APPLICATION GUIDANCE FOR NEW REFRIGERANT CLASSIFICATION SUBMISSION TO ASHRAE SSPC 34

TOXICITY INFORMATION

January 24, 2016

DISCLAIMER AND GENERAL GUIDANCE:

This refrigerant application guidance has been prepared by the Toxicity Subcommittee of ASHRAE SSPC 34 to assist applicants in the preparation of a refrigerant application in general accordance with the requirements of ANSI/ASHRAE Standard 34, *Designation and Safety Classification of Refrigerants*.

In cases where the refrigerant is a blend, the information requirements of ANSI/ASHRAE Standard 34 must be addressed for each blend component and for the complete blend, if information on the blend is available.

While every effort has been made to ensure the accuracy of information, this application guidance is provided to applicants for informational purposes only and is not a substitute for ASHRAE Standards. This document is intended to highlight the key technical input requirements of Standard 34 and published Addenda up to the date of this document. The applicant is responsible for accessing the ASHRAE Standards website for the latest published Addenda to Standard 34. ASHRAE and ASHRAE SSPC 34 are not responsible for errors made as a result of using this document. In cases of any discrepancy or omission, the requirements of ANSI/ASHRAE Standard 34 and its published addenda and errata shall prevail.

The applicant may copy the rows in the tables below to allow for the description of as many studies as needed. Remove the instructions under the heading “Data and Information” and insert the relevant data or information.

For further assistance or clarification, please contact the SSPC 34 Chairman at SSPC34Chair@ashrae.net.

See also: http://www.ashrae.org/aboutus/page/707

ASHRAE Standard 34 Toxicity Refrigerant Application Guidance for Toxicology Data		
	REFRIGERANT NAME:	
ASHRAE Standard Section		**Data and Information**
9.6.1	**ACUTE TOXICITY**	
	Short-term Exposure Limits or Ceiling Values	
9.6.1a	ACGIH TLV-C, if assigned (If no value assigned state "None assigned"	Provide value and source
9.6.1b	ACGIH TLV-STEL, if assigned, (If no value assigned state "None assigned"	Provide value and source
9.6.1c	NIOSH IDLH, if assigned, (If no value assigned state "None assigned"	Provide value and source

9.6.1d	**ACUTE INHALATION TOXICITY**	
	Study Type (e.g., LC50, Approximate Lethal Concentration or Limit Test)	
	Value (e.g., LC50 Value)	
	Species	
	# Animals per group	
	Vehicle (if used)	
	Exposure concentrations	
	Exposure time (e.g., minutes, hours)	
	GLP (Yes/No)	
	Method	Cite appropriate Guideline (e.g., OECD, EPA, etc.), if applicable. Provide any additional study details as needed.
	Result/Conclusions	Describe other effects observed throughout the study, including clinical signs, body weight effects, etc.
	Additional Comment	Provide any other study detail as needed
	Reference	For journal articles cite the author(s); year; title and journal citation. For information sources such as websites, give complete listing including date information was accessed. For unpublished reports use "Anonymous" in place of the author's name to protect confidentiality and privacy.

9.6.1e	**OTHER ACUTE TOXICITY (for example, oral, dermal)**	
	Study Type (e.g., LD50)	
	Value (e.g., LD50 Value)	
	Species	
	# Animals per group	
	Vehicle (if used)	
	Doses	
	GLP (Yes/No)	
	Method	Cite appropriate Guideline (e.g., OECD, EPA, etc.), if applicable. Provide any additional study details as needed.
	Result/Conclusions	Describe other effects observed throughout the study, including clinical signs, body weight effects, etc.
	Additional Comment	Provide any other study detail as needed
	Reference	For journal articles cite the author(s); year; title and journal citation. For information sources such as websites, give complete listing including date information was accessed. For unpublished reports use “Anonymous” in place of the author’s name to protect confidentiality and privacy.

9.6.1f	**CARDIAC SENSITIZATION**	
	Study Type	
	NOAEL/NOEL	
	LOAEL/LOEL	
	Species	
	# Animals per group	
	Vehicle (if used)	
	Exposure concentrations	
	Exposure time (e.g., minutes, hours)	
	GLP (Yes/No)	
	Method	Provide study details. Mention epinephrine challenge details: i.e., dose of epinephrine used.
	Result/Conclusions	Describe other effects observed throughout the study, including clinical signs, body weight effects, number of animals responding at each dose level, etc. We don’t measure body weights

	Additional Comment	Provide any other study detail as needed
	Reference	For journal articles cite the author(s); year; title and journal citation. For information sources such as websites, give complete listing including date information was accessed. For unpublished reports use “Anonymous” in place of the author’s name to protect confidentiality and privacy.

