Ramazzini Days 2023

Global Glyphosate Study:

First Results from the Long-term Integrated Study

Bologna, October 25th, 2023

Global Glyphosate Study

www.glyphosatestudy.org

GGS: PARTNERS

Boston College, USA

University of California, USA

University of Padua, Italy

Icahn School of Medicine at Mount Sinai, USA

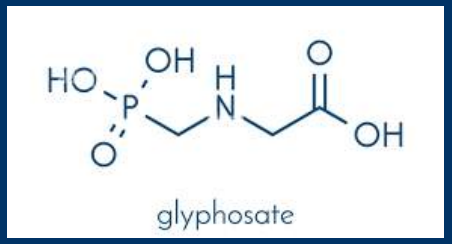
George Mason University, USA

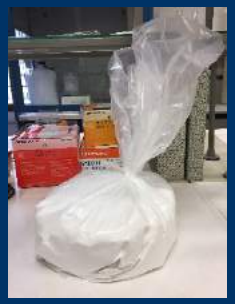
Federal University Of Parana, BR

University of Copenhagen, DNK

King's College, UK

GGS: INTEGRATED STUDY





Active ingredient
Isopropylamine salt of N-(phosphonomethyl)glycine; {Isopropylamine salt of glyphosate}

Composition

COMPONENT	CAS No.	% by weight (approximate)
Isopropylamine salt of glyphosate	38641-94-0	41
Other ingredients		59

The specific chemical identity is being withheld because it is trade secret information of Monsanto Company.

Active ingredient
Isopropylamine salt of N-(phosphonomethyl)glycine; {Isopropylamine salt of glyphosate}

Composition

Components	CAS No.	EC No.	EU Index No. / REACH Reg. No. / C&L ID No.	% by weight (approximate)	Classification
Isopropylamine salt of glyphosate	38641-94-0	933-426-9	015-184-00-8 / - / 02-2119693876-15-0000	41.5	Aquatic Chronic - Category 2; H411; {c} N; R51/53; {b}
Ethoxylated tallowamine			- / - / -	15.5	Xn, N; R22, 41, 51/53; {a}
Water	7732-18-5	231-791-2	- / - / -	43	

The specific chemical identity is being withheld because it is trade secret information of Monsanto Company.

Glyphosate dose (mg/kg bw/day)	
0.5	ADI EU
5	ADI EU 10X
50	NOAEL EU

9 TREATED + 1 CONTROL GROUP

GGS: INTEGRATED STUDY

Breeders — Dams (GD6)

Generation 1

- Long- term & Carcinogenesis
- Sub-chronic toxiciy
- Reproductive developmental toxicicty

Matching, delivery, weaning

Generation 2

- Reproductive developmental toxicity
- Immunotoxicity
- Neurobehavioural-neurotoxicity

GGS: LONG TERM STUDY

- 51 SD rats per sex, per group
- 3 doses (ADI, ADIx10, NOAEL)
- 3 compounds (glyphosate, Roundup, RangerPro)

RESULTS

LONG TERM CARCINOGENICITY: LEUKEMIA

Treatment	Dose (mg/Kg bw/day) / Sex		Lymphoblastic L.			Monocytic L.			Myeloid L.			TOTAL L.		
			N	%	P value	N	%	P value	N	%	P value	N	%	P value
Control	-	M	0	-		0	-		0	-		**0**	**-**	
		F	0	-		0	-		0	-		0	-	
		M+F	**0**	**-**		0	-		0	-		**0**	**-**	
Roundup	0.5	M	0	-		0	-		0	-		**0**	**-**	
		F	0	-		0	-		0	-		0	-	
		M+F	**0**	**-**		0	-		0	-		**0**	**-**	
Roundup	5	M	0	-		0	-		0	-		**0**	**-**	
		F	0	-		0	-		0	-		0	-	
		M+F	**0**	**-**		0	-		0	-		**0**	**-**	
Roundup	50	M	1	2.0		1	2.0		0	-		**2**	**3.9**	**# 0.0142**
		F	1	2.0		0	-		0	-		1	2.0	
		M+F	**2**	**2.0**	**# 0.0142**	1	1.0		0	-		**3**	**2.9**	**# 0.0027**

