



FOOD SAFETY AND STANDARDS
AUTHORITY OF INDIA

Inspiring Trust, Assuring Safe & Nutritious Food
Ministry of Health and Family Welfare, Government of India



FSSAI – IITR – CHIFSS Technical Workshop

FSSAI, New Delhi 22nd June, 2018

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Case Study – Food Colours and Artificial sweeteners

Identify food additive



Toxicity tests



**Determine No Observed Adverse
Effect Level(NOAEL)**



Select safety factor



Calculate Acceptable Daily Intake(ADI)



Calculate Exposure



**Compare the exposure and the ADI
When exposure exceeds ADI, Risk
mitigation is required**

Food Colours



Concerns and Perceptions

Colours - Natural vs Synthetic

Permitted vs Non permitted

Regulatory limits vs technological function

Prevention of fraud

Good Manufacturing Practices (GMP) for food additives

- 1. Lowest possible level necessary to accomplish its desired effect**
- 2. The additive is prepared and handled in the same way as a food ingredient.**

Assumptions

1. All the colours are used at permitted levels
2. A person consumes all the foods where these additives are added

Food consumption data:

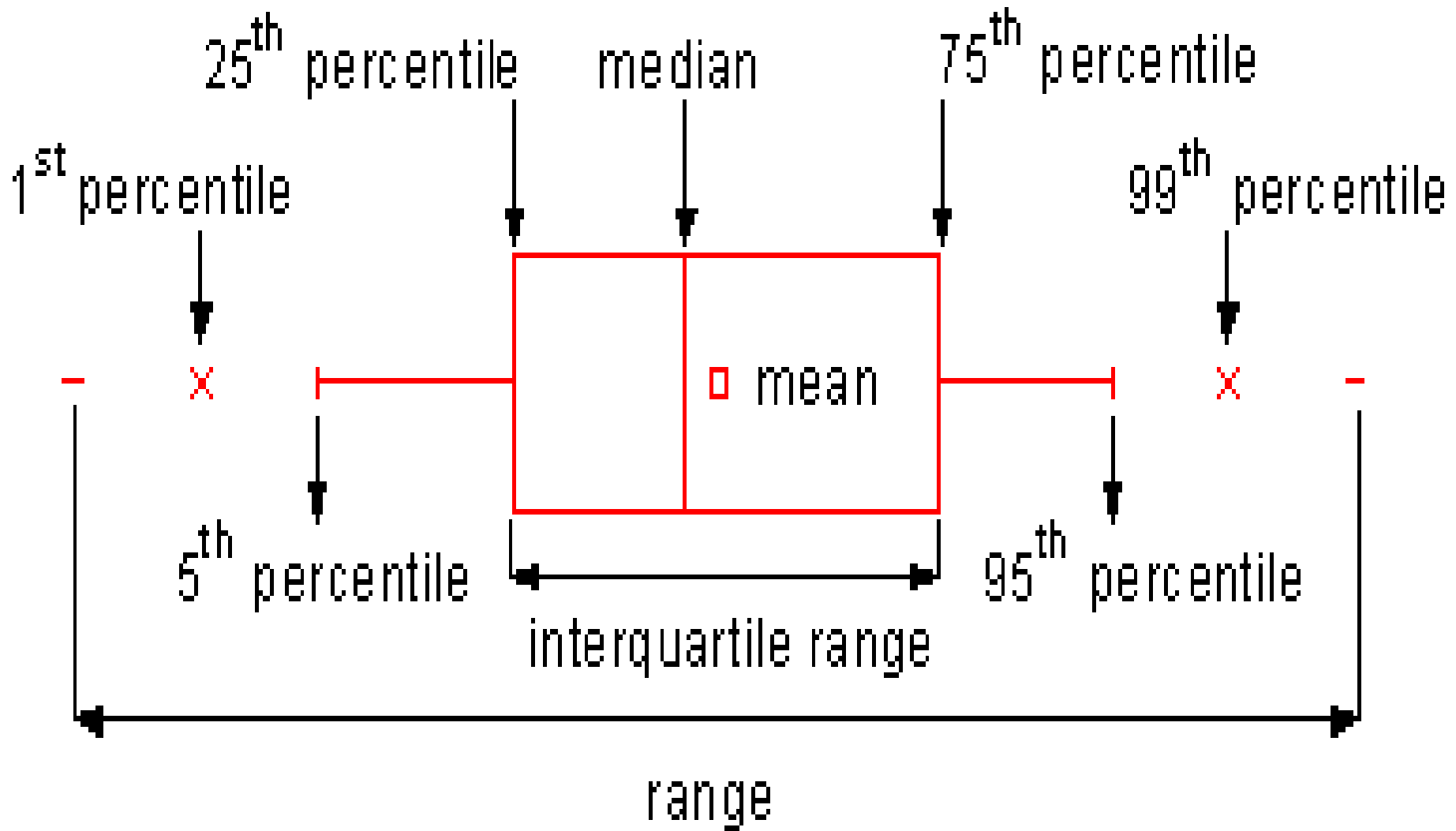
1. Food consumption data is taken from recently(2012) completed study
2. Data is computed only on foods where the consumption data is available

