United States Environmental Protection Agency

Office of Prevention, Pesticides and Toxic Substances (7501C)

Pesticide Fact Sheet

Name of Chemical: **Kasugamycin**
Reason for Issuance: **New Chemical Tolerance Established**
Date Issued: **September 2005**

Description of Chemical

Generic Name:	3-O-[2-amino-4-[(carboxyiminomethyl) amino]-2,3,4,6-tetradeoxy-α-D-arabino-hexopyranosyl]-D-chiro-inositol
Common Name:	Kasugamycin
Trade Name:	Kasumin® 2L
Chemical Class:	Aminoglycoside Antibiotic Fungicide
EPA Chemical Code:	230001
Chemical Abstracts Service (CAS) Number:	6980-18-3
Registration Status:	Not Registered, Import Tolerance Established
Pesticide Type:	Fungicide
U.S. Agent:	Arysta Lifescience North American Corporation (*Formerly known as Arvesta Corporation*) 100 First Street, Ste. 1700 San Francisco, CA 94105
International Producer:	Hokko Chemical Industry Co. Ltd. 4-2 Nihonbashi Hongoku-Cho, Chuo-Ku Tokyo, Japan

Tolerances Established

Tolerances were established in the 40 CFR §180.614 for Vegetable, Fruiting Group 8 at 0.04 ppm.

Use Pattern and Formulations

Kasugamycin is not registered in the U.S., however, tolerances were established to cover residues on imported tomatoes and peppers from Mexico where the registrant is seeking to register Kasumin® 2L, a liquid formulation comprised of 2% kasugamycin (by weight) as the active ingredient (ai), for use on rice, potato, pepper, and tomato in Mexico. The product is formulated from kasugamycin hydrochloride hydrate (2.3%) and contains 2% kasugamycin (0.1667 lb ai/gal) as the free base. Kasugamycin is also formulated as a co-active ingredient (at 5%) along with copper oxychloride (at 45%, expressed as copper) in a wettable powder (WP), designated Kasumin Cobre®. Additionally, the Kasumin® formulation is a WP containing 8% kasugamycin. The principal target organisms are bacteria rot (*Erwinia atroseptica*) and leaf mold (*Cladosporium fulvum*) on tomato, and bacteria spot (*Xanthomonas campestris*, pv *vesicatoria*) on both tomato and pepper.

TABLE 1 Summary of Directions for Use of Kasugamycin in Mexico.

Trade Name Formulation [EPA Reg. Number]	Application Type/Timing and Equipment	Application Rate (lb ai/A)	Maximum Number of Applications per Season	Maximum Seasonal Application Rate (lb ai/A)	PHI (Days)	Use Directions and Limitations
Proposed Use on Fruiting Vegetables (Group 8) Imported from Mexico						
Kasumin® 2L [None]	Foliar broadcast/ none specified	0.018	3	0.054	1	None specified

Science Findings

Available product chemistry and toxicology data supporting the proposed tolerance are summarized below.

Physical/Chemical Structure:

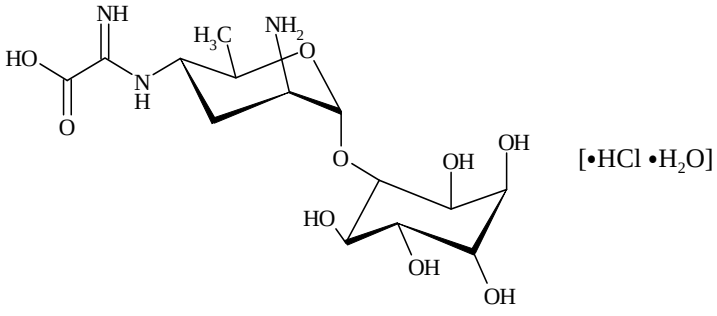

TABLE 2 Physicochemical Properties of the Technical Grade Compound (Kasugamycin Hydrochloride Hydrate).		
Parameter	**Value**	**Reference**
Molecular Weight	433.8	MRIDs # 45910004 and -05
Melting Point/Range	202-230°C (decomposing)	
pH	4.35 at 24.5°C (1% wt/vol solution)	
Density	0.43 g/mL at 24.5°C	
Water Solubility	g/100 mL pH 5 20.7 pH 7 22.8 pH 9 43.8	
Solvent Solubility	g/100 mL Methanol 0.744 Hexane $<1 \times 10^{-5}$ Acetonitrile $<1 \times 10^{-5}$ Methylene chloride $<1 \times 10^{-5}$	
Vapor Pressure	<0.013 mPa at 25°C	
Dissociation Constant (pK_a)	$pK_{a1} = 3.23$ $pK_{a2} = 7.73$ $pK_{a3} = 11.0$	
Octanol/Water Partition Coefficient (Log [K_{OW}])	<1.96 at 23°C and pH 5	
UV/Visible Absorption Spectrum	Not available	

