FDA Sunscreen Absorption Study Part 2

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Disclaimer

This presentation reflects the views of the presenter and should not be construed to represent FDA's views or policies

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Overview

- Recap - Study 1
- Study Design Study 2
- Outcomes
- Summary

Recap: Study 1 Design

- Subjects: Healthy Volunteers; 18 – 60 years
- Open-label, randomized 4 group parallel study

Dose: 2 mg/cm^2
75% of body

Duration: Every two hours,
4 doses/day; 4 days

PK sample: 30 samples
pre-dose to 144 h
(intensive on days 1 & 4)

Recap: Findings from Study 1

- Systemic exposure data of most commonly used ingredients under maximal usage conditions
- 6 subjects were adequate to detect systemic exposure of these sunscreen active ingredients
- All the tested active ingredients in all tested products reached systemic exposures above 0.5 ng/mL
  - All active ingredients reached above 0.5 ng/mL on day 1
- All tested ingredients have long terminal half-lives
  - Skin could be serving as a depot

Unknowns

- Systemic exposure after a single application
- Systemic exposures of additional active ingredients

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JAMA | Preliminary Communication

Effect of Sunscreen Application Under Maximal Use Conditions on Plasma Concentration of Sunscreen Active Ingredients

A Randomized Clinical Trial

Murali K. Matta, PhD; Robbert Zusterzeel, MD, PhD, MPH; Nageswara R. Pilli, PhD; Vikram Patel, PhD; Donna A. Volpe, PhD; Jeffry Florian, PhD; Luke Oh, PhD; Edward Bashaw, PharmD; Issam Zineh, PharmD, MPH; Carlos Sanabria, MD; Sarah Kemp, RN; Anthony Godfrey, PharmD; Steven Adah, PhD; Sergio Coelho, PhD; Jian Wang, PhD; Lesley-Anne Furlong, MD; Charles Ganley, MD; Theresa Michele, MD; David G. Strauss, MD, PhD

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Tested Products

Avobenzone 3%
Oxybenzone 4%
Octocrylene 6%

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Oxybenzone 6%
Octocrylene 10%
Homosalate 15%
Octisalate 5%

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Skin sampling: Tape stripping (Day 7 and 14)

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- **Exploratory Outcomes:**
  - C_{max} on day 1 and 4
  - Time at which Cmax occurs on day 1, 4 and overall
  - AUC on day 1, 4 and overall
  - Residual concentrations on each day
  - Half-life of each ingredient
  - Data was reported with standard descriptive statistics

Demographics

Demographics		Population Total (N=48)
Age, years (Mean ± SD)		38.7 ± 13.2
Female sex N (%)		24 (50%)
Race N (%)	Black or African American	23 (48 %)
	White	23 (48 %)
	Asian	1 (2%)
	Unknown	1 (2%)
Ethnicity N (%)	Hispanic or Latino	3 (6%)
	Not Hispanic or Latino	45 (94%)
Body mass index, kg/m2 (Mean ± SD)		26.0 ± 2.9
Body surface area, m^2 (Mean ± SD)		1.9 ± 0.2

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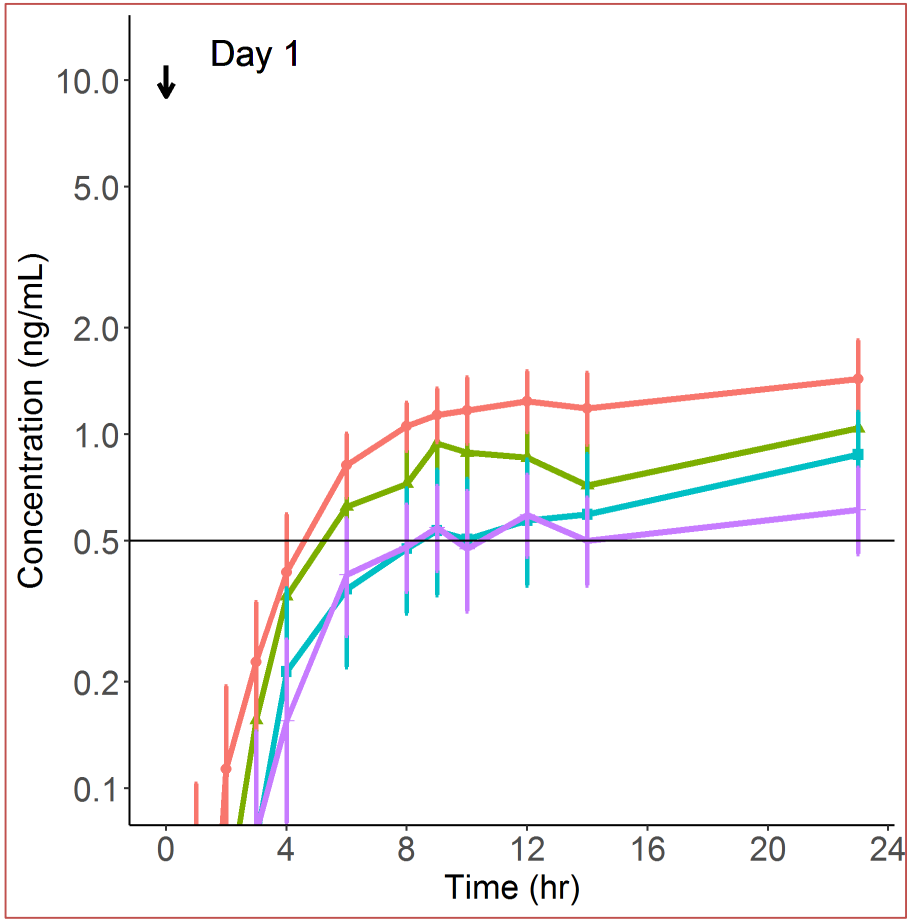
Systemic Exposure of Avobenzone