#: Cochran-Armitage (trend) test

LONG TERM CARCINOGENICITY: LEUKEMIA

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			N	%	P value	N	%	P value	N	%	P value	N	%	P value
Control	-	M	0	-		0	-		0	-		0	-	
		F	0	-		0	-		0	-		0	-	
		M+F	0	-		0	-		0	-		0	-	
Glyphosate	0.5	M	0	-		1	2.0		0	-		1	2.0	
		F	0	-		0	-		1	2.0		1	2.0	
		M+F	0	-		1	1.0		1	1.0		2	2.0	
Glyphosate	5	M	0	-		1	2		0	-		1	2.0	
		F	0	-		0	-		0	-		0	-	
		M+F	0	-		1	1.0		0	-		1	1.0	
Glyphosate	50	M	1	2.0		0	-		0	-		1	2	
		F	0	-		0	-		0	-		0	-	
		M+F	1	1.0		0	-		0	-		1	1.0	

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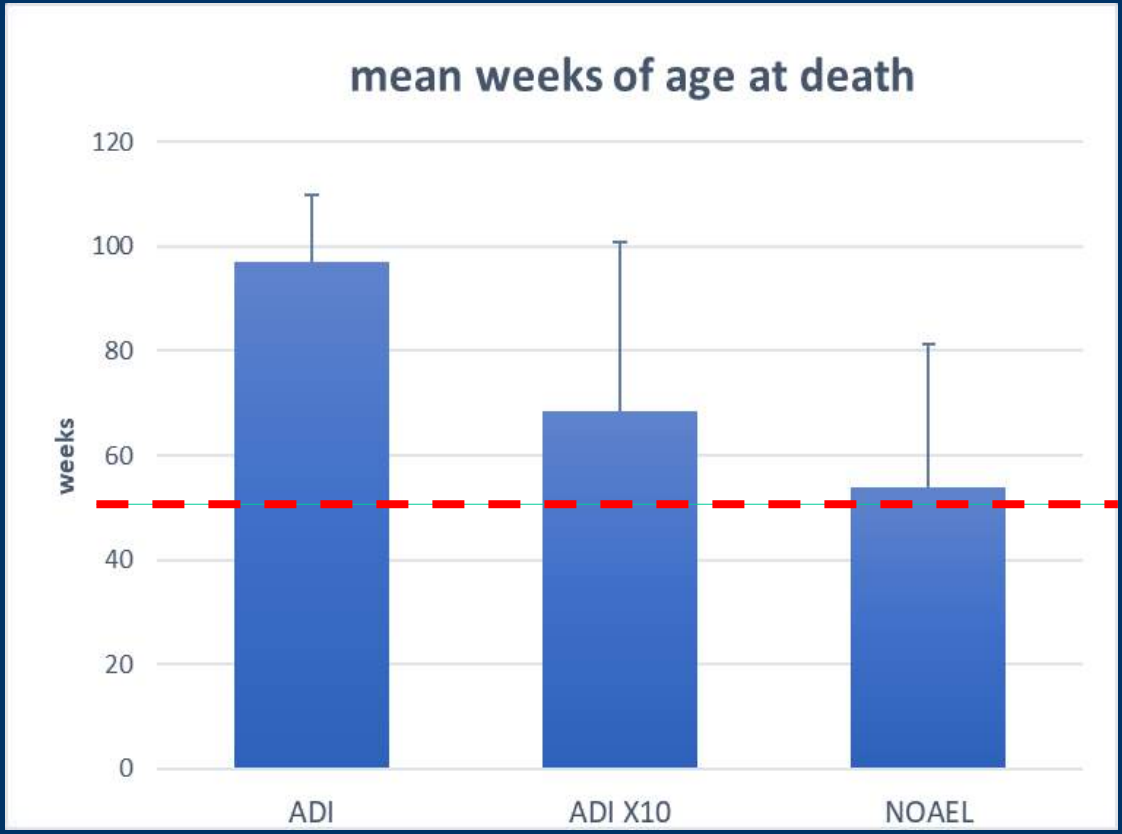
Treatment	Dose (mg/Kg bw/day) / Sex		Lymphoblastic L.			Monocytic L.			Myeloid L.			TOTAL L.		
			N	%	P value	N	%	P value	N	%	P value	N	%	P value
Control	-	M	**0**	**-**		0	-		0	-		**0**	**-**	
		F	0	-		0	-		0	-		0	-	
		M+F	**0**	**-**		0	-		0	-		**0**	**-**	
RangerPro	0.5	M	**0**	**-**		0	-		1	2.0		**1**	**2.0**	
		F	0	-		0	-		0	-		0	-	
		M+F	**0**	**-**		0	-		1	1.0		**1**	**1.0**	
RangerPro	5	M	**0**	**-**		0	-		1	2.0		**1**	**2.0**	
		F	0	-		1	2.0		0	-		1	2.0	
		M+F	**0**	**-**		1	1.0		1	1.0		**2**	**2.0**	
RangerPro	50	M	**2**	**3.9**	**# 0.0142**	1	2.0		0	-		***3***	***5.9***	***# 0.062***
		F	1	2.0		0	-		0	-		1	2.0	
		M+F	**3**	**2.9**	**# 0.0027**	1	1.0		0	-		**4**	**3.9**	**# 0.039**