TABLE 3 Acute Toxicity Profile for Kasugamycin.					
Test Material* [% ai]	**Guideline Number**	**Study Type**	**MRID Number**	**Results**	**Toxicity Category**
Technical Product [71]	**870.1100**	Acute oral - rat	45910012	LD_{50} (♂+♀) > 5000 mg/kg	IV
End-Use Product (EP) [2.0]	**870.1100**	Acute oral - rat	45910014	LD_{50} (♂+♀) > 5000 mg/kg	IV
EP [2.0]	**870.1100**	Acute oral - mouse	45910013	LD_{50} (♂+♀) > 5000 mg/kg	IV
EP [2.0]	**870.1200**	Acute dermal - rat	46030301	LD_{50} (♂+♀) > 2000 mg/kg	III
EP [2.2]	**870.1300**	Acute inhalation - rat	45910018	LC_{50} (♂+♀) > 4.892 mg/L	IV
EP [2.0]	**870.2400**	Acute eye irritation - rabbit	45910015	Mild eye irritant (iritis at 1 hour, resolving by 24 hours; conjunctivitis at 1 hour, resolving by 24 hours).	IV
EP [2.0]	**870.2500**	Acute dermal irritation - rabbit	45910017	Not irritating to the skin.	IV
EP [2.0]	**870.2600**	Skin sensitization - guinea pig	45910016	Not a sensitizer under the conditions of this study.	Not applicable

* Bracketed values are % ai as kasugamycin free base.

TABLE 4 Subchronic, Chronic, and Other Toxicity Profile for Kasugamycin.				
Guideline Number	**Study Type/ *Classification***	**MRID Number**	**Doses**	**Results**
870.3100	90-Day oral toxicity rodents - rat *Acceptable/guideline*	45910020	0, 300, 1000, 3000, 6000 ppm **M:** 0, 17.5, 58.2, 176.7, 354.8 mg/kg/day **F:** 0, 20.3, 69.2, 201.0, 395.5 mg/kg/day	**NOAEL** = 176.7/201.0 mg/kg/day (M/F) **LOAEL** = 354.8/395.5 mg/kg/day (M/F) based on decreased body weights and body weight gains.
870.3100	90-Day oral toxicity rodents - mouse *Acceptable/guideline*	45910019	0, 300, 1000, 3000, 10000 ppm **M:** 0, 41.2, 135.4, 408.5, 1559 mg/kg/day **F:** 0, 58.0, 170.9, 565.6, 1834 mg/kg/day	**NOAEL** = 135.4/170.9 mg/kg/day (M/F) **LOAEL** = 408.5/565.6 mg/kg/day (M/F) based on increased mortality and anal lesions (M&F), and kidney lesions (F). At 1559/1834 mg/kg/day (M/F), decreased body weights and body weight gains (M&F), testicular tubular dilatation and degeneration, perianal/perigenital staining (F), and extramedullary hematopoiesis of the spleen (M) were seen.
870.3150	90-Day oral toxicity in nonrodents - dog *Acceptable/guideline*	46030302	0, 300, 3000, 6000/0/4500* ppm **M:** 0, 10.6, 106.0, 182 mg/kg/day **F:** 0, 11.4, 107.9, 179 mg/kg/day * The high-dose group was exposed to 6000 ppm on weeks 1-5, control diet on weeks 6-8, and 4500 ppm on weeks 8-13.	**NOAEL** = 10.6/11.4 mg/kg/day (M/F) **LOAEL** = 106.0/107.9 mg/kg/day (M/F) based on tongue lesions, few feces, swollen mouth, excessive salivation, and thickened skin at the commissure of the mouth. At 182/170 mg/kg/day (M/F), decreased body weights, body weight gains, and food consumption were seen.

TABLE 4 Subchronic, Chronic, and Other Toxicity Profile for Kasugamycin.				
Guideline Number	**Study Type/ *Classification***	**MRID Number**	**Doses**	**Results**
870.3700	Pre-natal developmental in rodents - rat *Acceptable/guideline*	45910022	0, 40, 200, 1000 mg/kg/day	**Maternal** **NOAEL** = 200 mg/kg/day **LOAEL** = 1000 mg/kg/day based on decreased body weights, body weight gains, and food consumption; increased incidence of loose stool; and distention of the large intestine with stool in the cecum. **Developmental** **NOAEL** = 1000 mg/kg/day **LOAEL** = >1000 mg/kg/day
870.3700	Pre-natal developmental in nonrodents - rabbit *Acceptable/guideline*	46030303	0, 1, 3, 10 mg/kg/day	**Maternal** **NOAEL** = 10 mg/kg/day **LOAEL** = >10 mg/kg/day Note: Abortions and decreased maternal body weights, body weight gains, and food consumption were seen at 30 mg/kg/day in a range-finding study. **Developmental** **NOAEL** = 10 mg/kg/day **LOAEL** = >10 mg/kg/day