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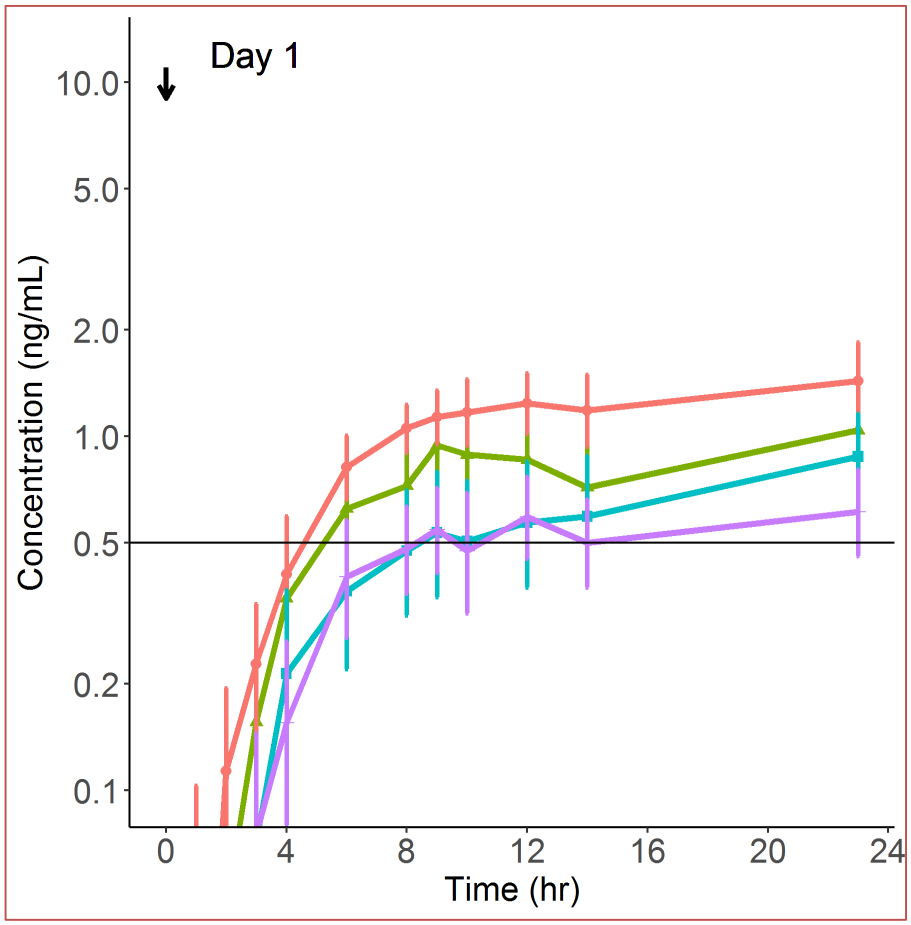
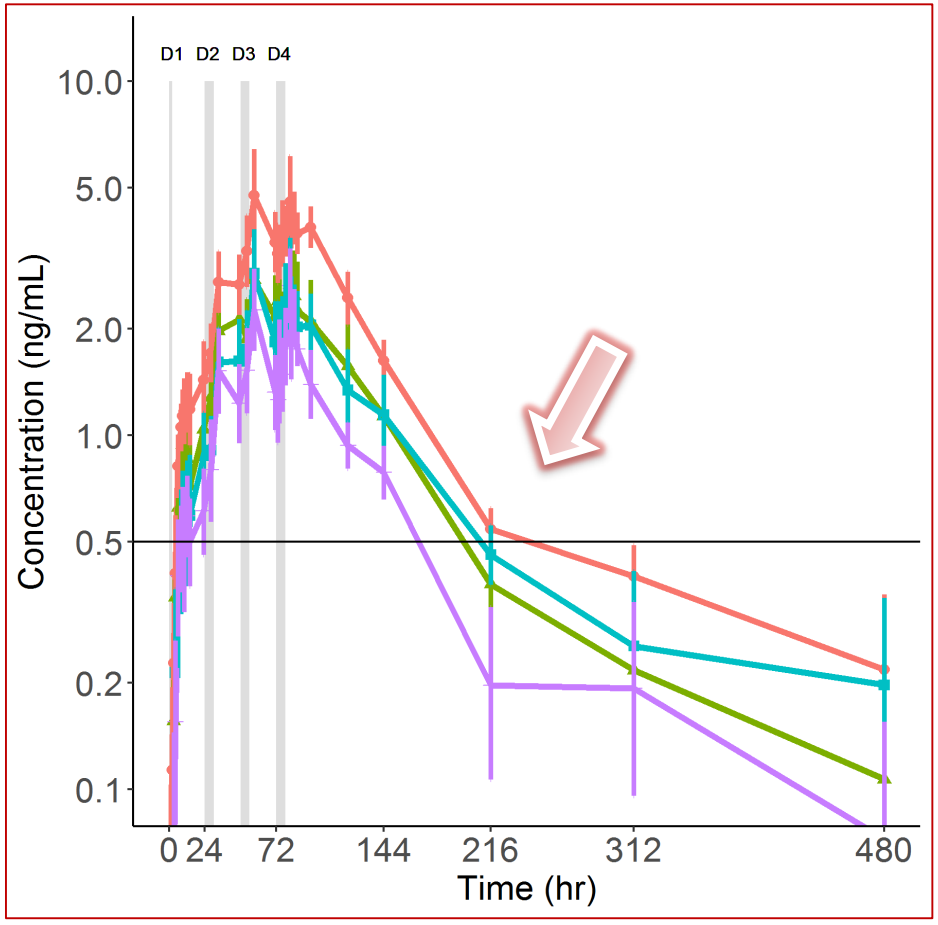
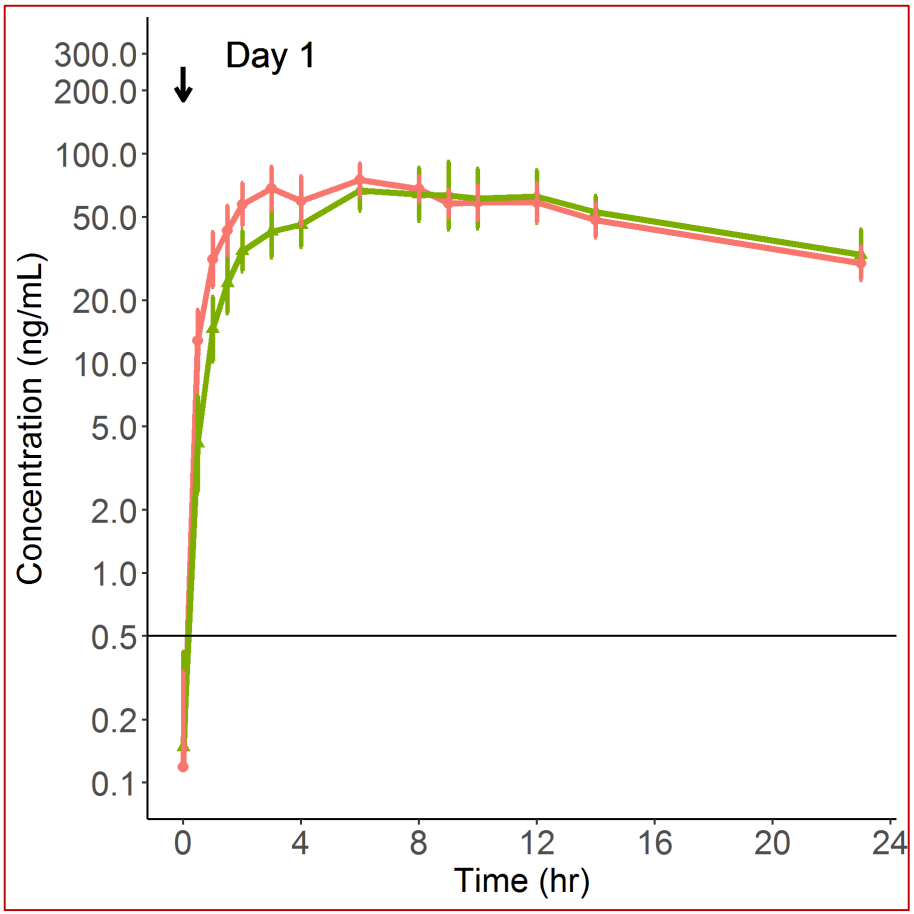
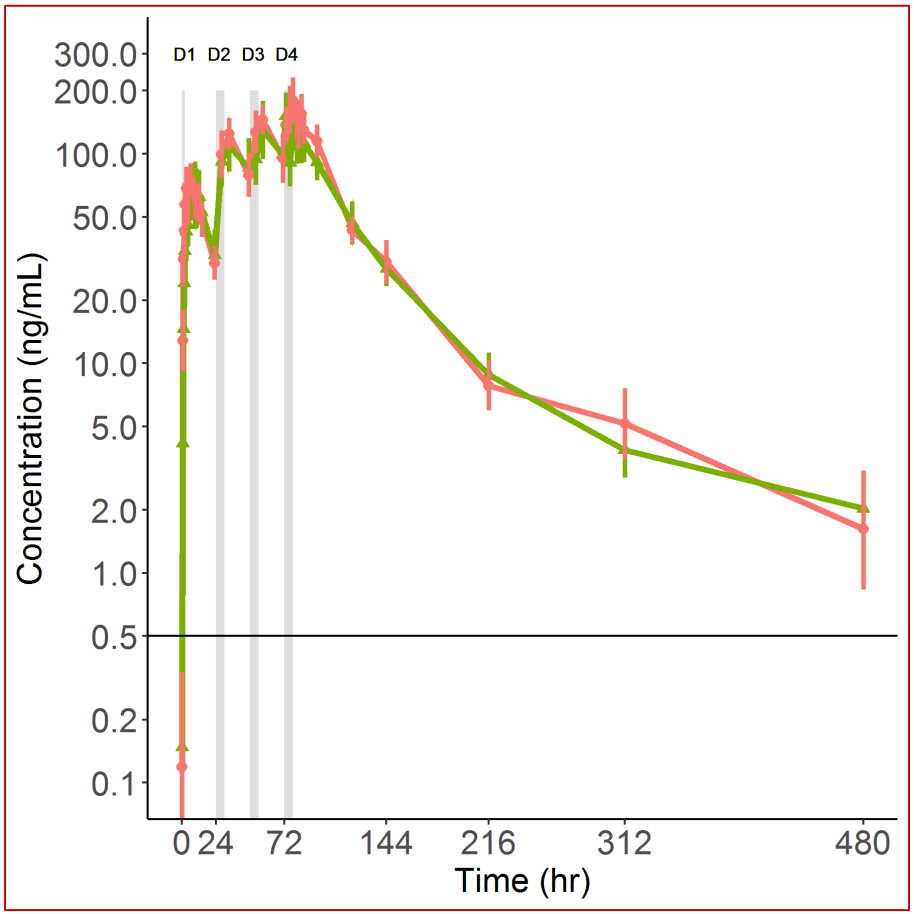




