

REPORT FORMAT (updated 4/20/16)

ABSTRACT

INTRODUCTION

CHEMISTRY

Definition and Structure

Plant Identification (*to be used in botanical reports*)

Physical and Chemical Properties (*present measured properties first, computational second*)

Method of Manufacture

Composition (*generally, included for botanicals*)

Impurities

Other Sub-Sections as Appropriate (for example: Natural Occurrence; UV Absorption; Nitrosation)

USE

Cosmetic

Non-Cosmetic

TOXICOKINETIC STUDIES

Dermal Penetration

In Vitro

Animal

Human

Penetration Enhancement

Absorption, Distribution, Metabolism, and Excretion (ADME)

In Vitro

Skin Samples

Cell Cultures

Animal

Dermal

Oral

Inhalation

Other Routes, when relevant

Human

Dermal

Oral

Inhalation

Other Routes, when relevant

Computational (examples provided here)

Physiologically Based Pharmacokinetic (PBPK) Modelling

In Vitro/In Vivo Extrapolation (IVIVE)

Quantitative Structure-Activity Relationship (QSAR)/Quantitative Structure-Property Relationship (QSPR) Calculations

TOXICOLOGICAL STUDIES (for this section, if there are only animal studies, “Animal” is not needed as a subheading)

Acute Toxicity Studies (*single exposure*)

Dermal

Oral

Inhalation

Other (when relevant)

Short-Term Toxicity Studies (*0-3 mos exposure*)

Animal

Dermal

Oral

Inhalation

Other (when relevant)
Human
Dermal
Oral
Inhalation
Other (when relevant)

Subchronic Toxicity Studies (≥ 3 - 6 mos exposure)

Animal
Dermal
Oral
Inhalation
Other (when relevant)

Human
Dermal
Oral
Inhalation
Other (when relevant)

Chronic Toxicity Studies (≥ 6 mos exposure)

Animal
Dermal
Oral
Inhalation
Other (when relevant)

Human
Dermal
Oral
Inhalation
Other (when relevant)

DEVELOPMENTAL AND REPRODUCTIVE TOXICITY (DART) STUDIES

Dermal
Oral
Inhalation

Computational Analyses/ Predictions (as these tools become available and validated)

GENOTOXICITY STUDIES

In Vitro

In Vivo

Computational Analyses/Predictions

CARCINOGENICITY STUDIES

Dermal
Oral
Inhalation

Co-Carcinogenicity

Dermal
Oral
Inhalation

Tumor Promotion

Dermal
Oral
Inhalation

Computational Analyses/ Predictions (as these tools become available and validated)

ANTI-CARCINOGENICITY STUDIES

OTHER RELEVANT STUDIES (only included when applicable)

Comedogenicity

Effects on Pigmentation

Endocrine Effects

Cytotoxicity

Anti-Microbial

Other Endpoints, when relevant (for example, Neurotoxicity, Immunotoxicity, Behavioral Toxicity)

DERMAL IRRITATION AND SENSITIZATION STUDIES

Irritation

In Vitro

Animal

Human

Sensitization

In Vitro

Animal

Human

Photosensitization/Phototoxicity

In Vitro

Animal

Human

Computational Analyses/Predictions (as these tools become available and validated)

OCULAR IRRITATION STUDIES

In Vitro

Animal

Human (including use studies)

Computational Analyses/Predictions (as these tools become available and validated)

MUCOUS MEMBRANE IRRITATION STUDIES

In Vitro

Animal

Human

CLINICAL STUDIES

Retrospective and Multicenter Studies

Case Reports

Adverse Event Reports

Other Clinical Reports, if relevant

EPIDEMIOLOGICAL STUDIES (included when appropriate)

Cancer Endpoints

Primary Studies

Prospective Studies

Retrospective Studies

Meta-Analyses

Non-Cancer Endpoints

Primary Studies

Prospective Studies

Retrospective Studies

Meta-Analyses

SUMMARY

DISCUSSION

CONCLUSION

TABLES (or, FIGURES AND TABLES)

REFERENCES

PLEASE NOTE:

Risk Assessment data: risk assessment data are included when appropriate

- When risk assessment data are available and appropriate for inclusion, that information should be included in the relevant section of the report
 - o For example, if Quantitative Risk Assessment (QRA) for dermal sensitization is to be included, that information should be included in the **Sensitization** section of the report

Analogs: Analogs are included in the report as a source of read-across data when appropriate.

- When used, it is important to identify the analog, the endpoints that the analog address, and the rationale as to why it is appropriate for use (this information is provided in a table)
 - o In each section of the report that uses an analog for read-across purposes, the data should be summarized in that section, and a hyperlink to the table (discussed above) should be provided

Threshold of Toxicological Concern: TTC may be appropriate at times

- When it is appropriate to include TTC, a link to a description of the methodology should be included