TABLE 4 Subchronic, Chronic, and Other Toxicity Profile for Kasugamycin.				
Guideline Number	**Study Type/ *Classification***	**MRID Number**	**Doses**	**Results**
870.3800	Reproduction and fertility effects - rat *Acceptable/guideline*	45910023	0, 200, 1000, 6000 ppm **M:** 0, 13.7, 70.3, 425.3 mg/kg/day **F:** 0, 16.2, 82.9, 503.4 mg/kg/day	**Parental/Systemic** **NOAEL** = 13.7/16.2 mg/kg/day (M/F) **LOAEL** = 70.3/82.9 mg/kg/day (M/F) based on decreased body weights and body weight gains. At 425.3/503.4 mg/kg/day (M/F), red and swollen skin around the anal opening (M&F) and testicular atrophy/degeneration in F1 males were seen. **Reproductive** **NOAEL** = 70.3/82.9 mg/kg/day (M/F) **LOAEL** = 425.3/503.4 mg/kg/day (M/F) based on decreased fertility and fecundity in the F1 parents for both litters and increased pre-coital interval during the mating period for the F2 litter. **Offspring** **NOAEL** = 425.3/503.4 mg/kg/day (M/F) **LOAEL** = >425.3/503.4 mg/kg/day (M/F)
870.4100	Chronic toxicity - rodents			See 870.4300. This study includes requirements of both 870.4100 and 870.4200.
870.4100	Chronic toxicity - dog *Acceptable/guideline*	46185901	0, 300, 1000, 3000 ppm **M:** 0, 10.5, 30.5, 99.6 mg/kg/day **F:** 0, 9.4, 33.4, 103.6 mg/kg/day	**NOAEL** = 99.6/103.6 mg/kg/day (M/F) **LOAEL** = >99.6/103.6 mg/kg/day (M/F)
870.4200	Carcinogenicity - rat			See 870.4300. This study includes requirements of both 870.4100 and 870.4200.
870.4200	Carcinogenicity - mouse *Acceptable/guideline*	46030304	0, 50, 300, 1500 ppm **M:** 0, 5.93, 34.94, 186.3 mg/kg/day **F:** 0, 7.25, 42.29, 215.2 mg/kg/day	**NOAEL** = 186.3/215.2 mg/kg/day (M/F) **LOAEL** = >186.3/215.2 mg/kg/day (M/F) *No evidence of carcinogenicity*

TABLE 4 Subchronic, Chronic, and Other Toxicity Profile for Kasugamycin.				
Guideline Number	**Study Type/ *Classification***	**MRID Number**	**Doses**	**Results**
870.4300	Combined chronic toxicity/ carcinogenicity - rat *Acceptable/guideline*	45910024	0, 30, 300, 3000 ppm **M:** 0, 1.1, 11.3, 116 mg/kg/day **F:** 0, 1.4, 13.4, 140 mg/kg/day	**NOAEL** = 11.3/140 mg/kg/day (M/F) **LOAEL** = 116/>140 mg/kg/day (M/F) based on increased testicular softening and atrophy in males. *No evidence of carcinogenicity*
870.5100	Gene mutation - bacterial reverse mutation assay *Unacceptable/ upgradable*	45910028	0, 5, 10, 50, 100, 500 ug/plate for *Salmonella typhimurium* strain G46 (his^-) 0, 5, 10, 50, 100, 200 ug/plate for all other strains tested	No mutagenic activity in bacteria (*Salmonella typhimurium* and *Escherichia coli*) under conditions of this assay. Not tested up to the limit dose, no indication of cytotoxicity, and no defined limit of solubility.
870.5300	Cytogenetics - *in vitro* mammalian cell gene mutation test (CHO Cells) *Acceptable/guideline*	45910026	0, 0.5, 1, 2, 4, 6, 8, 10 mg/ml	No increase in mutant frequency at the HGPRT locus, in the presence or absence of S9 activation.
870.5375	Cytogenetics - *in vitro* mammalian cell chromosome aberration test *Unacceptable/not upgradable*	45910025	0, 1, 2, 3, 4, 5 mg/ml	No increase in mutant frequency, in the presence or absence of S9 activation. The time from treatment to cell harvest was insufficient.
870.5395	Cytogenetics - mammalian erythrocyte micronucleus test (mice) *Acceptable/guideline*	46030305	0, 200, 1000, 5000 mg/kg	No evidence of induced chromosomal damage or other damage leading to micronucleus formation.
870.5550	Other effects - unscheduled DNA synthesis in mammalian cells in culture (rats) *Acceptable/guideline*	45910027	First assay: 0-2.5 mg/ml Second assay: 0-10 mg/ml Third assay: 0-10 mg/ml	No evidence that unscheduled DNA synthesis was induced.