Lotion Nonaerosol Spray Aerosol Spray Pump Spray

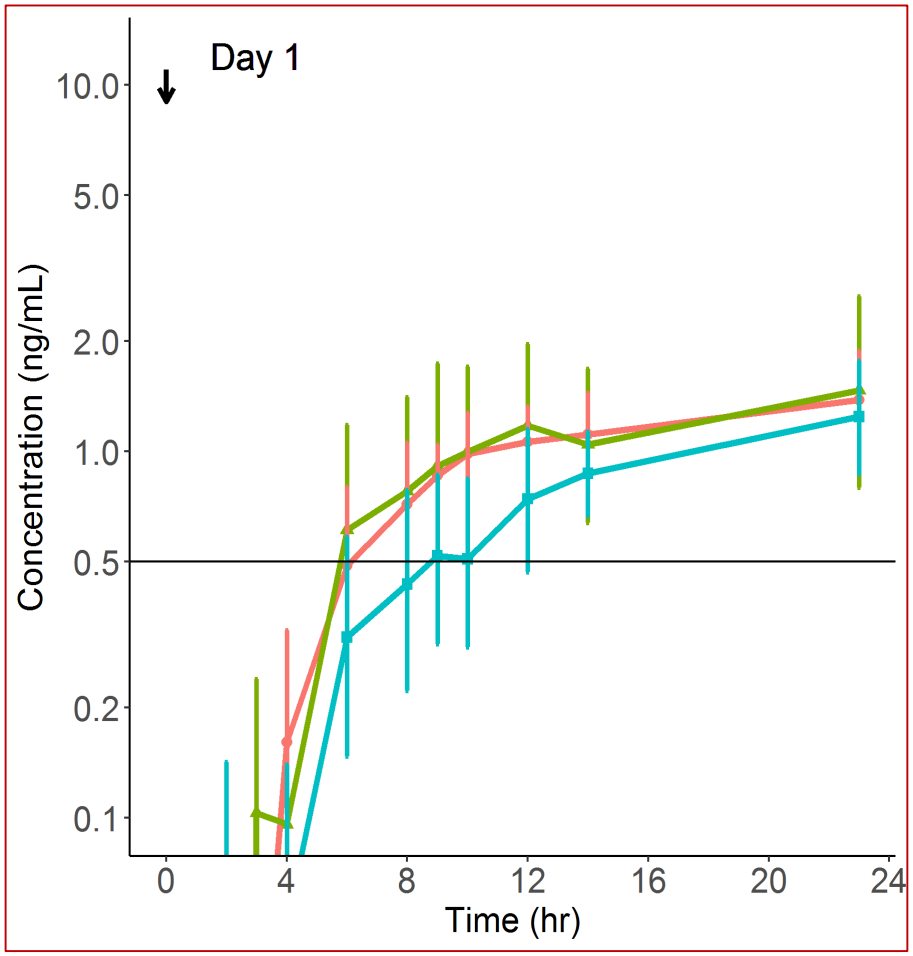
Systemic Exposure of Oxybenzone

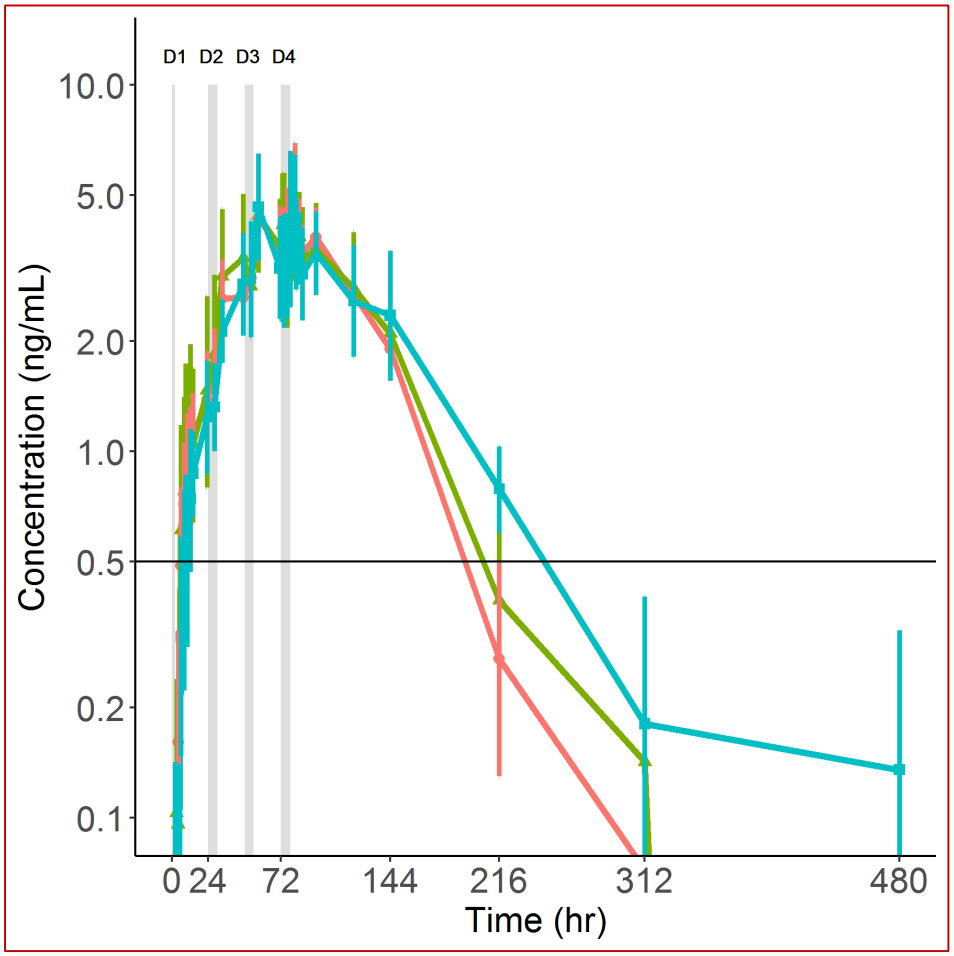




Lotion Aerosol Spray

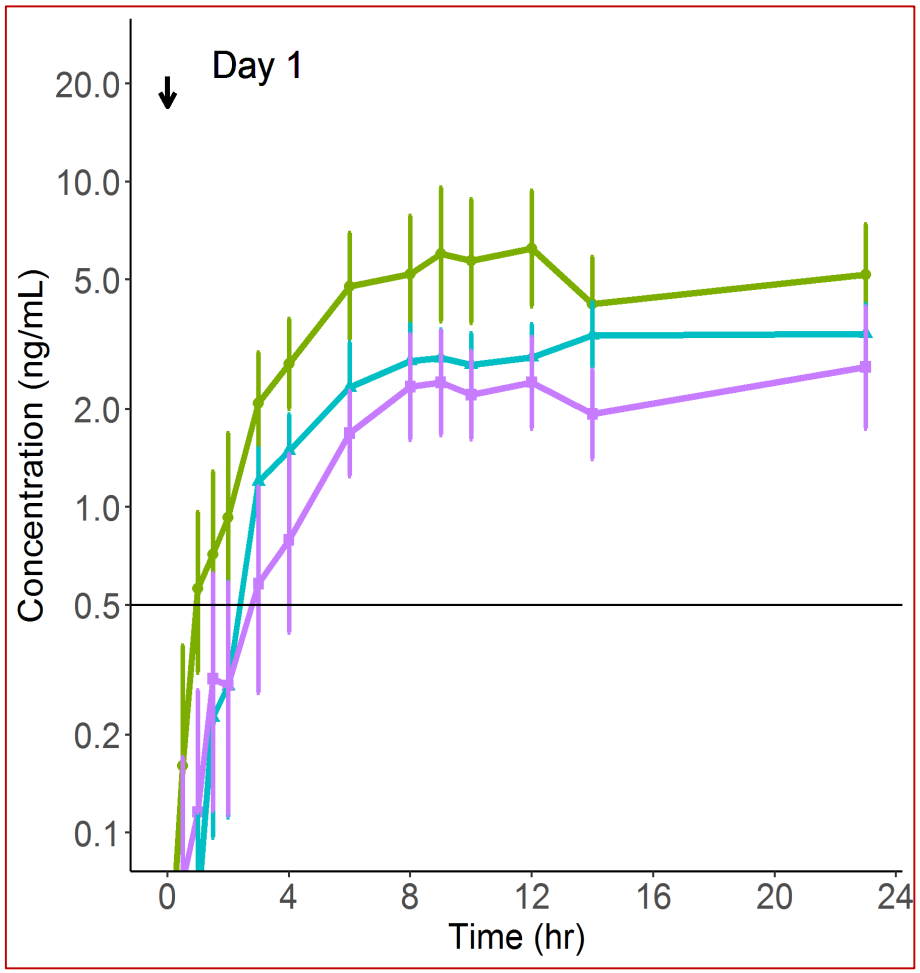
