



Ingevity
5255 Virginia Avenue
North Charleston, SC 29406

ingevity.com

CONTAINS NO CBI

VIA CDX e-TSCA

May 31, 2016

Document Processing Center (TS-790)
(Attn: Section 8(e) Coordinator)
Office of Toxic Substances
U.S. Environmental Protection Agency
401 M Street SW
Washington, DC 20460

Re: TSCA Section 8(e) Submission for Rosin (CAS# 8050-09-7)

Dear Section 8(e) Coordinator,

Ingevity Corporation is hereby submitting the enclosed information in accordance with Section 8(e) of TSCA for Rosin (CAS# 8050-09-7).

The H4R REACh Consortia, of which Ingevity is a member, recently conducted a prenatal developmental toxicity study (according to OECD 414 & EPA 870.3700) with rosin. Pregnant rats were fed a diet containing rosin resulting at doses of 2500 ppm (199.3 mg/kg/day), 5000 ppm (387.2 mg/kg/day) or 7500 ppm (561.1 mg/kg/day) from gestation days 3-19. The draft report contained findings of significant decreases in fetal weights (both sexes) at 7500 ppm. A statistically significant reduction in the number of fetuses/litters showing incomplete ossification of the squamosal bone of the skull was evident at 7500 and 5000 ppm was also found and there was also a statistically significant reduction in the number of fetuses/litters showing no ossification of the hyoid in the skull at 2500 and 7500 ppm. There was also a statistically significant increase in the number of fetuses/litters showing dumb-bell shaped thoracic centrum at 5000 ppm and a statistically significant increase in the number of fetuses/litters showing ossification center associated with the 1st lumbar vertebra was evident in all three treated groups.

These data are still being reviewed in light of the historical controls at the laboratory and no determination has been made if these findings represent an adverse event.

Ingevity produces rosin from tall-oil. The majority of this rosin is internally derivatized. The rosin that is sold is also believed to be derivatized. The notified substance is used solely in industrial applications.



This information is intended to discharge any TSCA Section 8(e) obligations that might exist for these findings.

Should you have any questions or require clarification of any information presented in the enclosed package, please feel free to contact me at 843-740-2171.

Sincerely,

A handwritten signature in blue ink that reads "Frederick H. Gouzoules".

Frederick H. Gouzoules, Ph.D.
Director - Product Stewardship
Ingevity
fred.gouzoules@ingevity.com

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Report

Tall Oil Rosin CAS 8050-09-7: Oral (Dietary) Pre-Natal Developmental Toxicity Study in the Rat

Envigo Study Number: 41403712

Sponsor Name: Hydrocarbon Resins and Rosin Resins
REACH Consortium

Version ID: Draft

Issue Date:

Study Director: J Allt

Testing Facility: Envigo Research Limited
Shardlow Business Park
Shardlow
Derbyshire
DE72 2GD
UK

