

MANUAL FOR INVESTIGATION OF HPV CHEMICALS

CHAPTER 4: INITIAL ASSESSMENT OF DATA

4.1 Introduction¹

1. Following data gathering, testing and data evaluation as described in chapters 2 and 3, the hazards of a given HPV chemical need to be assessed and described in the SIDS Initial Assessment Report (SIAR). Guidance on the structure and content of the SIAR can be found in Chapter 5.

2. There are currently two documents in the Manual for Investigation of HPV Chemicals that give guidance on how to assess the hazards of a chemical substance:

- Section 4.2: Guidance for the Initial Assessment of Aquatic Effects. This guidance document was updated in 2002 and provides guidance on how to use all available data on toxicity to aquatic organisms to estimate a concentration where no unacceptable adverse effects on the ecosystem are expected (i.e. Predicted No Effect Concentration, PNEC). At present, no guidance is yet available on the assessment of effects towards terrestrial and benthic organisms.
- Section 4.3: Guidance for the Initial Assessment of Health Effects. This guidance document was updated in 2003. It provides guidance on how to assess the available results on acute toxicity, irritation, sensitisation, repeated dose toxicity, genetic toxicity and reproduction/developmental toxicity. It also provides guidance on the necessity of further work on genetic toxicity in the OECD HPV Chemicals Programme, depending on the available test results and/or the outcome of *in vitro* studies.

3. Useful guidance on the interpretation and assessment of aquatic and human health hazard assessment can also be found in the Harmonised Integrated Classification System for Human Health and Environmental Hazards of Chemical Substances and Mixtures:

(<http://webnet1.oecd.org/EN/documents/0,,EN-documents-524-14-no-5-no-0,00.html>).

It should be kept in mind though that no actual hazard classification should be performed within the OECD HPV Chemicals Programme. The terminology found in the classification criteria can nevertheless be used.

4. Guidance on how to describe and structure the result of the assessment can be found in section 5.2.2 : Structure and content of the SIAR.

¹ This document was prepared by the OECD Secretariat based on the agreements reached in the OECD Existing Chemicals Programme up to October 2003.