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JECFA	19
FDA	21
EU	21
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.....	24
.....	29

2007 2 6

0206001

2007 2 8 177

2008 3 24 56

2008 4 15 57

2007 3 31

2007 4 1

2007 9 30

2007 10 1

25383-99-7

CAS

4.0% 2,000 mg/kg /

NOAEL 1

ADI 20 mg/kg / 100

1 2

1 2

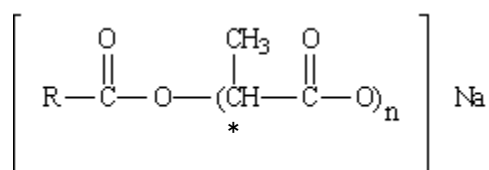
Sodium stearyl lactylate, Sodium stearyl-2-lactylate
CAS 25383-99-7

1 2

2

1

2



D

	R-CO	n	¹	
C ₂₁ H ₃₉ O ₄ Na		1		378.53
	CH ₃ (CH ₂) ₁₆ CO			
C ₁₉ H ₃₅ O ₄ Na		1		350.47
	CH ₃ (CH ₂) ₁₄ CO			
C ₂₄ H ₄₃ O ₆ Na		2		450.59

1 3

36~47

¹ JECFA

4 5

1964

2004

2002 7
FAO / WHO

JECFA

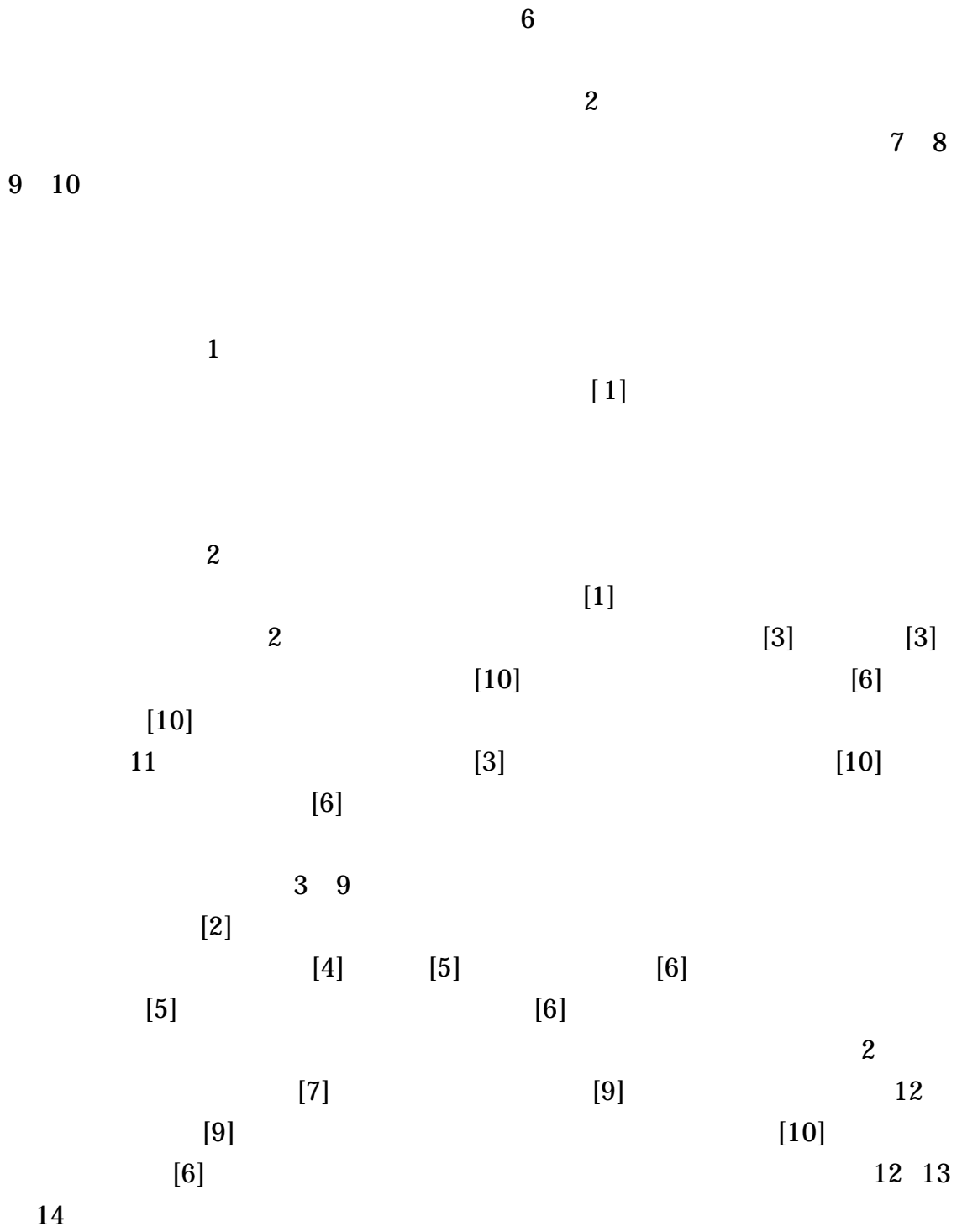