Body weight

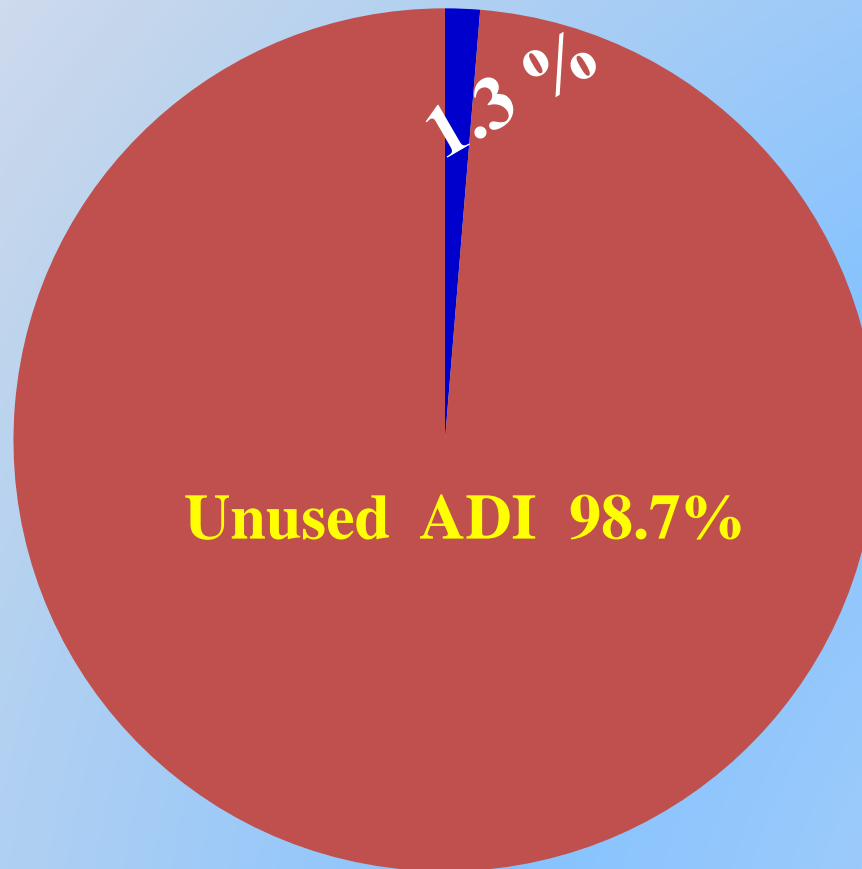
1. Body used for ADI calculation is 50kg

