

ICS 71.100.40

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GB/T XXXXX—XXXX

Guideline for safety assessment of oral hygiene products

XXXX - XX - XX

XXXX - XX - XX

中华人民共和国国家质量监督检验检疫总局
~~中国国家标准化管理委员会~~ 发布

1

2

In-vivo

Ex-vivo

In-vitro

In-silico

2.1

2.2 hazard

2.3 risk

2.4 risk assessment

2.5 — quantitative structure-activity relationship, QSAR

2.6 dose

mg/kg bw

2.7 threshold dose

2.8 no observed adverse effect level, NOAEL

2.9 lowest observed adverse effect level, LOAEL

2.10 threshold of toxicological concern, TTC

2. 17 acceptable exposure level, AEL

2. 18 margin of safety, MoS

NOAEL

2. 19 acceptable risk

10^{-6} 10^{-5}

2. 20 T_{25}

25%

3

3. 1

3. 1. 1

INCI CAS EINCES

3. 1. 2

3. 1. 3

3. 1. 4

3. 1. 5

3. 1. 6

10

Log Pow

3. 1. 7

3. 1. 8

pk

3. 1. 9

3. 1. 10

3. 1. 11

3. 1. 12

3. 1. 13

3. 1. 14

3. 2

3. 3

3. 3. 1

3.3.2

4.

5

(hazard identification)

(dose-response assessment)

(exposure assessment)

(risk characterization)

5.1

5.1.1 (hazard identification)

5.1.1.1

a)

b)

c)

5.1.1.2

5. 1. 2 - (dose-response assessment)

5. 1. 2. 1 -

NOAEL

NOAEL

NOAEL

LOAEL

BMD

GPMT Buehler

local lymph node assay, LLNA

weight of

evidence no expected sensitization induction level , WoE NESIL

5. 1. 2. 2 -

T₂₅

5. 1. 3 (exposure assessment)

5. 1. 3. 1

a)

b)

c)

d

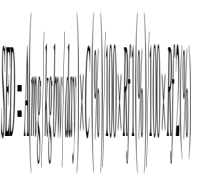
e

f

17.4 g/day 269 mg/kg bw/day

g)

h)



A ---

C --- (%)

Rf1---



5. 1. 3. 3

CEL



MoS ---

NOAEL---

SED --- mg/kg.day

NOAEL LOAEL BMD LOAEL

3

b) AEL/CEL



WoE NESIL SAF AEL

$$AEL = \frac{WoE \cdot NESIL}{SAF}$$

AEL ---

μ g/cm²

WoE NESIL---

μ g/cm²

SAF ---

10-1000

100

CEL

5. 1. 4. 2

lifetime cancer risk LCR

T₂₅

T₂₅ HT₂₅

$$HT_{25} = \frac{T_{25}}{(BW / BW)^{0.25}}$$

T₂₅ --- 25%

HT₂₅ --- T₂₅ T₂₅

BW ---

$$LCR = \frac{SED}{4 \times HT_{25}}$$

LCR—

SED—

mg/kg bw/day

5.2

5.2.1 GB22115

5.2.2 GB22115

5.4 TTC

5.4.1 TTC

5.4.1.1 TTC

5.4.1.2 TTC

5.4.1.3 TTC

5.4.1.4 TTC

5.4.2 TTC

TTC 1.5µg/ day

TTC 0.15µg/ day

5.4.3

1.5 µg/ day

0.15 µg/day

6

6.1

6.2

6.2.1

6.2.2

6.2.3

6.2.4

Human Oral Desquamation Study

Clinical Oral Soft Tissue Study)

Relative dental abrasivity, RDA/Profilometry

6.2.4

6.3

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6.4

6.4.1

6.4.2

6.4.3

6.5

6.5.1

6.5.2

6.6