Table 9 Group Mean Litter Data Values

Dietary Concentration (ppm)		Number of Corpora Lutea	Number of Implants	Number of Embryonic/Foetal Deaths			Implantation Loss %		Number of Live Implants			% Male Foetuses	Mean Male Foetal Weight (g)	Mean Female Foetal Weight (g)	Mean Foetal Weight (g)	Mean Placental Weight (g)	Litter Weight (g)	Total Placental Weight (g)
				Early	Late	Total	Pre	Post	Male	Female	Total							
0 (Control)	mean	14.2	14.0	0.0	0.0	0.0	1.0	0.3	7.3	6.7	14.0	51.5	4.012	3.826	3.922	0.640	54.715	8.903
	sd	2.2	2.3	0.2	0.0	0.2	2.6	1.5	2.7	1.6	2.3	13.5	0.272	0.233	0.244	0.080	8.361	1.594
	n	23	23	23	23	23	23	23	23	23	23	23	23	23	23	23	23	23
2500	mean	14.0	13.7	0.1	0.2	0.3	1.8	1.9	6.4	7.0	13.4	47.1	3.925	3.756	3.840	0.626	51.483	8.394
	sd	1.7	1.7	0.3	0.5	0.7	3.2	5.0	2.1	1.4	1.8	12.3	0.229	0.241	0.231	0.100	6.861	1.671
	n	23	23	23	23	23	23	23	23	23	23	23	23	23	23	23	23	23
5000	mean	12.8	12.6	0.0	0.2	0.3	2.1	2.1	6.3	6.1	12.4	49.3	3.952	3.742	3.855	0.694	47.691	8.417
	sd	2.8	3.0	0.2	0.5	0.6	7.7	5.4	2.4	1.9	3.0	14.5	0.304	0.308	0.289	0.144	11.991	2.176
	n	24	24	24	24	24	24	24	24	24	24	24	24	24	24	24	24	24
7500	mean	14.3	14.1	0.1	0.2	0.3	1.4	2.6	7.1	6.6	13.7	51.8	3.712**	3.550**	3.635**	0.559*	49.803	7.650
	sd	2.0	2.0	0.3	1.0	1.0	2.9	8.5	2.2	2.0	2.1	13.1	0.313	0.329	0.309	0.079	8.285	1.588
	n	24	24	24	24	24	24	24	24	24	24	24	24	24	24	24	24	24

Table 12 Summary Incidence of Foetal Skeletal Findings

Skeletal Findings	Dietary Concentration (ppm)											
	0 (Control)			2500			5000			7500		
	Number of Foetuses (litters) Examined											
	157 (23)			147 (23)			143 (24)			159 (24)		
	NF	NL	%†	NF	NL	%†	NF	NL	%†	NF	NL	%†
Skull												
Nasal - incomplete ossification	10	6	6.0	13	7	8.2	9	4	8.6	7	4	4.6
Frontal - incomplete ossification	7	5	4.0	8	5	5.5	8	4	6.7	5	3	3.5
Frontal - unossified area	2	2	1.1	0	0	0.0	1	1	1.4	0	0	0.0
Intraorbital process of frontal - incomplete ossification	0	0	0.0	0	0	0.0	0	0	0.0	1	1	0.6
Parietal - incomplete ossification	17	9	10.5	7	5	4.6	13	6	10.1	8	6	5.0
Parietal/Interparietal - sutural bone	1	1	0.6	0	0	0.0	2	2	1.4	2	2	1.1
Interparietal - incomplete ossification	37	14	22.4	21	13	14.0	28	15	21.1	23	11	14.4
Occipital (Supra-occipital) - incomplete ossification	29	16	19.4	20	13	13.1	25	14	19.4	30	13	19.6
Occipital (Supra-occipital) - unossified area(s)	8	7	5.6	5	4	3.3	5	5	3.2	10	8	6.5
Squamosal - incomplete ossification	41	18	26.7	23	12	15.0	18	10	12.5*	22	12	14.3*
Squamosal - unossified area(s)	5	4	3.5	2	1	1.2	3	3	3.2	5	5	3.2
Jugal - incomplete ossification	17	12	11.5	7	5	4.6	9	5	6.3	5	4	3.3
Zygomatic process of maxilla - incomplete ossification	12	10	8.1	10	8	6.3	9	6	6.5	5	5	3.7
Zygomatic process of squamosal - incomplete ossification	6	3	4.1	4	3	2.6	3	2	2.3	1	1	0.6
Premaxilla - incomplete ossification	1	1	0.6	2	2	1.5	4	1	3.3	4	2	3.1