TABLE 4 Subchronic, Chronic, and Other Toxicity Profile for Kasugamycin.				
Guideline Number	**Study Type/ *Classification***	**MRID Number**	**Doses**	**Results**
870.7485	Metabolism and pharmacokinetics - rat *Acceptable/guideline*	46030306	**(1)** 100 mg/kg radiolabeled, single dose by oral gavage. **(2)** 100 mg/kg unlabeled, 14 days in the diet, PLUS 100 mg/kg radiolabeled, single dose by oral gavage. **(3)** 1000 mg/kg radiolabeled, single dose by oral gavage. **(4)** 1000 mg/kg unlabeled, 14 days in the diet, PLUS 1000 mg/kg radiolabeled, single dose by oral gavage.	The mean radioactivity recovery 168 hours after exposure ranged between 90.6-96.7%, with the majority of the dose recovered within 48 hours in the feces (81.9-93.9%) and urine (1.26-3.07%). The maximum concentration found in the plasma of both males and females occurred approximately one hour after the administration of a single low or high dose. Between one and six hours after a single low or high dose, more kasugamycin accumulated in the kidneys, urinary bladder, and lymph nodes than in the blood, but after 168 hours, little or no kasugamycin was found in these tissues. The absorption and metabolism of kasugamycin in rats was limited (<5% dose) and was not affected by sex, dose level, or duration of dosing. Parent compound was the major component identified in the urine, feces, liver, kidney, and plasma. Minor amounts (<1% dose) of the metabolite kasuganobiosamine were identified in urine, liver, kidney, and plasma, but none was detected in the feces. Elimination occurred primarily in the feces (87.7-94.5%); however, kasugamycin was not excreted in the bile (enterohepatic circulation did not occur).

Toxicological Endpoints

TABLE 5 Summary of Toxicological Doses and Endpoints for Kasugamycin Used in the Human Health Risk Assessments.			
Exposure Scenario	**Dose Used in Risk Assessment and UF [1]**	**Special FQPA SF [2] and Level of Concern for Risk Assessment**	**Study and Toxicological Effects**
Acute Dietary (females 13 to 49 years of age)	None	None	**Not selected** No appropriate dose and endpoint could be identified for these population groups.
Acute Dietary (general population including infants and children)	None	None	**Not selected** No appropriate dose and endpoint could be identified for these population groups.
Chronic Dietary (all populations)	NOAEL = 11.3 mg/kg/day UF = 100 **Chronic RfD** = 0.113 mg/kg/day	FQPA SF =1 **cPAD** = chronic RfD / FQPA SF = 0.113 mg/kg/day	**Combined chronic toxicity/oncogenicity study in rats** LOAEL = 116 mg/kg/day based on increased testicular softening and atrophy.
Cancer (oral, dermal, inhalation)	**Classification:** No oncogenic potential was noted in the mouse oncogenicity or in the rat combined chronic/carcinogenicity studies; additionally, no mutagenic potential was noted in any of the five mutagenicity studies. Classification of kasugamycin is "not likely to be carcinogenic to humans".		

1. UF = Uncertainty Factor.
2. FQPA SF = special FQPA Safety Factor.
3. NOAEL = No Observed Adverse Effect Level.
4. RfD = Reference Dose.
5. PAD = Population-Adjusted Dose (a = acute, c = chronic).
6. LOAEL = Lowest Observed Adverse Effect Level.

Food Quality Protection Act Considerations

FQPA Safety Factor:

Based on the hazard and exposure data, the Agency has reduced the special FQPA SF to 1X because there are no/low concerns and no residual uncertainties with regard to pre- and/or post-natal toxicity. This recommendation is based on the following:

(1) there are no data gaps for the assessment of the effects of kasugamycin following *in utero* and/or post-natal exposure; a developmental neurotoxicity study is not required;

(2) there is no indication of increased quantitative or qualitative susceptibility of rats or rabbits to *in utero* and/or post-natal exposure to kasugamycin;

(3) the acute and chronic dietary food exposure assessments utilize proposed tolerance level or higher residues and 100% crop treated information for all commodities; and

(4) there are no existing or proposed residential uses for kasugamycin at this time.

