

(案)

添加物評価書

ステアロイル乳酸ナトリウム

2008年4月

食品安全委員会添加物専門調査会

目次

審議の経緯	2
食品安全委員会委員名簿	2
食品安全委員会添加物専門調査会専門委員名簿	2
要 約	3
I. 評価対象品目の概要	4
1. 用途	4
2. 化学名	4
3. 分子式、分子量、構造式	4
4. 性状等	4
5. 評価要請の経緯	5
6. 添加物指定の概要	5
II. 安全性に係る知見の概要	5
1. 体内動態（吸収、分布、代謝、排泄）	5
(1) 吸収及び代謝	5
(2) 分布及び排泄	8
2. 毒性	10
(1) 急性毒性	10
(2) 反復投与毒性・発がん性	11
(3) 生殖発生毒性	15
(4) 遺伝毒性	15
(5) 抗原性	17
(6) ヒトにおける知見	18
3. 一日摂取量の推計等	19
(1) EUにおける評価	19
(2) 米国における評価	19
(3) わが国における評価	20
III. 国際機関等における評価	20
1. JECFA における評価	20
2. FDA における評価	22
3. EU における評価	22
4. わが国における評価	22
<別紙：ステアロイル乳酸ナトリウム 安全性試験結果>	24
<参照>	30

1	<審議の経緯>				
2	2007	2	6		
3					0206001
4	2007	2	8	177	
5	2008	3	24	56	
6	2008	4	15	57	
7					
8					
9	<食品安全委員会委員名簿>				
	2007	3	31		2007 4 1

10					
11	<食品安全委員会添加物専門調査会専門委員名簿>				
	2007	9	30		2007 10 1

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要 約

25383-99-7

CAS

1 5. 評価要請の経緯

5 7

4 1964

6 2004

8 2002 7

9 FAO / WHO

JECFA

11 EU

12 46

18 6. 添加物指定の概要

20 JECFA

24 II. 安全性に係る知見の概要

25 1. 体内動態（吸収、分布、代謝、排泄）

32 2

37 (1) 吸収及び代謝

38 *in vitro*

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14 18
20 22

①乳酸の数が 1 個の場合

[1]

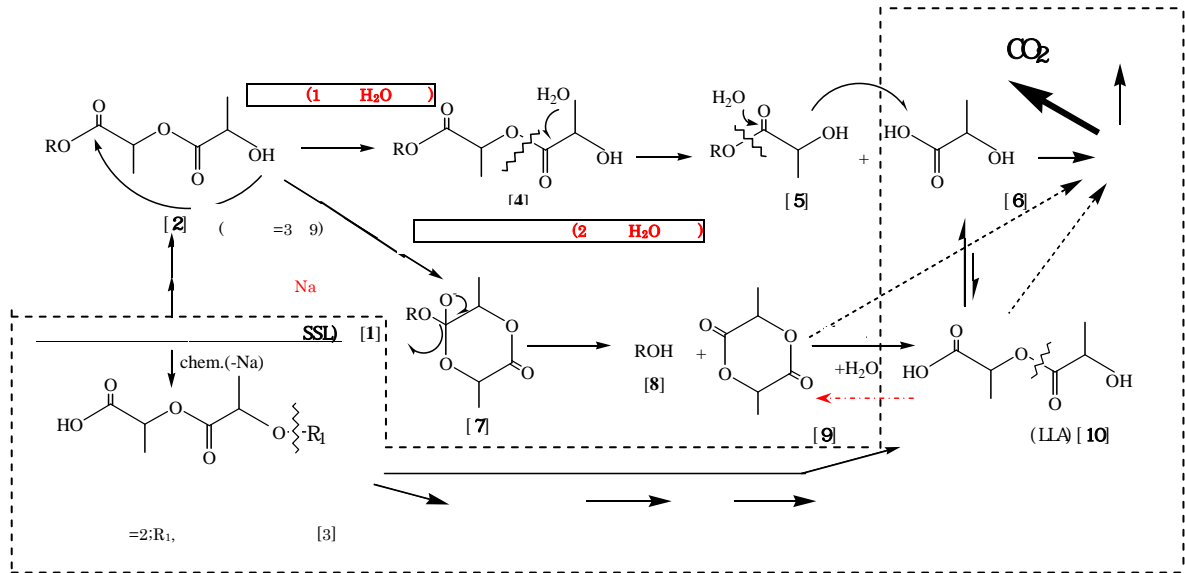
②乳酸の数が 2 個の場合

[1]