EU

46

JECFA

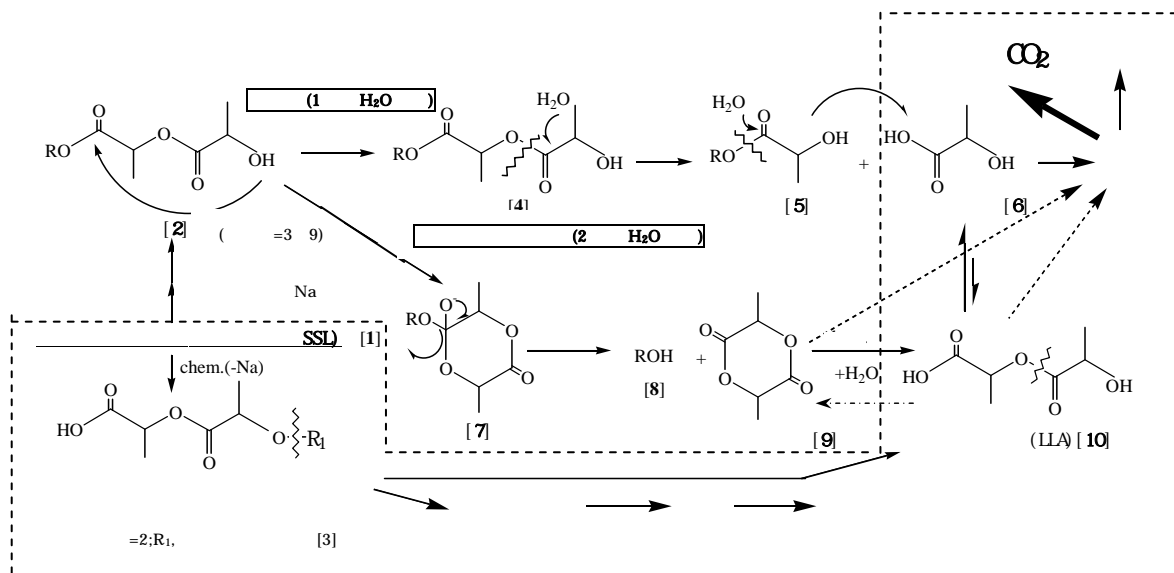
2

in vitro



/Cori

15 16



Wistar albino	Tuck To	Dunkin-Hartley
<i>in vitro</i> 37	¹⁴ C	4
mg/0.1 mL 5 × 10 ⁶ dpm		1
20%		30 40%
60%		40
24.7 μmol/g	/hr	7.5 μmol/g /hr
10%		
	0.27 μmol/g /hr	0.8 μmol/g /hr
		13

Tuck To 3 4 Dunkin-Hartley 14C

900 mg/kg
mg/kg

24

900 mg /kg
48

¹⁴C

DL-

325

13 1

1. ¹⁴C

DL-

48

%

¹⁴ C	0.79	0.91	0.26	0.04	2.07	2.01	4.11	0.24	0.16	6.66
¹⁴ C DL-	0.84	0.98	0.21	0.04	2.14	1.87	7.87	0.18	0.10	10.17

¹⁴CO₂

DL-

DL-

92.2%

82.6%

4.0%

16.2%

13 2

2. ¹⁴C

¹⁴C

DL-

48

%

	CO ₂			
¹⁴ C	82.6	16.2	2.1	98.4
¹⁴ C DL-	92.2	4.0	1.1	97.3

¹⁴C

¹⁴C

24

CO₂

¹⁴C

58%

60

¹⁴C

6 3

3.