Systemic Exposure of Octocrylene

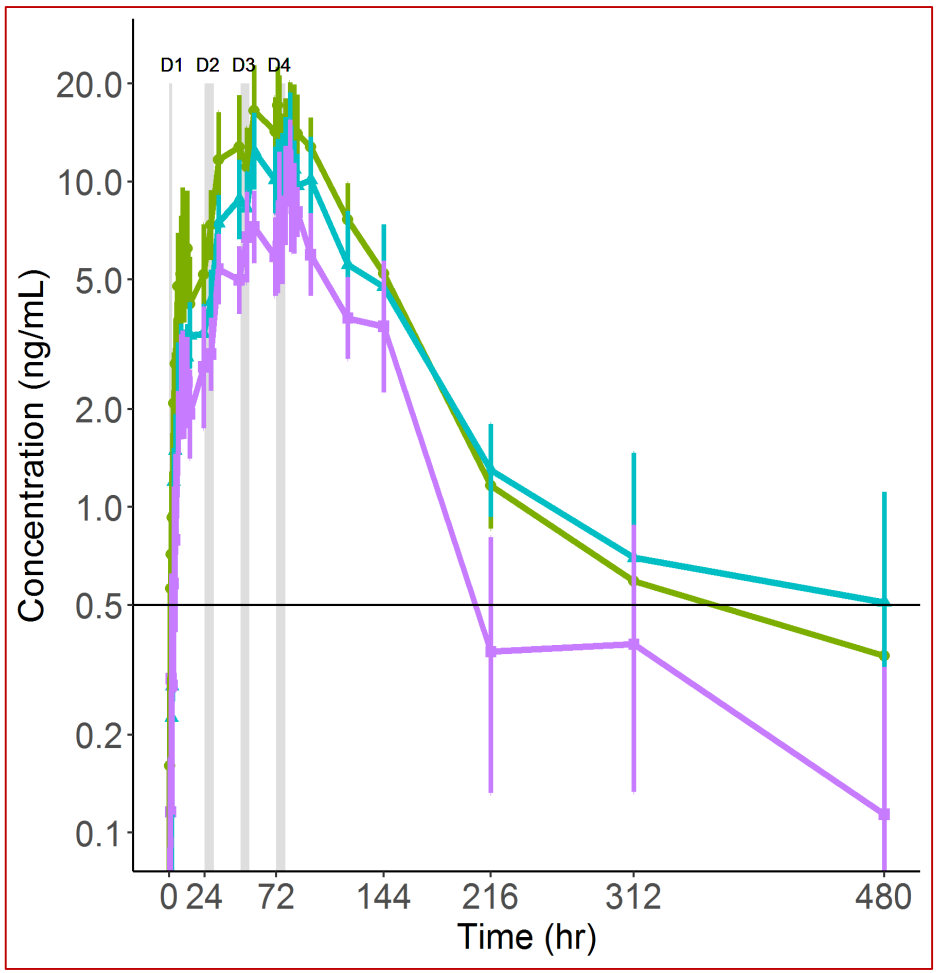




Lotion Nonaerosol Spray Aerosol Spray

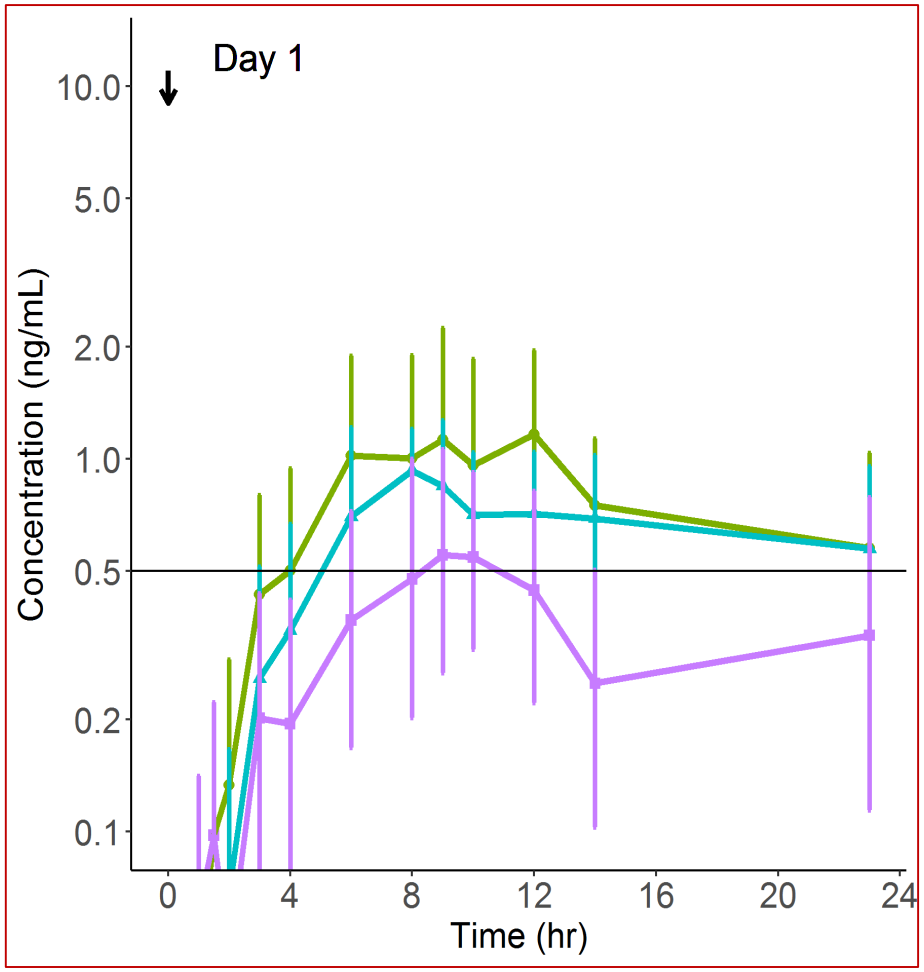
Systemic Exposure of Homosalate

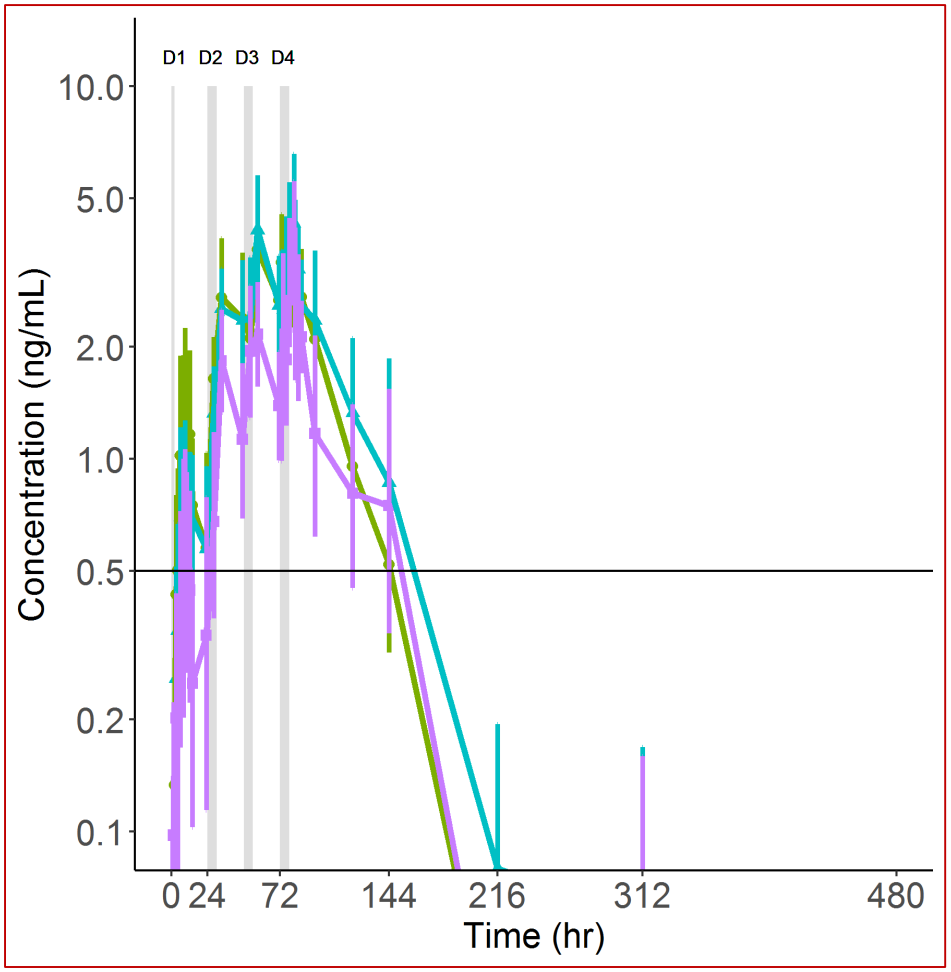