2 [3] [3]
[10] [6]
[10] [3] [10]
17 [6]
3 9
[2]
[4] [5] [6]
[5] [6]
[7] [9] 2
[9] [10] 19
[6] 9 19
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/Cori

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	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
			9
		10% 10 g/kg	/ ² 7 8

² JECFA

a

	(kg)	(g/ /)	(g/kg /)
	0.02	3	150
()	0.4	20	50
	0.1	10	100
	10	250	25

1 24% 14), 11

2

3 94% 56

4

5 (2) 分布及び排泄

6

7

8

9

10

11 Tuck To 3 4 Dunkin-Hartley

12 3 4 ~~14C~~ 14C 14C

13 900 mg/kg 14C DL-

14 325 mg/kg 900 mg /kg

15 24 48

16

17

18 9 1

19

20 1. 14C DL- 48

21 %

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

22

23 14CO2

24

25 DL-

26 DL-

27

28 82.6% 92.2%

29 4.0% 16.2%

30 9 2

	60	1500	25
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2. ¹⁴C DL-

	CO ₂			
¹⁴C <u>¹⁴C</u>	82.6	16.2	2.1	98.4
¹⁴ C DL-	92.2	4.0	1.1	97.3

~~¹⁴C~~ ¹⁴C ¹⁴C

24 CO₂ ¹⁴C 58%

60

3 3

3. ¹⁴C ~~¹⁴C~~ ¹⁴C

¹⁴C 48 CO₂ %

	CO ₂
+ ¹⁴ C	58
¹⁴C <u>¹⁴C</u>	60

10 12%

9 43

~~1,000 2,000 mg/kg / 14~~

~~16 18^{33b}~~

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2 1 1 3,000 mg
3 14 20 30%
4 27
5
6
7 +C
8 24 1-4-

2. 毒性

JECFA
JECFA
2

(1) 急性毒性

20 25 30 g/kg
30 g/kg 8 4 20 25 g/kg
8 LD₅₀

1 12.5% 0 250 2,500 6,250 mg/kg / 2 98
 2 12.5%
 3 2 3 49
 4 25 0 0.1 1.0 2.0
 5 3.0 4.0 5.0 7.5% 0 50 500 1,000 1,500 2,000 2,500 3,750 mg/kg
 6 / 2 1 5.0%
 7 2 3 49
 8
 9
 10
 11 2 3 49
 12
 13 1 3 0 7.5%
 14 0 1,875 mg/kg / 2 2
 15
 16 2 3 49
 17
 18
 19 2 0 10 100 400 1,000
 20 2,500 mg/kg / D- 5% 2
 21 2,500 mg/kg 1,000 mg/kg
 22 100 mg/kg 1
 23 2,500 mg/kg 1,000 mg/kg
 24 1,000
 25 mg/kg
 26 400 2,500 mg/kg
 27
 28 2,500 mg/kg
 29
 30
 31 1,000 mg/kg
 32 400 mg/kg
 33 18⁴²
 34
 35 4 0 4 20 100 mg/kg
 36 / D- 5% 13 100
 37 mg/kg
 38 100 mg/kg

1 18⁴¹, 42)

2 NOAEL — 1996 100 mg/kg

3 1 20 mg/kg

4 / 18⁴¹ 1999 Food and Chemical Toxicology

5 100 mg/kg

6 ⁴ 18⁴²⁾ 100 mg/kg

7

8 1

9

10 18⁴²

11

12

13 6 F344 (50) 0 2.5 5.0%

14 0 1,250 2,500 mg/kg / ² 2 2

15 2.5% 5%

16 5%

17

18 (

19 5)