Exposure Assessment

The sole anticipated exposure route to Kasugamycin for the US population is via dietary (food only) exposure. There are no proposed US registrations for kasugamycin and there is no expectation that kasugamycin residues would occur in surface or ground water sources of drinking water. Therefore, no aggregate nor occupational exposure is expected. A summary of exposure assessments follows:

- An acute exposure assessment was not preformed as no appropriate dose and endpoint was selected for any population subgroup.
- A chronic exposure assessment was conducted assuming tolerance level residues and 100% crop treated. The chronic population adjusted dose for all population subgroups including the general U.S. population was < 1%.
- A cancer exposure assessment was not preformed as kasugamycin was classified as "not likely to be carcinogenic to humans".

Public Health Summary

Kasugamycin is a new active ingredient and, as such, no public health data are currently available. Kasugamycin operates via a mode of action different from that of the other aminoglycoside antibiotics such as streptomycin. Because kasugamycin is active only against phytopathogenic fungi and bacteria, it has never been employed as a human or veterinary-use antibiotic.

The Agency is aware that FDA and CDC have concerns regarding the potential for antibiotics to induce bacterial resistance arising from their use as pesticides. The Agency has met with these other agencies recently to discuss resistance issues and an ongoing dialogue is anticipated. The Agency's level of concern is low regarding development of resistance (associated with kasugamycin's use as a fungicide) arising from tolerances for kasugamycin on imported fruiting vegetables because:

- proposed use rates for kasugamycin are low, and residues following its application are either very low or non-detectable
- the proposed uses are only on imported fruiting vegetables, with no proposed domestic uses, and
- there are no human or veterinary uses of kasugamycin as an antibiotic.

SUMMARY OF DATA GAPS

860.1340 Residue Analytical Method: The analytical enforcement method uses ion exchange resins for clean up and reverse-phase ion-pairing liquid chromatography with ultra-violet detection (HPLC/UV). This method was validated by an independent laboratory. The Agency's laboratory also conducted a laboratory trial of this method and has suggested that the substitution of solid-phase extraction for the ion-exchange process could possibly improve the method. The Agency will request that changes be made to the method.

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DISCLAIMER: The information in this Pesticide Fact Sheet is for information only and is not to be used to satisfy data requirements for pesticide registration. The information is believed to be accurate as of the date on the document.

APPENDIX I:

GLOSSARY OF TERMS AND ABBREVIATIONS

ADNT	**Acute delayed neurotoxicity**
a.i.	**Active Ingredient**
aPAD	**Acute Population Adjusted Dose**
ARI	**Aggregate Risk Index**
BCF	**Bioconcentration Factor**
CAS	**Chemical Abstracts Service**
ChE	**Cholinesterase**
ChEI	**Cholinesterase inhibition**
cPAD	**Chronic Population Adjusted Dose**
%CT	**Percent crop treated**
DAT	**Days after treatment**
DEEM-FCID	**Dietary Exposure Evaluation Model - Food Consumption Intake Database**
DNA	**Deoxyribonucleic acid**
DNT	**Developmental neurotoxicity**
DIT	**Developmental immunotoxicity**
DWLOC	**Drinking Water Level of Comparison.**
EC	**Emulsifiable Concentrate Formulation**
EEC	**Estimated Environmental Concentration. The estimated pesticide concentration in an environment, such as a terrestrial ecosystem.**
EPA	**U.S. Environmental Protection Agency**
FQPA	**Food Quality Protection Act**
GLC	**Gas Liquid Chromatography**
GLN	**Guideline Number**
LC_{50}	**Median Lethal Concentration. A statistically derived concentration of a substance that can be expected to cause death in 50% of test animals. It is usually expressed as the weight of substance per weight or volume of water, air or feed, e.g., mg/l, mg/kg or ppm.**
LD_{50}	**Median Lethal Dose. A statistically derived single dose that can be expected to cause death in 50% of the test animals when administered by the route indicated (oral, dermal, inhalation). It is expressed as a weight of substance per unit weight of animal, e.g., mg/kg.**
LOAEL	**Lowest Observed Adverse Effect Level**
LOAEC	**Lowest Observed Adverse Effect Concentration**
LOC	**Level of Concern**
LOD	**Limit of Detection**
LOQ	**Limit of quantitation**
mg/kg/day	**Milligram Per Kilogram Per Day**
mg/L	**Milligrams Per Liter**
MOE	**Margin of Exposure**
MRID	**Master Record Identification (number), EPA's system of recording and tracking studies submitted**
MTD	**Maximum tolerated dose**
NA	**Not Applicable**