^{14}C

^{14}C

48

CO_2

%

	CO_2
+ ^{14}C	58
^{14}C	60

10 12%

13 14

JECFA

10

JECFA

JECFA

2

9

5
 0 250 1,000 6,250 mg/kg / ² 43
 12.5% 2.0%
³ 1969 17 2.0%
 12.5% 6 17 19
 NOAEL 2.0 12.5%

12.5%
 ADI

10
 12.5% 0 250 2,500 6,250 mg/kg / ² 98
 12.5%
 6 17
 19

25
 3.0 4.0 5.0 7.5% 0 50 500 1,000 1,500 2,000 2,500 3,750 mg/kg
 / ² 1 5.0%
 6 17 19
 NOAEL 4.0% 2,000 mg/kg /

1 3
 0 1,875 mg/kg / ² 2 0 7.5%
 6 17 19

ADI

³ 1969 JECFA ADI NOAEL 0.5% 250
 mg/kg / 1973
 2.0% 1,000 mg/kg /

Wistar 20 0 5.0
 10 20% 0 2.5 5.0 10 g/kg / 2 90
 20% 8 1
 20% 4 2
 10 20%
 13
 20%

NOAEL 5.0% 2,500 mg/kg /
 4 20 21 22

2 0 10 100 400 1,000
 2,500 mg/kg / D- 5% 2 2,500
 mg/kg 1,000 mg/kg
 100 mg/kg 1
 2,500 mg/kg 1,000 mg/kg
 1,000 mg/kg
 400 2,500 mg/kg
 2,500 mg/kg
 1,000 mg/kg
 400 mg/kg

23

4 0 4 20 100 mg/kg /
 D- 5% 13 100
 mg/kg

4

23 24
 NOAEL 1996 100 mg/kg
 1 20 mg/kg /
 24 1999 Food and Chemical Toxicology
 100 mg/kg 5
 23 100 mg/kg
 1
 23

6 F344 (50) 0 2.5 5.0%
 0 1,250 2,500 mg/kg / 2 2
 2.5% 5.0%
 5%
 25

CD-1 6 15 12 570 mg/kg /
 10
 26

5
 ADI

Salmonella typhimurium TA92 TA94 TA98 TA100 TA1535
 TA1537 300 µg/plate 27 28
 1,000 µg/plate 29 S9mix
 62.5 µg/mL S9mix CHL 48
 27 28 30

a.

S. typhimurium TA98 TA100 TA1535 TA1537 TA1538
 50 µg/plate
 S9 mix 31

S. typhimurium TA98 TA 1535 TA1537 *E. coli* WP2 *uvrA*
 5,000 µg/plate S9mix
 23 24 32

b.

S. cerevisiae D6 500 µg/mL
 500 µg/mL
 33

c.

CHL
 S9 mix 50 µg/mL S9 mix
 1,000 µg/mL 24 10 µg/mL 48
 5 µg/mL S9mix
 23 24
 34

d.

Crj:CD-1(ICR)

2,000 mg/kg

24

23 24 35

a.

S. typhimurium TA92 TA94 TA98 TA100 TA1535 TA1537

10 mg/plate S9mix

27 28

S. typhimurium

Saccharomyces cerevisiae

0.18% S9mix

37

50%

S. typhimurium TA94 TA98 TA100 TA2637

100 mg/plate S9mix

28 38

S. typhimurium TA94 TA98 TA100

50,000 µg/plate S9mix

39

S. typhimurium TA97 TA102

10 mg/plate S9mix

40

S. typhimurium

S. cerevisiae

(0.625) S9mix

37

S. typhimurium TA98 TA100 TA1535 TA1537 *Escherichia coli*

WP2 *uvrA*

5,000 µg/plate

S9mix

41

b. Rec-assay

	<i>Bacillus subtilis</i> M45	Rec-		H17	Rec+
Rec-assay	20 mg/disk		S9mix		
	42				

c.

L5178Y TK+/-				1
4,000 µg/mL	2	3,000 µg/mL		S9mix
		43		

d.

		CHL			
1,000 µg/mL	S9mix		24	48	
				27	28 44

	50%				
2,000 µg/mL	S9mix	CHL	24	48	
				28	38 44

		CHL			
3.0 mg/mL	S9mix		24	48	
				42	44

e.