20

21

22 8 7 80% 0.05 mL

23 100 g — 100 mL — 14

24

25 — 18^{38d}

26

27 10% 4 mL 20 g 90

28

29 CO₂ 18^{38a}

30 F344 5 1,950 mg/kg

31 30

32 38

33 0.1 0.2 g/kg 100 150 mL 2 5 0.1

34 0.7 g/kg 50 100 mL 2 13

35 18^{38f}

4

ADI

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250 1,000 mg/kg / 9
201 mg/kg / 250
NOAEL 1,000 mg/kg / 5 113

Wistar 20 0 5
10 20% 0 2.5 5 10 g/kg / 2 90
20% 8 1
20% 4 2 4
10 20% 13
20%

NOAEL 5% 2,500 mg/kg /
5
5%
ADI 2 3
115

5 50% 2,500 25,000 mg/kg / 2
26
5% 50%

5
ADI
56
ADI

1 (3) 生殖発生毒性

2
3
4
5
6 CD-1 6 15 12 570 mg/kg /
7 10
8 18^{38g}

9
10
11 (4) 遺伝毒性

12
13
14
15
16 *Salmonella typhimurium* TA92 TA94 TA98 TA100 TA1535
17 TA1537 300 µg/plate 28 29
18 20 1,000 µg/plate 30 S9 mix
19
20 CHL
21 62.5 µg/mL S9 mix 48
22 28 29 31

23
24
25
26
27 (*Bacillus subtilis*) M45 (Rec-) H17 (Rec+)
28 Rec-assay 20 mg/disk S9mix
29 6
30 (CHL) 0.75
31 1.5 3.0 mg/ml S9 mix 24 48
32 6 7)

33
34 50%
35 *S.typhimurium* TA94 TA98 TA100 TA2637
36 100 mg/plate S9 mix
37 8 —929)
38 *S. typhimurium* TA94 TA98 TA100

1 5,000 50,000 µg/plate S9 mix
2 10
3 (CHL) 500
4 1,000 2,000 µg/ml S9 mix 24 48
5 7 8 ~~929~~
6
7
8 *S. typhimurium* TA97 TA102 0.1
9 0.5 1 5 10 mg/plate S9 mix
10 11
11 *S. typhimurium* *Saccharomyces cerevisiae*
12 (0.625) S9 mix
13 33
14
15
16 *S.typhimurium* TA92 TA94 TA98 TA100 TA1535 TA1537
17 10 mg/plate S9 mix
18 28 29
19 *S. typhimurium* *S. cerevisiae*
20 0.18% S9 mix 33
21 CHL 250
22 500 1,000 µg/mL S9 mix 24 48
23 28 29 7
24
25
26 *S. typhimurium* TA98 TA 1535 TA1537 *E.coli* WP2uvrA
27 5 15 50 150 500 1,500 5,000 µg/plate
28 156 313 625 1,250 2,500 5,000 µg/plate S9mix
29 1²² 2 3
30 CHL S9
31 mix (-) 1.56 3.12 6.25 12.5 25 50 µg/mL S9 mix(+) 31.3 62.5
32 250 500 1,000 µg/mL 24 0.313 0.625 1.25
33 2.5 5 10 µg/mL 48 0.156 0.313 0.625 1.25 2.5 5 µg/mL
34 S9mix
35 1²³ 2 3
36 Crj:CD-1(ICR) 500 1,000 2,000 mg/kg
37 24
38 1²⁴ 2 3

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S. cerevisiae D6 500 µg/mL
500 µg/mL 34
S. typhimurium TA98 TA100 TA1535 TA1537 TA1538
50 µg/plate
S9 mix 35
S. typhimurium TA98 TA100 TA1535 TA1537 *E. coli* WP2 uvrA
100 333 1,000 3,300 5,000 µg/plate
S9mix 18⁴³
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 S9 mix
18⁴⁴
CrI;CD-1BR 5 837.5
1,675 3,350 mg/kg 18⁴⁵