Nonaerosol Spray Aerosol Spray Pump Spray

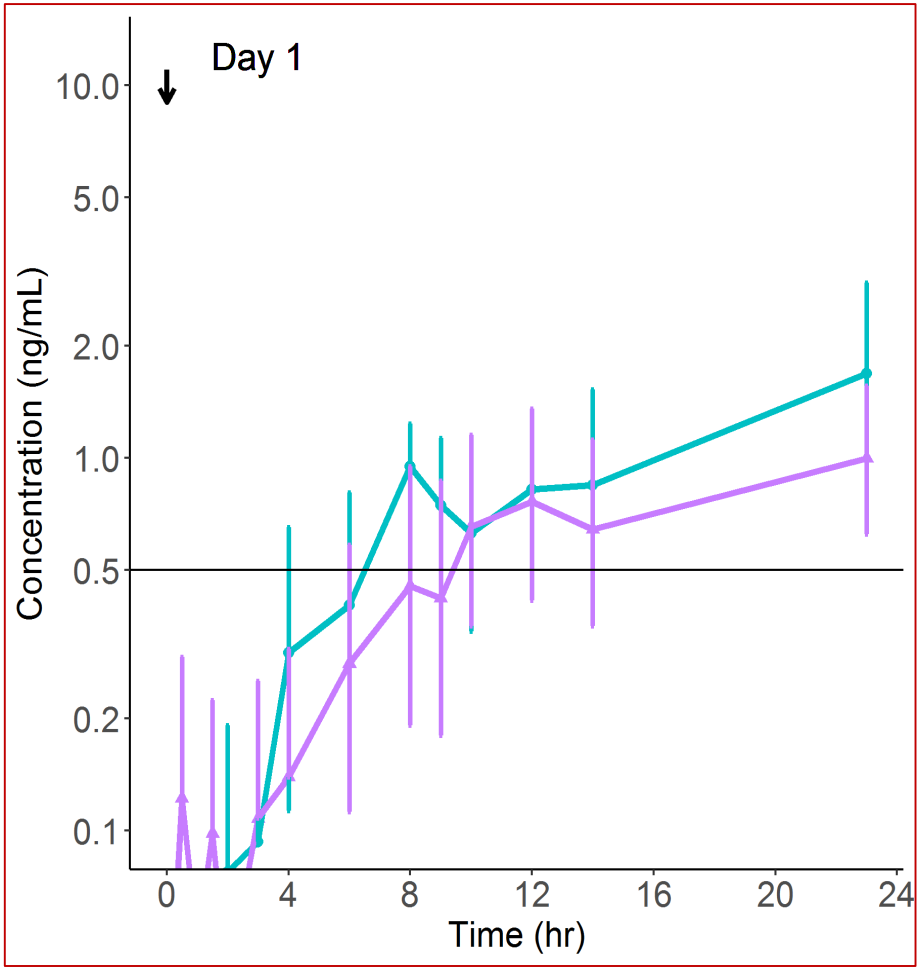
Systemic Exposure of Octisalate

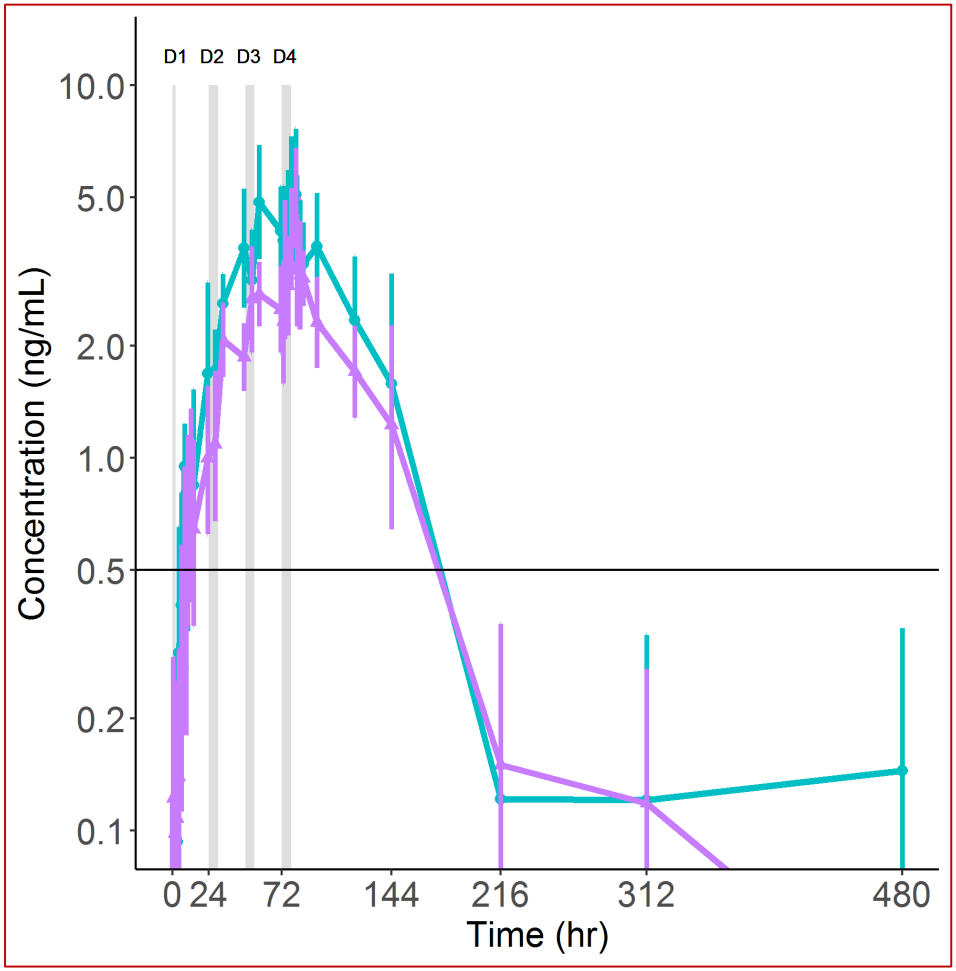




Nonaerosol Spray Aerosol Spray Pump Spray