#: Cochran-Armitage (trend) test

LONG TERM CARCINOGENICITY: LEUKEMIA BY AGE AT DEATH

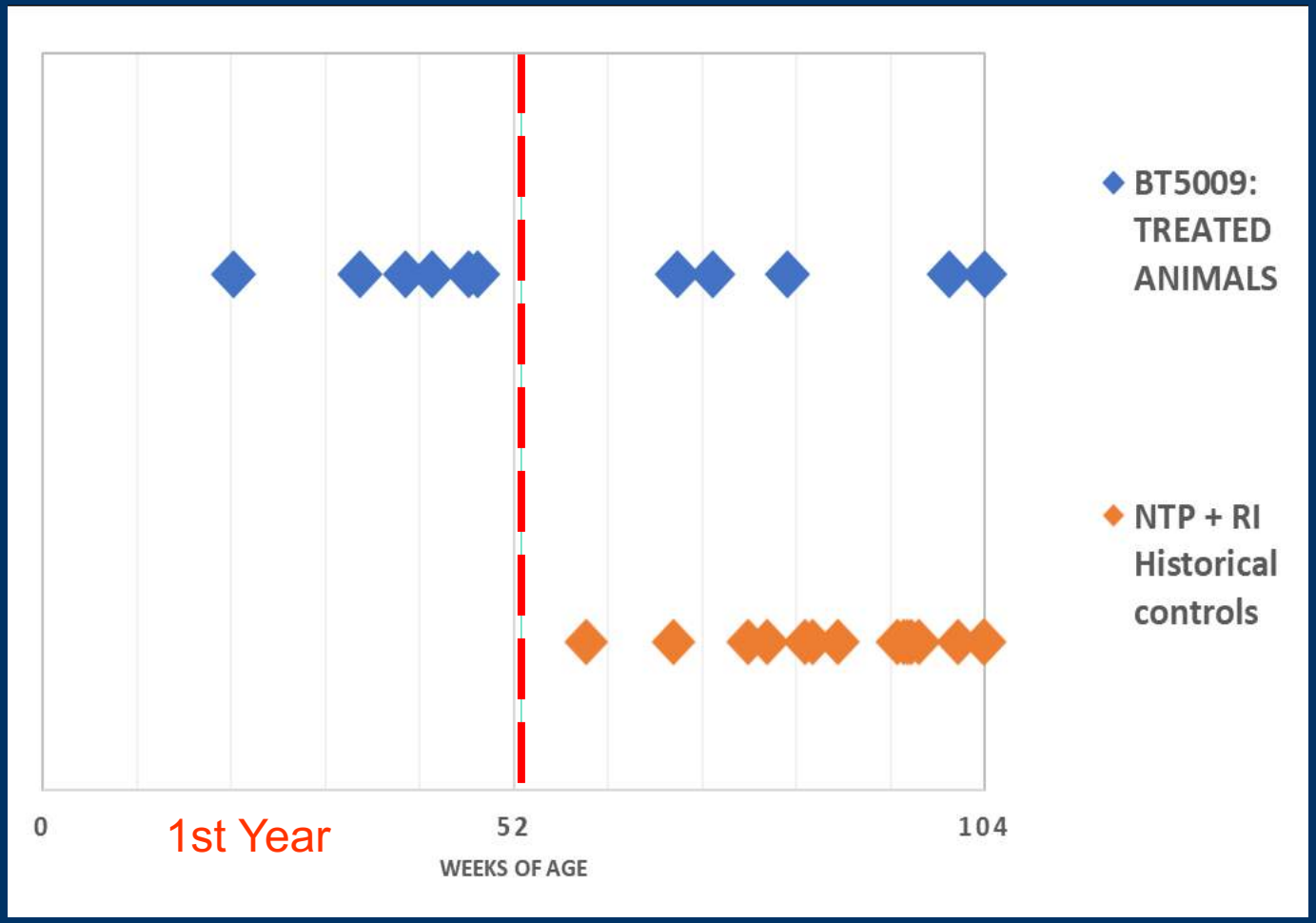


Treatment	Dose (mg/kg bw/day)	Weeks
Glyhposate	50	21
Glyhposate	5	35
RangerPro	50	40
RangerPro	50	43
Roundup	50	47
Roundup	50	48
RangerPro	5	70
RangerPro	50	74
RangerPro	0.5	82
RangerPro	5	100
Glyhposate	0.5	104
Glyhposate	0.5	105
Roundup	50	105

Weeks of age at death (mean) by dose

ADI (0.5 mg/kg bw/day)	ADI x 10 (5 mg/kg bw/day)	NOAEL (50 mg/kg bw/day)
97±13 weeks	68±33 weeks	54±27weeks

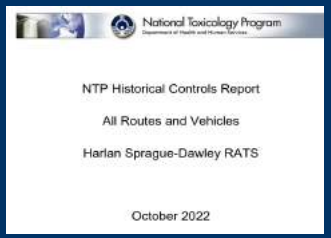
LONG TERM CARCINOGENICITY: LEUKEMIA BY AGE AT DEATH



BT5009:
1.42% (13/918)
MM 1.96%
FF 0.65%

RI:
0.82% (4/490)
MM 1.63%
FF 0%

NTP:
1.02% (12/1179)
MM 1.19%
FF 0.85%


National Toxicology Program

NTP Historical Controls Report

All Routes and Vehicles

Harlan Sprague-Dawley RATS

October 2022

RESULTS

- Low doses of glyphosate-based herbicides at exposure levels below the current NOAEL caused a statistically significant **dose-related trend in leukemia incidence**, which is a very rare malignancy in Sprague-Dawley rats.

- An additional very important finding is that about **half of the leukemias deaths** seen in the glyphosate and glyphosate-based herbicides groups **occurred at less than one year of age**. No case of leukemia was observed in the first year of age on more than 1600 historical controls in carcinogenicity studies conducted by either the Ramazzini Institute or the US National Toxicology Program (NTP)

Thank you!