CHL

(5) 抗原性・局所刺激性

a
Hra:SPF 1 0.05 g
Draize

72

1		18 ³⁰							
2									
3	b								
4	Hra:SPF			3				0.5 g	
5	4		Draize						
6									
7								48	
8		18 ³¹							
9									
10									
11		CrI:(HA)BR		10					
12			0.2 g		1	6			
13	3		2	6					
14	Buehler								
15						18 ⁴⁸			
16									
17	(6) ヒトにおける知見								
18									
19									
20									
21									
22		3		10 g		250 mL			
23						5 g			
24			36						
25									
26									
27	27		33%	100 mL					
28	12							1,530	
29	mg/kg			18 ^{33c,d}					
30	26~51		34.3	7	D-	57.7	95.5 mg/kg		
31			—	—					37
32									
33									
34								—	
35						38			
36									
37			40	DL-	0.4%	0.4 g/			
38			2	4					

1 27
 2 10 12 DL- 0.35% 0.35 g/ 6
 3 L- 3 D-
 4 12
 5 L- 80% D- 20%
 6 D-
 7
 8 Plasma bicarbonate
 9
 10 27
 11
 12 3 DL- 0.4% 0.5% 0.4 0.5 g/
 13 6 10 pH
 14 80%
 15 2 33%
 16
 17 27
 18

19 3. 一日摂取量の推計等

20 (1) EUにおける評価

21 1984
 22 1986
 23 14.7 mg 0.2 mg
 24 25
 25 EU SCF ADI
 26
 27
 28 ADI 20 mg/kg 2
 29 114%— 136 268% —
 30

31 23

32
 33 (2) 米国における評価

34 1989 NAS/NRC
 35 1970 244,000 110.7 1976

6

100 g

1	1,730,000	784.7	1982	793,000	359.7	1987	
2	5,660,000	2,567					
3					1970	338,000	
4	153.3	1975	60,000	27.2	1976	1070,000	485.4
5		1982	193,000	87.5	1987	330,000	149.7
6							
7							
8					1970	2,330	1.1
9	1976	1,500	0.7	1982	800	0.4	1987
10	37	0.02					
11				1970	297,000		134.7
12	1975	213,000	96.6	1976	287,000		130.2
13	1982	114,000	51.71	1987	132,000		59.87
14						24	

(3) わが国における評価

16	16			2001		
17						
18						
19		3.9 mg		13	41	
20						
21						
22						
23			1998	1999		
24	649 mg		527mg	1,176 mg		
25	4					
26	1995	1996				
27	98.1 mg					
28						
29						4