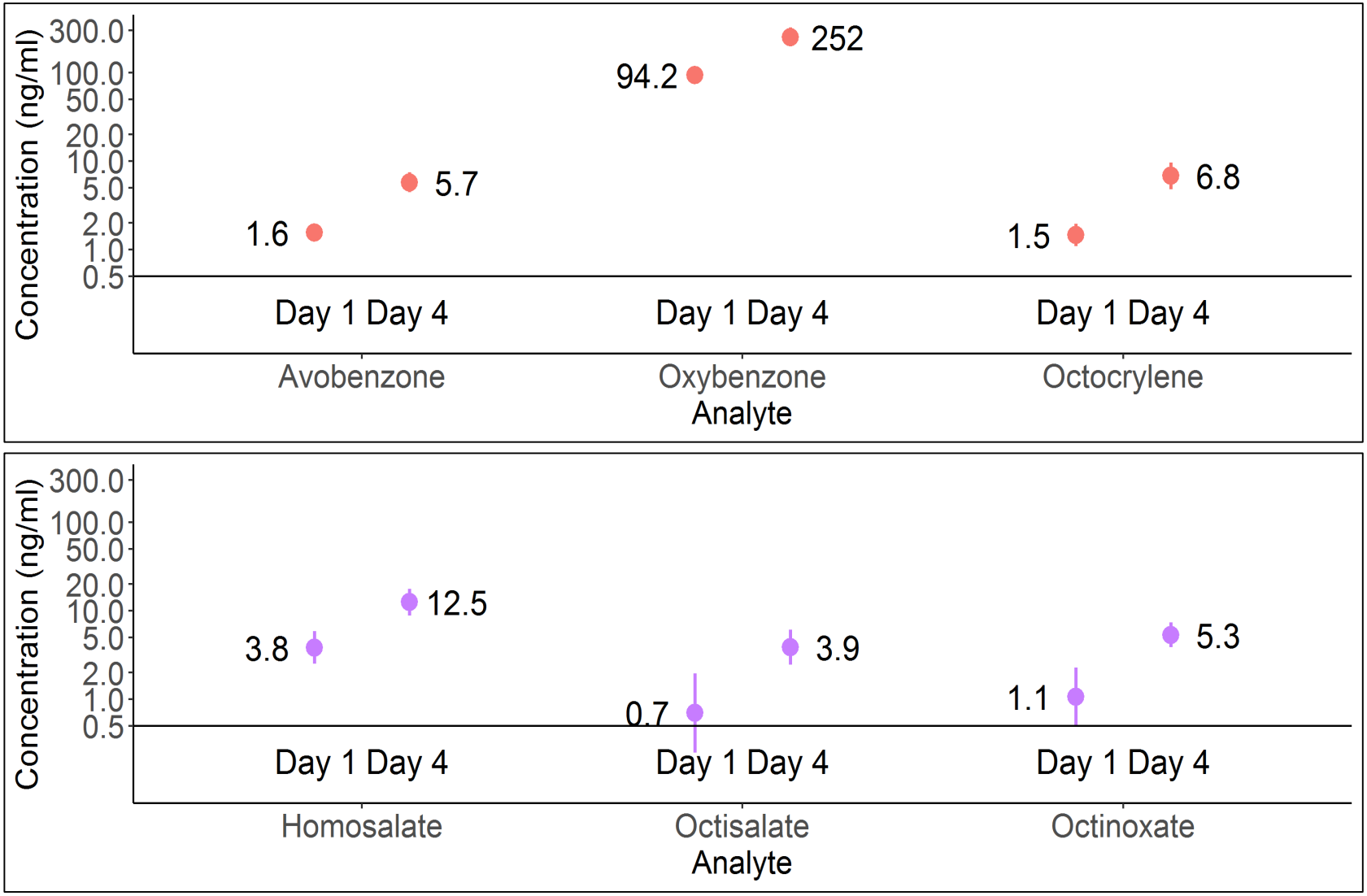
Systemic Exposure of Octinoxate





Nonaerosol Spray Pump Spray

C_{max} on Day 1 versus Day 4



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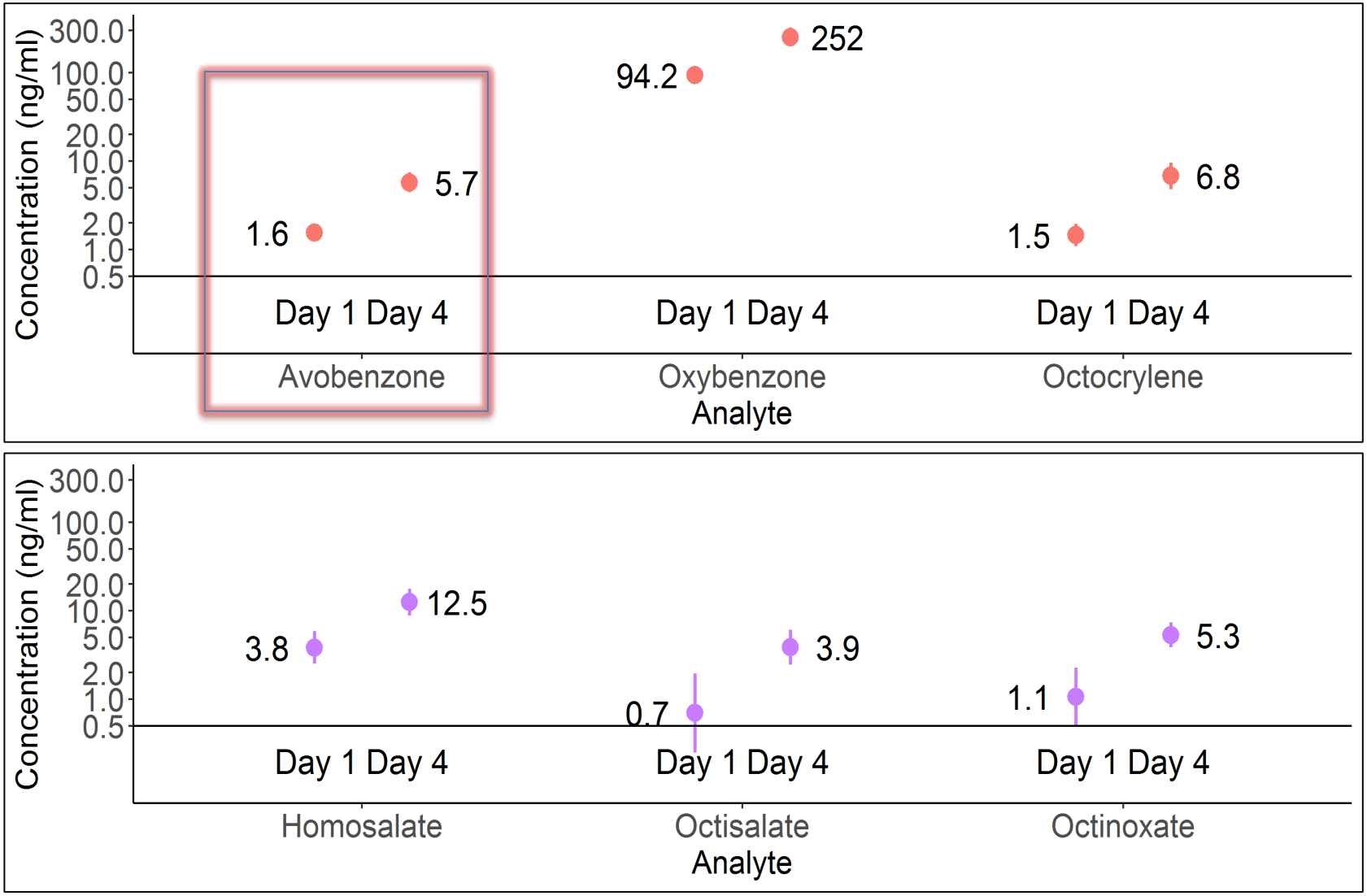

