

Figure A.2.1: Tiered evaluation of skin corrosion and irritation potential

Step	Parameter	Finding	Conclusion
1a	Existing human or animal data ¹	→ Skin corrosive	→ Category 1 ²
	Not corrosive or no data		
1b	Existing human or animal data ¹	→ Skin irritant	→ Category 2 ²
	Not an irritant or no data		
1c	Existing human or animal data ¹ No/Insufficient data	→ Not a skin corrosive or skin irritant	→ Not classified
2:	Other, existing skin data in animals ³	→ Skin corrosive Skin irritant	→ Category 1 ² Category 2 ²
	No/Insufficient data		
3:	Existing skin corrosive <i>ex vivo</i> / <i>in vitro</i> data ⁴	→ Positive: Skin corrosive	→ Category 1 ²
	Not corrosive or no data		
	Existing skin irritation <i>ex vivo</i> / <i>in vitro</i> data ⁴	→ Positive: Skin irritant → Negative: Not a skin irritant ⁵	→ Category 2 ² Not classified
4:	Existing skin irritation <i>ex vivo</i> / <i>in vitro</i> data ⁴		
	No/Insufficient data		
4:	pH-Based assessment (with consideration of buffering capacity of the chemical, or no buffering capacity data) ⁵	→ pH ≤ 2 or ≥ 11.5	→ Category 1 ²
	Not a pH extreme, No pH data or extreme pH with low/no buffering capacity		
5:	Validated Structure/Activity Relationship (SAR) models	→ Skin corrosive → Skin irritant	→ Category 1 ² Category 2 ²
	No/Insufficient data		
6:	Consideration of the total Weight of Evidence ⁶	→ Skin corrosive → Skin irritant	→ Category 1 ² Category 2 ²
	No concern based on consideration of the sum of available data		
7:	Not Classified	→	Not classified

Notes to Figure A.2.1:

¹ Evidence of existing human or animal data may be derived from single or repeated exposure(s) in occupational, consumer, transportation, or emergency response scenarios; from ethically-conducted human clinical studies; or from purposely-generated data from animal studies conducted according to scientifically validated test methods (at present, there is no internationally accepted test method for human skin irritation testing).

² Classify in the appropriate harmonized category, as shown in Tables A.2.1 and A.2.2.