S.No	Name of the food colour	INS No	ADI (mg/ kg bw)	Percentage of ADI at Mean value	Percentage of ADI at 95 th percentile value
1	Erythrosine (No. of permitted food items = 14; No. of consumption data available permitted food items = 5)	127	0-0.1	96 %	537.6 %
2	Ponceau 4R (No. of permitted food items = 40; No. of consumption data available permitted food items = 7)	124	0-4	3.11 %	15.44 %
3	Carmoisine (No. of permitted food items = 14; No. of consumption data available permitted food items = 5)	122	0-4	2.4 %	13.44 %
4	Sunset Yellow FCF (No. of permitted food items = 15; No. of consumption data available permitted food items = 5)	110	0-4	2.4 %	13.44 %
5	Indigo carmine (No. of permitted food items = 14; No. of consumption data available permitted food items = 5)	132	0-5	1.92 %	10.75 %
6	Tartrazine (No. of permitted food items = 14; No. of consumption data available permitted food items = 5)	102	0-7.5	1.28 %	7.1 %
7	Brilliant blue FCF (No. of permitted food items = 14; No. of consumption data available permitted food items = 5)	133	0-12.5	0.7 %	4.3 %
8	Fast green FCF (No. of permitted food items = 14; No. of consumption data available permitted food items = 5)	143	0-25	0.38 %	2.15 %

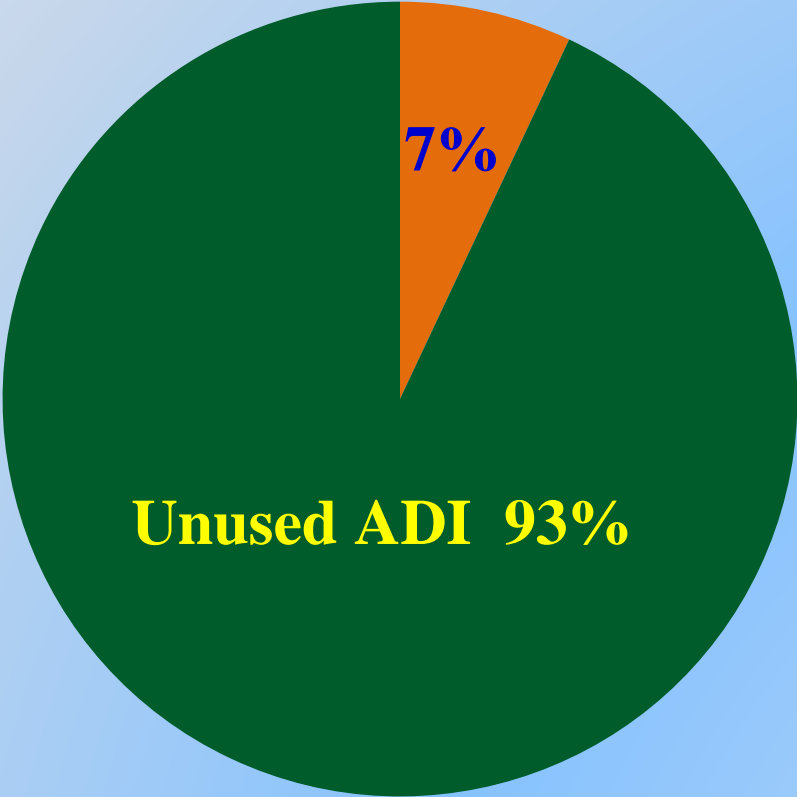
S.No	Name of the food colour	INS No	ADI (mg/ kg bw)	Percentage of ADI at Mean value	Percentage of ADI at 95 th percentile value
1	Canthaxanthin (No. of permitted food items = 4; No. of consumption data available permitted food items = 2)	161g	0-0.03	81.3 %	285.3 %
2	Riboflavin (No. of permitted food items = 7; No. of consumption data available permitted food items = 2)	101	0-0.5	4.88 %	17.1 %
3	Curcumin (No. of permitted food items = 9; No. of consumption data available permitted food items = 2)	100ii	0-4	0.8 %	2.85 %
4	Beta carotene (No. of permitted food items = 20; No. of consumption data available permitted food items = 2)	160a	0-5	0.48 %	1.71 %
5	Beta - apo - 8' – carotenal (No. of permitted food items = 10; No. of consumption data available permitted food items = 5)	160e	0-5	0.48 %	1.71 %
6	Ethylester of Beta apo-8 carotenic acid (No. of permitted food items = 2; No. of consumption data available permitted food items = 1)	160f	0-5	0.16 %	0.57 %
7	Annatto extracts (No. of permitted food items = 22; No. of consumption data available permitted food items = 2)	160b	0-12	0.2 %	0.71 %
8	Caramel (No. of permitted food items = 5; No. of consumption data available permitted food items = 2)	150	0-160	0.3 %	1.08 %