NOEC	**No Observable Effect Concentration**
NOEL	**No Observed Effect Level**
NOAEL	**No Observed Adverse Effect Level**
NOAEC	**No Observed Adverse Effect Concentration**
NPDES	**National Pollutant Discharge Elimination System**
OP	**Organophosphate**
OPP	**EPA Office of Pesticide Programs**
OPPTS	**EPA Office of Prevention, Pesticides and Toxic Substances**
PAD	**Population Adjusted Dose**
PAG	**Pesticide Assessment Guideline**
PAM	**Pesticide Analytical Method**
PHED	**Pesticide Handler's Exposure Data**
PHI	**Preharvest Interval**
ppb	**Parts Per Billion**
PPE	**Personal Protective Equipment**
ppm	**Parts Per Million**
PRZM/ EXAMS	**Tier II Surface Water Computer Model**
RAC	**Raw Agriculture Commodity**
RBC	**Red Blood Cell**
RED	**Reregistration Eligibility Decision**
REI	**Restricted Entry Interval**
RfD	**Reference Dose**
SCI-GROW	**Tier I Ground Water Computer Model**
SF	**Safety Factor**
TGAI	**Technical Grade Active Ingredient**
UF	**Uncertainty Factor**
µg	**micrograms**
µg/L	**Micrograms Per Liter**
µL/g	**Microliter per gram**
USDA	**United States Department of Agriculture**
WPS	**Worker Protection Standard**

Appendix II

Citations Considered to be Part of the Data Base Supporting the Registration of Kasugamycin

45910000	Hokko Chemical Industry Co., Ltd. (2003) Submission of Product Chemistry, Residue, Fate and Toxicity Data in Support of the Petition for Tolerance of Kasugamycin on Fruiting Vegetables, Crop Group 8, Except Cucurbits. Transmittal of 28 Studies.
45910001	Bujor, D. (2003) Kasugamycin--Food Quality Protection Act Supplemental Information to Support Use on Fruiting Vegetables, Crop Group 8: Lab Project Number: KAS-FQPA-01. Unpublished study prepared by Arvesta Corporation. 45 p.
45910002	Pesselman, R. (1993) Analysis of Product Ingredients in Kasugamycin: Lab Project Number: TMN-073: HWI 6293-115. Unpublished study prepared by Hazleton Wisconsin, Inc. 102 p.
45910003	Curry, K.; Brookman, D.; Bujor, D. (2003) Kasugamycin Technical: Product Properties--Group A: Product Identity and Composition, Materials Used to Produce the Product, Description of Production, Discussion of Formation of Impurities, Preliminary Analysis: Lab Project Number: TMN-074. Unpublished study prepared by Technology Sciences Group, Inc. 66 p. {OPPTS 830.1550, 830.1600, 830.1620, 830.1670, 830.1700, 830.1650}
45910004	Brookman, D.; Curry, K. (2003) Group B: Product Properties--Kasugamycin Technical: Color, Physical State, Odor, Melting Point, Boiling Point, pH, Density, Dissociation Constant, Octanol/Water Partition Coefficient, Water Solubility, Vapor Pressure, Stability to Normal and Elevated Temperature, Metals, and Metal Ions: Lab Project Number: TMN-073A. Unpublished study prepared by Technology Sciences Group, Inc. 7 p. {OPPTS 830.6302, 830.6303, 830.6304, 830.6313, 830.7000, 830.7200, 830.7300, 830.7370, 830.7550, 830.7560, 830.7570, 830.7840, 830.7860, 830.7950}
45910005	Pesselman, R. (1993) Series 63 Product Chemistry Determination of Kasugamycin: Color, Physical State, Odor, Melting Point, Density, Solubility, Vapor Pressure, Dissociation Constant, Octanol/Water Partition Coefficient, pH, Stability: Lab Project Number: TMN-0072: HWI 6293-16. Unpublished study prepared by Hazleton Wisconsin, Inc. 110 p.
45910006	Cooke, J. (2002) Metabolic Fate and Distribution of (Carbon 14)-Kasugamycin in Tomato: Lab Project Number: TMN-0063: 1442/12/D2149. Unpublished study prepared by Covance Laboratories, Ltd. 98 p. {OPPTS 860.1300}
45910007	Faltynski, K. (2002) Independent Laboratory Validation (ILV) of Morse Laboratory's Method for the Analysis of Kasumin (TM-416) in Crop: Lab

Project Number: TMN-0082A: 01-0047: METH-146. Unpublished study prepared by En-Cas Analytical Laboratories. 88 p. {OPPTS 860.1340}

45910008 Westberg, G. (2003) Validation of the Analytical Method for the Determination of Kasugamycin in Tomatoes, Potatoes and Peppers: Lab Project Number: TMN-0081 A: MLIR-03-01: METH-146. Unpublished study prepared by Morse Laboratories, Inc. 61 p.