Crl;CD-1BR		5		
3,350 mg/kg				45

3
Buehler

Ctrl: HA BR

0.2 g

2

10

6

1 6

45

46

Hra:SPF

Draize

1

0.05 g

72

47

Hra:SPF

Draize

3

0.5 g 4

48

27

33%

100 mL

12
mg/kg
26 51 34.3 7 48 49
D- 57.7 95.5 mg/kg
1,530
50

51

40 DL- 0.4% 0.4 g/ ⁶
2 4
52
10 12 DL- 0.35% 0.35 g/ ⁶
L- 3 D-
12
L- 80% D- 20%
D-

Plasma bicarbonate

52
3 DL- 0.4% 0.5% 0.4 0.5 g/ ⁶
10 pH
80%
2 33%
52

3 10 g 250 mL
5 g

53

1986

14.7 mg

54

EU

1984

0.2 mg

SCF

ADI

ADI 20 mg/kg

2 114%

136 268%

55

1989 NAS/NRC

1970 244,000

110.7 1976

1,730,000 784.7 1982 793,000 359.7

1987 5,660,000 2,567

1970 338,000

153.3 1975 60,000 27.2 1976 1,070,000

485.4 1982 193,000 87.5 1987 330,000

149.7

16

2001

3.9 mg

56

JECFA

JECFA 1969 13

5

0 0.5 2.0 12.5% 43

2.0% 12.5%

250 mg/kg /

0.5%

Hodge,1953 100 ADI 0 2.5 mg/kg /
 6 17 19
 JECFA 1971 15 1973 17
 1 25 5.0%
 NOEL 2.0%
 1,000 mg/kg /

0 20 mg/kg / 50 ADI
 6 17 19 57
 58 59

15 ADI

59

JECFA
 1969 13 1973 17 1969
 D- ADI D
 60 1973
 3 DL
 D 27
 6 19 57 58 59

FDA

5

EU

SCF

ADI 20 mg/kg /

4 61

EU

E481

E482

2 10 g/kg

4 62

90

22

10%

5%

ADI

21 22

22 41

43 44 63 64 65 66 67

63

NOAEL

ADI

68

13

20

21 NOAEL 100 mg/kg /
mg/kg /

1,000

ADI 0.1

D-

ADI

D-

DL-

8

JECFA

10

JECFA

JECFA

JECFA

43

NOAEL 2.0 12.5%

12.5%

ADI

1

NOAEL

4.0% 2,000 mg/kg /

NOAEL

4.0% 2,000 mg/kg

/

100

ADI 20 mg/kg /

ADI 20 mg/kg /
ADI 1

NOAEL

JECFA
100

D-

D

試験種類	動物種	試験期間	投与方法	動物数/群	被験物質	投与量	試験結果	参照No
急性毒性				8		20 25 30 g/kg	30 g/kg 8 4 20 25 g/kg 8 LD ₅₀	17
				5		5,000 mg/kg	LD ₅₀ >5,000 mg/kg	18
反復投与毒性		28		20		0 0.5% (0 2,500 mg/kg / 2	90	17
		7.5% 12.5% 2 15% 1		1		7.5% 1,875 mg/kg / 12.5% 3,125 mg/kg / 15% 3,750 mg/kg / 2		6 17 19
		43		5		0 0.5 2.0 12.5% 0 250 1,000 6,250 mg/kg / 2	2.0% 12.5% 2.0% 1969 2.0% 12.5% NOAEL 2.0 % 1,000 mg/kg / JECFA	6 17 19
		98		10		0 0.5 5.0 12.5 % 0 250 2,500 6,250 mg/kg / 2	12.5%	6 17 19
				雄各 25		0 0.1 1.0 2.0 3.0 4.0 5.0 7.5% 0 50 500 1,000 1,500 2,000 2,500 3,750 mg/kg / 2	5.0% NOAEL 4.0 % 2,000 mg/kg /	6 17 19
		2		1 3		0 7.5% 0 1,875 mg/kg / 2		6 17 19

試験種類	動物種	試験期間	投与方法	動物数/群	被験物質	投与量	試験結果	参照No
反復投与毒性(つづき)		90		20		0 5 10 20% 0 2.5 5 10 mg/kg / 2	20% 8 1 20% 4 2 4 10 20% 13 20% NOAEL 5% 2,500 mg/kg /	20 21 22
		2		2		0 10 100 400 1,000 2,500 mg/kg / D- 5%	2,500 mg/kg 1,000 mg/kg 100 mg/kg 1 2,500 mg/kg 1,000 mg/kg 1,000 mg/kg 2,500 mg/kg 2,500 mg/kg 1,000 mg/kg 400 mg/kg	23
		13		4		0 4 20 100 mg/kg / D- 5%	100 mg/kg 100 mg/kg 1 NOAEL 100 mg/kg /	23 24
発がん性		2		50		0 2.5 5% 0 1,250 2,500 mg/kg / 2	2.5% 5% 5%	25
生殖発生毒性	6-15	10		12		570 mg/kg /		26