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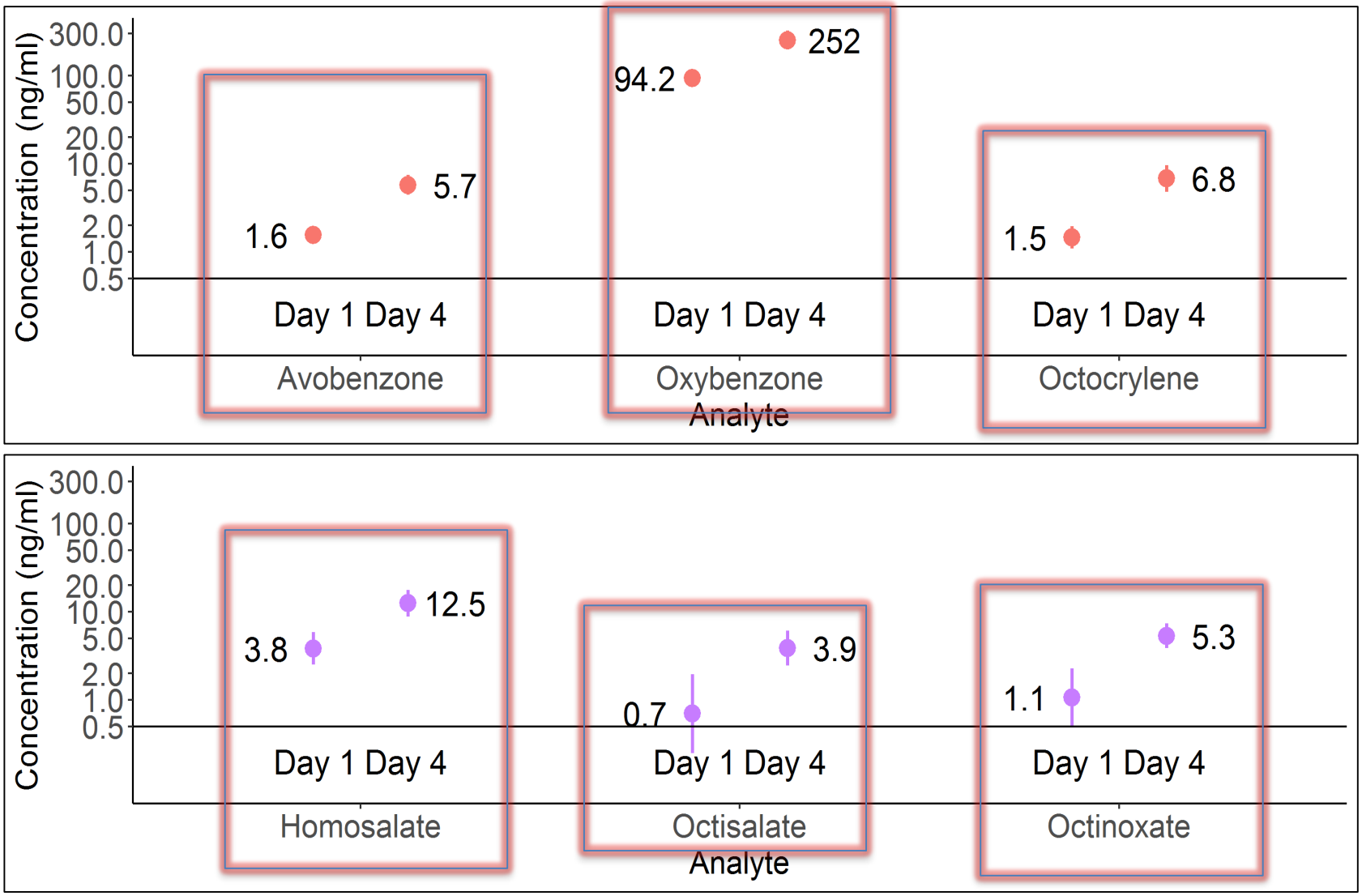
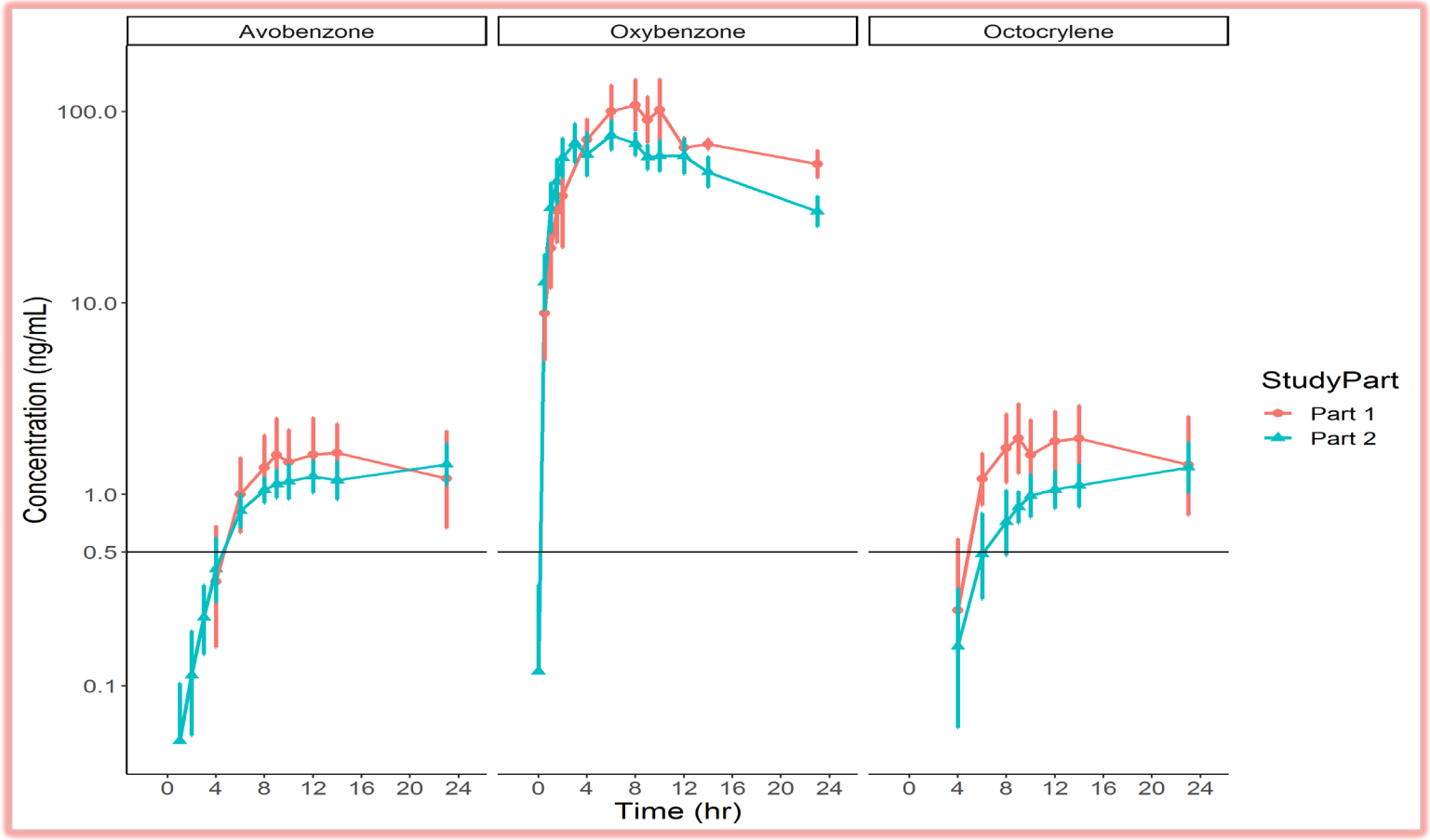
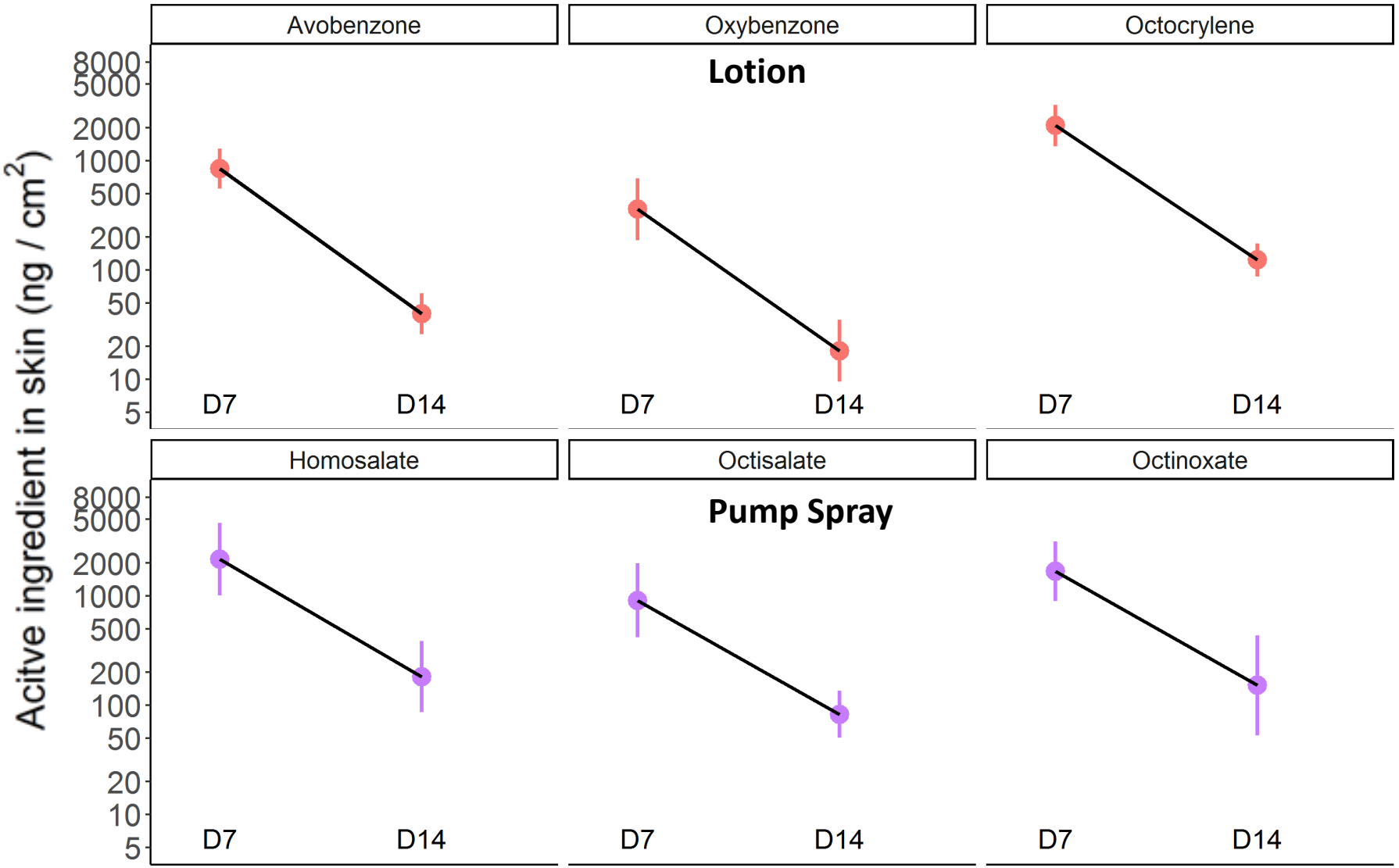


