outpatient Visit?	Reported Complaint To?	Need addnl. FDA Contact?
Yes	12/10/2019	Yes		Yes	Reported to Manufacture r	Yes

Remarks

How much of this product was consumed from the open package? It was a 40 pack case and 11 cans were used over a period of approx. One week. The last can fed was of the Mixed Grill pate. How much product is remaining? 29 full cans (also has the empty can from the last fed.) Do you have the product packaging with UPC code, lot number and expiration date? YES.Brand Name: Special Kitty (wet) Product: Pate (mixed case, see remarks)
 Mixed Grille Pate Serial#: 9263803 WM8 81 1137, 9263803 WM8 82 1137, 9268303 WM8 81 1138/1139, 9263803 WM8 82 1138
 Savory Salmon Pats Serial # 9283803 SKS 81 2254, 9283803 SKS 82 2254 , 9283803 SKS 82 2252/2253
 Ocean Whitefish Pate Serial # 9281803 WW8 81 1735, 9281803 WW8 82 1735
 Chicken & Tuna Dinner Pate Serial # 9281803 SKC 81 2212, 9281803 SKC 82 2211/2212
 UPC CODE:332627 EXP/USE BY DATE: Mixed Grill 9-19-21, Salmon 10-9-21, Ocean Whitefish 10-7-21, Chicken & Tuna 10-7-21.Was your pet treated by a veterinarian following illness? Yes If yes, what was the diagnosis? Ethylene Glycol Toxicity. Were diagnostic tests performed? Yes. If yes, what tests? Idexx Catalyst One Chemistry/ Procyte CBC (5 yr old F) and Quick Check Ethylene Glycol Testing by RapiSense, Inc. Burlingame, CA USA (on all 4 cats) Do you know the results? Yes Does the pet have any pre-existing conditions? NO What is the current health status of the pets? All healthy. Identity other foods, treats, dietary supplements or drugs given to pet in the past 14 days.Purina Cat Chow (dry) and Temptations Tempting Tuna treats. Are there other pets i n the household? YES. If yes, did any consume this product? NO.(except for 4 mentioned in complaint) Does your pet spend unsupervised time outdoors? YES.

Complaint Symptoms

Sympton	System Affected	Onset Time	Duration	Remarks
Vomiting	GASTROINTESTINAL	10 Hours	3 Days	
NEC - Identify in Remarks	NEC	10 Hours	3 Days	vocalizing, hypersalivation, wobbling/ataxia, tremors/seizure-like activity

Health Care Professional

Provider Name	Address	Phone	Occupation
Dr. Michele Bartus	408 Grace Lane Rostraver Township PA 15012	724,929.5425	Veterinarian

Hospital Information

Hospital Name	Address	Phone	Dates of Stay

Emergency Room/Outpatient Visit

Hospital Name	Address	Phone	ER Date
Valley Veterinary Services	408 Grace Lane Rostraver Township PA 15012	724.929.5425	11/30/19

Product and Labeling

Brand Name	Product Name	Product Code	Product Description	PAC	UPC Code
Special Kitty	Mixed Grill Canned Cat Food	72AEY05	Comb Prod Pet Cat Food;Metal;NEC	71R801	332627

Qty / Unit / Package	Lot/ Serial #	Exp/Use by Date	Purchase Date	Product Used	Amount Consumed/Used
5.5 Ounces Can	various	various	wk of 11/17	Yes	11 cans

Date Used	Date Discontinued	Amount Remained	Imported Product?	Country of Origin	Label Remarks
11/20/19	11/30/19	20 cans from cs of 40	No	United States	Lot #s and Exp. Dates in REMARKS page 1

Retail

Problem Ingredient Group

Name	Address
Walmart	355 Walmart Drive Tel. 724.428.3344 Uniontown PA 15401

Manufacturer/Distributor

FEI	Name & Address	Home District	Firm Type
1519206	The J.M. Smucker Company, Inc. 1 Strawberry Ln Orrville Ohio United States 44667-1241	CIN-DO	Corporate Headquarters
3004291002	Big Heart Pet Brands, Inc. 6670 Lowe St Bloomsburg Pennsylvania United States 17815-8613	PHI-DO	Manufacturer

Initial Evaluation/Initial Disposition

Problem Keyword	Problem Keyword Details
Chemical Reaction	possible Ethylene Glycol Nausea, vomiting, hypersalivation, vocalization, tremors/seizure like activity, wobbling/ataxia.

Initial Evaluation	Initial Disposition	Disposition Made By	Disposition Date
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Initial Disposition Remarks

Manufacturer identified by CCC Rolodex

Referrals

Org Name	HHS Mail Code
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There are no Cosmetics details for this Complaint.

ADVERSE EVENT DETAILS	Product Name Mixed Grill Canned Cat Food	Product Code 72AEY05
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Birth Date **Age** **Gender** **Race** **Previous Adv Effects of Product?**
No

Consumption Site **Recommended Dosage/Serving Size** **Label Indications for Use**
Home

Recommended Duration of Use **Product Label Available?** **Sample Available?**
Yes Yes

Product Ingredients
Various cat food varieties

Duration of Product Used **Frequency of Product Used** **How was Product Taken?**
Days Twice a day orally

Remarks

Symptoms Occurrence

Did event abate after stopping use of product? **Did symptoms recur after product reintroduction?** **Did symptoms recur after using products with same ingredients?**
No N/A N/A

Did adverse event result in Congenital Anomaly? **Did adverse event require intervention to prevent permanent impairment / damage?**
No Yes

Medications / Other Products Used

Medical Test Performed **Results**
Quick check ethylene Glycol testing Positive for 4 cats

Medical History

Preexisting Conditions **Treatment** **Remarks**

Medical Diagnosis **Medical Treatment**

COMPLAINTS FOLLOW - UP

Grouped Follow - Up Operations

Operation Id	Operation Code	Assignment Number	Accomplishing Organization	Performing Organization	Sample Number	PAF	Status	Status Date
10545187	12	11984146	HAFE2	HAFE2-GRP4			Completed	01/29/2020

Disposition Summary

Is Consumer Responsible?	Responsible FEI	Address	Name	Firm Type
No	3004291002	6670 Lowe St Bloomsburg Pennsylvania United States 17815-8613	Big Heart Pet Brands, Inc.	Manufacturer

Follow-Up Disposition	Disposition Made By	Disposition Date
Completed During EI	Gess,Jacquelyn	01/31/2020

Disposition Remarks

Assign. 11984146, EIR 1.9.20, OAI

Follow-Up Sent To

Organization Name	HHS Mail Code
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