Ⅲ. 国際機関等における評価

1. JECFA における評価

35	JECFA	1969	13				
36					5		
37		0	0.5	2.0	12.5%	43	2.0%
38	12.5%				2.0%		

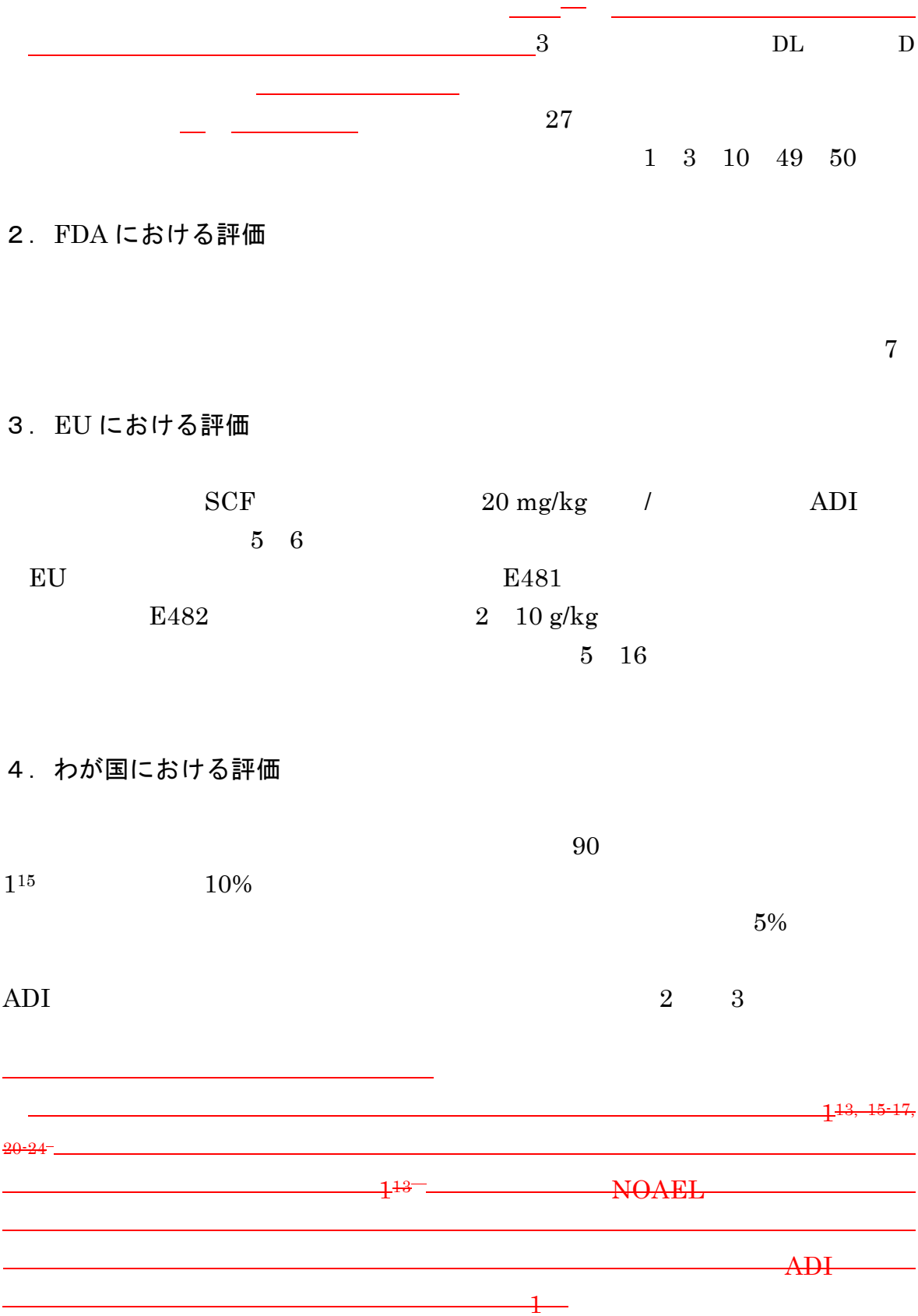
1 0.5% 250 mg/kg / 100
 2 Hodge,1953
 3 ADI 0 2.5 mg/kg /
 4 ~~D~~ ADI
 5 ~~D~~ ADI
 6 2 3
 7 1549
 8 JECFA 1971 15 1973 17
 9
 10
 11
 12
 13
 14
 15 1 25 5.0%
 16 13
 17 2.0% 1,000 mg/kg / NOEL
 18 JECFA
 19
 20 50 ADI 0 20 mg/kg
 21 /
 22 1 2 3 10 49 50
 23
 24 15 ADI
 25
 26
 27
 28
 29
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 31 50
 32
 33
 34 JECFA
 35 1969 13 1973 17 1969
 36 ~~D~~ ADI ~~D~~
 37
 38 15 1973

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2. FDA における評価

3. EU における評価

4. わが国における評価



1			13		18 ^{41, 42}	NOAEL 100
2	mg/kg	/		1,000	ADI	0.1 mg/kg /
3						
4			D-			
5				ADI		
6	D-	DL-				
7		18				

<別紙：ステアロイル乳酸ナトリウム 安全性試験結果>

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	2
				5		5,000mg/kg	LD ₅₀ >5,000 mg/kg	18 ³⁹
反復投与毒性・発がん性		28		20		0 0.5%(0 2,500 mg/kg / 2	90	2 3 49
		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		2 3 49
		43		5		0 0.5 2.0 12.5 % 0 250 1,000 6,250 mg/kg / 2	2.0 % 12.5% 2.0% NOAEL 2.0 % 1,000 mg/kg /	2 3 49
		98		10		0 0.5 5.0 12.5 % 0 250 2,500 6,250 mg/kg / 2	12.5%	2 3 49
				雄各 25		0 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 %	2 3 49
		2		1 3		0 7.5 % 0 1,875 mg/kg / 2		2 3 49
		2		50		0 2.5 5% 0 1,250 2,500 mg/kg / 2	2.5% 5% 5%	5
		14		8 7		80% 0.05 mL 100 g 100 mL		18 ^{38d}