試験種類	動物種	試験期間	投与方法	動物数/群	被験物質	投与量	試験結果	参照No
遺伝毒性	<i>In vitro</i>	+/ S9mix	TA92 TA94 TA98 TA100 TA1535 TA1537			300 μg/plate	S9mix	27 28
			TA92 TA94 TA98 TA100 TA1535 TA1537			1,000 μg/plate	S9mix	29
				CHL			62.5 μg/mL	S9mix
	<i>In vitro</i>	(+/ S9mix)	TA98 TA100 TA1535 TA1537 TA1538			50 μg/plate	S9mix	31
			TA98 TA 1535 TA1537 <i>E.coli</i> WP2uvr A			5 15 50 150 500 1,500 5,000 μg/plate 156 313 625 1,250 2,500 5,000 μg/plate	S9mix	21 22 32
	<i>In vitro</i>		(<i>S. cerevisia</i> eD6)			500 μg/mL	S9mix 24 48	33
	<i>In vitro</i>		CHL			S9 mix (-) 1.56 3.12 6.25 12.5 25 50 μg/mL S9 mix (+) 31.3 62.5 250 500 1,000 μg/mL 24 0.313 0.625 1.25 2.5 5 10 μg/mL 48 0.156 0.313 0.625 1.25 2.5 5 μg/mL	S9mix	21 22 34
						500 1,000 2,000 mg/kg 24		21 22 35

試験種類	動物種	試験期間	投与方法	動物数/群	被験物質	投与量	試験結果	参照No		
遺伝毒性(つうき)	<i>In vitro</i>	(+/S9mix)	TA92 TA94 TA98 TA100 TA1535 TA1537			200 10,000 µg/plate	S9mix	27 28		
			<i>S.typhi murium</i>			0.18%	S9mix	37		
			<i>S.Cerevisiae</i>							
			TA94 TA98 TA100 TA2637			100,000 µg/plate	S9 mix	28 38		
			TA94 TA98 TA100			5,000 50,000 µg/plate	S9 mix	39		
			TA97 TA102			10,000 µg /plate	S9 mix	40		
			<i>S.typhi murium</i>			0.625	S9mix	37		
			<i>S.Cerevisiae</i>							
			TA98 TA100 TA1535 TA1537 <i>E.coli</i> WP2 <i>uvrA</i>			100 333 1,000 3,300 5,000 µg/plate	S9mix	41		
			<i>In vitro</i>	Rec-assay	<i>B.subtilis</i> M45 (Rec-) H17 (Rec+)			mg/disk 20		42
			<i>In vitro</i>		L5178Y TK+/-			1 :1,000 2,000 2,500 3,000 3,500 4,000 µg/mL 2 : 500 1,000 2,000 2,500 3,000 µg/mL	S9mix	43
			<i>In vitro</i>					1,000 µg /mL	S9mix 24 48	27 28 44
		CHL			500 1,000 2,000 µg/mL	S9mix 24 48	28 38 44			
		CHL								

試験種類	動物種	試験期間	投与方法	動物数/群	被験物質	投与量	試験結果	参照No	
遺伝毒性(つづき)	<i>In vitro</i>					30,000 µg/mL	S9mix 24 48	42 44	
	マウス		(CHL)	雌雄各5		837.5 1,675 3,350 mg/kg		45	
抗原性				10		0.2 g		36	
局所刺激性				1		0.05 g	72	46	
				3		0.5 g 4	48	47	
ヒトにおける知見				1 27		33% 100 mL	12 1,530 mg/kg	48 49	
				7名(26 ~ 51 歳、平均 34.3歳)	D-	57.7 95.5 mg/kg		50	
								51	
				40名	DL-	DL- 0.4% 0.4 g/ 6	2 4		52
	10 12				DL-	DL- 0.35% 0.35 g/ 6	L- 12 3 D- bicarbonate Plasma		52
	3	10			DL-	DL- 0.4 0.5% 0.4-0.5 g/	pH 80% 2 33%		52
				男性 3 名		10 g 5 g	10 g 250 mL 5 g		53

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