45910009 Fomenko, J. (2002) Evaluation of TM-416 through the FDA Multiresidue Methods: Lab Project Number: TMN-0081: A055.002. Unpublished study prepared by Maxim Technologies, Inc. 43 p. {OPPTS 860.1360}

45910010 Carringer, S. (2002) Magnitude of the Residue of Kasugamycin in Pepper Raw Agricultural Commodities: Lab Project Number: TMN-0092: TCI-01-012: ML01-0989-TOM. Unpublished study prepared by Morse Laboratories, Inc. 209 p. {OPPTS 860.1500}

45910011 Carringer, S. (2002) Magnitude of the Residue of Kasugamycin in Tomato Raw Agricultural Commodities: Lab Project Number: TMN-0099B: TCI-01-011: ML01-0987-TOM. Unpublished study prepared by Morse Laboratories, Inc. 283 p. {OPPTS 860.1500}

45910012 Glaza, S. (1992) Acute Oral Toxicity Study of Kasugamycin Hydrochloride Technical in Rats: Lab Project Number: HWI 20504630: TMN-0113: TP3013. Unpublished study prepared by Hazleton Wisconsin, Inc. 24 p.

45910013 Cuthbert, J.; Jackson, D. (1992) Kasumin Liquid: Acute Oral Toxicity (Limit) Test in Mice: Lab Project Number: TMN-0106: 553046-9018. Unpublished study prepared by Inveresk Research International. 90 p.

45910014 Cuthbert, J.; Jackson, D. (1992) Kasumin Liquid: Acute Oral Toxicity (Limit) Test in Rats: Lab Project Number: TMN-0107: 553046-9017. Unpublished study prepared by Inveresk Research International. 16 p.

45910015 Cuthbert, J.; Jackson, D.; Pallas, E. (1992) Kasumin Liquid: Primary Eye Irritation Test in Rabbits: Lab Project Number: TMN-0110: 553046-9021. Unpublished study prepared by Inveresk Research International. 18 p.

45910016 Cuthbert, J.; Jackson, D. (1992) Kasumin Liquid: Buehler Sensitization Test in Guinea Pigs: Lab Project Number: TMN-0111: 553046-9022. Unpublished study prepared by Inveresk Research International. 24 p.

45910017 Cuthbert, J.; Jackson, D.; Pallas, E. (1992) Kasumin Liquid: Primary Skin Irritation Test in Rabbits: Lab Project Number: TMN-0109: 553046-9020. Unpublished study prepared by Inveresk Research International. 16 p.

45910018 Sheperd, N. (2001) Kasumin 2 L: Single Exposure (Nose Only) Toxicity Study in the Rat: Lab Project Number: TMN-0112: 1442/8-D6145: 1442/8. Unpublished study prepared by Covance Laboratories. 84 p. {OPPTS

870.1300}

45910019 Holmes, P. (1990) Kasugamycin: Toxicity Study by Dietary Administration to CD-1 Mice for 13 Weeks: Lab Project Number: TMN-0156: LSR 90/0345. Unpublished study prepared by Life Science Research Limited. 301 p. {OPPTS 870.3100}

45910020 Nakashima, N. (1991) Kasugamycin: 13-Week Oral Subchronic Toxicity Study in Rats: Lab Project Number: TMN-0154: IET 89-0083. Unpublished study prepared by The Institute of Environmental Toxicology. 228 p.

45910021 Fujii, S. (1990) Teratogenicity Study in Rats with Kasugamycin: Preliminary Study: Lab Project Number: TMN-0135: IET 89-0084: KK 02-12. Unpublished study prepared by The Institute of Environmental Toxicology. 74 p.

45910022 Fujii, S. (1991) Teratogenicity Study in Rats with Kasugamycin: Lab Project Number: TMN-0136: IET 89-0085. Unpublished study prepared by The Institute of Environmental Toxicology. 72 p.

45910023 Henwood, S. (1993) Two-Generation Reproduction Study with Kasugamycin in Rats: Lab Project Number: TMN-0126: HWI 6434-102: TP2025. Unpublished study prepared by Hazleton Wisconsin, Inc. 1349 p.

45910024 Kitazawa, T. (1987) Kasugamycin: 24-Month Oral Chronic Toxicity and Oncogenicity Study in Rats: Lab Project Number: TMN-0120: ID-09-1987. Unpublished study prepared by The Institute of Environmental Toxicology. 880 p.

45910025 Ivett, J. (1985) Mutagenicity Evaluation of Kasugamycin Technical (Purity 67.1% Lot. No. KP-570) in an in Vitro Cytogenetic Assay Measuring Chromosome Aberration Frequencies in Chinese Hamster Ovary (CHO) Cells: Lab Project Number: TMN-144: 20990: 437. Unpublished study prepared by Litton Bionetics, Inc. 21 p.