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・発がん性(つづき)		90				10% 4 mL 20 g	CO ₂	18 ^{38a}
				5		1,950 mg/kg 30		38
		5				0.1 0.2 g/kg 100 150 mL		18 ^{38f}
		13				0.1 0.7 g/kg 50 100 mL		
		9				250 1,000 mg/kg / 201	250 mg/kg / NOAEL 1,000 mg/kg /	1 ¹³
		90			20	0 5 10 20% 0 2.5 5 10 mg/kg / ²	20% 8 1 20% 4 2 4 20% 10 20% 13	1 ¹⁵ 2 3
				3 6	5 50 %; 2,500 25,000 mg/kg / ²		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
反復投与毒性・発がん性(つづき)		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 400 2,500 mg/kg 2,500 mg/kg 1,000 mg/kg 400 mg/kg	18 ⁴²
		13		4		0 4 20 100 mg/kg / D- 5%	100 mg/kg 100 mg/kg NOAEL 100 mg/kg /	18 ⁴¹ 18 ⁴²
生殖発生毒性	6-15	10		12		570 mg/kg /		18 ^{38g}
遺伝毒性	<i>In vitro</i>	(+/S9mix)	TA92 TA94 TA98 TA100 TA1535 TA1537		300 µg/plate 20 10,000 µg/plate	S9mix	28 29	
			TA92 TA94 TA98 TA100 TA1535 TA1537		20 10,000 µg/plate	S9mix	30	
			CHL		63 µg/ml	S9mix	28 29 31	
	<i>In vitro</i>		TA98 TA100 TA1535 TA1537 <i>E.coli</i> WP2 uvrA		100 333 1,000 3,300 5,000 µg/plate	S9mix	18 ⁴³	

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)	In vitro	Rec- assay	(B subtilis) M5 (Rec-) H17 (Rec+)			20 ng/disk		6
						30,000 µg/nh	S9 mix 24 48	6 7
	In vitro		TA94 TA98 TA100 TA2637			100,000 µg/plate	S9 mix	8 929
			TA94 TA98 TA100 TA2637			5,000 50,000 µg/plate	S9 mix	10
	In vitro					500 1,000 2,000 µg/nh	S9 mix 24 48	7 8 929
	In vitro		TA97 TA102			10,000 µg/plate	S9 mix	11
			Saccharomyces cerevisiae S. typhimurium			0.625	S9 mix	33
	In vitro	(+/S9mix)	TA92 TA94 TA98 TA100 TA1535 TA1537			200 10,000 µg/plate	S9mix	28 29
		(+/S9mix)	(Saccharomyces cerevisiae) (S. typhimurium)			0.18%	S9mix	33

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)			CHL			1,000 µg/mL	S9 mix 24 48	28 29 7
			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	1 ²² 2 3
	<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	1 ²³ 2 3
						500 1,000 2,000 mg/kg 24		1 ²⁴ 2 3
	<i>In vitro</i>		(<i>S. cerevisiae</i> D6)			500 µg/ml	S9mix 24 48	34
		(+/S9mix)	TA98 TA100 TA1535 TA1537 TA1538			2,500 µg/plate	S9mix	35
			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	S9 mix	18 ⁴⁴

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)	マウス			雌雄各 5		837.5 1,675 3,350 mg/kg		18 ⁴⁵
抗原性				1		0.05 g	72	18 ³⁰
				3		0.5 g 4	48	18 ³¹
				10		0.2 g		18 ⁴⁸
ヒトにおける知見				男性 3 名		10 g 5 g	10 g 250 ml 5 g	36
						33% 100 mL	12 1,530mg/kg	18 ^{33c,d}
				7名(26 ~51歳 平均 34.3歳)	D-	57.7 95.5 mg/kg		37
								38
				40名	DL-	DL- 0.4% 0.4 g/	2 4	27
	10 12				DL-	DL- 0.35% 0.35 g/	L- 3 D- 12 bicarbonate Plasma	27
	3	10			DL-	DL- 0.4 0.5% 0.4~0.5 g/	pH 80% 2 33%	27

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