NOTE: a foetus may appear in more than one category

Table 12 (continued) Summary Incidence of Foetal Skeletal Findings

Skeletal Findings	Dietary Concentration (ppm)											
	0 (Control)			2500			5000			7500		
	Number of Foetuses (litters) Examined											
	157 (23)			147 (23)			143 (24)			159 (24)		
	NF	NL	%†	NF	NL	%†	NF	NL	%†	NF	NL	%†
Skull (continued)												
Hyoid - incomplete ossification	21	12	13.4	16	9	10.5	10	7	6.9	8	6	5.2
Hyoid - not ossified	36	16	22.5	13	10	8.4*	17	11	11.0	13	8	8.3**
Mandible - incomplete ossification	0	0	0.0	0	0	0.0	1	1	0.8	1	1	0.6
Tympanic annulus - incomplete ossification	0	0	0.0	0	0	0.0	1	1	0.8	0	0	0.0
Presphenoid - incomplete ossification	1	1	0.6	4	3	2.8	4	3	2.8	3	3	2.0
Presphenoid - not ossified	1	1	0.6	0	0	0.0	0	0	0.0	1	1	0.8
Basisphenoid - incomplete ossification	2	2	1.1	0	0	0.0	3	3	2.0	1	1	0.8
Vertebral Column												
Ventral arch of vertebra 1 - ossification present	39	15	24.8	40	14	27.3	38	18	25.0	44	18	26.8
Cervical (neural) arch - incomplete ossification	10	6	6.1	6	5	4.0	8	6	5.6	5	4	3.3
Cervical (neural) arch - misshapen	0	0	0.0	2	1	1.1	0	0	0.0	0	0	0.0
Cervical (neural) arch - fused	0	0	0.0	0	0	0.0	1	1	0.7	0	0	0.0
Thoracic centrum - incomplete ossification	10	6	6.8	11	8	7.6	14	9	11.4	24	11	15.8
Thoracic centrum - not ossified	2	1	1.0	2	1	1.1	3	3	2.9	5	4	3.4
Thoracic centrum - bipartite ossification	1	1	0.5	2	2	1.3	4	4	2.6	8	7	5.2
Thoracic centrum - dumb-bell-shaped	19	11	12.1	13	10	8.4	31	18	22.5*	37	16	24.0
Thoracic centrum - asymmetrically ossified	3	3	1.4	2	2	1.2	4	4	2.4	10	7	6.7

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Table 12 (continued) Summary Incidence of Foetal Skeletal Findings

Skeletal Findings	Dietary Concentration (ppm)											
	0 (Control)			2500			5000			7500		
	Number of Foetuses (litters) Examined											
	157 (23)			147 (23)			143 (24)			159 (24)		
	NF	NL	%†	NF	NL	%†	NF	NL	%†	NF	NL	%†
Vertebral Column (continued)												
Thoracic centrum - hemicentric	0	0	0.0	1	1	0.5	0	0	0.0	1	1	0.8
Thoracic (neural) arch - incomplete ossification	0	0	0.0	2	1	1.1	0	0	0.0	0	0	0.0
Lumbar centrum - incomplete ossification	0	0	0.0	0	0	0.0	1	1	0.8	0	0	0.0
Lumbar centrum - bipartite ossification	0	0	0.0	0	0	0.0	1	1	0.5	0	0	0.0
Lumbar (neural) arch - incomplete ossification	1	1	0.6	0	0	0.0	1	1	0.8	0	0	0.0
Sacral centrum - incomplete ossification	0	0	0.0	0	0	0.0	1	1	0.8	0	0	0.0
Sacral (neural) arch - incomplete ossification	36	15	24.5	33	13	20.8	21	11	15.5	17	7	11.4
Sacral (neural) arch - not ossified	3	2	2.0	2	2	1.5	0	0	0.0	2	1	1.2
Number of pre-sacral vertebrae = 25/27 (D = pelvic displacement)	0	0	0.0	2	2	1.2	0	0	0.0	6	4	3.6
Caudal vertebrae - less than 4 ossified	33	12	20.3	51	19	33.2	42	16	29.8	58	16	36.5
Conjoined twin foetuses	0	0	0.0	1	1	0.5	0	0	0.0	0	0	0.0
Ribs												
14th rib - extra - associated with 1st lumbar vertebra	0	0	0.0	2	1	1.1	0	0	0.0	6	3	3.5
Ossification centre - associated with 1st lumbar vertebra	1	1	0.9	13	8	8.9*	24	13	15.8***	56	18	33.9***
One or more ribs - wavy	2	2	1.4	0	0	0.0	1	1	0.8	0	0	0.0
One or more ribs - thickened	2	2	1.4	0	0	0.0	0	0	0.0	0	0	0.0