Percentage of ADI used up for Tartrazine at mean intake of colored food

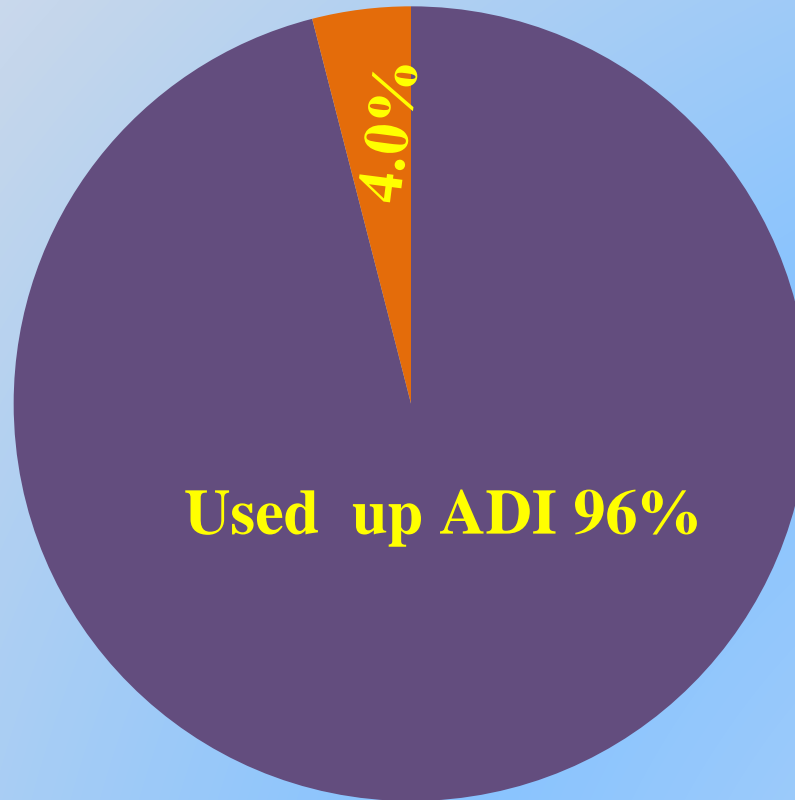


Percentage of ADI used up for Tartrazine at 95th percentile intake of colored food



Exposure assessment of Erythrosine

Percentage of ADI used up for Erythrosine at mean intake of colored food



Lowest Observed Adverse Effect Level (LOAEL) is 200mg oral dose/14days in humans had increased Thyroid secretions (Hyperthyroidism)

60mg oral dose had no effect -No Observed Adverse Effect Level(NOAEEL)

60/60= 1mg/kg bw with a safety factor of 10

ADI 0-0.1mg/kg bw

Body weights

Body weights of Adult men* (>18yrs) Rural

Percentiles	Body weight (in Kg)
5	41.10
10	43.70
25	49.17
50	55.85
75	63.02
95	76.30

* n=3538

Body weights of Adult men* (>18yrs) Urban

Percentiles	Body weight (in Kg)
5	44.84
10	48.20
25	54.00
50	62.40
75	70.30
95	86.00

* n= 1647

Body weights of Adult women* (>18yrs) Urban

Percentiles	Body weight (in Kg)
5	38.50
10	41.50
25	47.90
50	55.30
75	62.90
95	76.50