9.6.1g	**ANESTHETIC AND CENTRAL NERVOUS SYSTEM EFFECTS**	
	Study Type (e.g. EC50 or Threshold)	
	Value (e.g., LC50 or EC50 Value)	
	Species	
	# Animals per group	
	Vehicle (if used)	
	Exposure concentrations	
	Exposure time (e.g., minutes, hours)	
	Exposure duration (e.g., single dose, 5 days, 5 days/week, other)	
	GLP (Yes/No)	
	Method	Cite appropriate Guideline (e.g., OECD, EPA, etc.), if applicable. Provide any additional study details as needed.
	Result/Conclusions	Describe effects observed throughout the study, including clinical signs, body weight effects, etc.
	Additional Comment	Provide any other study detail as needed
	Reference	For journal articles cite the author(s); year; title and journal citation. For information sources such as websites, give complete listing including date information was accessed. For unpublished reports use “Anonymous” in place of the author’s name to protect confidentiality and privacy.

9.6.51h	**OTHER ESCAPE IMPAIRING EFFECTS AND PERMANENT INJURY**	
	Study Type (e.g., LC50; repeat-dose, developmental toxicity, etc.)	
	LOAEL/NOAEL Value	

	Species	
	# Animals per group	
	Vehicle (if used)	
	Exposure concentrations	
	Exposure time (e.g., minutes, hours)	
	Exposure duration (e.g., single dose, 5 days, 5 days/week, other)	
	GLP (Yes/No)	
	Method	Cite appropriate Guideline (e.g., OECD, EPA, etc.), if applicable Provide any additional study details as needed.
	Result/Conclusions	Describe effects observed throughout the study, including clinical signs, body weight effects, etc.
	Additional Comment	Provide any other study detail as needed
	Reference	For journal articles cite the author(s); year; title and journal citation. For information sources such as websites, give complete listing including date information was accessed. For unpublished reports use “Anonymous” in place of the author’s name to protect confidentiality and privacy.

9.6.2a	**REPEAT-EXPOSURE TOXICITY STUDIES, DEVELOPMENTAL TOXICITY, REPRODUCTIVE TOXICITY, CHRONIC TOXICITY (Note: For each key study, provide the information below.**	
	Study Type (e.g., 2-wk, 28-day, 90-day, developmental, reproductive, chronic)	
	Value (NOAEL, LOAEL)	
	Species	
	# Animals per group	
	Vehicle (if used)	
	Exposure concentrations	
	Exposure time (e.g., hr/day)	
	Duration of exposures (e.g., 5 days/week)	
	GLP (Yes/No)	
	Method	Cite appropriate Guideline (e.g., OECD, EPA, etc.), if applicable. Provide any additional study details as needed.
	Result/Conclusions	Describe effects observed throughout the study, including

		clinical signs, body weight effects, etc.
	Additional Comment	Provide any other study detail as needed
	Reference	For journal articles cite the author(s); year; title and journal citation. For information sources such as websites, give complete listing including date information was accessed. For unpublished reports use “Anonymous” in place of the author’s name to protect confidentiality and privacy.

9.6.2	**Occupational Exposure Limit (OEL)**	
9.6.2b	ACGIH TLV-TWA, if assigned	Provide value and source
9.6.2c	OARS WEEL, if assigned	Provide value and source
9.6.2d	OSHA PEL, if assigned	Provide value and source
9.6.2d	8-hr Time-Weighted Average (TWA) Occupational Exposure Limit (OEL), if available. Otherwise provide the applicant recommended 8-hr TWA OEL, with a detailed explanation of how the OEL was determined. If the refrigerant is a blend, the OEL should be calculated for the entire blend.	Provide value and source of OEL. If OEL is generated by applicant, details and assumptions used to generate the recommended OEL should be provided.

	Other Toxicity Endpoints (e.g., mutagenicity, developmental toxicity, or special studies of relevance)	Cite appropriate Guideline (e.g., OECD, EPA, etc.), if applicable. Provide a brief summary of studies and conclusions. Provide any additional study details as needed
	Reference	For journal articles cite the author(s); year; title and journal citation. For information sources such as websites, give complete listing including date information was accessed. For unpublished reports use “Anonymous” in place of the author’s name to protect confidentiality and privacy.

9.8	**Contaminants and Impurities**	Identify contaminants and impurities, including isomeric and decomposition impurities from manufacturing, transport and storage known to increase the potential toxicity with the precision of the RCL. Also identify the limits for those impurities if available.
	Reference	For journal articles cite the author(s); year; title and journal citation. For information sources such as websites, give complete listing

		including date information was accessed. For unpublished reports use “Anonymous” in place of the author’s name to protect confidentiality and privacy.

	Date of Final Literature Search	
	References	Provide a complete citation for all references cited above. For journal articles cite the author(s); year; title and journal citation. For information sources such as websites, give complete listing including date information was accessed. For unpublished reports use “Anonymous” in place of the author’s name to protect confidentiality and privacy.
9.6.3	**MSDS for each component. If refrigerant is a blend, also provide the MSDS for the blend.**	It is useful to include the most recent MSDS you have available.