【 附錄 (Appendix) A 】 v 2014.11.14

Regulation (EC) No. 1272/2008 (CLP)以及Regulation (EC) No. 1907/2006下的定義 分類 (Classification) (Definition under Regulation (EC) No. 1272/2008 (CLP)以及Regulation (EC) No. 1907/2006) CC 1A: 致癌物質 類已知會對人類致癌的物質。有足夠的證據證明人體暴露於該物質和癌症發展之間有相互的關聯性 (Substances known to be carcinogenic to man. There is sufficient evidence to establish a causal 别 1A (Carcinogen association between human exposure to a substance and the development of cancer) . Category 1A) 應被視為可能對人體會導致致癌的物質。有足夠的證據強力推論人體暴露於該物質可能導致癌症發展,上 CC 1B: 致癌物質 述基於下列研究所得之結果 (Substances which should be regarded as if they are carcinogenic to man. 别 1B (Carcinogen There is sufficient evidence to provide a strong presumption that human exposure to a substance may Category 1B) result in the development of cancer. Generally on the basis of): 適當的長期動物實驗 (appropriate long-term animal studies)。 其他相關資訊 (other relevant information)。 已知會對人類導致基因突變的物質。有足夠的證據證明人體暴露於該物質和遺傳基因損害之間有相互的關 MC 1A: 導致基因突變 類别 1A (Mutagen 聯性 (Substances known to be mutagenic to man. There is sufficient evidence to establish a causal Category 1A) association between human exposure to a substance and heritable genetic damage) . 應被視爲是否對人體會導致基因突變的物質。有足夠的證據強力推論人體暴露於該物質可能導致遺傳基因 MC 1B: 導致基因突 損害,上述基於下列研究所得之結果 (Substances which should be regarded as if they are mutagenic to 變 類别 1B (Mutagen Category man. There is sufficient evidence to provide a strong presumption that human exposure to the substance 1B) may result in the development of heritable genetic damage, generally on the basis of): 適當的長期動物實驗 (appropriate animal studies)。 其他相關資訊 (other relevant information)。 PBT 長期生物蓄積性 長期生物蓄積性及毒性物質(PBT)或高持久性和高生物蓄積性物質(vPvB)造成化學安全管理上特別挑戰。 及毒性物質 & vPvB 這些物質在環境中無法用一個"安全"濃度建立足夠的可靠度。/ Substances which are persistent, 高持久性和高生物蓄 bioaccumulative and toxic (PBT) or very persistent and very bioaccumulative (vPvB) pose a particular 積性物質 challenge to the chemicals safety management. For these substances a "safe" concentration in the environment cannot be established with sufficient reliability. EQC: 相同危害等級 ┃具内分泌混亂性質,或具持久性、生物累積性、毒性或vPvB性質但不符合PBT及vPvB的物質,且有等同 (Equivalent concern) 於CC 1A, CC 1B, MC 1A, MC 1B, TRC 1A, TRC 1B, PBT及vPvB所列物質對人體或環境可能的嚴重危害 性之科學證據之(而且依照第五十九條款所設步驟視個别案例進行確認)。/ Substances - such as those having endocrine disrupting (ED) properties or those having persistent, bioaccumulative and toxic properties or very persistent and very bioaccumulative properties, which do not fulfil the criteria of points PBT & vPvB - for which there is scientific evidence of probable serious effects to human health or the environment which give rise to an equivalent level of concern to those of other substances listed in points CC 1A, CC 1B, MC 1A, MC 1B, TRC 1A, TRC 1B, PBT & vPvB and which are identified on a case-by-case basis in accordance with the procedure set out in Article 59. 已知會損害人體生殖能力的物質。有足夠的證據證明人體暴露於該物質和生殖能力削弱之間有相互的關聯 TRC 1A: 對生殖系統 有害 類别 1A 性 (Substances known to impair fertility in humans. There is sufficient evidence to establish a causal (Toxic to relationship between human exposure to the substance and impaired fertility) . Reproduction 已知會在人體引起毒性的物質。有足夠的證據證明人體暴露於該物質和其後產生之毒性對後代造成影響有 Category 1A) 相互之關聯性 (Substances known to cause developmental toxicity in humans. There is sufficient evidence to establish a causal relationship between human exposure to the substance and subsequent developmental toxic effects in the progeny) •

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分類 (Classification)

Regulation (EC) No. 1272/2008 (CLP)以及Regulation (EC) No. 1907/2006下的定義 (Definition under Regulation (EC) No. 1272/2008 (CLP)以及Regulation (EC) No. 1907/2006)

有害 類别 1B (Toxic to Reproduction Category 1B)

TRC 1B: 對生殖系統 ┃應被視為可能會損害人體生殖能力的物質。有足夠的證據證明人體暴露於該物質可能導致損害人體生殖能 力的有力推論,上述基於下列研究所得之結果 (Substances which should be regarded as if they impair fertility in humans. There is sufficient evidence to provide a strong presumption that human exposure to the substance may result in impaired fertility on the basis of):

- 缺少毒性作用的生殖能力削弱動物實驗中的明顯證據,或在同使用量下其他毒性作用但不是其他毒性 作用的輔助非特定結果的生殖能力削弱證據 (clear evidence in animal studies of impaired fertility in the absence of toxic effects, or, evidence of impaired fertility occurring at around the same dose levels as other toxic effects but which is not a secondary nonspecific consequence of the other toxic effects)
- 其他相關資訊 (other relevant information)

應被視爲可能在人體引起毒性發展的物質有足夠的證據提供人體暴露於該物質可能引起毒性發展的有力推 論,整體而言是基於 (Substances which should be regarded as if they cause developmental toxicity to humans. There is sufficient evidence to provide a strong presumption that human exposure to the substance may result in developmental toxicity, generally on the basis of):

- 在適當動物實驗研究所進行缺乏顯著母體毒性徵象或在同使用量下其他毒性作用但不是其他毒性作用 的輔助非特定結果的生殖能力削弱證據觀察,所得到之明顯結果 (clear results in appropriate animal studies where effects have been observed in the absence of signs of marked maternal toxicity, or at around the same dose levels as other toxic effects but which are not a secondary non-specific consequence of the other toxic effects) •
- 其他相關資訊 (other relevant information)