NOTE: a foetus may appear in more than one category



United States Environmental Protection Agency
Washington, DC 20460

Section 8(e) Notice

This is an original submission:



This is an amendment:



CERTIFICATION

I hereby certify to the best of my knowledge and belief that (1) all information entered on this form is complete and accurate; and (2) any confidentiality claims are true and correct as to that information for which they have been asserted. Any knowing and willful misinterpretation is subject to criminal penalty pursuant to 18 USC 1001.

Signature:

ES/Frederick H. Gouzoules

Official Title:

Director - Product Stewardship

Contact Person:

Frederick H. Gouzoules

Email Address:

fred.gouzoules@ingevity.com

Date Signed:

05/31/2016

PART 1

Contact Information

Submission Information

Case Number:

Submission Alias:

Rosin 2016 May 31 09:26:08 EDT
2016

Date Submitted:

05/31/2016

Submitter Information

CBI:

Yes: No:

Company Name:

Ingevity Corporation

Address:

5255 Virginia Avenue
North Charleston, SC, 29406
United States

Contact Person:

Frederick H. Gouzoules

Phone Number:

8437402171

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Technical Contact

CBI:

Yes: No:

Company Name:

Ingevity Corporation

Address:

5255 Virginia Avenue
North Charleston, SC, 29406
United States

Contact Person:

Dr Frederick H. Gouzoules

	Phone Number: 8437402171	Email Address: fred.gouzoules@ingevity.com
PART 2	Chemical Reports	
Chemical Identification	Chemical Report Folder Alias: Rosin	
	Chemical Identifying #: CASRN: 8050-09-7	CBI: Yes: <input type="checkbox"/> No: <input checked="" type="checkbox"/>
	Chemical Name: Rosin	
Attached Document(s)	Report Study Title: Tall Oil Rosin CAS 8050-09-7: Oral (Dietary) Pre-Natal Developmental Toxicity Study in the Rat	
	Original Document: TSCA 8e Submission Rosin May 2016.pdf	Submission Type: Initial Submission
	Summary Original Document: TSCA 8e Letter Rosin May 2016.pdf	
	Effects: Health Effects	Endpoints: Developmental Toxicity/teratogenicity

Paperwork Reduction Act

The information collection requirements contained in the information collection request (ICR) have been submitted for OMB approval under 15 U.S.C. 2607(e). The ICR prepared by EPA, identified under EPA ICR No. 0794.13 and OMB control number 2070-0046, is available in the docket for the ICR. ICR No. 0794.13 addresses the incremental changes to the currently approved ICR documents that cover the existing reporting and record keeping programs that are approved under OMB control number 2070-0046. An agency may not conduct or sponsor, and a person is not required to, respond to a collection of information unless it displays a currently valid OMB control number.

Authority

The Government Paperwork Elimination Act (GPEA) (44 U.S.C. 3504) provides that, when practicable, Federal organizations use electronic forms, electronic filings, and electronic signatures to conduct official business with the public. EPA's Cross-Media Electronic Reporting Regulation (CROMERR) (40 CFR part 3) (Ref. 2), provides that any requirement in title 40 of the CFR to submit a report directly to EPA can be satisfied with an electronic submission that meets certain conditions once the Agency published a document in the **Federal Register** announcing that EPA is prepared to receive certain documents in electronic form. For more information about CROMERR, go to <http://www.epa.gov/cromerr/>.