* n=1921

Body weights of Adult women* (>18yrs) Rural

Percentiles	Body weight (in Kg)
5	34.90
10	37.40
25	41.80
50	48.00
75	55.60
95	69.00

* n= 4029

Artificial Sweeteners



Concerns and perceptions

Cancers - policy for permitting any additive –
Only threshold chemicals

Artificial/synthetic -Not safe

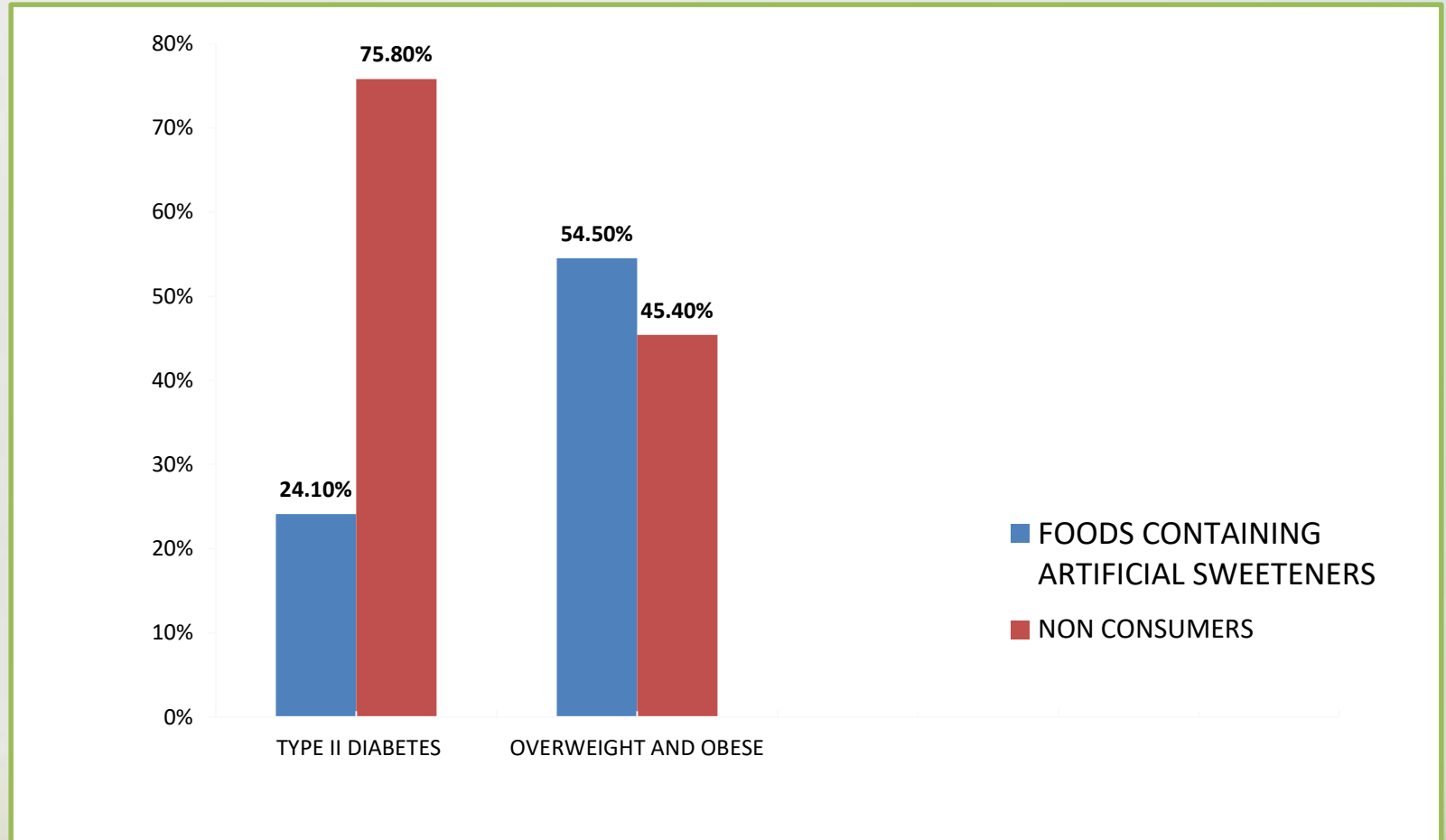
CHARACTERISTICS OF THE SWEETENERS

Sweetener	Sweetness (compared with sucrose)	JECFA ADI (mg/kg body weight/day)	Characteristics
Aspartame	180-200	0-40	white, odorless, crystalline powder, slightly soluble in water ,provides 4 kcal/g
Acesulfame-k	200	0-15	Odorless, white crystalline powder, flavor enhancer, but high concentrations may lead slight after taste.
Sucralose	600	0-15	Since 1998 it was in use as additive in 15 food categories, including tabletop sweetener, White to off-white, odorless crystalline powder, heat and ph stable
Saccharin	300	0-5	White crystals or a white, crystalline powder, odorless or with a faint, aromatic odor, bitter or metallic aftertaste,
Neotame	7000-13000	0-2	White to half white powder, manufactured from aspartame, heat stable & completely eliminated

