From:	Greg Gorder
To:	P65Public Comments
Cc:	Arthur Lawyer
Subject:	TSG: Proposed Enhancement to Animal Data Tables for the DART IC
Date:	Wednesday, January 22, 2014 6:35:39 PM
Attachments:	TSG Proposed template_toxdata.pdf Klimisch 1-s2.0-S0273230096910764-main.pdf

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Dear Ms Oshita,

Technology Sciences Group (TSG) would like to provide comments on the template for summarizing animal data in Hazard Identification Documents for the DART IC. ***Enhancements to the tables proposed by OEHHA are attached.*** The enhancements are primarily taken from Klimish et al. (1997) which is ***also attached***. Some potential adjustments are as follows:

1. **Study Design:** It may be helpful to include information on if the study was conducted according to a regulatory guideline and which guideline, if it was done under GLP, and include test condition details such as how the animals were housed, temperatures, if feeding was ad libitum, and for inhalation studies if exposures were whole body or limited to head and nose exposure.
2. **Dosing:** Was there analytical verification that the dosing was done as stated?
3. **All Endpoints:** Data reported in the study endpoints that are not reproductive of developmental endpoints should be retained because they may provide important information to assist in interpreting study results.
4. **Changes/Lesions Observations should be included:** It would be helpful to retain additional information recorded in the study.
5. **Statistics should be included:** This would apply to both the significance at each dose and the dose response trend.

We hope these additional suggestions are helpful.

REFERENCE

Klimisch et al., 1997. "A Systemic Approach for Evaluating the Quality of Experimental Toxicological and Ecotoxilogical Data" Regul. Toxicol. Pharmacol. 25:1-5.

Sincerely,
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OEHHA Proposed Template for tabulating data from developmental toxicity studies

Reference	Experimental Parameters					Endpoints Assessed [Parents/ Offspring]	Results (Effects/NOEL/LOEL)		Comments
	Chemical [Source/ Purity/ Preparation]	Animal Model [Species/ Strain/Sex/ Age] Number per dose group	Study Design	Exposure [Route/ Period/ Frequency/ Vehicle]	Doses or Concentrations		Parents	Offspring	
[Study 1: authors, date]									
[Study 2: authors, date]									

TSG Proposed Adjusted Template for developmental toxicity studies

Reference	Experimental Parameters					All Endpoints Assessed [Parents/ offspring including non-developmental endpoints] /Methods	Changes/ Lesions Observed	Incidence by Dose/Statistics (Method) (Effects/NOEL/LOEL)		Trend/ Statistics (stats method)	Comments
	Chemical [Source/ Purity/ Preparation]	Animal Model [Species/ Strain/Sex/ Age] Number per dose group	Study Design / Guideline (EPA, OECD, other)/ GLP? Test Conditions	Exposure [Route/ Period/ Frequency/ Vehicle]	Doses or Concentrations (Analytical verification?)			Parents	Offspring		
[Study 1: authors, date]											
[Study 2: authors, date]											

Template for tabulating data from male and female reproductive toxicity studies

Reference	Experimental Parameters						Results (Effects/NOEL/LOEL)		Comments
	Chemical [Source/ Purity/ Preparation]	Animal Model [Species/ Strain/Sex/ Age] Number per dose group	Study Design	Exposure [Route/ Period/ Frequency/ Vehicle]	Doses or Concentrations	Endpoints Assessed	Systemic Toxicity	Reproductive Toxicity	
[Study 1: authors, date]									
[Study 2: authors, date]									

TSG Proposed Adjusted Template for reproductive toxicity studies

Reference	Experimental Parameters					All Endpoints Assessed [Parents/ offspring including non-reproductive endpoints] /Methods	Changes/ Lesions Observed	Incidence by Dose/Statistics (Method) (Effects/NOEL/LOEL)		Trend/ Statistics (stats method)	Comments
	Chemical [Source/ Purity/ Preparation]	Animal Model [Species/ Strain/Sex/ Age] Number per dose group	Study Design / Guideline (EPA, OECD, other)/ GLP? Test Conditions	Exposure [Route/ Period/ Frequency/ Vehicle]	Doses or Concentrations (Analytical verification?)			Systemic Toxicity	Reproductive Toxicity		
[Study 1: authors, date]											
[Study 2: authors, date]											