Exposures of 1 vs 4 applications of Lotion



Skin Amounts



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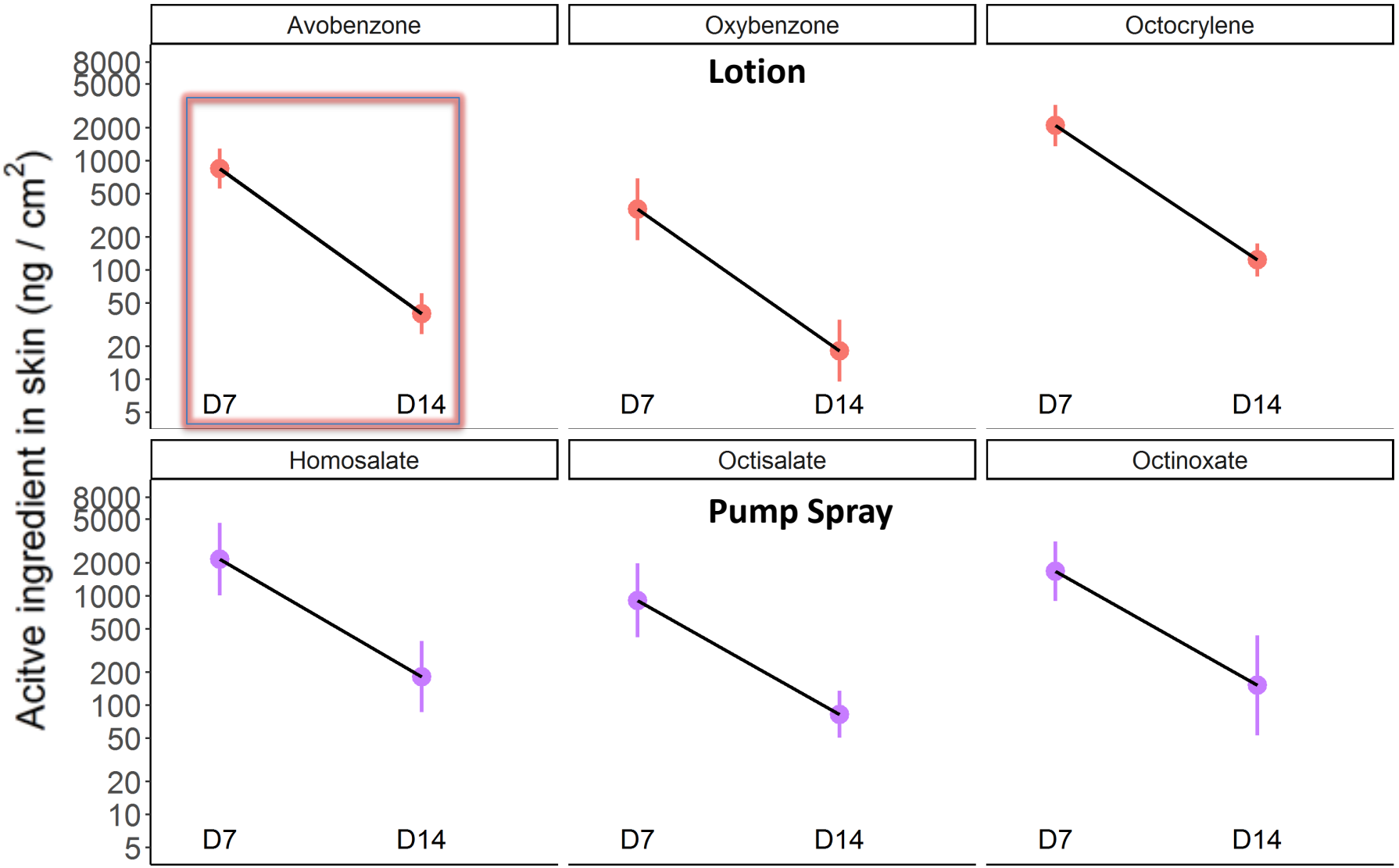

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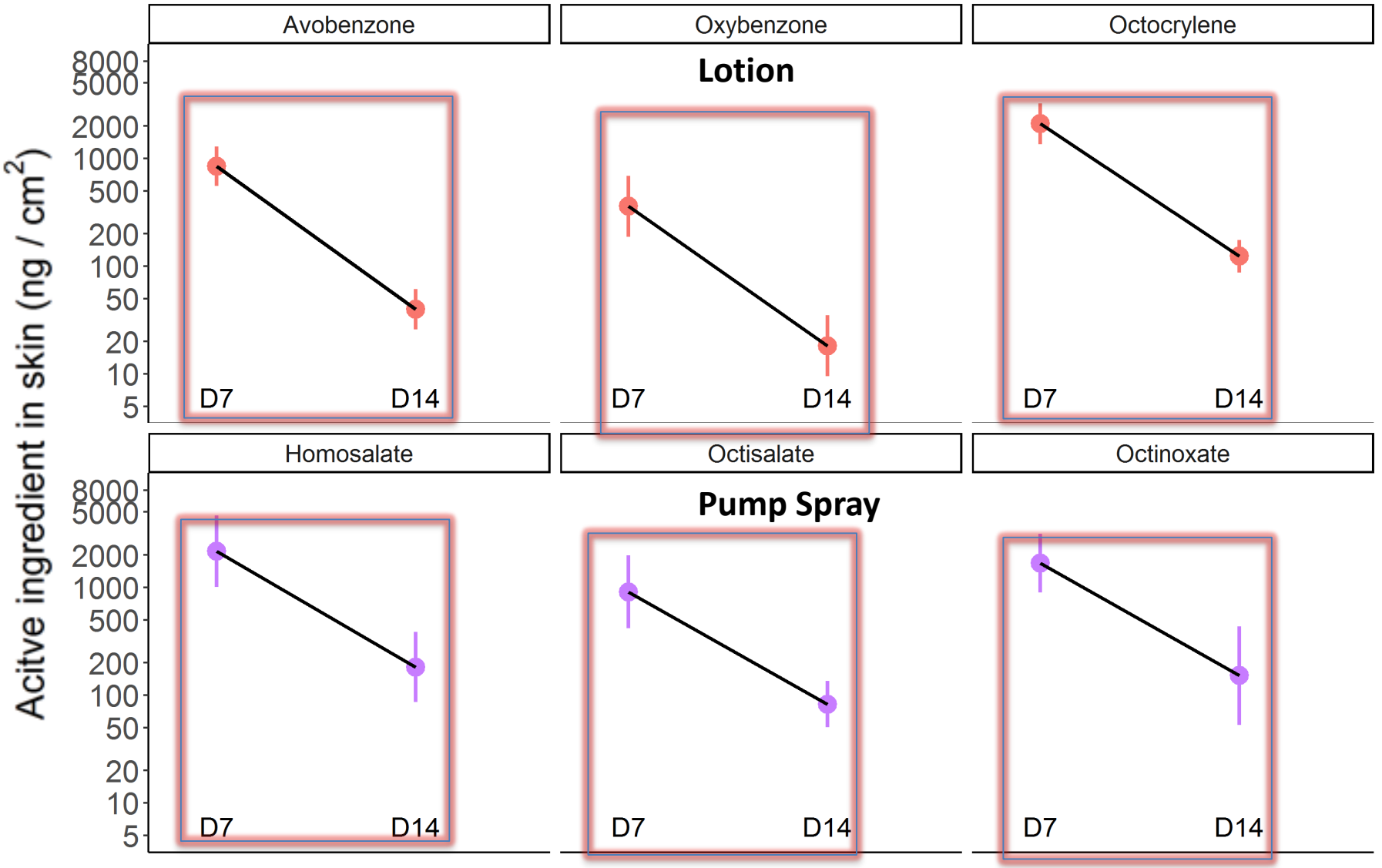

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- The active ingredients remained in plasma for extended time periods after the last application (3, 6, or 17 days, depending on the active ingredient), even in skin
- The fact that the sunscreen active ingredients are absorbed systemically does not mean they are unsafe. Rather, this finding calls for further testing to determine the safety of those ingredients for repeated use over a lifetime

Acknowledgements

DARS/OCP

David Strauss

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Vikram Patel

Nageswara Pilli

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DCPIII/OCP

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OCP

Dennis Bashaw

Issam Zineh

DNDP/OND

Steven Adah

Sergio Coelho

Jian Wang

Lesley-Anne Furlong

Charles Ganley

Theresa Michele

DPQR/OTR

Yang Yang

Ashraf Muhammad

Celia Cruz

JAMA | Original Investigation

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JAMA | Original Investigation

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Additional Slides….

Consort Diagram Study 2