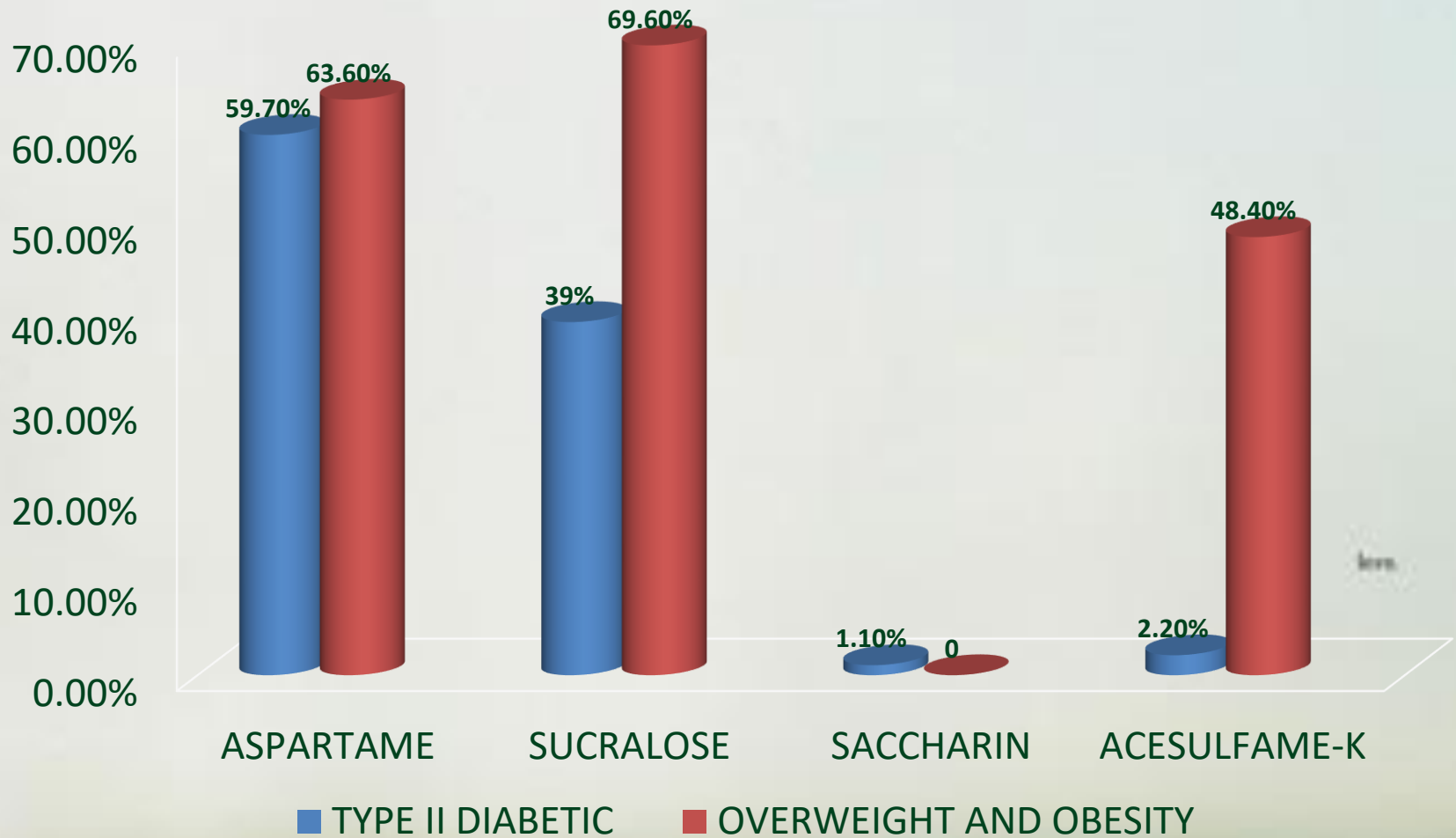
Commonly Prepared Sugar Free Sweets

Sweets	Sweetener used	Weight of each sweet (g)	Amount of sweetener in one unit of sweet (mg)
1.Sugarfree angeer rolls	relish(sucralose)	29.16±3.76	7.29±0.94
2.Sugarfree ragi laddu	relish(sucralose)	45.83±3.76	18.79±1.54
3.Sugarfree badusha	relish(sucralose)	52.66±5.35	21.96±2.23
4.Sugarfree agmeri kalakanda	relish(sucralose)	45±6.32	3.6±0.50
5.Sugarfree kaju barfi	relish(sucralose)	40±3.16	6.67±0.54
6.Sugarfree kajukathli	relish(sucralose)	9.83±0.40	6.67±0.54
7.Sugarfree gondh laddu	relish(sucralose)	50.16±1.60	20.56±0.65
8.Sugarfree mothichurladdu	relish(sucralose)	44.83±2.56	7.62±0.43
9.Sugarfree mysore pak	relish(sucralose)	35±5.17	11.68±1.72
10.Sugarfree sunnunda	relish(sucralose)	42.33±2.58	14.13±0.86
11.Sugarfree kova pure	relish(sucralose)	47.66±2.33	11.91±0.58
12. Sugarfree kalakanda	relish(sucralose)	45±6.32	3.6±0.50

Comparing percentage intake of foods containing artificial sweeteners and non consumers among the type 2 diabetic, overweight and obese individuals