45910026 Young, R. (1985) Evaluation of Kasugamycin (Lot. No. KP-570) in the V79/HGPRT Forward Mutation Assay: Lab Project Number: TMN-0142: 22207: 436. Unpublished study prepared by Litton Bionetics, Inc. 26 p.

45910027 Seeberg, A. (1985) Kasugamycin: Unscheduled DNA Synthesis in Human Cells Cell Line: Hela S3: Lab Project Number: TMN-0145: 161001-M-01885: 161-001. Unpublished study prepared by Life Science Research. 48 p.

45910028 Shirasu, Y.; Moriya, M.; Watanabe, Y. (1976) Mutagenicity Testing on Kasugamycin-HCL in Microbial Systems: Lab Project Number: TMN-0143: IET-11-15-1976. Unpublished study prepared by The Institute of Environmental Toxicology. 12 p.

46030300 Arvesta Corporation (2003) Submission of Toxicity Data in Support of the Petition for Tolerance of Kasugamycin on Fruiting Vegetables, Crop Group 8.

Transmittal of 6 Studies.

46030301 Cuthbert, J.; Jackson, D. (1992) Kasumin Liquid: Acute Dermal Toxicity (Limit) Test in Rats. Project Number: TMN/0108, 553046/9019, 553046. Unpublished study prepared by Inveresk Research International. 18 p.

46030302 Thomford, P. (1993) 13-Week Dietary Toxicity Study with Kasugamycin in Dogs. Project Number: TMN/0155, HWI/6434/101. Unpublished study prepared by Hazleton Wisconsin, Inc. 399 p.

46030303 Ross, F. (1986) Kasugamycin: Teratology Study in the Rabbit. Project Number: TMN/0134, 86/HKC004/114. Unpublished study prepared by Life Science Research. 63 p.

46030304 Holmes, P. (1992) Kasugamycin: Oncogenicity Study by Dietary Administration to CD-1 Mice for 78 Weeks: (Final Report). Project Number: TMN/0122, 91/HKC006/1010. Unpublished study prepared by Life Science Research. 673 p.

46030305 Hodson-Walker, G. (1985) Kasugamycin: Assessment of Clastogenic Action on Bone Marrow Erythrocytes in the Micronucleus Test: (Final Report). Project Number: TMN/0146, 85/HKC001/207. Unpublished study prepared by Life Science Research. 52 p.

46030306 Cheng, T. (1998) Metabolism of (Carbon 14)-Kasugamycin in Rats. Project Number: TMN/0059, 6434/110. Unpublished study prepared by: Covance Laboratories, Inc. 512 p.

46185900 Hokko Chemical Industry Co., Ltd. (2004) Submission of Toxicity Data in Support of the Petition for Tolerance of Kasugamycin. Transmittal of 1 Study.

46185901 Albertsen, J. (2003) 52-Week Dietary Toxicity Study with Kasugamycin in Dogs: (Final Report). Project Number: 6434/117. Unpublished study prepared by Covance Laboratories, Inc. 571 p.

46428700 Hokko Chemical Industry Co., Ltd. (2004) Submmission of Toxicity Data in Support of the Petition for Tolerance of Kasugamycin. Transmittal of 1 Study.

46428701 Tesh, J.; Ross, F.; Wright, P. (1986) Kasugamycin: Preliminary Teratology Study in the Rabbit. Project Number: 85/HKC003/783. Unpublished study prepared by Life Science Research. 47 p.

46444900 Hokko Chemical Industry Corp. (2005) Submission of Toxicity Data in Support of the Petition for Tolerance of Kasugamycin. Transmittal of 1 Study.

46444901 Burin, G. (2005) Study Waiver Request for Subchronic Dermal, Acute Neurotoxicity and Subchronic Neurotoxicity Studies of Kasugamycin. Unpublished study prepared by Technology Sciences Group, Inc. 5 p.

46448300	Hokko Chemical Industry Co., Ltd. (2005) Submission of Toxicity Data in Support of the Petition for Tolerance of Kasugamycin. Transmittal of 1 Study.
46448301	Holmes, P. (1992) Kasugamycin: Oncogenicity Study by Dietary Administration to CD-1 Mice for 78 Weeks. Project Number: TMN/0122, 91/HKC006/1010. Unpublished study prepared by Life Science Research. 1426 p.
46485500	Hokko Chemical Industry Co., Ltd. (2005) Submission of Environmental Fate Data in Support of the Petition for Tolerance of Kasugamycin for Use on Fruiting Vegetables. Transmittal of 1 Study.
46485501	Swales, S. (2003) (Carbon 14) Kasugamycin: Hydrolytic Stability. Project Number: 1442/21. Unpublished study prepared by Covance Laboratories, Ltd. 123 p.