consumption pattern of sweeteners among regular consumers



Comparison of mean daily intake of type 2 diabetic individuals [n=87] with ADI

Sweetener	Percentage consumption (%)	Intake (mg/kg/day) Mean±SD	Range	JECFA (mg/kg/day)	% ADI
Aspartame	52(59.7)	0.85±0.74	0.01-2.89	40	2.1
Sucralose	34(39)	0.41±0.46	0.01-1.87	15	2.6
Saccharin	1(1.1)	0.002±0.0	0-0.002	5	0.04
Acesulfame-k	2(2.2)	0.035±0.007	0.03-0.04	15	0.2

Total number of subjects exceed because, people had more than one sweetener through their foods

Mean daily intake of individual sweeteners among overweight and obese individuals [n=33] and its percentage comparison with ADI

Sweetener	Percentage consumption n (%)	Intake (mg/kg/day) Mean±SD	Range	JECFA (mg/kg/day)	% ADI
Aspartame	21(63.6)	0.65±0.52	0.06-1.38	40	1.62
Sucralose	23 (69.6)	0.41±0.11	0.29-0.61	15	2.73
Saccharin	0(0)	-	-	5	-
Acesulfame-k	16(48.4)	0.15±0.05	0.04-0.21	15	1.0

Total number of subjects exceeds, because some people were having more than one sweetener through their diet foods